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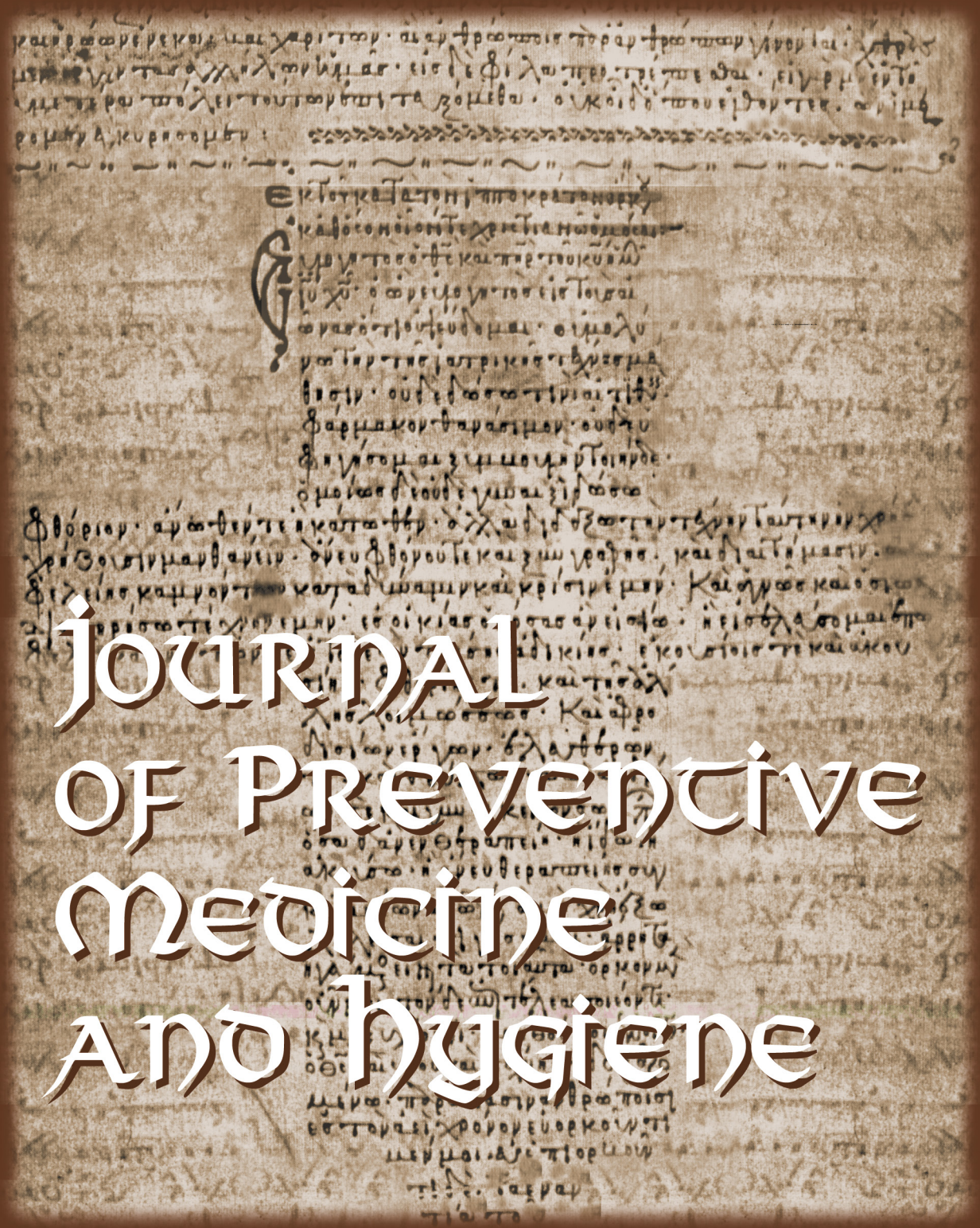

The original document of Hippocrates' oath

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Contents

EDITORIAL

Lot Quality Assurance Sampling (LQAS), an Efficient and Rapid Assessment Technique in Quality Assurance and Public Health Studies

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Keywords

Lot Quality Assurance Sampling • Quality assurance • Decision value • Public health • Bias

Dear Editor,
Effective management and appropriate decision-making of health systems require up-to-date information at the local level where health system programs are implemented. Health managers require to know which health center or area are achieved specific goals and objectives, and which are not achieved [1].
Lot Quality Assurance Sampling (LQAS) technique can be an appropriate idea to achieve this information. LQAS is a significant method for rapid monitoring and assessing preventive and curative health care, surveillance, and population programs. LQAS have been used initially as a quality control and assurance technique for produced in industrial units and developed in the early part of the 20th century. It got an abundant improvement in popularity during the Second World War when it was used as a technique for improving the quality of war materials. The developing interest in using LQAS technique was obtained by WHO as a review of 34 LQAS applications for measuring family physician planning, immunization coverage, the morbidity of disease, technical assessment of health workers performance, etc. LQAS technique is a field implementation. All worldwide organizations including UNICEF, WHO, World Bank use it. The main application of LQAS is to determine whether the subject's lots are acceptable or not [2].
LQAS method is poorly implemented in public health studies for evaluating the quality and adequacy of health services. There is poor evidence about the application of this technique in health care systems worldwide. The goal of simple random sampling is parameter estimation. It needs a large sample size. LQAS is also a random technique and it estimates both parameter and quality of service. Currently, LQAS has opened up unique opportunities for measuring the efficiency of various health services and also to obtain specific social and behavioral outcomes [3]. The sample size and decision values for LQAS calculate via cumulative probability of the binomial distribution based on the risks that the investigators are willing to take. The number of items that are selected from each lot is the sample size. The number of "defects" items that require to found earlier the lot is deemed unacceptable is the decision value.
There are two types of errors (risk) that should be considered: (a) Type I error (Alpha), the risk of accepting a (bad) lot, and (b) Type II error (Beta), the risk of not accepting a (good) lot. Alpha and beta do not exceed 0.10 at the thresholds. Alpha and beta have different values that are depicted in the operating characteristic curve.
To apply the above in the field, we calculated the probabilities of 80% and 50% coverage as upper and lower threshold of appropriate prescribed antimalarial by various sample sizes using the binomial formula. To explain the calculation, let us take the example of $n = 19$ and $d = 6$. To calculate the probability of wrongly classifying a work area as inappropriate, we first have to calculate the probability of having ≤ 6 untreated cases of 19 malaria patients in an area with 80% coverage is 0.93. This also implies that, with 80% coverage in the area, there is a likelihoods of 0.07 (1-0.93) to have ≤ 6 untreated patients. However, with 50% coverage, the probability of having ≤ 6 untreated patients is = 0.08. Thus, total error is = 0.15 as below 20% [4]. Currently, LQAS tables provided the best decision values for various sample sizes and with less than 10% alpha and beta errors across all coverage targets. For example, if there have 14 samples or more (decision value) in each lot with pass outcome, it lot is acceptable. Likewise, if we have more than 5 fail samples in each lot, unacceptable. Therefore, LQAS evaluates the quality and adequacy of health services by reducing cost and the sample size without causing a significant increase in error. In addition, the parameter can be estimated by summing LQAS lots. LQAS also provides a simple understanding for health managers at the local level.

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Authors' contributions
HA conceptualized the letter and developed all sections of the paper.

Ethics statement

This paper is letter to the editor so it did not need ethical consideration.

Conflict of interest

The author declares that there is no conflict of interests.

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COVID-19

Italian nurses' COVID-19 experiences from mass media interviews: a qualitative study

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Keywords

COVID-19 • Front-line nurses' experiences • Mass media • Qualitative study

Summary

Introduction. *The COVID-19 pandemic is heavily hitting healthcare systems around the world, and nurses are battling in the front line. Previous studies have reported nurses' responses to catastrophic situations, but also interviews released by Italian nurses to the main mass media channels could bear important messages for policy makers and stakeholders. This study describes Italian front-line nurses' experiences during the COVID-19 pandemic through television interviews.*
Methods. *This is a descriptive qualitative study. Data were collected through purposive sampling from Italian front-line nurses' interviews during the COVID-19 pandemic. Publicly available interviews between 7th and 29th March 2020 were collected from the websites of national and regional television stations. Thematic content analysis was used to describe, summarize, and classify data into macro themes. The study is compliant with Standards for Reporting Qualitative Research.*
Results. *A total of 21 television interviews were collected from front-line clinical nurses, nursing managers, nursing trade union representatives and representatives of the Nursing Regulator. Thematic analysis yielded four macro-themes: psycho-social effects of the COVID-19 pandemic on health professionals; altered patient relationships; personal safety; recognition and promotion of the profession.*
Conclusions. *The COVID-19 pandemic has exacerbated some problems already present, such as the shortage of nurses, but has also turned the spotlight on the nursing profession. Highly involved and affected by the pandemic, nurses have become better known by the public and often also protagonists of public discussions. It is important that nurses' value as allies of the public emerges stronger from this dramatic situation.*

Introduction

Nurses have been central to the health care response to the COVID-19 (CV-19) pandemic. After China, the most heavily affected country has been Italy. Overwhelming numbers of acutely ill patients have almost swamped hospitals. Health professionals have abandoned normal shift patterns and have been working under extreme pressure. Throughout this pandemic the press coverage has been the only window that the public have on the situation and how professionals are responding and affected by it. Many nurses have been interviewed on the Italian media – presenting a unique, real time' perspective on the CV-19 situation. These broadcasts have also been essential in showing the public how the pandemic is affecting hospitals and staff – the messages from nurses on the TV screens are emotive and powerful reflections of the pandemic as it was unfolding – often by practitioners who had just left the care environment or were preparing to enter it. In that way these broadcasts add another, more immediate, dimension to our understanding of CV-19. The contents of these TV interviews are more 'raw' than planned research interviews, more human than surveys and deserve to be recorded as part of the CV-19 legacy for nursing. Sharing the experiences and messages of Italian nurses can also be helpful for all those who are or will be facing this emergency around the globe. In addition, considering that similar pandemics may occur again in the future, the information emerging from this experience may be useful for further studies and to set up strategies and interventions in the field of clinical practice, management and education of nurses and other health professional who may find themselves in a similar situation.

Background

The new coronavirus (CV-19), an infection that affects the lower respiratory tract and manifests itself with pneumonia in humans, was recently declared by the WHO as a pandemic and represents one of the most complex situations ever experienced by modern healthcare. Despite the implementation of rigorous containment and quarantine measures, the incidence of CV-19 infections continued to steadily increase worldwide [1]. Italy was strongly hit by the CV-19 pandemic and was the second country to be affected after China, and for a long time was the one with the highest number of cases in the world [1]. Since the 21st February 2020, when the first case of CV-19 in Italy was confirmed, the Italian national health system has undergone increasing pressure with a total of 4,178,261 confirmed cases of Coronavirus and 124,810 deaths, as of the 21st May 2021 [2].

Nurses, along with physicians and other health professionals, have been the ones mostly involved in caring for patients with CV-19 and have faced unprecedented challenges from emotional, social, and professional perspectives. The pressure on the national health system led to the need to increase human and material resources to deal with the pandemic, therefore the Italian Government authorized the Regions to recruit 20,000 health professionals, by funding 660 million Euros [3, 4]. Given the prevalence of the pandemic in Italy the health professional response and their implementation of aspects related to clinical care and management related of the CV-19 cases are a salutary message to the rest of the world [3]. The TV cameras of the whole world were pointed on Italian hospitals and have broadcast the interviews of health professionals – including nurses – during the first wave of the pandemic. These interviews often included appeals to the population to encourage compliance with the rules of isolation – to help reinforce the movement known as #iorestoacasa (I stay at home), promoted by the Italian Ministry of Health [2].

This growing phenomenon of social and mass media communications by nurses and health professionals is a symptom of the growth of the media and the immediacy of reporting in times of public emergency [5]. Such media attention contributes to the development and evolution of the public image of the nursing profession [6].

It is therefore useful to know and understand, by analysing direct testimonials and interviews broadcast by the mass media, how Italian nurses – who have worked in the front lines (in the fields of clinical practice, management, education and research) during the emergency – have experienced this pandemic and how these interviews have been reported to the population by the mass media. This enables an analysis of the issues they present, identifying possible points of future action, and contributing to the research on how the media portrays nursing. This study presents an analysis of these media interviews to show an overview of the nature and content of these appearances and what they tell us about the key aspects of nursing from the CV-19 care situation. The study also provides a unique 'snapshot' of the immediate issues in the early epidemic – untampered by experience and reflections. It thereby also provides a basis for future research to make comparisons from later in the epidemic.

Methods

Design

A descriptive qualitative study.

Data collection

Data were collected through reasoned choice sampling. The most relevant and representative testimonies and interviews of Italian nurses involved in the front line against the CV-19 pandemic were included. Publicly available personal experiences by nurses in the CV-19 front-line were collected from the websites of RAI (Radio Televisione Italiana), the three channels Italian television broadcaster with national and regional programs from the 7th to 29th March 2020. Data collection was retrospective and proceeded until data saturation was reached. The inclusion criteria for the media interviews were that they had to be made by registered nurses from different Italian regions (at any level of responsibility, with no age limit, and any type of work experience) involved to some extent in caring for CV-19 patients in different settings; nursing leaders (e.g. a representatives of the Nursing Regulatory Body or the Nurses' Trade Union) who talked about other nurses' witnesses or problems/concerns related to them; representatives of public institutions who in their speeches to the public clearly referred to issues regarding the nursing profession or spoke on behalf of nurses.

The study was approved by the Liguria Regional Ethics Committee (Reg. N. 143/2020 - DB id 10456). The manuscript is compliant with Standards for Reporting Qualitative Research (SRQR) [7].

Data analysis

Data synthesis and the thematic analysis was informed by Braun and Clark's [8] six step model for thematic analysis which we adapted for visual media. The recorded TV clips were repeatedly viewed by members of the research team and key statements/important comments and accounts were identified and then transcribed.

Step 1: familiarizing with data

At this stage, the researchers involved in the analysis "immerse themselves" in the data. This happened through a careful watching and listening of the data to become familiar with what was reported – being careful not to omit any significant information. An initial list of ideas was generated about what is in the data and what is interesting about them.

Step 2: generating initial codes

This phase includes the initial production of the codes from the data, thus identifying some characteristics of the data that may be interesting to analyze.

Step 3: researching the themes

After generating all the codes, the researcher sorted the different codes into potential themes and also explored possible relationships between codes, themes, and sub-themes.

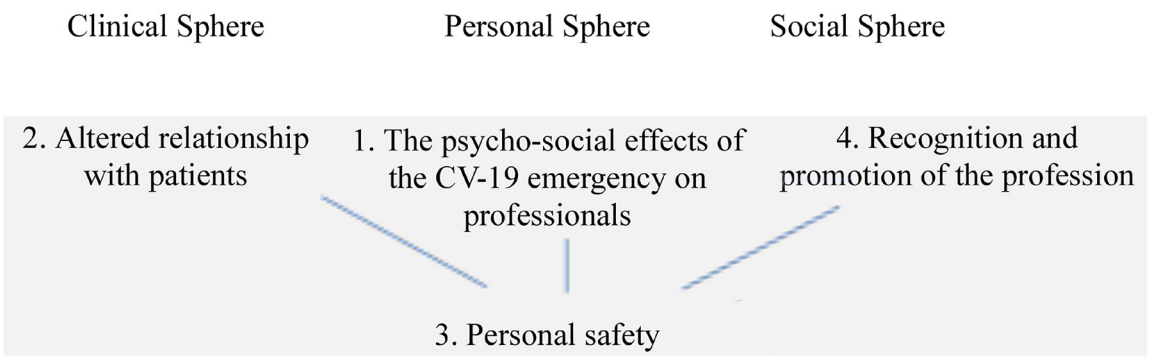
Step 4: reviewing the topics

Once the various possible themes have been identified, these issues are reviewed and redefined; some themes can be grouped together, separated, or eliminated.

Step 5: defining themes

In this phase, the themes for analysis are defined and refined by identifying the essence of each of them and

Fig. 1. Theme map.



determining which aspect of the data captures each theme.

Step 6: writing

A detailed report of the analysis process and the results was then created, specifying the analysis methodology conducted to demonstrate the methodological rigor followed.

The interviews were initially selected by title, then they were repeatedly listened to be fully understood, and finally summarized using a specifically designed summary matrix, which included the source, the speech date, participants' details, a summary of the content and the topics covered. Subsequently, an analysis matrix was created to obtain a general overview of all the collected interviews, through which we identified the sub-themes (starting from the topics) and the themes, which in turn were grouped into macro themes. Each macro theme has been described narratively and supported by quotations taken from the interviews (Fig. 1).

Results

The interviews were collected from a total of 14 sources (TV or online programs taken from RAI website), of which 5 included group interviews. The sample therefore consists of 23 interviews, specifically: 14 nurses working in the front line caring for patients affected by CV-19; 5 nursing directors or charge nurses; 3 nursing trade union representatives; and 1 representative of the Nursing Regulatory Body. Four macro-themes were identified describing the different facets of this health emergency.

The psycho-social effects of the CV-19 emergency on professionals

All the nurses, but particularly those who were currently caring for patients affected by CV-19, declared that they were living in a state of constant fear and anxiety, due to their inability to "do more" to help their patients and colleagues. The emotional impact that nurses were experiencing was evident – especially from a psychological perspective. This was apparent even in ICU staff used to dealing with very sick patients: *"This is a very heavy situation from a psychological point of view and absolutely disarming" (an ICU charge nurse).*

Fear was a frequently described emotion; fear for patients, for getting infected themselves and infecting their families. Under their uniforms and protective equipment health professionals are also human, they have the same thoughts and concerns as the rest of the population. CV-19 and the threat it posed to their loved ones was a constant companion: *"At home, you try to avoid hugging and also other things you would normally do with your dear ones… and in the meantime, you always think about it" (a clinical nurse).*

Those who were able to, lived separately from their families, to avoid infecting them, but this long period of persistent anxiety increased the psychological burden borne by health professionals and led to numerous personal sacrifices being made and dilemmas caused by conflicting loyalties and emotions: *"I have tried to limit as much as possible all my contacts with my parents, grandparents, and children… (…). We have had to let go of many things, but a father cannot avoid celebrating his son's birthday" (an ICU nurse).*

Various interviews highlighted the psychological strain that nurses were under. This also included nurse managers who – along with their own fears – were having to manage the stress of their staff colleagues: *"You bring home all the suffering because they suffer, and you see it all; I also always bring home the support and the smiles of my colleagues, smiles that are always there under their masks" (a nurse).*

"… it is a dramatic situation… the psychological strain is devastating… We do not have any structured psychological support, and we analyse ourselves at the end of the day, when we are tired and sit at a table with the cakes they bring us; and I collect their tensions and tears" (an ICU charge nurse).

"We get sick too. When you find out that someone is positive... you get seriously worried, and I have been

doing this job for 25 years. I look at my nurses who yesterday asked for psychological support. We all have elderly parents or children at home, and even if we take all the possible precautions, a moment of distraction due to tiredness can always occur" (a charge nurse).

The emotional burden of CV-19 was very evident. The exhausting shifts, low nurse-to-patient ratios for intensive care settings, and reduced time off, were all aspects of this war against CV-19, and like in all 'wars' – as this situation has often been defined – all available resources are used: *"What then weighs more, to me but above all to my nurses, as I have already told them directly, I will never stop thanking. At the end of this story which I hope will last as little as possible, I will take them somewhere. They are genuinely massacred (...) We don't have structured psychological support; we analyse ourselves at the end of the day when just tired, we put ourselves in front of a table with cakes that bring us, and I gather their tensions, their tears often. It is a very, very demanding test. At the end of this story, which I hope will last as little as possible, my nurses will work anyway" (head nurse).*

In addition, nursing managers, in hospitals, the community and nursing homes, were facing very stressful situations in their areas of responsibility – mainly as a result of staff sickness resulting in shortages and the additional infection control concerns created by CV-19: *"One day, I ended up having 102 nurses on sick leave, equal to 30% less staff on duty and obliged to do much more than they would normally do (…). I had to stay at home with a high temperature, but after three days, I went back to work. I intentionally did not do the swab test because otherwise, I would have run the risk of staying at home for 15 days, and this was impossible. One day I said to myself, «But I… what can I do? (with a broken voice) I can't stop this tsunami»" (nursing director of a nursing home).*

Altered relationship with patients

CV-19 also impacted on the core of the nurse patient relationship – a climate of fear connected with the problems caused by protective equipment were very evident in the nurse interviews: *"... because caring for and taking charge of a person passes through empathy and contact, but here there is no contact. Then you think of miming to show you are close to the patient and transmit a sense of safety and reassurance through non-verbal communication. When completely covered by protective clothing, non-verbal communication is useless because it is not noticed" (a nurse from the ambulance service).*

"The hall is full of scared patients. Lots of people with acute respiratory distress. People of all ages. People who suddenly had difficulty breathing, their temperature rapidly rose. Do you know what struck us most? That they did not say anything. They just lied in bed in silence, but their eyes were full of fear, which on their own spoke for all of them" (a clinical nurse).

Nurses were often the only person a patient with CV-19 could see and relate to, despite the difficulties caused by the disease and the protective equipment. In addition, physicians and nurses were also the only point of contact and source of information for patients' families. Therefore, a great amount of trust, hope and comfort was placed on health workers by patients and their families. Many nurses reported that they helped patients to video-call their loved ones, literally becoming the voices for those patients who were too weak to talk: *"Whenever possible, we try to facilitate communication: we call the next of kin twice a day, and we give to those patients who are awake the messages of love and affection sent by their sons, fathers, and mothers…" (an ICU charge nurse).*

"... we decided to stay next to her, so that as well as monitoring her we could accompany her, otherwise she would have been alone" (a nurse from the ambulance service).

"The only way we could communicate with patients was with our eyes… somehow, maybe touching a leg, trying to send a message to their children because they do not have other relatives, they don't have anyone" (a clinical nurse).

Personal safety

The correct use of Personal Protective Equipment (PPE) is essential to guarantee safety for patients and health professionals. In CV-19 the droplet nature of the infection meant that correct PPE use was essential – however, partly driven by the large amounts of infected patients' issues with PPE were very evident in the nurse interviews. The system of care often dictated that nurses organized themselves to work in pairs: one stays outside the protected zone, and the other stays inside – delivering direct care. This means that whoever is inside must deal with the issues of wearing PPE for an exceptionally long time – something not usually seen in normal times: *"… because having a mask over your face for 3-4 hours does not allow you to breathe well, you don't feel fresh air… this can cause a bit of a headache, and reduces the level of attention, the heat of the protective suits … It is like running for 6 hours, at a certain point you necessarily need a break if you don't want to collapse" (an ICU nurse).*

The lack of adequate PPE was a real concern for most health professionals. PPE is the only barrier between the virus and practitioners and having to care for infected patients without it many nurses became infected with CV-19. This is recognized as an accident at work, as declared by the president of the Italian National Institute for Insurance against Accidents at Work (INAIL), who described this as another "bad wound on the already tormented body of our National Health System". Nurses remarked on this as lacking the 'right armour': *"… we want the right armour to fight against this war, otherwise it is useless… PPE is lacking… we want to be safeguarded" (a clinical nurse).*

Nurses were working in conditions where their colleagues were becoming ill and dying – an issue that created enormous emotional stress: *"The number of deaths between doctors and colleagues is in front of everyone, the number of infected colleagues … we know. So yes, I'm afraid, but I also have a great desire to be able to help and try to help" (a clinical nurse).*

Alongside colleagues becoming infected and ill the lack of adequate PPE exacerbated the fear that many nurses had about taking the infection home to their families: *"Our biggest fear is not getting in touch with the virus, which is something we daily do. Our fear is that accidentally infecting ourselves and consequently bring the virus home and infect those who are the closest and dearest to us in the home" (a clinical nurse).*

Recognition and promotion of the profession

Within the interviews nurses often underlined how their response to this emergency was not merely the result of their heroic actions, but was one where they recognised, they had a pact of accountability with the public – this duty was at the core of their work. *"Helping others is at the basis of every healthcare profession, this is why I decided to be one (healthcare profession)" (an ambulance nurse).*

Despite their tiredness, fatigue and fear, nurses continued to honour the founding values of their profession – such as caring and staying close to people, emphasizing the 'non-extraordinary nature' of the job they were doing: *"I am physically tired because the protective equipment hurts me... I am psychologically exhausted, and so are all my colleagues who have been working in the same conditions for weeks, but this will not prevent us from doing our job as we have always done. I will continue to take care of my patients because I am proud to be a nurse and love my job" (a clinical nurse).*

Many nurses remarked on the expressions of gratitude by people and institutions for their work, but also noted the irony of these thanks when previously their concerns about violence in the workplace went unheeded – suggesting the fickle nature of public appreciation: *"The manifestations of gratitude these days are exceptional, and we are happy that people are close to us; they are our support. Unfortunately, however, only one month ago in our hospital, we had to stick up some notices to contrast acts of violence against health workers because we also have this kind of problem, but we hope that this emergency has now taught a lot of things to many people" (an ICU charge nurse).*

"… we were heroes also 4 months ago, because we are continuing our daily battle… and especially in the Emergency Departments, during the winter season, we were attacked, but nobody said that we are heroes" (an Emergency Department Charge Nurse).

Discussion

This study aimed to explore the experiences of the Italian nurses involved in the CV-19 emergency through interviews broadcast on national television. The intention was to collect important messages for the nursing profession immediately, when it was still immersed in the emergency – unstructured and natural comments that provide a 'raw' picture of the way nurses were experiencing the CV-19 pandemic. Analysing the interviews also played another role – exploring how nurses spoke to the population through the media. Appeals ranging from respect for rules, staying away from other people, washing your hands, to hashtags like #*stayathome*, and similar, have crowded the social and mass media channels during this pandemic. Many of these appeals are made by nurses, physicians, and health professionals in general who have seen and often personally experienced the consequences of this virus. The tone and the ways things were being communicated varied, but the key message is always the same: 'stay at home and do not foil our work'. The vivid images that the nurses interview depicted also presented a realistic picture of the risks to life brought by the CV-19 pandemic to a public that – in some instances – did not appreciate the extent of the health threat. The interviews form a sort of appeal to the sense of civic duty, respect for the rules imposed to contain the contagion, and respect for the sacrifices of all those workers who are trying to keep the country going. They also serve to raise the profile of the nursing profession nationally.

The interviews often occurred within a military type discourse – sometimes adopted by the nurses themselves. Newspapers and television often talked about "heroes" and "soldiers at war" in their reporting of the CV-19 pandemic [9]. Perhaps this choice is due to the need to be understood by non-professionals, by those who do not know the everyday life in hospitals. Yet nurses, as well as doctors, have always replied that they are "only" professionals and that they are acting exactly as usual. Perhaps we must seize the opportunity and take advantage of this media attention to get the correct messages across, to make nursing skills known [10]. Among the expressions of gratitude there are also many promises about changing and revaluing the nursing profession in Italy, for which nurses have been waiting a long time. As in the case of the response of the former Italian Prime Minister Giuseppe Conte, during his speech to the Parliament on 25th March 2020, to a letter addressed to him, published on the Facebook profile by a nurse working in the front line caring for CV-19 patients. In her public letter, she commented on the proposal included in the Legislative Decree n. 18 of 17th March 2020 (also known as the "Cure Italy Decree") to give a bonus of €100 to healthcare workers, where she requested genuine respect for the profession to be shown by organizing a meeting with the trade unions to amend the national collective labour agreement. During his speech, the Prime Minister, quoting the nurse's exact words, said that such requests will be remembered to

resolve some issues regarding nurses' organization and wages.

During this pandemic, Italian nurses, as well as those from all over the world, are facing Constant physical and emotional stresses like never: they work in hard and non-ordinary conditions with a different relationship with patients and families due to prevention measures. Nurses had to manage and create new ways of developing relationships with patients and families – using remote technology and message boards for example –. The pandemic has diminished the very workforce required to stem its progress – pushing both staff and healthcare systems to their limits [3, 11]. This has also been exacerbated by staffing issues highlighted before the pandemic [12, 13]. This emergency has made the vulnerability of health professionals visible to all and has perhaps also made the population aware of the responsibility they have in the correct and effective management of the health system. It has also shown how important it is to guarantee nurses and other health professionals the appropriate professional protection, both physical and psychological, through various interventions: establishing specific protocols to reduce the risk of contagion among health workers; providing adequate training; and psychological support, the issue of personal safety came across substantially from the interviews – highlighting resilience and courage, but also the risks nurses were taking [14, 15]. This experience must be considered as a lesson for everyone, not only as regards the more clinical or organizational aspects of the profession [16], but also for the protection of professionals, who will remain marked by this experience and will need prolonged support.

Limitations

As with all studies, this study has its limitations. First, the analysis of interviews broadcast on TV, were conducted by journalists not researchers, pursuing a different intent from ours. Furthermore, the limited period during which we collected the interviews may have missed other discursive themes. In addition, we only collected data from Italian TV – this may not reflect the messages portrayed by nurses in other countries – however, we feel that this study will allow others to make that comparison and extend this kind of study.

Conclusions

This study explored the experience of nurses involved in the CV-19 pandemic through the lens of the mass media. Future studies that directly involve nurses, but also patients and relatives, will be necessary to have a more complete picture of the complexity of the health emergency we are experiencing. In the year dedicated to nursing around the world, no one would have imagined that these would be the terms in which the importance of nurses within the health systems would be discussed. There has been talk of "heroes", but it is perhaps more correct to stop and talk about the professionals who gave everything, even sometimes their own lives in this pandemic, to ensure that their contribution is not wasted. The pandemic has not ended, but there are many lessons that we have already learned from this moment of crisis. One thing that this study underlines is the need to create an open and sincere communication channel with citizens. In Italy, but still in many countries around the world, nurses still struggle to define their role. The CV-19 pandemic has put nurses into the spotlight like never before – they have been able to portray their contribution and professionalism to the public in an unprecedented manner – hopefully this will be a positive outcome from this tragic pandemic. The need to ensure that health care systems are more pandemic ready is also a lesson from the painful stories of inadequate PPE. A key message for management therefore is the need to be prepared in terms of stocks of PPE but also staff training in its use. The strengthening of workplace policies and strategies to both physically and emotionally protect their staff is also essential. Workplace environments need to evaluate and strengthen their systems for providing staff emotional support. This needs to include tong term monitoring of staff stress. The pandemic also required nurses to be resilient, to be able to find new answers to new problems, changing the procedures in which they were competent to ensure that patients obtained the most appropriate care. However, it is imperative that health care organisations review skill mix and staffing numbers to ensure organisational resilience for future pandemic readiness. We also need to investigate whether nurse education programmes contain enough training on disaster or pandemic management – and enhance content accordingly. However, the impact this pandemic has had on nurses and nursing is not yet fully understood but based on the voice of nurses it seems clear that many things can no longer go back to what they were before.

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Conflict of interest statement

The authors declare no conflict of interest.

Authors' contributions

The individual contributions of authors to the manuscript are as follows: MZ, AB, GC, and LS contributed to the conception and the design of this study; ND, GO, GC, and MH contributed to data collection, analysis, and interpretation; MZ, GC, AB, GA, and MH have been involved in drafting, editing and revising critically this manuscript. All authors have read and approved the final manuscript.

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COVID-19

Investigation of a COVID-19 outbreak in a University Cardio-Thoracic Hospital in Cairo: exploration of the risk to healthcare workers and patients

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Keywords

COVID-19 • Outbreak • Healthcare workers • Hospital

Summary

Background. *Corona virus Disease 2019 (COVID-19) pandemic has posed a challenge to health sectors all over the world. The pandemic arrived in Egypt a few weeks after Europe and Asia, with rapidly rising numbers. Health care workers (HCWs) are front liners sustaining a major risk of acquiring the infection.*

Aim. *In this work, we analyse an outbreak of COVID-19 in a University hospital in Cairo involving HCWs of different categories, patients and patients' accompanying relatives.*

Methods. *Following the reporting of the first COVID-19 confirmed case; a 55-year-old nurse at the hospital, a total of 645 healthcare workers, patients and patients' accompanying relatives were tested for SARS-CoV-2 by real-time reverse transcription polymerase chain reaction (rRT-PCR) assay.*

Results. *Twenty-four out of 589 HCWs, 3 out of 42 patient and 4 out of 14 patients' accompanying relatives tested positive for COVID-19. No physicians, pharmacists or technicians were infected. Nursing staff and housekeeping staff were the most at risk of contracting the infection with a risk ratio of 4.99 (95% CI: 1.4-17.6) and 5.08 (95% CI: 1.4-18.4) respectively. Clustering of infected HCWs was observed in paediatrics' ICU and in the 6th floor of the hospital.*

Conclusions. *Nursing and housekeeping staff sustain a significantly higher risk of COVID-19 infection compared to other staff categories. The nature of their duties and the frequent unprotected contact between members of these categories may play a role in increasing their risk.*

Introduction

Several cases of pneumonia of unknown origin were reported on the 31st of December 2019 from Wuhan City in China and a new virus was identified on the 7th of January as the cause. The new virus (Known as SARS COV2) belongs to the same family of severe acute respiratory syndrome (SARS) and Middle East Respiratory Syndrome Coronavirus (MERS-CoV) [1]. By February 11, 2020, the World Health Organization (WHO) officially named the disease resulting from infection with SARS-CoV-2 as coronavirus disease 2019 (COVID-19). COVID-19 represents a spectrum of clinical manifestations that typically include fever, dry cough, and fatigue, often with pulmonary involvement, which progresses in some cases into severe illness and death [1, 2].

COVID-19 was declared a pandemic by the 12th of March 2020 [1]. Several studies have calculated the basic reproduction number R_0; that is used to estimate the average number of secondary cases generated by an infectious case in a fully susceptible population during the early phase of the outbreak. R_0 for COVID-19 was estimated to range between 2 and 3, suggesting the potential of sustained human-to-human transmission [3]. By the first days of April 2020, the total number of reported confirmed cases surpassed one million worldwide with over 47,000 associated deaths [4].

In Africa, the pandemic was delayed for a few weeks behind Europe and Asia, however the number of cases has been rapidly increasing. The small numbers reported initially in Africa may be attributed to a relatively low air travel density in addition to lower coverage with SARS-CoV-2 testing [5-7]. Egypt has reported its first COVID-19 case on February 14th, 2020 and the numbers have been rising ever since. By the first days of April, Egypt has reported more than 1,000 confirmed cases. On the 12th of May, the reported cases reached around 10,000 with more than 500 deaths [8].

Health care providers have been at the frontlines in the battle against COVID-19 and they sustain a major risk of acquiring the infection. There has been wide variation in the rates of infection reported among healthcare workers (HCWs) ranging between 2.1 and 29% [1, 9]. In Italy, as of April 3rd 2020, around 10,000 healthcare workers have been infected [5]. Healthcare workers are particularly vulnerable to infection from 'super-spreading events' of hospital transmission and exposure

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to a higher concentration of the virus from sustained contact in closed settings [3, 9, 10]. Infected healthcare workers also risk spreading the virus to their families and friends, especially those who are elderly or have chronic medical conditions [11].

If HCWs get sick and get out of work, hospital care could collapse, as seen in countries such as Italy and Spain [12]. Here, we describe an outbreak of COVID-19 in a University hospital in Cairo during the first wave of COVID-19 pandemic; which largely involved HCWs in the period from the 10th to the 24th of April 2020. We believe that documenting our experience from the earlier waves can inform healthcare facilities preparedness for the recurrent waves, given the constantly emerging SARS COV2 variants and the relatively slow progress in vaccination coverage in developing countries including Egypt [13-15]. Egypt is currently going through the fourth wave with over 300,000 recorded confirmed cases and over 17,000 recorded deaths [14].

Methods

The first confirmed COVID-19 case detected in Cardio-thoracic academy hospital was a 55-year-old senior female nurse on the 10th of April 2020. Cardio-thoracic academy hospital is a tertiary university hospital 151 beds, two distinct operating theatres, three Intensive care units (ICUs) and one Coronary care unit (CCU).

An outbreak investigation was initiated to trace the source of infection between the 10th and 24th of April 2020. Nasopharyngeal swabs were taken from all 589 health care workers at the hospital, and all 42 inpatients at that time along with 14 patients' accompanying relatives who stayed at the hospital. Nasopharyngeal swabs were tested at Ain Shams University hospitals' laboratory by real-time reverse transcription polymerase chain reaction (rRT-PCR) assay for the qualitative detection of nucleic acid from SARS-CoV-2. The current study protocol aimed to describe the outbreak of SARS-CoV-2 in the hospital without any changes in the policies of the hospital or interventions for the patients. Accordingly, it was exempted from the ethical reviewing. However confidentiality of patient's data was assured together with reporting of the disease to the Ministry of health.

Statistical analysis

Statistical analysis was done using SPSS version 24. Data were presented in frequency and related percentage. Chi square test and Fisher's exact test were used to compare categorical variables. The risk ratio was calculated for the exposed groups with 95% confidence interval. The risk ratio was adjusted for gender using the Mantel Haenzel technique. Significance level was considered at $p < 0.05$.

Results

Between the 10th and the 24th of April 2020, COVID-19 testing was done for 645 subjects distributed as follows: 42 patients and 14 of their relatives who accompanied them at the hospital, 147 of the nursing staff, 61 physicians, 6 pharmacists, 14 technicians, 118 housekeepers, 197 administrative officials and 43 security officers. A total of 31 COVID-19 cases were confirmed: 3 Patients and 4 of the patients' accompanying relatives in addition to 24 HCWs. Table I shows the distribution of confirmed COVID-19 cases across the hospital.

Tab. I. Cardio-thoracic hospital floors and number of cases in each floor.

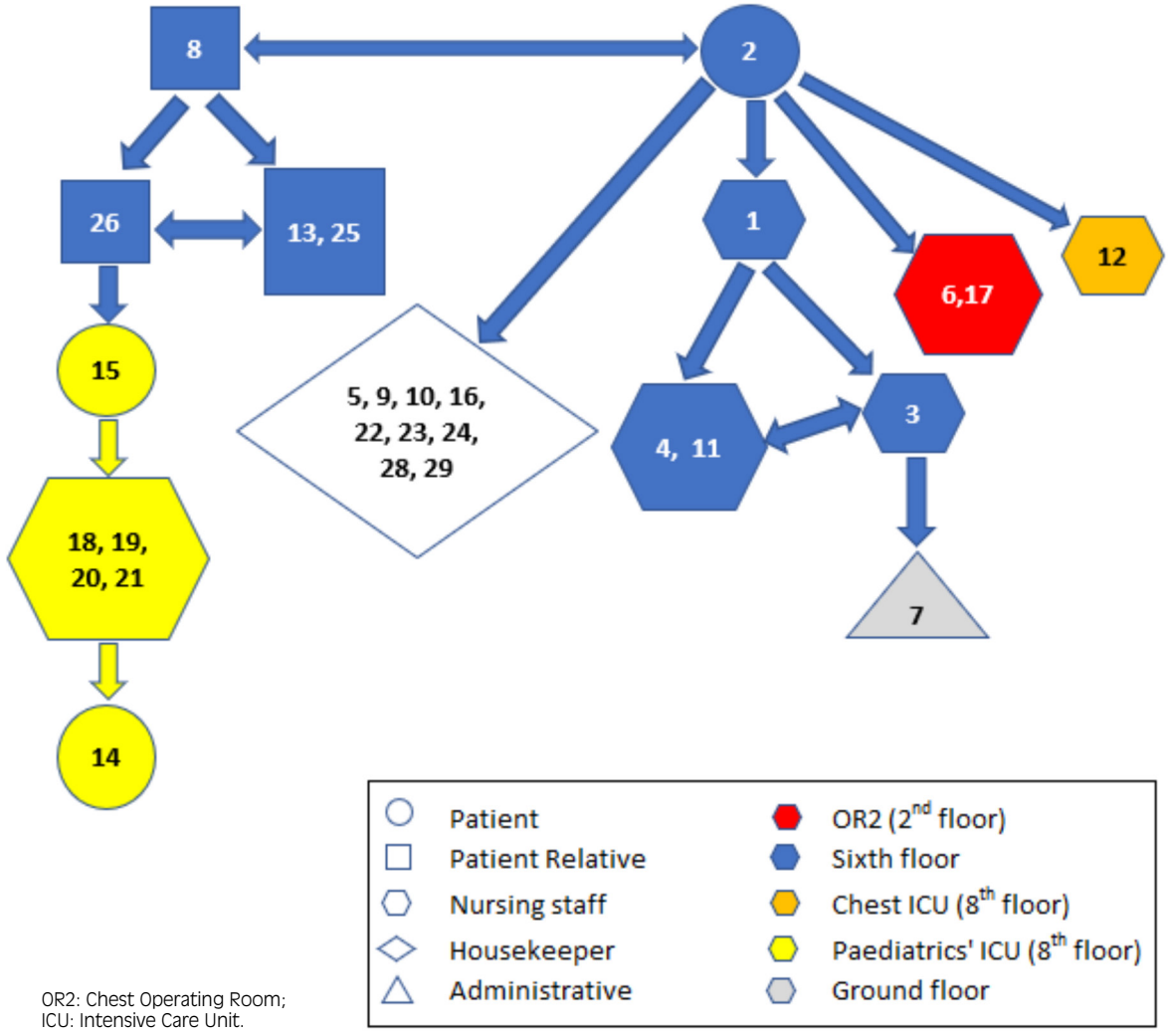
Floor	Departments/wards	Number of cases*
8th floor	Adult ICU Chest ICU (nurse) Pediatric ICU (2 patients and 4 nurses)	- • ••••••
7th floor	Private inpatient rooms (single rooms) Housekeepers	• •
6th floor	Double or triple inpatient rooms (index case) One room for accompanying family members Nursing staff office Housekeepers	• •••• •••• ••••
4th floor	Under renovation	-
5th floor	Under renovation	-
3rd floor	Central Sterile Supply Department (CSSD)	-
2nd floor	Coronary Care Unit (CCU) Cardiac Catheterization Lab Cardiac Operating Room OR1 Chest Operating Room OR2 (two nurses) Housekeepers	- - - •• •
1st floor	Lecture halls (the lectures were suspended)	
Ground floor	Administrative offices Outpatient Emergency Room	••• - -
Under ground	Kitchen Laundry	• -

* Three infected housekeepers who work on night shift moved across the Cardio-Thoracic hospital floors,

Description of the outbreak

On the 10th of April 2020, a senior nurse, 55 years old (denoted by number 1 in Fig. 1), started to complain of fever, severe malaise and minor cough. She tested positive for SARS-COV-2 by rRT-PCR. She had no contact with known cases of COVID-19. At that time, contact tracing was the strategy applied by Egyptian Ministry of Health. The Hospital administration started to test all patients and health care workers working in the hospital. One female patient (the suspected index case; denoted by number 2 in Fig. 1) was found positive. This patient had chylous pericardial effusion. She was admitted on February 17th, 2020 and was discharged on April 13th, 2020. She had received care in several areas in the hospital (Operation theatre, Chest ICU and inpatient ward). Figure 1 shows the proposed transmission map of COVID-19 outbreak in the hospital.

Fig. 1. Transmission Map of infected subjects during the COVID-19 outbreak in Cardio-Thoracic hospital. Numbers indicate the order of receiving laboratory confirmatory test results. Numbers are not necessarily associated with the date of infection or the appearance of symptoms.



OR2: Chest Operating Room; ICU: Intensive Care Unit.

Sixth floor for inpatient rooms

As seen in Table I, the sixth floor includes inpatient rooms with multiple beds. The suspected index case was admitted in one of these rooms. One or more nurses were infected during contact with the index patient. It is quite noticeable that four nurses acquired the infection and none of the patients in the same floor were infected although they were cared for by some of the infected nurses.

There is one small poorly ventilated office for nursing staff where they usually assemble. Nurses usually wear masks or other protective equipment when providing patient care, but they are not keen on following this practice when in contact with each other.

The mother of the assumed index case (denoted by number 8 in Figure 1 who accompanied her at the hospital also tested positive. She stayed together with nine other patients' relatives in one room in the sixth floor assigned for family members of child patients in the ICU who accompany the patients during their hospital stay. They used to gather in it where they shared meals and food utensils. Four out of ten of patient relatives in that room tested positive.

Chest Operation Room and Chest ICU

Two nurses from the chest operation suite and one nurse from the chest ICU were infected. They were probably infected during contact with the suspected index case that received care in these areas.

Paediatric ICU

The paediatrics ICU is intended for care of post-operative paediatric cardiac patients. Two patients in paediatrics ICU tested positive. The mothers of three children, who stayed in the sixth floor were infected. One infected child (denoted by number 15 in Fig. 1) had a COVID-19 positive mother (denoted by number 26 in Fig. 1). The second child (number 14 in Fig. 1) probably contracted the infection from infected nurses.

Four nurses in the paediatrics ICU were infected. They may have transmitted the infection to each other or have been infected while caring for the first infected child (denoted by number 15 in Fig. 1). Nursing care for children in paediatric ICU is different from care in the regular inpatient ward, as it involves closer contact with

Tab. II. Incidence of infection during the hospital COVID-19 outbreak.

	No. screened	Infected	Risk ratio	
		No. (%)	RR (95% CI)	
Total subjects	645	31 (4.8)		
Age				
< 20	15	2 (13.3)	4.6 (0.9-25.3)	
20-< 30	150	9 (5.6)	1.9 (0.7-5.5)	
30-< 40	187	6 (3.2)	1	
≥ 40	283	14 (4.9)	1.6 (0.6-4.2)	
Gender				
Male	363	10 (2.8)	1	
Female	282	21 (7.4)	2.7 (1.3-5.6)	
Screened hospital groups				
Patients	41[a]	2 (4.9)	4.4 (0.7-27.3)	
Family members*	14	4 (28.3)		
Healthcare workers				
Nursing staff	147	11 (7.5)	6.98 (1.9-25.5)	4.99 (1.4-17.6)[c]
Housekeepers	118	9 (7.6)	7.1 (1.89-26.8)	5.08 (1.4-18.4)[c]
Physicians	61	0	-	
Other workers[b]	262	3 (1.15)	1	

[a] The index case removed from the calculation; [b] One case (the husband of an infected nurse) was removed from the calculation; [c] adjusted RR for gender; * This group has peculiar situation of close contact and thus was not compared with other groups.

patients and frequent performance of Aerosol generating procedures (AGPs) such as suction and ventilation.

Housekeepers

The incidence of infection in the housekeeping workers was 7.6%. During investigating this outbreak, we found that housekeepers gather frequently for example, during mealtimes. During these gatherings, housekeepers didn't wear masks or practice social distancing.

Other infected HCWs

There were no infections among physicians or pharmacists. Four infections were detected among other non-clinical health care workers. One administrative worker (denoted by number 7 in Fig. 1) contracted the infection from his wife, a nurse working in the sixth floor (denoted by number 3 in Fig. 1). The acquired infection in the other three non-clinical workers; namely one security personnel, one kitchen worker and a medical equipment engineer could not be tracked to a hospital source of infection.

None of the infected subjects died except the 2 paediatric cases in the ICU; probably as a result of their primary conditions.

Table II shows that young age was associated with higher risk of infection. This finding is probably specific to our hospital where vulnerable paediatric patients with underlying cardio-thoracic conditions are admitted. Our investigation also shows that women are twice as likely to get infected compared to men. This may be attributed to the type of exposure female nurses and female relatives are subjected to during caring for patients or coming in contact with each other.

The risk ratio of acquiring the infection among the nursing staff and housekeepers was almost seven times that of non-clinical hospital workers. The risk was still statistically significant after adjusting for gender (Tab II).

Discussion

The described outbreak occurred at the time when the number of confirmed COVID-19 cases announced by the Egyptian Ministry of Health (MOH) was substantially low making community transmission less likely [16].

Infection of HCWs during care of COVID-19 patients has been documented in previous studies. In a study in the USA, 35.5% of HCWs who have been exposed to a single infected patient, in one hospital, developed symptoms [9]. Foci of SARS-COV-2 infections in the hospital, especially in undetected or asymptomatic cases, pose a potential risk for healthcare workers and other hospitalized patients as well.

Our investigation has shown that nursing staff and housekeepers sustained the highest risk of infection. It is well established that the risk of HCWs infection can be reduced by adherence to infection control precautions within health facilities. Essentially, the use of personal protective equipment (PPE) including gowns, gloves, facemasks, and a face shields or goggles especially when performing AGPs [17]. If they are made available, the proper use of PPE requires training and supervision, especially at the wake of an epidemic when healthcare workers may not have be familiar with intensive use of PPE [18].

Nurses and housekeepers are assumed to be aware of the importance of PPE and trained to wear them. We could question whether they were adequately protected. Also, It is well known that PPE resources are scarce in the first place, and given the current pandemic both high-income

and low-income countries are witnessing shortages [19]. HCWs don't only communicate with infected patients and contaminated patients' surroundings, but they also communicate with each other. We have observed in our investigation that nurses in the 6th floor (where four of them have been infected), stayed in a small poorly ventilated office. Nurses spent a long time in that room together without wearing PPE. They also shared meals and utensils and did not practice proper social distancing. One study showed that clinical healthcare workers dealing directly with patients, like doctors and nurses, perceive that the main mode of acquiring COVID-19 infection is through inadequate protection when working at a close distance with infected case [20]. This may draw the belief that healthcare workers in our hospital considered infected patient as the main source of infection but were less cautious, if at all, when dealing with each other. Prolonged unprotected exposure between HCWs who stay in such proximity, carries a risk of rapid and widespread transmission among hospital staff. In addition to wearing PPE at all times, HCWs should also adhere to cough etiquette and hand washing and should maintain at least two meters distance from others [5]. At the time of this investigation, the recommendations were that HCWs who have an unprotected exposure to an infected person were advised to remain in quarantine for 14 days since last exposure [17]. If several HCWs were exposed at once and had to be quarantined, this could have resulted in hospital care collapse.

In this investigation we found that the incidence of acquired SARS-CoV-2 among hospital cleaning staff was comparable to that observed among the nursing staff. This would highlight the significant risk of COVID-19 transmission in this, often neglected, category of hospital workers. Most infection control guidelines published during this COVID-19 pandemic realized this risk and recommended the necessary PPE use [21, 22]. It is possible that transmission of infection among housekeepers has been associated with hospital environmental exposures – as cleaning and handling waste without proper PPE use – or through incautious behaviour when housekeeping staff came together. So, this category of healthcare workers needs continuing supply of PPE as well as focused repeated infection control training and supervision.

Two child patients contracted the infection postoperatively in the paediatrics ICU during this hospital outbreak. Unfortunately, these two patients had high probability of dying as a result of their underlying cardiac conditions; which eventually occurred. Critical illness and childhood age were found to be risk factors for acquiring COVID-19 infection in our hospital [23]. On the other hand, it appears that ICU patients are an important source of infection to HCWs especially nursing staff. This is expected given the fact that nurses perform more frequent AGPs to ICU patients [17, 18].

Another category that took on special importance in the context of this COVID-19 hospital outbreak is the patients' family companions. Four out of fourteen family companions have been infected. Family companions posed risk to each other since they stayed in the same room, without any form of PPE or any concept of social distancing. Also, these family companions could have posed a risk to the patients they tended to, to the HCWs and to their own families when they return home. The policy of allowing a family companion inside the hospital may need to be restricted throughout the COVID-19 pandemic. If allowed to stay, the numbers of companions in the one room available at the hospital may need to be reduced. Family companions allowed to stay need to receive clear instructions on how to prevent COVID-19 transmission inside the hospital.

The non-medical administrative staff seems to be at risk of infection, although we couldn't trace a hospital source of infection except for one of them: the husband of an infected nurse. This raises concerns about HCWs carrying the infection to their family members at home.

In conclusion, nursing and housekeeping staff in our hospital sustained a significantly higher risk of COVID-19 infection compared to other staff categories. The nature of their duties and the frequent interaction between members of these categories may play a role in increasing their risk. Reducing unprotected contact between hospital staff members and emphasising the use of PPE and adherence to infection control practices at all times is essential to prevent future hospital COVID-19 outbreaks Since family companions also appear to be especially at risk, permission for their stay in the hospital should be restricted.

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The authors declare no conflict of interest.

Authors' contributions

Samia A Girgis: Conception and design of the study, Head of outbreak investigation team, Acquisition of data
Moshira Halim: Conception and design of the study, member of outbreak investigation team, Acquisition of data.
Ihab S Habil: Conception and design of the study, Data management, Data analysis and interpretation, Drafting the article.
Wafaa M. Hussein: Data management, Drafting the article
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Ahmed Abdel-Aziz: Overseeing administrative approvals for the study, Field preparation for the outbreak investigation, Critical revision of the article.
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administrative approvals for the study, Critical revision of the article and final approval.
Mahmoud El-Meteini: Overseeing administrative approvals for the study, Critical revision of the article and final approval of the submitted version.

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COVID-19

Risk factors for COVID-19 severity and mortality among inpatients in Southern Iran

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Keywords

COVID-19 • Mortality • Severity • Risk factors • Case fatality rate • Inpatients

Summary

Introduction. *COVID-19 is a highly contagious respiratory disease and many factors can affect its severity and mortality. This study aimed to investigate the risk factors associated with the severity and mortality of COVID-19.*

Methods. *In this cross-sectional study, 311 cases with COVID-19 approved by the CORONALAB database in the Center for Disease Control and Prevention (CDC) in southern Iran were selected using systematic random sampling from 15 May to 13 June 2020. The data were collected through interviews and phone calls using a researcher-made questionnaire.*

Results. *The mean age of the participants was 45.82 ± 17.92 years, and the male to female ratio was 1.57:1. In addition, the Case Fatality Rate (CFR) was 4.50%, and the disease was severe in 47.5% of the cases. The most common clinical symptoms were cough (39.22%), fever (31.83%), and dyspnea (24.76%). The severity of COVID-19 was significantly associated with age and history of Cardiovascular Disease (CVD). Besides, the mortality of COVID-19 was significantly related to age, gender, hypertension, CVD, and Chronic Kidney Disease (CKD). The mean interval between the onset of the first symptom and referral to a health center was 3.02 ± 2.82 days. Additionally, the mean interval between the referral to health centers and testing was 0.88 ± 2.20 days.*

Conclusion. *Older patients, males, and those who had CVD, CKD, and hypertension required accurate healthcare and early intervention to prevent the exacerbation of COVID-19. Furthermore, the interval between the onset of the first symptom and testing was relatively long. Overall, early diagnosis, isolation, and treatment of patients were found to be essential to control COVID-19.*

Introduction

Coronavirus 2019 (COVID-19) is highly contagious and spreads rapidly from one individual to another [1]. This disease has become a global concern and an important health problem, as the number of infected people and affected countries has been increasing rapidly [2]. The dramatic increase in the number of severe infections in Acute Coronavirus Respiratory Syndrome 2 (SARS-CoV-2) has led to "an urgent need to expand public health activities to clarify the epidemiological characteristics of this new virus and to identify its potential effects" [3]. Given the fact that the mortality rate of COVID-19 is about 3% and more than 20% of patients develop a severe disease, COVID-19 has been considered a global health emergency [4].

This disease is highly contagious and each infected person can infect at least three other people on the average [5]. Most cases have mild symptoms such as fever, cough, sore throat, and myalgia. However, some cases experience severe conditions such as multiple organ involvement, acute respiratory syndrome, pulmonary edema, and pneumonia [6-8]. Due to the transmission of COVID-19 from person to person, the virus can be transmitted to other susceptible people from the cases who have not been undiagnosed or were not diagnosed soon, which increases the risk of the transmission of COVID-19 infection.

There is currently no evidence of Randomized Controlled Trials (RCTs) recommending any specific anti-SARS-CoV-2 treatment for patients with COVID-19 infection. Hence, rapid and accurate diagnosis of COVID-19 is very important to control its prevalence in the community and hospitals [9]. Yet, it is not easy to diagnose COVID-19 and the delay between the onset of symptoms and accurate diagnosis has been frequently observed. Except for confirmed cases of pneumonia, there are still many undiagnosed infections and delayed diagnoses due to the lack of diagnostic reagents as well as long waiting times for diagnosis [10]. Therefore, it is very important to be able to diagnose and treat the infection in a timely manner. Different studies have shown that the progression or mortality of COVID-19 could be affected by various factors including old age, male gender, history of diabetes, hypertension, CVD, and kidney disease [11-13]. Moreover, the mortality rate of COVID-19 varied between the patients admitted in Intensive Care Units (ICU) and non-ICU patients as well as between severe and non-severe cases. Accordingly, the mortality rate was

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higher among the patients admitted to ICUs and severe cases compared to non-ICU and non-severe ones [14, 15]. Since the severity and mortality of COVID-19 disease can be affected by various factors, the present study aims to investigate the risk factors associated with the severity and mortality of COVID-19 with regard to the time interval between the onset of the first symptom and referring to health centers for testing.

Methods

Study design and data collection

The Center for Disease Control and Prevention (CDC) for COVID-19 was established in Fars province on February 20, 2020 to monitor the spread of COVID-19. Fars province is the fourth most populous province in Iran, with Shiraz as its capital, that is located in south of the country. In this study, 311 COVID-19 cases approved by the CORONALAB database at the CDC of Shiraz University of Medical Sciences were selected using systematic random sampling from 15 May to 13 June 2020. Diagnosis of COVID-19 for the suspected cases was confirmed using throat and nose samples and Real-Time Polymerase Chain Reaction (RT-PCR) test.

The data were collected using a researcher-made questionnaire. The reliability of the questionnaire was evaluated among 25 individuals via the test-retest method with a two-week interval. The intra-cluster correlation coefficient was 0.79, revealing the acceptable reliability of the questionnaire.

During active care, the patients received a phone call at home or were visited in the hospital. Then, their information was collected and completed via interviews. The history of diseases and medical records were checked for hospitalized patients. The patients who were isolated at home were called, as well. In case they mentioned the history of diseases, they were asked to refer to the health centers with their medical records for further examinations after the isolation period.

The demographic characteristics of all the cases were recorded, which included age, gender, occupation, disease severity, patient care status, symptoms (fever, cough, shortness of breath, cyanosis, gastrointestinal problems, sore throat, and runny nose), comorbidities (diabetes, hypertension, cancer, CVD, and CKD), history of physical contact with patients, time of onset of the first symptom, and time of referring to health centers and testing. The patients were divided into severe and non-severe groups according to the severity of their disease and the American Thoracic Society guidelines for community-acquired pneumonia [16, 17].

Statistical analysis

Relative and absolute frequencies were calculated for grouping the variables. Mean and standard deviation were calculated for quantitative variables. The relationships between the qualitative variables were determined by chi-square test. In addition, the interval between the onset of the first symptom and referral to health centers, the interval between referral to health centers and testing, and the interval between the onset of the first symptom and testing were calculated and their relationships with gender, disease severity, and mortality were assessed using t-test. The significance level was set at 0.05.

Results

The mean age of the cases was 45.82 ± 17.92 years. The youngest case was one year old and the oldest case was 87 years old. Most cases (49.02%) belonged to ≤ 45 age group. In addition, 61.09% of the cases were male, with the male to female ratio of 1.57:1.98. Besides, 39% of the cases were Iranian, and 9.65% were healthcare personnel. Moreover, 47.5% of the cases had severe disease and were admitted to the ICU. The most common clinical symptoms included cough (39.23%), fever (31.83%), and dyspnea (24.76%). The mortality rate was 4.50%. Furthermore, 15.76% of the patients had a history of physical contact with an infected person, 7.72% had diabetes, 6.75% had CVD, and 5.47% had hypertension.

The results showed a statistically significant relationship between the severity of COVID-19 and age ($p = 0.017$) and CVD ($p = 0.021$). There was also a statistically significant relationship between the mortality of COVID-19 and gender ($p = 0.046$), age ($p = 0.001$), hypertension ($p = 0.034$), CVD ($p = 0.01$), and CKD ($p = 0.002$). Cough was the prognostic factor for the severity of COVID-19, but had no significant relationship with mortality. The results also revealed no statistically significant relationship between nationality and occupation and COVID-19 severity and mortality ($p > 0.05$) (Tab. I).

The interval between the onset of the first symptom and referral to health centers and testing based on gender, disease severity, and mortality of COVID-19 has been presented in Table II. Accordingly, the mean interval between the onset of the first symptom and referral to health centers was 3.02 ± 2.82 days (range: 0-12 days), the mean interval between referral to health centers and testing was 0.88 ± 2.20 days (range: 0-12 days), and the mean interval between the onset of the first symptom and testing was 3.90 ± 3.55 days (range: 0-18 days). The results indicated a statistically significant relationship between the interval between the onset of the first symptom and testing and the mortality of COVID-19 ($p < 0.001$). The mean interval between the onset of the first symptom and testing was longer in the cases who were still alive than in the dead cases (3.99 ± 3.55 *vs* 0.63 ± 1.18).

Discussion

This study was conducted on 311 cases with COVID-19 approved by the CORONA database in southern Iran in order to determine the risk factors of COVID-19 severity and mortality. The results showed a statistically significant relationship between the severity of COVID-19 and age

Tab. I. Demographic and clinical characteristics of the COVID-19 cases.

		Disease severity			Disease mortality		
Variables	Total n = 311	Non-severe n = 294	Severe n = 17	P-value*	Alive n = 297	Dead n = 14	P-value*
Gender							
Male	190 (61.09)	179 (94.21)	11 (5.79)	0.753	185 (97.37)	5 (2.63)	0.046
Female	121 (38.91)	115 (95.04)	6 (4.96)		112 (92.56)	9 (7.44)	
Age (years)							
< 25	26 (8.36)	25 (96.15)	1 (3.85)		26 (100)	0 (0)	
25-44	132 (42.44)	130 (98.48)	2 (1.52)	0.017	132 (100)	0 (0)	0.001
≥ 45	153 (49.20)	139 (90.85)	14 (9.15)		139 (90.85)	14 (9.15)	
Occupation							
Healthcare worker	30 (9.65)	30 (100)	0 (0)	0.388	29 (96.67)	1 (3.33)	1
Non-healthcare worker	281 (90.35)	264 (93.95)	17 (6.05)		268 (95.37)	13 (4.63)	
Nationality							
Iranian	306 (98.39)	289 (94.44)	17 (5.56)	1	292 (95.42)	14 (4.58)	1
Non-Iranian	5 (1.61)	5 (100)	0 (0)		5 (100)	0 (0)	
Signs and symptoms**							
Cough	122 (39.23)	111 (90.98)	11 (9.02)	0.027	116 (95.08)	6 (4.92)	0.776
Fever > 38	99 (31.83)	95 (95.96)	4 (4.04)	0.450	96 (96.97)	3 (3.03)	0.560
Sore throat	61 (19.61)	60 (98.36)	1 (1.64)	0.211	59 (96.72)	2 (3.28)	1
Dyspnea	77 (24.76)	70 (90.91)	7 (9.09)	0.144	74 (96.10)	3 (3.90)	1
Gastrointestinal problems	37 (11.90)	35 (94.59)	2 (5.41)	1	37 (100)	0 (0)	0.388
Rhinorrhea	18 (5.79)	17 (94.44)	1 (5.56)	1	18 (100)	0 (0)	1
Cyanosis	4 (1.29)	4 (100)	0 (0)	1	4 (100)	0 (0)	1
Other	7 (2.25)	7 (100)	0 (0)	1	7 (100)	0 (0)	1
History of contact with infected cases (yes)	49 (15.76)	48 (97.96)	1 (2.04)	0.684	48 (97.96)	1 (2.04)	0.293
Medical history							
Diabetes	24 (7.72)	22 (91.67)	2 (8.33)	0.630	21 (87.50)	3 (12.50)	0.084
Hypertension	17 (5.47)	15 (88.24)	2 (11.76)	0.236	14 (82.35)	3 (17.65)	0.034
Cardiovascular disease	21 (6.75)	17 (80.95)	4 (19.05)	0.021	17 (80.95)	4 (19.05)	0.010
Chronic kidney disease	7 (2.25)	5 (71.43)	2 (28.57)	0.050	4 (57.14)	3 (42.86)	0.002
Cancer	3 (0.96)	3 (100)	0 (0)	1	3 (100)	0 (0)	1
Other diseases**	12 (3.86)	8 (66.67)	4 (33.33)	0.002	8 (66.67)	4 (33.33)	0.001

* Chi-square test; ** Other diseases included psychiatric diseases, cerebral palsy, rheumatoid arthritis, neurodegenerative diseases, stroke, etc.

Tab. II. The interval between the onset of the first symptom and testing for COVID-19 detection.

		Gender			Disease severity			Disease mortality		
Interval (day)	Total	Male	Female	P -value*	Non-severe	Severe	P -value*	Alive	Dead	P -value*
The first symptom to admission (μ ± SD)	3.02 ± 2.82	2.99 ± 2.81	3.06 ± 2.83	0.845	3.03 ± 2.79	2.73 ± 3.52	0.726	3.02 ± 2.83	3 ± 2.20	0.984
Admission to testing (μ ± SD)	0.88 ± 2.20	0.87 ± 2.24	0.90 ± 2.16	0.923	0.90 ± 2.23	0.36 ± 1.21	0.429	0.84 ± 2.18	2.63 ± 2.44	0.078
The first symptom to testing (μ ± SD)	3.90 ± 3.55	3.88 ± 3.49	3.93 ± 3.65	0.897	3.93 ± 3.55	3.09 ± 3.65	0.443	3.99 ± 3.55	0.63 ± 1.18	< 0.001

* T-test.

and CVD. In addition, the mortality of COVID-19 was significantly related to gender, age, hypertension, CVD, and CKD. The interval between the onset of symptoms and referral to health centers and testing was also assessed in the present study. The results demonstrated that COVID-19 mortality was significantly related to the interval between the onset of the first symptom and testing.

In the present study, the mean age of the cases was 45.82 ± 17.92 years. In another study, the mean age of the cases was 55.50 ± 15.15 years [18], which was higher

compared to the present study. In addition, the male to female ratio was 1.57:1, but this measure was found to be 1.93:1 and 1.6:1 in the studies conducted in Tehran and Shiraz, respectively [17, 18].

In the current investigation, 5.47% of the cases had the severe form of the disease. In another study, approximately 14% of the people infected with COVID-19 had severe disease and 6% had very severe disease [19]. In the current study, severe cases included those admitted to the ICU. Furthermore, 9.65% of the cases were healthcare personnel, while this measure was found to be 2.8% in another research [17].

The current study findings revealed that the Case Fatality Rate (CFR) was 4.50% in all the cases and 35.29% in severe ones. The results of a systematic review and meta-analysis indicated that CFR was 13% in hospitalized cases [6]. In other studies conducted in Iran, CFR was reported to be 8.06 and 55.6% in hospitalized patients [17, 18]. This measure was found to be 15 and 11% in China [7, 20]. Overall, the CFR was lower in the present study than in other studies, which might be due to the prompt and timely treatment of severe COVID-19 cases.

The present study findings revealed a significant relationship between age and COVID-19 severity and mortality. Accordingly, COVID-19 was more severe and resulted in higher mortality in older ages. Other studies have also shown a higher risk of mortality in older ages [18, 21]. The reasons for the higher severity and mortality of COVID-19 at older ages could be the higher prevalence of comorbidities in this age group. It has also been stated that old age was associated with the decreased immune system capacity [22].

The present study findings demonstrated a significant relationship between gender and COVID-19 mortality ($p = 0.046$). Based on the results, nearly 35% of the severe cases and 63% of the dead ones were female. However, other studies indicated that the mortality rate was higher in males than in females [17, 18, 23]. In a prior research, estrogen protected against such pathogens as HIV, hepatitis C virus, Ebola, and human cytomegalovirus in females [24]. Estrogen receptor signaling also played an essential role in coronavirus infection and mortality [25]. Another study demonstrated that estrogen signaling could be one of the reasons for the rapid recuperation and low mortality due to COVID-19 amongst females [26]. The discrepancy between the results might be associated with the comorbidities or higher age of the females suffering from COVID-19 in the present study.

The current study results showed that the severity of COVID-19 was significantly associated with CVD and its mortality was correlated to hypertension, CVD, and CKD. The results of a meta-analysis also revealed that the mortality of COVID-19 was higher in patients with CVD and CKD [27]. Countries with the highest mortality rates such as the United States, Europe, and China have been shown to have the highest incidence of these chronic diseases [28]. The results of another study proved that hypertension increased the risk of severity or mortality of COVID-19 by almost 2.5 times [29]. Moreover, the risk of developing severe COVID-19 was three times higher in the CKD patients than in those without CKD. The suppressed immune system might significantly predispose CKD patients to infectious complications. Likewise, having a chronic systemic inflammation could increase their mortality [30]. In addition to the explored variables, a high genetic burden was strongly related to the severity and hospitalization risk of COVID-19, particularly amongst people with few recognized risk factors [31].

In the present study, cough (39.23%) was the most common clinical symptom as well as a prognostic factor for the disease severity ($p = 0.027$). Similarly, other studies indicated that cough was a common clinical symptom of COVID-19 [8, 32, 33]. Another research also revealed that cough was associated with the severity of COVID-19 [32, 34], which was in agreement with the current study findings [8, 33].

The results of the present investigation showed that the mean interval between the onset of the first symptom and referral to health centers was 3.02 ± 2.82 days, the mean interval between referral to the health centers and testing was 0.88 ± 2.20 days, and the mean interval between the onset of the first symptom and testing was 3.90 ± 3.55 days. There was a statistically significant relationship between the interval between the onset of the first symptom and testing and the mortality of COVID-19 ($p < 0.001$). Accordingly, the mean interval between the onset of the first symptom and testing was longer in the alive cases than in the dead ones (3.99 ± 3.55 *vs* 0.63 ± 1.18 days). In fact, the patients who died had more severe symptoms at the onset of the disease and, consequently, they had referred to health centers for treatment earlier, while it took longer to take the test from the patients who did not have severe symptoms. Since the people who are asymptomatic or have mild symptoms are still able to transmit the disease, it is necessary to examine all the patients immediately after their referral to health centers. Due to the fact that the mean interval between the onset of the first symptom and referral to health centers and testing was relatively long, there is a need for public education and raising public awareness about the symptoms of COVID-19 and referral to health centers for testing as soon as possible.

One of the strong points of the present research was that it evaluated the relationship between the severity and mortality of COVID-19 and the interval between the onset of the first symptom and referral to health centers, interval between referral to health centers and testing, and interval between the onset of the first symptom and testing. However, one of the limitations of the study was that the patients' biochemical test results and lung CT scans were not available. Therefore, further studies are required to consider other risk factors such as laboratory and radiological markers in addition to demographic and clinical factors. Moreover, the researchers did not have access to the patients' complete information about the history of diseases such as diabetes (HbA1c, controlled or not), cancer status (current or past, type of cancer, stage, and course of therapy), and CKD stages. Another study limitation was related to the interview method. In fact, the history of diseases and medical records were checked for the hospitalized patients, while phone calls

were made to contact the patients who were isolated at home. In case they mentioned the history of diseases, they were asked to refer to the health centers with their medical records for further examinations.

Conclusions

Old age and CVD were associated with the severity of the disease in patients with COVID-19. Therefore, these patients required accurate healthcare as well as early intervention to prevent the exacerbation of the disease. Moreover, older age, female gender, and having a history of hypertension, CVD, and CKD might increase the risk of COVID-19 mortality. Since the interval between the onset of the first symptom and testing was relatively long, it is essential to make a timely diagnosis, stay in quarantine, and treat the patients as soon as possible to control COVID-19. Future studies are suggested to evaluate the predictors of COVID-19 severity and mortality based on the risk factors revealed in the present research.

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Conflict of interest statement

The authors declare no conflict of interest.

Authors' contributions

All authors contributed to the study conception and design. AMA and HG participated in the design of the study. MGG and FR performed data collection, wrote the manuscript, helped with statistical analysis, and prepared the illustrations. AH and FR edited the manuscript. All authors read and approved the final manuscript.

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COVID-19

Self-management of patients with chronic diseases during COVID19: a narrative review

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Keywords

Self-management • Chronic diseases • COVID-19

Summary

Introduction. *COVID-19 pandemic has affected the self-management of patients with chronic disease all over the world. The present study COVID-19 is a review to investigate the chronic patient self-management challenges during the corona epidemic, and providing solutions to solve this problem.*
Methods. *The relevant literature on chronic patient self-management is investigated (from March 2019 to Jan 2021). Databases including Google Scholar, PubMed, Science Direct, Springer were used to search articles from the Latin articles. Also, keywords in this study included self-management, chronic disease, COVID-19. Finally, 26 relevant articles were used in this study.*
Results. *Studies assessed the effective role of self-management in control and prevention of complications of chronic diseases and the challenges related to self-management programs during COVID-19, in addition the role of the health team in patients' self-management during the corona epidemics.*
Conclusion. *the main challenges for chronic patients during the COVID-19 include decreased healthcare service and regular follow-ups because of physical restrictions; economic problems, change in lifestyle, and lack of rapid compliance with the changes. In this regard, the health team should provide the best healthcare services using the available resources to reduce suffer and pain of the patients.*

Introduction

On 11 March 2020, the World Health Organization (WHO) announced the COVID-19 disease as a pandemic. The disease has caused a high mortality rate across the world to date. In the meantime, the risk of morbidity and mortality due to the COVID-19 is high in people with chronic diseases such as diabetes, hypertension, cardiovascular diseases, chronic obstructive pulmonary disease, and weakened immune system compared to the normal population [1-5]. Many efforts have been taken to produce the vaccine and definite treatment of the COVID pandemic in the world. These efforts have led to restricted access to the vaccine. According to academic evidence, specific drugs for COVID are not available. Hence, the best option here is trying to use preventive methods and to take self-management behaviors in chronic patients [1, 6]. According to the declaration of the WHO, 35% of women and 29% of men suffer from chronic diseases such as cardiovascular diseases, chronic pulmonary diseases, or diabetes. Such prevalence of chronic diseases has left abundant negative effects on the workforce of different countries. Self-management is very important to save resources and improve the ability of patients. The results of interventions under the title of Chronic Disease Self-Management Program (CDSMP) made by the Stanford University of America in this country and more than 20 other countries (Canada, Australia, Argentina, England, Denmark, Spain, Coast Arica, and China) 40 years ago show that included individuals have acted successfully in the field of self-management of health [7].

The implementation of health instructions and protocols, such as social distancing and quarantine for reducing the spread of COVID-19 disease and transmission between carriers and healthy individuals has disrupted the treatment and self-management process of chronic patients. For example, the implementation of social distancing and quarantine has result in a significant reduction in regular visits of a patient with specialists to check their health status. Also, the pharmaceutical reserves have been decreased in some regions because of the closure of drug production plants. On the other hand, many patients have lost their insurance coverage because of unemployment caused by the corona pandemic and have encountered problems with treatment costs [8, 9]. Besides, as the sources, equipment, and healthcare forces of states to control the COVID-19 pandemic, the chronic patients have trouble in access to healthcare services [10-12].

Health service providers are vital elements of societies, the health, and security of whom are significant not only for the continuous care of patients but also to control the prevalence of diseases. For example, the description presented by the health service providers of China based on their face-to-face experience on fighting COVID-19 was a responsibility to reduce pain and suffer from the patients and common effort to protect the country against the virus. This is because they believed in this sentence "everyone is responsible for the advent or collapse of

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his-her country". Health service providers play a key role in the treatment of COVID-19 patients. The majority of these healthcare providers have little clinical experience working in the units of special infectious diseases. However, when healthcare systems are not ready to fight infectious disease, the health service providers help the system by gaining knowledge and skill and improving their communications in intensive training courses by accepting the risks and injuries caused by this disease. Health service providers need continuous medical training to cope with emergencies and to become ready under conditions like the corona pandemic. Healthcare systems must seek inter-professional, and inter-organizational cooperation to provide high-quality and efficient care because of the variety of organizational culture [13-17].
We aimed to assess the global impact of COVID-19 on self-management in chronic diseases and its challenges and evaluate the role of health care workers to support and improve patient care.

Method

Search strategy

This study is a narrative review conducted in 2019-2020. This study is focused on relevant works of chronic patient self-management during the corona pandemic from March 2019 to Jan 2021. To search Latin articles, databases including Google Scholar, PubMed, Science Direct, and Springer were used. The search strategy consisted of the combination of the following Boolean keywords and operators: (COVID-19 OR "Coronavirus 2" AND "chronic disease" OR "chronic condition" AND ("self-management"). Figure 1 shows the flowchart relating to the process of finding and selecting the studies included in this narrative.

Eligibility criteria

The articles were used in the study based on inclusion criteria including being relevant to the research objective, using structures framework including keywords including self-management, chronic disease, and COVID-19 in the abstract. Also, Latin articles with the availability of full text entered into the study. Figure 1 shows the flowchart of the search and selection process for the included studies. The exclusion criteria included works on diseases other than chronic diseases, repetitive works, and unavailable books.

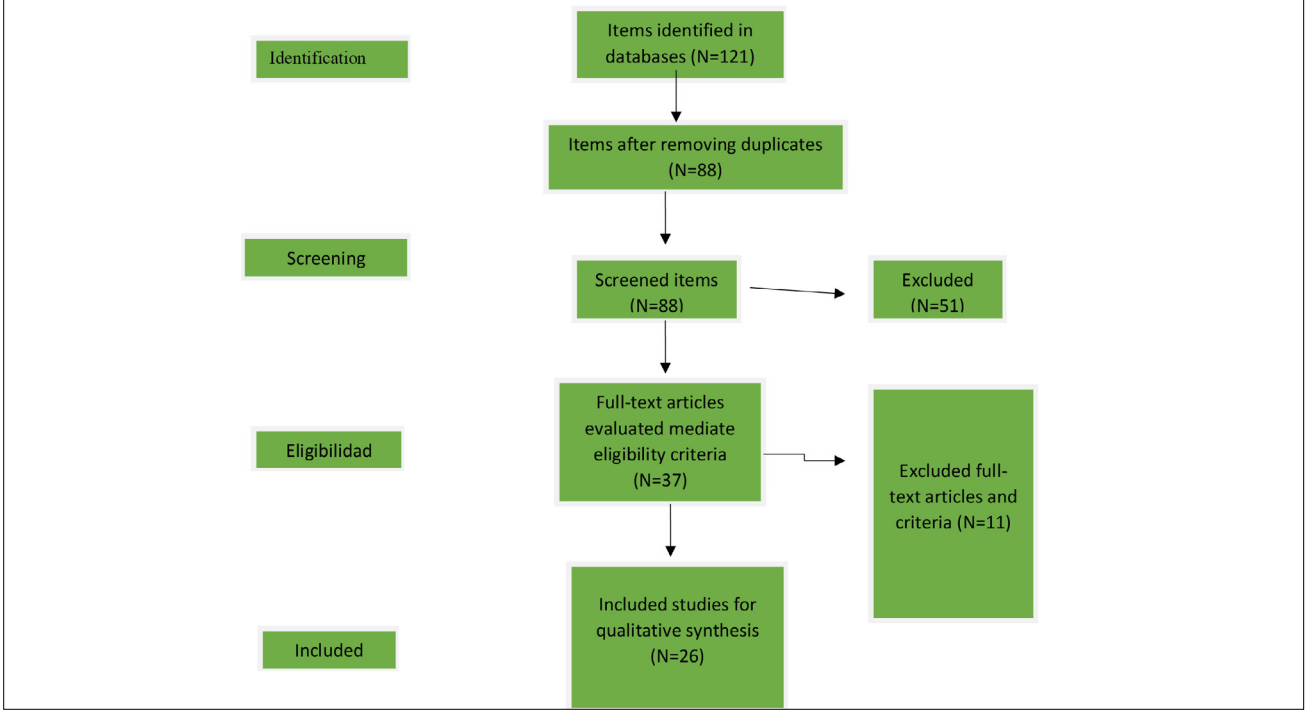
Removing and analyzing data

In the initial search based on the said keywords, 121 articles were collected. by studying the abstract and full text, 26 articles were selected based on inclusion and exclusion criteria, and elimination of repetitive and irrelevant cases. Two researchers who independently reviewed the titles have evaluated the data extracted and summaries of the articles found, considering the eligibility criteria. Disagreements were resolved by discussion, or in the event of no agreement by a four reviewers or researcher.

Results

In this study, 26 qualified Latin articles were used. The results obtained from the reviewed studies were classified into 3 major domains

Fig. 1. Flowchart of the process of searching and selecting the studies.



Significance of self-management in chronic diseases

8 out of the 26 articles used in the study explained self-management in chronic diseases. Self-management in chronic patients is one of the best solutions to promote health and improve the quality of life (Tab. I). Sharif Ali et al presented a review on analyzing the positive effects of self-management on the emotional, behavioral, and social-mental domains, and the individual skills of diabetes patients [18]. Al Grant et al conducted a systematic and meta-analysis review on chronic patients such as diabetes, cardiovascular, and arthritis patients. In this study, they referred to the role of self-management to improve the quality of life and to reduce using healthcare system resources [19]. Banerji et al mentioned in a review that training self-management by healthcare cadre during the corona pandemic to diabetes patients plays a key role in the achievement of treatment purposes of these patients [20].

Self-management challenges during the COVID epidemic

10 out of 26 articles were focused on self-management challenges during the COVID-19 epidemic (Tab. II). According to the nature of chronic diseases and imposing unwanted and unpleasant conditions of the disease such as tolerating continuous pain and stress, and long-term treatment process causes necessity of frequent references to the healthcare systems, attachment of these systems to healthcare team to control the disease, and regular

Tab. I. The specifications relevant to the significance of self-management in chronic diseases.

Row	Author/ place/ year	Purpose	Article type	Target population	Results
1	Tan SS, et al. 2019 [7]	Evaluation of self-management programs in chronic patients	Clinical trial	Chronic patients	Implementation of a self-management program (CDSMP) could increase the ability of patients in self-management
2	Van de Velde D, et al. 2019 [26]	Analysis of the self-management concept in chronic diseases	Concept analysis	Relevant articles on the self-management concept	The self-management should be considered in healthcare systems as an educational program
3	Wainwright T, Low M 2020 [27]	Analysis of the reason for participatory self-management and its role in rehabilitation programs of COVID-19 patients	Letter to editor	-	Participatory self-management should be considered as an essential element in the rehabilitation programs of COVID-19 patients
4	Ghosh A, Gupta R, Misra A 2020 [28]	The effect of telemedicine in diabetes self-management during the COVID epidemic	Review	Relevant articles	Telemedicine is a useful tool for self-management of diabetes patients during the COVID epidemic
5	Izzedine H, Jhaveri KD, Perazella MA 2020 [29]	Analysis of the treatment options of COVID-19 in kidney patients	Letter to editor	Renal patients with COVID-19	Pharmacological treatment in kidney patients with COVID-19 should be modified concerning side effects of medicine and effects on kidney function
6	Plevinsky JM, et al. 2020 [30]	Analysis of the effect of COVID-19 on self-management and treatment follow-up in kids	Original paper	Kids with chronic diseases	Supporting kids with chronic diseases and their families is essential for the healthcare team to enhance their coping with the changes caused by the COVID epidemic, and access to modern medications, such as telemedicine programs
7	Leonardi M, et al. 2020 [31]	Analysis of the effect of self-management strategies on symptoms of patients with endometriosis during the corona epidemic	Original paper	Endometriosis patients	Effectiveness of using non-pharmacological methods, along with using diet regime, to reduce the symptoms of endometriosis patients
8	Kaye L, et al. 2020 [32]	Analysis of change in treatment follow-up procedures and self-management of COPD and asthma patients during the corona epidemic	Original paper	Patients with COPD and asthma	Following treatment in COPD and asthma patients in the first weak of corona lead to reduced need to treat the severe pulmonary complications of these patients

monitoring of self-management program [21]. However, the healthcare systems have reduced access to hospitals and visits for chronic patients during the corona epidemic because of managing the disease. This can make disruption in quality of life, and the treatment process of these patients [22]. For example, Banerji et al have conducted a study and referred to challenges such as a change in lifestyle, on-time unavailability of resources, and health

Tab. II. The specifications of relevant studies of self-management challenges during the COVID-19 pandemic.

Row	Author/ place/ year	Purpose	Article type	Target population	Results
1	Brigo F, et al. 2020 [8]	Analysisof self-management challenges of epilepsy disease during the corona epidemic	Letter to editor		Telemedicine is an effective tool for the management of epilepsy under severe conditions such as the COVID-19 epidemic
2	Hartmann-Boyce J, et al. 2020 [9]	Analysis of risks and management of diabetes during the COVID epidemic using the experiences of past crises	Review	Diabetes patients with COVID-19	According to the effects of COVID-19 on diabetes, it is necessary to reduce the risks of the crisis with proper management based on past experiences
3	Huang S, et al. 2020 [11]	Analysis of the effect of using online management on two patients with COVID-19	Case report	COVID-19 patients	The positive effect of using online management on the improvement of symptoms and self-management of COVID patients
4	Karasavvidis T, et al. 2020 [12]	Analysis of the effect of using home-oriented management in knee osteoarthritis patients during the COVID epidemic	Systematic review	Patients with knee osteoarthritis	The results show the effectiveness of home-oriented management in knee osteoarthritis patients during the corona epidemic
5	Elbeddini A, Tayefehchamani Y 2020 [22]	Analysis of the limitations and challenges in COPD patients during the COVID epidemic	Original paper	Copd patients	The challenges and limitations for these patients include limitations in self-management, advanced medication programs, online service providing because of decreased access of patients to healthcare services in person, and lack of specialized guidelines for doctors in the field of changes in disease management during the COVID epidemic
6	Chang AY, et al. 2020 [33]	Analysis of the effect of COVID-19 on chronic patients	Review	Chronic patients	The complications of COVID-19 in chronic patients may be continued for a long time after acute phase treatment
7	Goodsall TM, Sangwoo H, Bryant RV 2020 [34]	Analysis of the attitude, health behaviors, and concerns of patients with inflammatory bowel disease during the COVID-19 epidemic	Original paper	Patients with inflammatory bowel disease	Using methods such as telemedicine, non-invasive analysis, education, and informing patients can reduce concerns and cause desirable changes in the health behaviors of these patients during the COVID epidemic
8	Shimada N, et al. 2020 [35]	Analysis of the effects of COVID-19 on ESKD patients	Review	ESKD patients	Some changes should be made in the treatment methods of ESKD patients with COVID-19 so that they can continue living under corona epidemic conditions
9	Liu Q, et al. 2020 [16]	Analysis of the experiences of the healthcare team during the COVID-19 epidemic in China	Original paper	Healthcare team	According to the unpleasant consequences of COVID-19 on the physical and mental conditions of the healthcare team. And its impact on the management and medical interventions in the epidemic, comprehensive supports are needed
10	Korytkowski M, et al. 2020 [36]	Analysis of practical approaches in the management of diabetic patients during the COVID epidemic	Original paper	Diabetic patients	Positive results of using various treatments in the management of diabetic patients, such as positive effect on self-management of these patients

team reducing the awareness of diabetes patients to control the disease and the mental effects of these restrictions [20].

The role of the health team in the self-management of patients during the corona epidemic

Among entered studies, 9 articles were focused on the role of the healthcare team in the self-management of patients during the corona pandemic (Tab. III). The increased number of chronic diseases has made abundant challenges for the healthcare team. As the healthcare team tends to use specialized sources and facilities to support the patients and create high-quality life, providing information and making self-confidence in patients to take proper self-care behavior can be some part of the supportive plan of personnel for self-management of these patients. This can finally improve the quality of life, reduce anxiety and stress, and improve the adaptability and physical performance of patients under special conditions [23]. Hence, according to the outcomes of the COVID-19, the health team should provide programs and facilities for the patients and their families to support the self-management plans of chronic patients [24].

Discussion

The present study was conducted to analyze the status of self-management of chronic patients n the COVID-19.

Tab. III. The specifications of studies relevant to the role of the healthcare team in the self-management of patients during the COVID pandemic.

Row	Author/ place/ year	Purpose	Article type	Target population	Results
1	Arlt W, et al. 2020 [37]	Analysis of the role of the healthcare team in the improvement of clinical conditions of patients with adrenal insufficiency	Original paper	Patients with adrenal insufficiency	The efforts of the healthcare team to improve self-management of patients using methods such as training, empowerment, and providing equipment, and required medicine of these patients in the epidemic
2	Xu H, et al. 2020 [38]	Analysis of the effect of telemedicine via WeChat applications for monitoring and management of COVID patients during the home quarantine	Retrospective cohort	COVID-19 patients	Using telemedicine based on We-Chat application by the healthcare team to reduce the prevalence of COVID in the society
3	Bajwah S, et al. 2020 [39]	Analysis of the role of the healthcare team for management and meeting supportive needs of COVID-19 patients	Original paper	COVID-19 patients	The healthcare team should use available resources to provide the best care to decrease the suffering and mortality of patients
4	Garg SK, et al. 2020 [40]	Analysis of the challenges and opportunities for management of patients with type 1 diabetes during the COVID epidemic	Original paper	Patients with type 1 diabetes	The healthcare team should use telemedicine as an effective approach for the management of patients with type 1 diabetes
5	Bhutani M, et al. 2020 [41]	Analysis of the effect of implementing educational programs to improve performance of health team for self-management of patients with COPD during the corona epidemic	Original paper	Healthcare team	The results can be used in similar environments to empower the healthcare team to improve the self-management of COPD patients during the COVID-19 epidemic
6	Ballard M, et al. 2020 [42]	Analysis of the priority of healthcare team functions during the COVID epidemic	Original paper	Healthcare team	The performances of the healthcare team should be in line with the goals and protocols determined in the health system, along with matching all health departments for proper management of COVID-19
7	Bhaumik S, et al. 2020 [43]	Analysis of the responsibilities of the healthcare team during the COVID epidemic	Review	Healthcare team	Change in functions and responsibilities of the healthcare team during the corona epidemic compared to other epidemics showed that the responsibility of the healthcare team has been increased
8	Goldfarb N, et al. 2021 [44]	Analysis of the relevant factors of increase in professional promises of nurses during the COVID-19 epidemic	Original paper	Nurses	Factors such as increasing awareness, group work, mental support, and increased self-efficacy of personnel play a key role in increasing professional promises of nurses as the main member of the healthcare team in the COVD-19 epidemic

According to the results of reviewed articles, they were classified into 3 major groups.

Significance of self-management in chronic diseases

The role of self-management interventions has been increasing in the field of providing healthcare services for chronic patients. The results of a systematic review conducted by Panagioti et al. showed that self-management interventions in patients can improve health consequences and decrease the amount of using healthcare services. According to recent studies, it could be found that the definition of health has become more dynamic, and self-management is one of the key concepts in this field [25]. Self-management interventions applied from various methods and programs such as physical activity, educational interventions, and fitness programs among chronic patients have caused high ability of them for management of the disease [26].

Self-management is the best method for caring for chronic patients refers to the active participation of the patient in the management of disease and controlling the lifestyle [27]. Besides, self-management encompasses behaviors including food diet behaviors, pharmacological treatment, monitoring symptoms, sleeping, physical activity, fitness, growing the skills, setting goals, problem-solving, reducing stress, and using operating plans. Chronic patients use self-management as a part of their life, which can enhance the quality of life and can make patients feel healthy [24]. The most important consequences of self-management include an adaptation of chronic patients to the health problems related to their disease. This is because; the patients can diagnose the symptoms of the disease by self-management and awareness of relevant problems, and take effective measures to control them [28]. This can prevent more disabilities and development of the health of these individuals; because self-management in chronic diseases is not just focused on treatment and rehabilitation. It should be noted that achievement to desirable self-management is dependent on facilitating the health services, and meeting communicative barriers between the healthcare team and the patient. Also, it is dependent on providing more cooperation between patients and the healthcare team [29]. This issue has been changed into a challenge for the healthcare team and the patients, and the results have affected the self-management strategies [30-32].

Self-management challenges during the COVID epidemic

According to the risk of COVID-19 prevalence in Canada in the in-person visits of patients to doctors' offices, online medical and health services are provided for the patients. For example, online triaging services are provided for COPD patients. Some limitations like cognitive and hearing disorders of patients, unavailability of technology, the lingual barriers, and problems of working with the system have reduced the quality of virtual healthcare compared to in-person healthcare. This problem is highly manifested in aged patients with COPD. Besides, quarantine and social distancing by the governments to reduce the prevalence of the virus has resulted in dysfunction in the management of patients with chronic neural disorders like epilepsy despite reducing the pulmonary infections caused by the disease. This is because; the patients suffer from anxiety and depression caused by decreased times of in-person visits with their doctors [22].

The restrictions have resulted in self-management behaviors such as nutrition, physical activity, and controlling chronic patients during the treatment process. This is because; these patients need special treatment and regular visits to various specialists to control their disease because of complicated clinical conditions. Hence, decreased access to healthcare services, medicine, and changes in their lifestyle can result in abundant problems for them [9, 33, 34]. Therefore, the healthcare team needs to control and support self-management programs due to the worry of these patients about the negative effects of the conditions on their health status and based on the significance of monitoring their health status [34, 35].

The role of the healthcare team in the self-management of patients during the corona pandemic

During the corona pandemic, the healthcare team has to decrease in-person visits with chronic patients (especially diabetes patients) with COVID-19 and tries to train self-management to these patients. These patients have welcomed this method recently. However, it should be mentioned that some hospitals have caused the risk of high blood sugar by applying restrictive strategies in the activities of diabetic patients. The healthcare team, especially those with diabetic patients or newly diagnosed hyperglycemia with COVID-19, has to set their management strategies in such a way that the needs of patients are met and the personnel has been also protected [36].

Arlt et al. have mentioned that the healthcare team should pay attention to 3 elements including training, equipment, and empowerment to support chronic patient self-management.

In the field of training: the patients should be trained sufficiently about coping with the changes in their health status, such as conditions caused by the corona pandemic in their life. Through this, the patients can be prepared to pass the crisis.

Equipment: equipment aims to provide the needs of these patients such as medicine and medical equipment, which should be under careful supervision.

Empowerment: empowerment means making patients ready to encounter critical conditions and take urgent interventions when needed. Also, the healthcare team tries to enhance the self-confidence and ability of the patients to take the self-management process properly [37].

The main limitations in this study include a few numbers of studies in this field because of the newness of the disease. Also, it could be mentioned that reviewed articles were Latin because no similar study existed in Persian. Hence, it would be better for further studies to emphasize chronic patient self-management during the COVID-19 pandemic.

Conclusions

In general, the healthcare team should identify the restrictions, problems, and concerns of self-management of patients, and evaluate the solutions and effective interventions to meet and control the barriers. They should also provide the best options to facilitate self-management of chronic patients during the corona pandemic. Besides, the health centers should be urgently equipped with relevant technologies of virtual healthcare including online and offline electronic consulting, providing educational sources through the website of the universities and social media, phone follow up, presenting educational papers, providing non-pharmacological methods like relaxation, and effective breathing practices to reduce anxiety. Multiple studies have proved the effectiveness of using technology (telemedicine) for the self-management of chronic patients during the COVID 19.

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Conflict of interest statement

The authors declare no conflict of interest.

Authors' contributions

Conceptualization: TGH. Data curation: JS. Funding acquisition: None. Visualization: EAK. Writing-original draft: MGG, JS. Writing-review & editing: TGH.

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COVID-19

COVID-19 pandemic: an assessment of risk perception and the implementation of precautionary measures in a group of primary care workers in Nigeria

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Keywords

COVID-19 • General Practice Clinic • Precautionary measures • Primary care worker • Risk perception

Summary

Introduction. *The world is currently faced with the challenge of the COVID-19 pandemic, with healthcare workers at high risk of contracting infection. This study assessed the risk perception of COVID-19 and practice of precautionary measures against its spread by primary care workers.*
Methods. *This was a descriptive cross-sectional study of primary care workers in the General Practice Clinic (GPC) of University of Benin Teaching Hospital (UBTH), Nigeria, sub-Saharan Africa. A pretested self-administered semi-structured questionnaire was employed to obtain data on Socio-demographic characteristics, Risk perception of COVID-19, and Practice of precautionary measures from the respondents. Obtained data were analysed using IBM SPSS Statistics version 22.0 (Chicago, IL, USA). Chi-square test, Ordinal regression analysis and logistic regression analysis were performed. A p-value of less than 0.05 was considered statistically significant. Ethical clearance was obtained from the Health Research Ethics Committee.*
Results. *Most respondents (39.6%) had moderate risk perception of COVID-19. High risk perception was more frequent in females than males (27.8 vs 11.9%; Chi-square test; p-value = 0.001). Majority (76.0%) of the respondents had good practice of precautionary measures against COVID-19.*
Conclusions. *Most HCWs surveyed in this study had moderate-risk perception of COVID-19 and good practice of precautionary measures. It is recommended that formal training and retraining on Infection Prevention and Control (IPC) of infections, including COVID-19, should be regularly provided for all cadres of healthcare staff.*

Introduction

Like at various times in human history when different pandemics were experienced [1], the world is currently challenged with the COVID-19 pandemic which originated from China [2, 3] but spread to many other countries of the world, necessitating the World Health Organization (WHO) to respectively declare the disease a Public Health Emergency of International Concern (PHEIC) and a pandemic [4, 5]. Africa's first case was recorded in Egypt on the 14th of February 2020 [6], while Nigeria recorded her first case on the 27th of February 2020 [7]. Caused by a new strain of coronavirus called Severe Acute Respiratory Syndrome Corona Virus-type 2 (SARS-CoV-2), Coronavirus disease 2019 (COVID-19) is an acute respiratory and highly infectious disease that spreads through various modes, including person to person contact [2, 8], and with most infected individuals developing symptoms such as dry cough, sore throat, breathlessness, etc. [9].
COVID-19 has greatly affected individuals, families, health systems, and the governance and socio-economic state of many countries [10, 11]. Though healthcare workers have generally been exemplary frontline 'soldiers' in the global fight against the COVID-19 pandemic, not a few have died after contracting COVID-19 [12]. A report published on September 3, 2020 by Amnesty international revealed that at least 7, 000 healthcare workers had died globally, after contracting COVID-19 [13]. In Nigeria, a report published on September 10, 2020, by WHO Africa region put the number of healthcare workers infected by COVID-19 in Nigeria at 2, 175 [14]. These unfortunate trends are not unconnected with the fact that healthcare workers are at high risk of contracting infection during pandemics [15-17]. A main source of contracting infection is usually from patients at the workplace where they come in contact with COVID-19 patients in the course of exercising their clinical duties [18]. This is usually due to poor provision of personal protective equipment, insufficient knowledge and training on Infection Prevention and Control (IPC) measures (with the resultant poor practice of precautionary measures), inability to effectively practice physical distancing in the workplace, shortage of healthcare workers (with the few available healthcare workers made to run more shifts, thus exposing them to the risk of infection), and non-disclosure by patients of their COVID-19 status [16-21]. Unfortunately, some of the infected healthcare workers may not be aware of their infective status, especially in situations where the COVID-19 screening tests are not made readily available to the healthcare workers. They may therefore unknowingly become sources of infection to their colleagues and their households.
In a nationwide linkage cohort study that assessed

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the risk of COVID-19 infection amongst 158, 445 Scottish healthcare workers aged 18-65 years and 229, 905 household members, Shah and colleagues found that during the first three months of the first wave of the COVID-19 pandemic in Scotland, patient-facing healthcare workers were three times more likely to be admitted with COVID-19 than non-patient facing healthcare workers and that the risk of COVID-19 infection was doubled among household members of patient/front-facing healthcare workers [22]. The above observations and realities are likely to engender some trepidation amongst healthcare workers about their risk of becoming infected in the workplace [23]. This may also affect their practice behaviours. It is therefore important to assess their risk perception and practice of precautionary measures against the spread of COVID-19.
Aim: this study sought to assess the risk perception of COVID-19 and practice of precautionary measures against the spread of COVID-19 by healthcare workers working in the primary care clinic (General Practice Clinic) of a tertiary hospital in Nigeria. This study was conducted with the hope of having a better understanding of the healthcare workers' risk perception and practice behaviours and making recommendations to improve hospital policy on infection prevention and control, safety measures and practice behaviours, as well as policies to protect the health workforce and control the rate of transmission to households and communities.

Methods

This was a descriptive cross-sectional study of healthcare workers in the General Practice Clinic (GPC) of a tertiary hospital in Nigeria, the University of Benin Teaching Hospital (UBTH). The study was conducted over a three-week period in the month of June, 2020, during the first wave of the COVID-19 pandemic. The General Practice Clinic is a primary care clinic and one of the hospital's entry points through which patients make first contact with primary care physicians (such as Family physicians) and other health professionals for their healthcare needs. The healthcare workers surveyed in this study were Medical doctors, Nurses, Pharmacists, Medical Laboratory Scientists, and other allied health professionals and health workers. A pretested self-administered semi-structured questionnaire, which took about 5 minutes to complete, was employed to obtain data from the respondents. The questionnaire was divided into the following parts: Socio-demographic characteristics, Risk perception of COVID-19, and Practice of precautionary measures against the spread of COVID-19. The question: 'How will you assess your risk of contracting COVID-19 in your workplace?', was used to assess risk perception. The respondents were requested to reply 'low', 'moderate', 'high' or 'not sure', to the question. 17 yes or no questions were used to assess the respondents' practice of precautionary measures, with each correct response scored "1" and each wrong response scored "0". The scores ranged from 0 to 17, with the respondents' practice of precautionary measures against the spread of COVID-19 classified as poor (≤ 9) or good (≥ 10).
All the obtained data were checked for completeness and were coded, grouped and analysed using IBM SPSS Statistics version 22.0 (Chicago, IL, USA). Descriptive statistics was used to obtain frequencies and percentages of the categorical variables (such as gender and marital status) of the respondents, while mean and standard deviation was used to present continuous variables. Chi-square test was used to determine association between categorical variables and risk perception and practice. Ordinal regression analyses and logistic regression analyses were performed to identify the factors predictive of risk perception and practice of precautionary measures against COVID-19 infection. A p-value of less than 0.05 was considered statistically significant. Ethical clearance was obtained from UBTH Health Research Ethics Committee. Informed written and voluntary consent was obtained before recruiting any participant. The purpose, procedure, and benefits of the study were explained to the participants. They were informed that the study had no attendant adverse effects or risks. To ensure confidentiality, the questionnaires were given coded means of identification, while the participants' names were not used during the research.

Results

Sociodemographic characteristics of respondents

Out of a total of 115 healthcare workers in the General Practice Clinic of University of Benin Teaching Hospital (UBTH), 96 gave consent to participate in the study. Respondents aged 25 years and below were the least represented age group, 11 (11.5%). Most of the respondents had practiced in UBTH for 10 years and below (77.1%) and had tertiary education (Tab. I).

Risk awareness and attitude towards COVID-19

All the respondents were aware of COVID-19 and their risk of infection. Majority of the respondents (60.4%) agreed that necessary preventive and protective measures against COVID-19 had been put in place in their work place. Less than half (43.8%) of the health workers felt safe and secure at their workplace, 38.5% said they did not feel safe and secure, while 17.7% were not sure if they were safe and secure at their workplace. Only 26.0% felt like stopping work for fear of contracting COVID-19, even though sixty-three (65.6%) of the healthcare workers (HCWs) agreed that they were afraid of contracting COVID-19, while 28.1% were not afraid, and 6.3% were not sure. Only about a third (32.3%) of the respondents reported that they had received training on infection prevention and control against COVID-19. Majority of the respondents (85.4%) believed that use of personal protective equipment (PPE) can reduce the

Tab. I. Sociodemographic characteristics of respondents.

Sociodemographic characteristics	Frequency, n = 96	Percentage (100%)
Age (years)		
≤ 25	11	11.5
26-35	25	26.0
36-45	36	37.5
> 45	24	25.0
Gender		
Female	54	56.2
Male	42	43.8
Marital status		
Married	67	69.8
Single	28	29.2
Widowed	1	1.0
Religion		
Christianity	95	99.0
Traditional religion	1	1.0
Occupation		
Medical doctor	31	32.3
Administrative staff	15	15.6
Nurse	13	13.6
Pharmacist	10	10.4
Medical Laboratory scientist	10	10.4
Technician	9	9.4
Others	8	8.3
Level of education		
Tertiary	83	86.5
Secondary	12	12.5
Primary	1	1.0
Length of practice (years)		
≤ 10	74	77.1
> 10	22	22.9

Others: CHEW, health attendants, dieticians and drivers.

risk of contracting COVID-19, while 7.3% didn't and 7.3% were not sure. While 69 (71.9%) respondents used PPE at work, 27 (28.1%) did not. Most of the healthcare workers (77.1%) in this study reported that there had been COVID-19 cases in their places of work, while 12.5% were not sure. A total of 17 (17.7%) had contact with a confirmed COVID-19 case as at the time of this study, while 54 (56.3%) had no contact and 25 (26.0%) were not sure. More respondents however had contact with suspected cases of COVID-19 at the time of this study (29.1%), and 54.2% had no contact with a suspected case, while 16.6% were not sure. After contact with confirmed or suspected cases, 14.6% of respondents continued with their routine work, while 12.5% went on isolation after informing the hospital management. Only 8 (8.3%) reported that they had been infected by the virus, while 9 (9.4%) were not sure. 17 (18%) respondents had been screened for COVID-19. Of these, 7.3% were screened because they had contact with a COVID-19 patient and as part of a routine screening respectively, while 2.1, 1.0 and 1.0% were screened because they had contact with a secondary contact, with a COVID-19 positive colleague and with contaminated fluids, respectively. Only 5 (5.2%) respondents had been isolated for COVID-19.

Respondents' risk perception of COVID-19

Respondents were asked to assess their perceived risk of contracting COVID-19. More of the respondents had moderate risk perception (39.6%), followed by low (29.2%) and high (20.8%). About a tenth (10.4%) of the respondents however were not sure of their risk perception. Significantly more females had high risk perception (27.8%) compared to males (11.9%) ($p = 0.001$). There was no significant association between age, occupation, marital status, level of education and length in practice and risk perception (Tab. II).

Factors associated with respondents' risk perception of COVID-19

Ordinal regression analysis (Tab. III) revealed that 'other' staff had significantly lower odds of having high risk perception compared to all other category of staff, with pharmacists having an odds ratio of 5.366 (95% CI: 1.776-6.450). Training on infection prevention and control against COVID-19 was significantly associated with reduced odds of high-risk perception (OR: -2.162; 95% CI: -3.203 - -1.120).

Respondents' practice of precautionary measures against COVID-19

With respect to the practice of precautionary measures against COVID-19 by respondents, most of them agreed that regular hand washing with soap and water (96.9%), use of alcohol-based hand sanitizer (88.5%), and physical distancing (61.5%) were practiced in their workplace. Regular disinfection of surfaces and fumigation were practiced in 58.3 and 55.2% of work places respectively. Majority, 52 (54.2%) always follow recommendations from health authorities on prevention of COVID-19, while 29 (30.2%) often followed recommendations. Nine (9.4%) sometimes, 4 (4.2%) rarely and 2 (2.1%) did not follow recommendations. The commonly practiced precautionary measures by the respondents include avoiding the touching of eyes, nose and mouth with unwashed hands (86.5%), washing hands regularly with soap and water for 20 seconds (85.4%), wearing face mask in public (81.3%) and use of alcohol-based hand sanitizer (80.2%). Over a quarter (27.1%) took vitamin supplements and only 3 (3.1%) reported using herbal and traditional medicines.

The average score for practice of precautionary measures against COVID-19 was 11.3 ± 2.4. Doctors (93.5%), pharmacists (90.0%) and medical laboratory scientists (90.0%) had significantly higher proportion of good practice of precautionary measures compared to other occupations ($p = 0.040$). A significant difference was also seen between length of practice in current workplace and practice of precautionary measures against COVID-19 ($p = 0.007$). Respondents who had practiced 10years or less had the highest proportion of good practice of precautionary measures (45.5%).

Analysis with binary logistic regression showed that occupation and length of practice were significant predictors of precautionary practice behaviour ($p = 0.040$ and 0.014 respectively) (Tab. IV).

Tab. II. Distribution of respondents' risk perception of COVID-19 by sociodemographic characteristics.

Sociodemographic characteristics	Risk perception categories				Test statistic /p-value
	Low n = 28 (29.2%)	Moderate n = 38 (39.6%)	High n = 20 (20.8%)	Not sure n = 10 (10.4%)	
Age (years)					
≤ 25	4 (36.4)	4 (36.4)	2 (18.2)	1 (9.1)	Fisher's exact = 786 P = 0.548
26-35	6 (24.0)	8 (32.0)	9 (36.0)	2 (8.0)	
36-45	13 (36.1)	16 (44.0)	4 (11.1)	3 (8.3))	
> 45	5 (20.8)	10 (41.7)	5 (20.8)	4 (16.7)	
Gender					
Female	11 (20.4)	18 (33.3)	15 (27.8)	10 (18.5)	Fisher's exact = 15.127 P = 0.001*
Male	17 (40.5)	20 (47.6)	5 (11.9)	0 (0.0)	
Marital status					
Married	17 (25.4)	18 (41.8)	14 (20.9)	8 (11.9)	Fisher's exact = 3.801 P = 0.750
Single	10 (35.7)	10 (35.7)	6 (21.4)	2 (7.1)	
Widowed	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	
Occupation					
Medical doctor	10 (32.3)	15 (48.4)	4 (12.9)	2 (6.5)	Fisher's exact = 20.919 P = 0.198
Administrative staff	4 (26.7)	6 (40.0)	3 (20.0)	2 (13.3)	
Nurse	2 (15.4)	4 (30.8)	5 (38.5)	2 (15.4)	
Pharmacist	0 (0.0)	4 (40.0)	5 (50.0)	1 (10.0)	
Medical Laboratory scientist	3 (30.0)	4 (40.0)	2 (20.0)	1 (11.1)	
Technician	3 (33.3)	4 (44.4)	1 (11.1)	1 (11.1)	
Others	6 (75.0)	1 (12.5)	0 (0.0)	1 (12.5)	
Level of education					
Tertiary	23 (27.7)	35 (42.2)	17 (20.5)	8 (9.6)	Fisher's exact = 3.948 P = 0.613
Secondary	4 (33.3)	3 (25.0)	3 (25.0)	2 (16.7)	
Primary	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	
Length of practice (years)					
≤ 10	22 (29.7)	32 (43.2)	15 (20.3)	5 (6.8)	Fisher's exact = 5.329 P = 0.149
> 10	6 (27.3)	6 (27.3)	5 (22.7)	5 (22.7)	

Others: CHEW, health attendants, dieticians and drivers; ***** Statistically significant.

Tab. III. Regression analysis for factors associated with risk perception of COVID-19.

	Risk perception	
	OR (95% CI)	P-value
Age (years)		
≤ 25	-0.735 (-2.653-1.183)	0.453
26-35	0.611 (-0.767-1.989)	0.385
36-45	-0.292 (-1.462-0.878)	0.625
> 45	Ref	
Gender		
Male	-0.143 (-1.006-0.720)	0.745
Female	Ref	
Occupation		
Medical doctor	3.380 (0.401-4.369)	0.018*
Nurse	3.221 (1.447-6.136)	0.002*
Pharmacist	5.366 (1.776-6.450)	0.001*
Medical Laboratory scientist	2.462 (0.287-4.564)	0.026*
Technician	2.928 (0.246-4.399)	0.028*
Administrative staff	3.530 (0.216-4.061)	0.029*
Others	Ref	
Level of education		
Primary	2.942 (-1.440-7.323)	0.188
Secondary	0.979 (-0.467-2.426)	0.185
Tertiary	Ref	
Length of practice (years)		
≤ 10	-0.91 (-0.312-2.776)	0.118
> 10	Ref	0.057
Training on infection prevention and control		
Yes	-2.162 (-3.203 - -1.120)	0.000*
No	Ref	
Constant	56.755	
Adjusted R^2	0.483 (48.3%)	
P-value	0.000*	
Standard error of estimate	7.154	

Others: CHEW, health attendants, dieticians and drivers; OR: Odds ratio; CI: Confidence interval; * Statistically significant.

Tab. IV. Distribution of respondents' practice of precautionary measures against COVID-19 by their socio-demographic characteristics.

Variables	Practice of precautionary measures[a]		Test statistic /p-value	OR (95% CI)	P-value
	Good n = 73 (76.0%)	Poor n = 23 (24.0%)			
Age (years)					
≤ 25	7 (63.6)	4 (36.4)	Fisher's exact = 3.353 P = 0.340	0.664 (0.293-1.503)	0.325
26-35	20 (80.0)	5 (20.0)			
36-45	30 (83.3)	6 (16.7)			
> 45	16 (66.7)	8 (33.3)			
Gender					
Female	40 (74.1)	14 (25.9)	χ^2 = 0.262 P = 0.609	1.244 (0.484-4.946)	0.721
Male	33 (78.6)	9 (21.4)			
Marital status					
Married	52 (77.6)	15 (22.4)	Fisher's exact = 0.733 P = 0.697	0.738 (0.193-2.094)	0.658
Single	20 (71.4)	8 (28.6)			
Widowed	1 (100.0)	0 (0.0)			
Occupation					
Medical doctor	29 (93.5)	2 (6.5)	Fisher's exact = 17.174 P = 0.040*	1.394 (1.015-1.915)	0.040*
Administrative staff	10 (66.7)	5 (33.3)			
Nurse	8 (61.5)	5 (38.5)			
Pharmacist	9 (90.0)	1 (10.0)			
Medical Laboratory scientist	9 (90.0)	1 (10.0)			
Technician	4 (44.4)	5 (55.6)			
Others	4 (50.0)	4 (50.0)			
Level of education					
Tertiary	65 (78.3)	18 (21.7)	Fisher's exact = 3.988 P = 0.160	1.699 (0.393-7.399)	0.478
Secondary	8 (66.7)	4 (33.3)			
Primary	0 (0.0)	1 (100.0)			
Length of practice (years)					
≤ 10	61 (82.4)	13 (17.6)	χ^2 = 7.239 P = 0.007*	7.081 (1.496-33.519)	0.014*
> 10	12 (54.5)	10 (45.5)			

[a] Total score ranged from 0 to 17. A score of ≤ 9 was set for poor and ≥ 10 set for good practice of precautionary measures against COVID-19; Others: CHEW, health attendants, dieticians and drivers; OR: Odds Ratio; CI: Confidence Interval; * Statistically significant.

Tab. V. Further predictors of respondents' practice of precautionary measures against COVID-19.

Respondents' characteristics	OR	95% CI	P-value
Chronic medical condition	0.520	0.097-2.785	0.445
Training on infection prevention and control against COVID-19	1.814	0.445-7.389	0.407
Risk perception of COVID-19	1.797	0.785-2.601	0.108
Perceived susceptibility to COVID-19	0.656	0.330-1.306	0.230
Constant	28.524		
Adjusted R^2	0.411 (41.1%)		
P-value	0.000*		
Standard error of estimate	8.372		

OR: Odds Ratio; CI: Confidence Interval; * Statistically significant.

Further analysis as shown in Table V showed that risk perception of COVID-19, training on infection prevention and control against COVID-19, and having a chronic medical condition were not significant predictors of practice of precautionary measures.

Discussion

This study was conducted during the first wave of the COVID-19 pandemic and was aimed at assessing the risk perception and practice of precautionary measures against COVID-19 by health care workers (HCWs) in the primary care clinic (General Practice Clinic) of a tertiary hospital in Nigeria, the University of Benin Teaching Hospital (UBTH). Concerning the respondents' risk perception of COVID-19, this study found that only about 20% of the respondents stated they had high risk, while majority stated they had moderate risk. This differs from findings among the general Ghanaian population where majority of the participants had a high-risk perception towards COVID-19 [24]. However, a study in Portugal comparing the risk perception of COVID-19 among HCWs and the general population found more HCWs (54.9%) believed they were at higher risk compared to the general population (24.0%) and it was opined that this was due to their close contact with suspected or confirmed cases of COVID-19 [25]. In the present study, only a minority had

contact with suspected or confirmed cases of COVID-19 and only twenty six percent (26%) felt like stopping work due to fear of being infected. This may explain why most of the respondents had moderate risk perception of COVID-19. Significantly more females in this study had high risk perception of COVID-19 compared to males. This is particularly interesting in the light of study findings that indicate that males have higher risk of severity and mortality from COVID-19 compared to females [26]. Younger age groups have been associated with lower risk perceptions compared to older age groups [26, 27]. This is expected as the risk of infection, severity and mortality from COVID-19 increases with age [26, 28]. This study however found that those with the least proportion of low-risk perception of COVID-19 were respondents over 45 years of age, even though a good number of them were not sure of their self-perceived risk.

A study on staff risk stratification in UBTH found that core clinical staff such as doctors and nurses made up over 75% of workers in the high-risk category [29]. In the present study however, pharmacists had the highest odds of having high risk perception (OR: 5.4; 95% CI = 1.776-6.450). Risk perception of infectious diseases has been found to correlate positively with practice of preventive health measures, especially during outbreaks [30]. This was seen in the present study as higher risk perception of the HCWs improved precautionary measure score by an odd of 1.8 (95% CI: 0.79-2.60). This was however not statistically significant (p = 0.108).

This study showed that majority of the HCWs had good practice of precautionary measures against COVID-19 (76.0%), similar to findings on Coronavirus in Uganda [31], and in Saudi Arabia [32], as well as findings in Guinea on Ebola virus [33]. The practice of preventive measures against COVID-19 differed significantly across respondents' occupation and length of practice in their current work place (p = 0.040 and 0.014 respectively). Worthy of note is that a higher percentage of respondents who worked fewer years had good practice compared to those who worked greater than 10years. This may be because more of the studied HCWs who have worked longer had poor COVID-19 knowledge. A study in Italy associated positive attitude to and practice of disinfection procedures with lower number of years of service among Nurses [34]. Over 25% of HCWs in the present study reported that they did not use personal protective equipment (PPE) at work. This is alarming as PPEs have been found to curb the spread of the disease [35]. However, this finding may be due to lack of sufficient PPEs for use by the healthcare workers, as well as the fact that only about 32.3% of the studied HCWs reported that they had training on infection prevention and control. The vast majority of respondents followed the WHO recommendation on use of facemask, hand washing, and use of alcohol-based hand sanitizer. However, fewer respondents covered their mouths when they coughed or sneezed and practiced social distancing. The practice of social distancing amongst HCWs in a health care setting may be challenging, as they are constantly in close contact with patients and other health workers in their line of duty.

Limitations

This study had some limitations, the first being that the study design used was cross-sectional and therefore causality cannot be deduced as the data were collected at one point in time. Secondly, only HCWs in the General Practice Clinic of University of Benin Teaching Hospital were surveyed, and therefore the results of this study may not be generalizable. However, the perspectives and data obtained from this study can be leveraged upon to conduct further studies and empanel policies and programmes to protect healthcare workers and guarantee workplace safety.

Recommendations

It is recommended that there should be regular and sustained supplies of personal protective equipment (PPEs) in every health facility, with healthcare staff regularly provided with the PPEs, to limit the spread of COVID-19. Furthermore, appropriate workplace safety policies and COVID-19 IPC protocols/guidelines should be put in place in every health facility, with medical doctors and other healthcare staff adequately compensated with encouraging welfare, remuneration, and insurance packages to motivate them to continuously discharge their clinical duties during the COVID-19 pandemic. It is advocated that more studies, preferably multi-centre studies, be conducted to address some of the study limitations.

Conclusions

Most of the healthcare workers (HCWs) surveyed in this study had moderate-risk perception of COVID-19 and good practice of precautionary measures. It is recommended that formal training and retraining on Infection Prevention and Control (IPC) of infections, including COVID-19, should be regularly provided for all cadres of healthcare staff to increase their knowledge and practice of precautionary measures, as well as reduce their risk of infection.

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Conflict of interest statement

The authors declare no conflict of interest.

Authors' contributions

OE did the conception, design, literature search, manuscript drafting, review, editing, and preparation for intellectual content.

MA did the definition of intellectual content, literature search, and data collection.

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COVID-19

Knowledge and practice of Protective Personal Equipment (PPE) among healthcare providers in Saudi Arabia during the early stages of COVID-19 pandemic in 2020

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Keywords

COVID-19 • Pandemic • Protective personal equipment • Donning • Doffing • Healthcare providers

Summary

Introduction. *Healthcare providers are at high risk of becoming infected when taking care of patients who have COVID-19, especially while attending aerosol generating procedures. Protective personal equipment must be used in the correct manner to prevent transmission of the disease. Published protocols on protective personal equipment (PPE) donning and doffing have been issued by disease control agencies. Methods. A questionnaire-based cross-sectional study was designed. An online anonymous questionnaire, which was validated and tested for reliability, focused on PPE related knowledge, donning and doffing practices of healthcare providers across the eastern region of Saudi Arabia. Results. A total of 312 healthcare providers across the eastern region of Saudi Arabia participated in the study, 208 physicians (66.7%) and 104 non-physicians (33.3%). Results indicate poor practice regarding PPE donning (13.8% reported the correct sequence) and PPE doffing (3.5% reported the correct sequence) among participants. In addition, practice and confidence scores regarding other issues with PPE were analyzed. Based on questionnaire responses, being male (T = 2.825; p = 0.008), being a non-physician (T = -2.120; p = 0.014) and being an allied medical professional (F = 5.379; p = 0.003) were significantly associated with higher confidence levels. Also, being a consultant was significantly associated with higher practice scores (F = 4.774; p = 0.008). Conclusion. The study demonstrates deficiencies among healthcare providers in following the recommended practices for correctly using PPE during the pandemic. Poor practice in PPE donning and doffing necessitates additional educational and training programs focused on infection control practices.*

Introduction

In December 2019, the world became aware of a highly contagious respiratory infectious disease that first presented itself in Wuhan, China [1]. The disease is caused by a novel coronavirus known as severe acute respiratory virus 2 (SARS-COV-2) [2]. While the original source of the virus remains unidentified, available genetic data suggest a zoonotic origin [3], and human-to-human transmission has been confirmed. Respiratory infection can be transmitted by respiratory droplet particles, which range from 5-10 micrometers in diameter. Droplet transmission occurs when an individual moves into close proximity to an infected person who is exhibiting respiratory symptoms such as sneezing and coughing. The transmission of COVID-19 can occur either directly through mucosal surfaces, such as the mouth, nose, and conjunctiva, or indirectly, by touching the patient's surroundings where the droplets have fallen [4]. Airborne particles are capable of being suspended in the air for long periods of time, ranging between 1.5 h for 3 μm diameter particles to 12 h for 1 μm diameter particles, compared to 10 μm diameter particles that will settle in 8.2 minutes [4, 5]. Airborne particles can also travel more than one meter [5]. As one mode of transmission of COVID-19 is droplet particles [6], airborne transmission might be possible during aerosol generating procedures including the following: endotracheal intubation, open suction, bronchoscopy, nebulized treatment, manual ventilation, turning the patient to a prone position, disconnecting the patient from the ventilator, non-invasive positive pressure ventilation, tracheostomy, and cardiopulmonary resuscitation [5].

On February 11, 2020, the World Health Organization (WHO) named the disease, Corona Virus Disease 2019 (COVID-19) [7]. In March 2020, Saudi Arabia registered its first case of COVID-19 [8]. Due to the rapid spread of the disease, on March 11, 2020, WHO recognized COVID-19 as a global pandemic [9]. As of the date of this manuscript's writing, the total number of cases across the globe had reached more than 80 million, with more than one million deaths occurring worldwide [10]. Healthcare providers (HCPs) are at high risk of becoming infected themselves while caring for patients who are positive for COVID-19. The main mode of transmission is respiratory droplets; therefore, being in close proximity to an individual who has

 https://doi.org/10.15167/2421-4248/jpmh2021.62.4.2177

tested positive for the virus while they sneeze and/or cough, or performing aerosol generating procedures on these patients such as intubation, tracheostomy, and endotracheal suction on, are considered to be very high sources of transmission of the disease to HCPs [6]. Healthcare providers of any age who have certain chronic medical illness have a higher chance of severe COVID-19 infection. These medical conditions include the following: moderate to severe asthma, chronic kidney disease, chronic lung disease, diabetes mellitus, hemoglobin disorders, immune compromised state, liver disease, pregnancy, serious cardiac and cerebrovascular conditions, obesity (BMI > 30), and smoking [3].

Because of the high risk of exposure to SARS-COV-2, as well as a variety of other pathogens, protective personal equipment (PPE) is an important tool for preventing disease transmission, when used in the correct manner [11]. The United States Centers for Disease Control and Prevention (CDC) has published a protocol that describes how to put on (don) and take off (doff) PPE when caring for patients with COVID-19 [12]. Lack of basic knowledge about how to properly use PPE might increase the risk of infection, even when the provider wears all the required equipment. WHO has estimated that 89 million medical masks, 76 million gloves, and 1.6 million face masks have been needed worldwide each month during the pandemic [13].

Rise in demand without a secure chain of supply, as well as misuse of equipment, increases the chance of exhausting PPE supplies. Therefore, healthcare providers need to know how and when to best use PPE to get maximum protection, while preserving resources.

In our study we want to evaluate whether HCPs in this region of the world have the required knowledge to practice safe and efficient PPE usage especially during this pandemic. To the best of our knowledge, there is currently only one published study, conducted in Canada, where PPE donning and doffing sequences among HCPs during COVID-19 were evaluated. A total of 175 HCPs in Toronto, Canada completed a survey on knowledge and usage. Only 86 participants (50%) put on (donned) the PPE in the correct order and only 60 participants (35%) took off (doffed) PPE in the correct order [5]. These figures are quite shocking and carry a high risk of cross contamination due to inappropriate use of PPE which increase the chance of infections in HCPs. Our aim is to study PPE practice and knowledge among HCPs in Saudi Arabia during COVID-19 and to compare our results to the world's published figures.

Methods

Study design and data collection

Our study protocol was approved by the Institutional Review Board of King Fahd University Hospital, Khobar, Saudi Arabia. It employed a descriptive, cross-sectional design. Our literature review did not found any previously published validated questionnaire that specifically assess the practice of donning and doffing PPE. We created a new questionnaire that is simple, short and written in language familiar to the healthcare providers. The items of the questionnaire were tested on a small sample (about 50) of respondents to ensure that the items can be understood and correctly interpreted by the intended respondents. A panel of experts in the field from infection control specialty and infectious disease medical specialty were tasked with evaluating the validity of the questionnaire. We prepared an online anonymous questionnaire using Google forms. In this study we included all healthcare providers across the eastern region of Saudi Arabia. The questionnaire covered demographic data including age and gender, and profession, as well as preexisting medical conditions and other risk factors. Importantly, we focused on the respondents' knowledge of PPE practice, especially how to put on (don) and take off (doff) PPE. Participants were also asked about the sources of their information about COVID-19-related safety measures, as well as whether PPE was available in their institute, and what types were available. Using convenience and snowball sampling methods, the questionnaire was distributed using electronic email lists of healthcare providers working at the three major COVID-19 centers in the eastern region of Saudi Arabia. Contact information was obtained from the Saudi Commission for Health Specialties (SCFHS) and recognized medical societies. Informed consent was obtained from all participants. The questionnaire was sent to 1710 healthcare providers. Data were collected between June 21 to August 30, 2020. A total of 350 healthcare providers voluntarily responded to the questionnaire, which correspond to a response rate of 20.4%. We included all HCPs who sent back completed forms, and excluded those who were medical volunteers or medical students who were not allowed to provide direct medical care for patients at that time. Finally, 312 participants were enrolled in the study.

Scoring

Information regarding the confidence in and actual practice of the HCPs using the recommended PPE during the COVID-19 pandemic was taken from 4 questions included on the questionnaires. 2 questions were about practices, and 2 questions were about confidence. The answer "yes" was coded as 1, and "no" was coded as 0. Total confidence and practice scores were obtained by adding the values for each question separately, with a maximum of 2 points possible for each variable. These were then interpreted as the higher the score, the higher the level of practice or confidence regarding the use of recommended PPE during the COVID-19 pandemic. We considered the levels of practice and confidence of the HCPs on each variable as low if their score was 0 points, moderate if their score was 1 point, and high if their score was 2 points.

Statistical analysis

Data are presented using number, percentage, mean, and standard deviation, as appropriate. For between group

comparisons, the Mann-Whitney U test or the Kruskal Wallis test was applied. A P-value of < 0.05 was considered statistically significant. Normality tests were conducted using the Shapiro Wilk test. A correlation procedure was conducted to determine linear agreement between confidence and practice scores. All data analyses were performed using Statistical Packages for Social Sciences (SPSS) version 21 Armonk, NY: IBM Corporation.

Results

Responses from a total of 312 HCPs were included in the study. Table I shows the demographic characteristics of the participating healthcare providers. More than two thirds (67.9%) of respondents were in the youngest age group (24-34 years), more than half (55.1%) were female, and a majority were physicians (66.7%). The most common participating job positions were resident physician (27.9%) and consultant physician (22.1%). Of the 87 residents, more than one-third (34.5%) were first year level (R1), followed by third year (R3) (24.1%) and fourth year (R4) (19.5%). Figure 1 shows the department specialties of the participated HCPs. The most frequently participated specialty was ear, nose, and throat (ENT) (13.5%), followed by both nursing and family medicine (9.9% each). Physical therapy, oral and maxillofacial surgery, neurosurgery, and intensive care were the least participated specialties (0.3% each).

Figure 2 shows the COVID-19 related risk factors among the participants. Responses show that the most common COVID-19- related risk factor among the HCPs was

Tab. I. Socio demographic characteristics of the participated healthcare providers (n = 312) during the early stages of COVID-19 pandemic in 2020, Saudi Arabia.

Study data	N (%)
Age group	
24-34 years	212 (67.9%)
35-44 years	60 (19.2%)
45-54 years	26 (08.3%)
55-64 years	11 (03.5%)
≥ 65 years	03 (01.0%)
Gender	
Male	140 (44.9%)
Female	172 (55.1%)
Practitioner type	
Physician	208 (66.7%)
Non-physician	104 (33.3%)
Job description	
Resident Physician	87 (27.9%)
Consultant Physician	69 (22.1%)
Specialist/Fellow Physician	44 (14.1%)
Nurse	31 (09.9%)
Radiology technician	24 (07.7%)
Laboratory technician/specialist	20 (06.4%)
Respiratory therapist	14 (04.5%)
Emergency medical technician	10 (03.2%)
General practitioner	02 (0.60%)
Other	11 (03.5%)
Resident level (n = 87)	
R1	30 (34.5%)
R2	15 (17.2%)
R3	21 (24.1%)
R4	17 (19.5%)
R5	04 (04.6%)

Fig. 1. Participated department specialties.

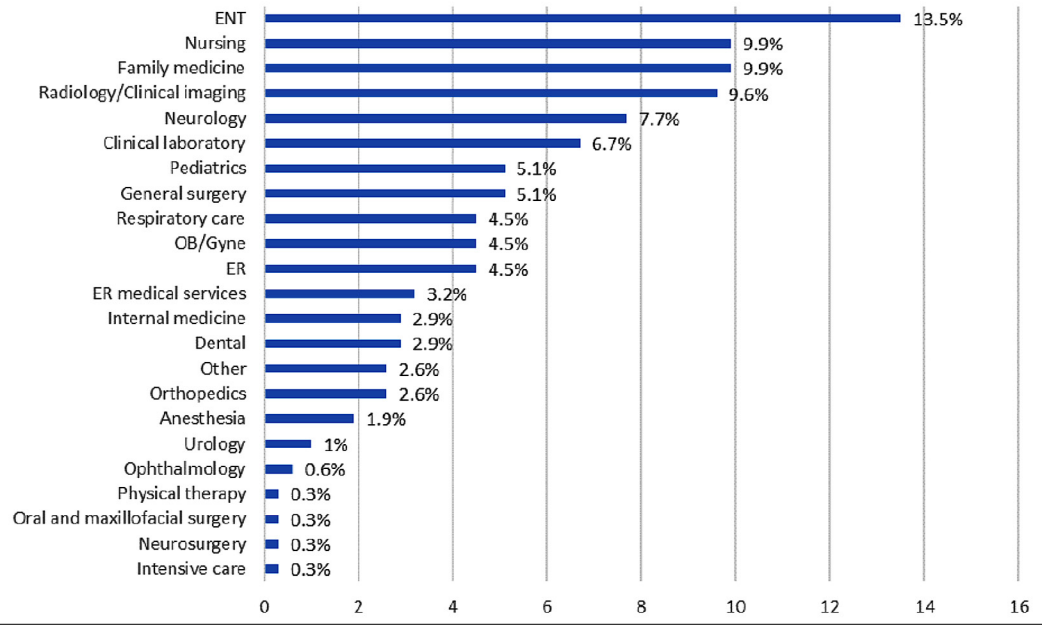


Fig. 2. Diseases associated with higher risk of COVID-19 among the study participants.

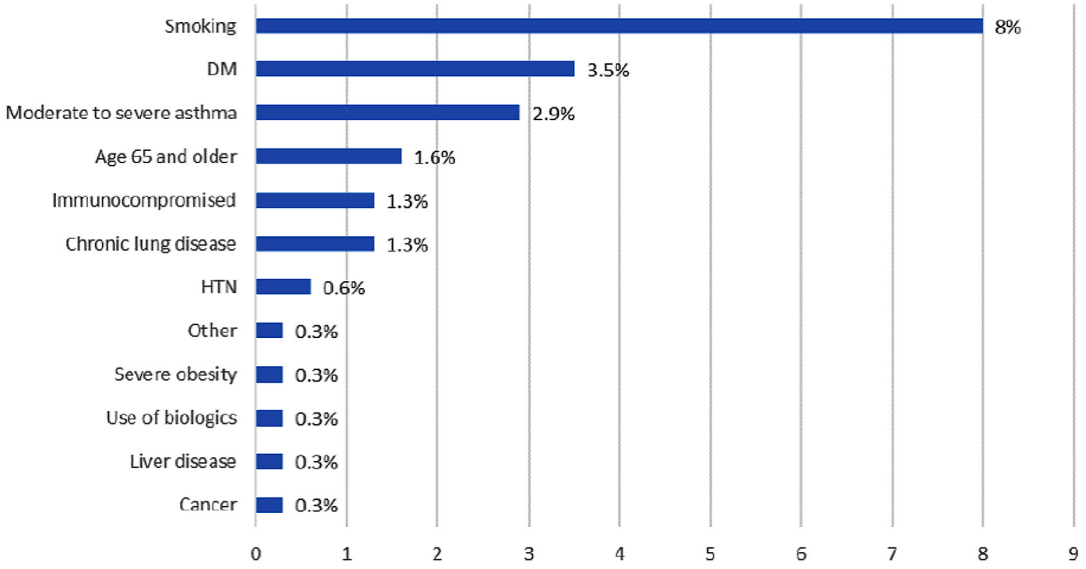


Fig. 3. Generating procedures performed on suspected COVID-19 patients by the participants.

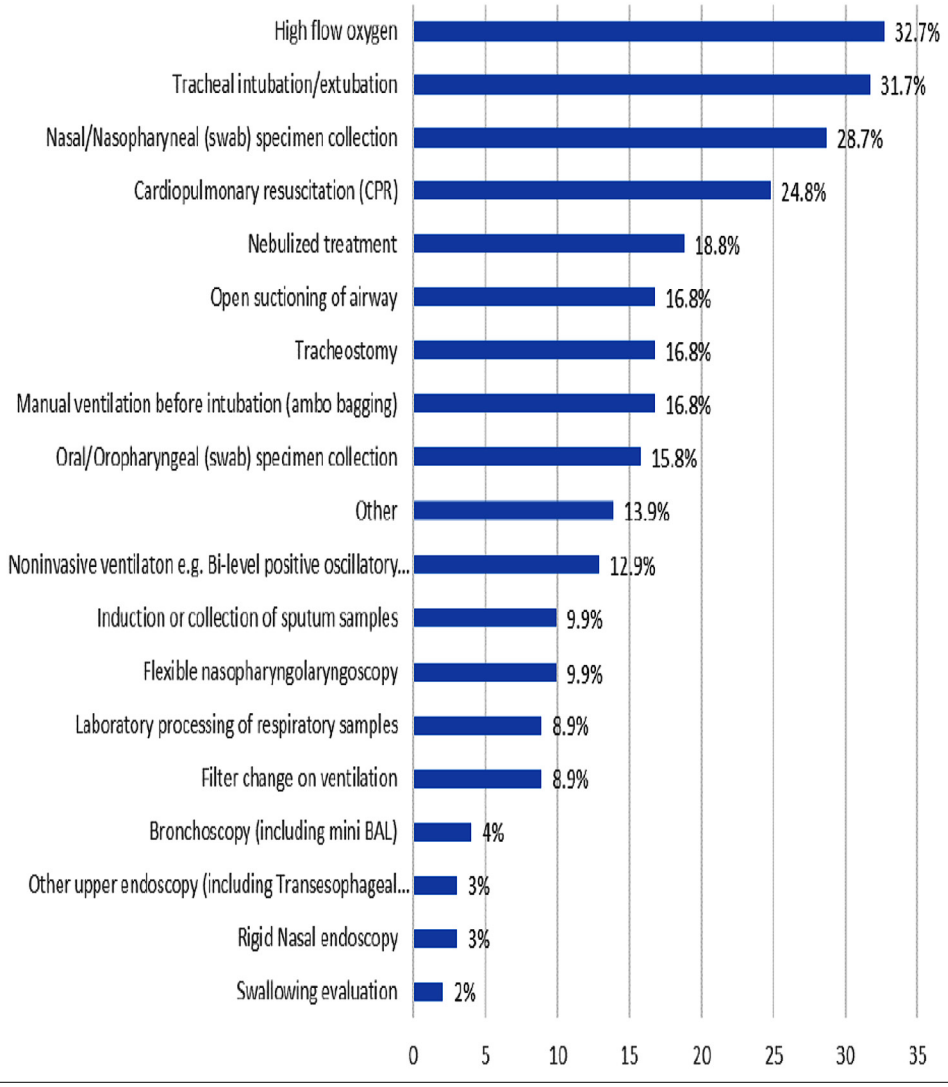


Fig. 4. Reported sources of information regarding COVID-19 safety practices.

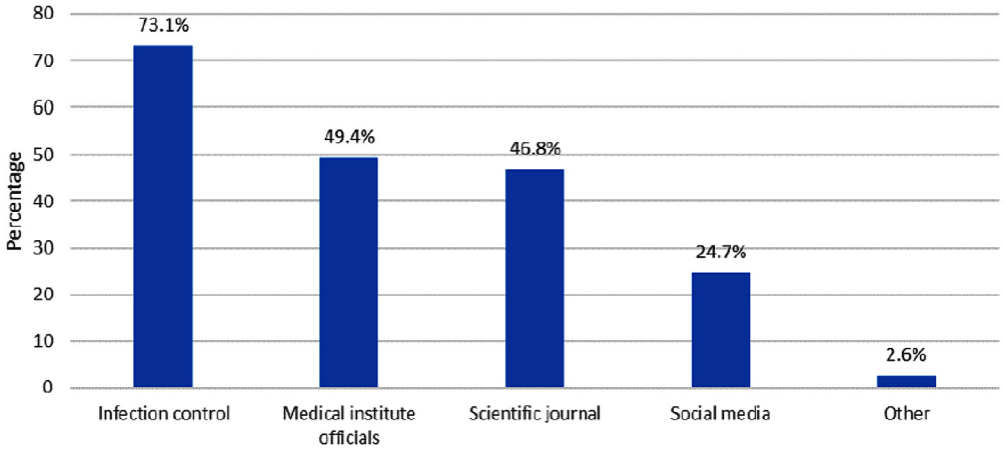
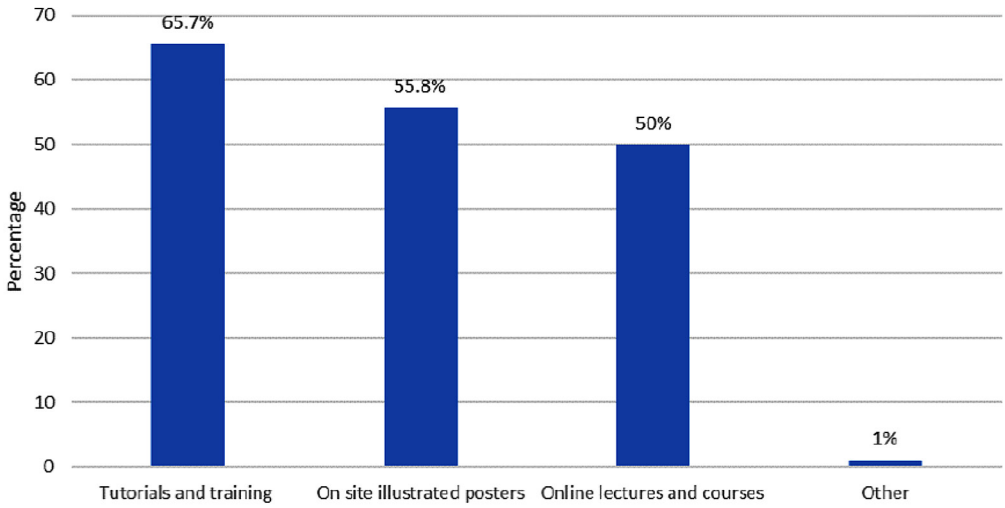


Fig. 5. Necessary sources of knowledge and skills needed to improve performance on appropriate infection control practices reported by the participants.



smoking (8%), followed by Diabetes Mellitus (DM) (3.5%) and bronchial asthma (2.9%) (Fig. 2). Figure 3 shows the aerosol generating procedures performed and/or attended by the participants on a suspected COVID-19 patients. The most frequently reported procedures performed on suspected COVID-19 patients were high flow oxygen (32.7%), followed by tracheal intubation/extubation (31.7%) and nasal/nasopharyngeal (swab) specimen collection (28.7%). Swallowing evaluation was the least reported procedure (2%) (Fig. 3).

Figure 4 describes the sources of information regarding COVID-19 safety practices reported by the participants. The most reported sources of information regarding COVID-19 safety practices were infection prevention and control information leaflets (73.1%), followed by medical institute officials (49.4%) and scientific journals (46.8%). Figure 5 shows the participants favorable sources of knowledge and skills needed to improve performance on appropriate infection control practices. The need for tutorials and training were major concerns reported by the HCPs (65.7%) in regard to how their performance on appropriate infection control practices could be improved, on-site illustrated posters was reported second (55.8%) and online lectures and courses were reported third (50%).

Table II describes the assessment of the participating HCPs' general knowledge of COVID-19 and the recommended PPE. The results indicate that the HCPs had good knowledge of the following statements: "knowledge about the sequence of donning (putting on) and doffing (taking off) of PPE" (74% yes), "had been tested for an N95 mask/respirator in the past 2 years" (70.2% yes), and "received formal training regarding the use of recommended PPE for airborne transmitted

infection at the current institution" (66.3% yes). On the other hand, HCPs indicated poor knowledge with regard to the statement "knowledge about the indications of re-fit testing prior to 2 years" (36.2% yes).

Each participant's answers to the sequence of PPE donning and doffing were reviewed and scored as correct or incorrect based on the CDC guidelines. Table III describes the assessment of participant's practices toward the recommended PPE during the early stages of the pandemic. HCPs responses indicated poor practices regarding the correct sequence of donning of PPE (13.8%) and the correct sequence of doffing of PPE (3.5%). Table IV shows the assessment of the level of confidence of HCPs in using the recommended PPE during the COVID-19 pandemic. Based on our investigations, HCPs showed high confidence in both statements, "confident wearing the right level of equipment to keep safe" and "confident in practicing the right PPE donning and doffing techniques" (94.6% each).

Table V presents descriptive statistics on confidence in and practice of using recommended PPE during the COVID-19 pandemic. According to the results, the total mean confidence score was 1.89 (SD 0.42) out of 2 points, and, based on the given criteria, 92.9% were classified as having high confidence, 3.2% as having moderate confidence, and 3.8% as having low confidence levels. With regard to practice, the total mean score was 0.017 (SD 0.39) out of 2 points, with 83.3% having a low practice level, while the remaining HCPs had moderate (16%) or high (0.6%) practice levels.

Figure 6 depicts the correlation (Pearson-r) between confidence and practice level scores. Based on these results, there was no significant correlation observed

Tab. II. Participant's General knowledge about COVID-19 and the recommended PPE (n = 312).

Statement	Yes (%)
Have you ever provided care to a suspected or confirmed COVID-19 patient?	181 (58.0%)
Were you present when any aerosol generating procedures (AGP) was performed on a suspected or confirmed COVID-19 patient?	101 (32.4%)
Have you received formal training in the use of recommended PPE for airborne transmitted infections at your institute?	207 (66.3%)
Have you been fit tested for an n95 mask/respirator in the past 2 years?	219 (70.2%)
Do you know the indications for re-fit testing prior to 2 years?	113 (36.2%)
Do you know the sequence of donning (putting on) and doffing (taking off) PPE?	231 (74.0%)

Tab. III. Assessment of practices toward the recommended PPE during the early stage of COVID-19 pandemic (n = 312).

Statement	Correct answer N (%)
Correct sequence of donning (putting on) of PPE	43 (13.8%)
Correct sequence of doffing (taking off) of PPE	11 (03.5%)

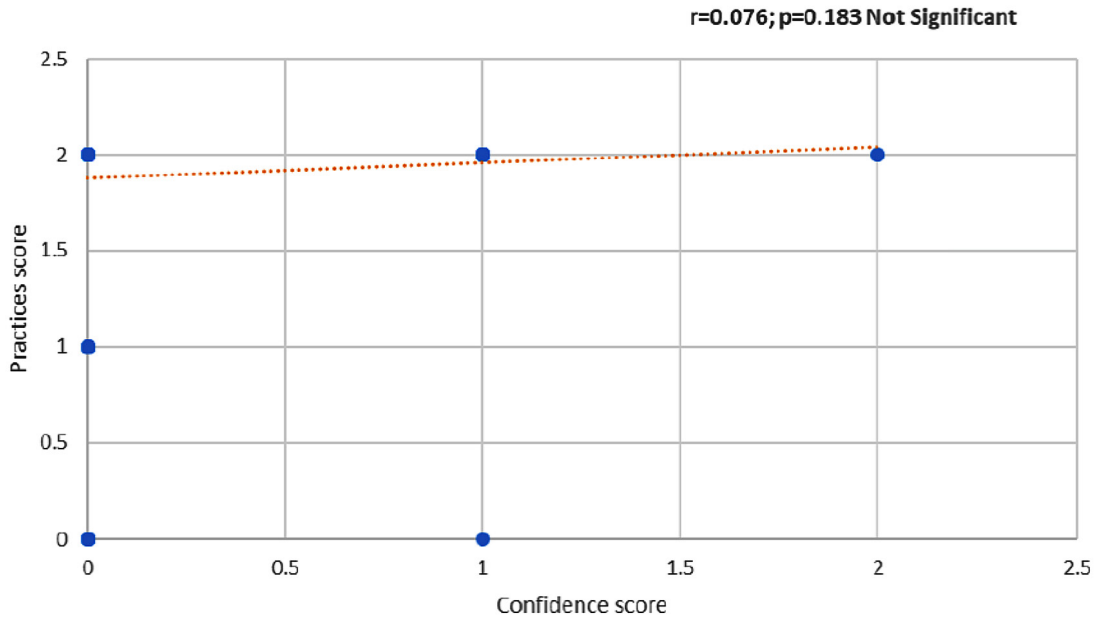
Tab. IV. Assessment of confidence in using the recommended PPE during the early stage of COVID-19 pandemic (n = 312).

Statement	Correct answer N (%)
Confident wearing the right level of equipment to keep you safe	295 (94.6%)
Confident practicing the right PPE donning and doffing techniques	295 (94.6%)

Tab. V. Descriptive statistics of the practice of and confidence in using the recommended PPE during the early stage of COVID-19 pandemic (n = 312).

Variables	N (%)
Confidence score (mean ± SD)	1.89 ± 0.42
Level of confidence	
Low	12 (03.8%)
Moderate	10 (03.2%)
High	290 (92.9%)
Practice score (mean ± SD)	0.17 ± 0.39
Level of practice	
Low	260 (83.3%)
Moderate	50 (16.0%)
High	02 (0.60%)

Fig. 6. Correlation (Pearson-r) between confidence and practices score among the participating healthcare providers.



Tab. VI. Statistical association between confidence and practice scores in relation to the sociodemographic characteristics of the participated healthcare providers (n = 312).

Factor	Confidence score		Practices score	
	Mean ± SD Total (2)	T/F-test; p-value	Mean ± SD Total (2)	T/F-test; p-value
Age group 1				
< 35 years	1.92 ± 0.33	T = 1.778; 0.306	0.20 ± 0.43	T = 1.943; 0.062
≥ 35 years	1.83 ± 0.55		0.11 ± 0.31	
Gender [1]				
Male	1.96 ± 0.22	T = 2.825; **0.008 [3]**	0.16 ± 0.40	T = -0.641; 0.340
Female	1.83 ± 0.52		0.19 ± 0.39	
Healthcare provider [1]				
Physician	1.86 ± 0.47	T = -2.120; **0.014 [3]**	0.17 ± 0.40	T = 0.000; 0.859
Non-physician	1.96 ± 0.28		0.17 ± 0.38	
Job description [2]				
Resident	1.92 ± 0.31	F = 5.379; **0.003 [3]**	0.11 ± 0.32	F = 4.774; **0.008 [3]**
Consultant	1.84 ± 0.48		0.34 ± 0.57	
Specialist/fellow	1.74 ± 0.66		0.09 ± 0.28	
Allied medical	1.98 ± 1.89		0.21 ± 0.41	
Resident level (n = 87) [2]				
R1	1.80 ± 0.48	F = 1.842; 0.116	0.10 ± 0.31	F = 0.308; 0.866
R2	2.00 ± 0.00		0.07 ± 0.26	
R3	2.00 ± 0.00		0.14 ± 0.36	
R4	1.94 ± 0.24		0.12 ± 0.33	
R5	2.00 ± 0.00		0.25 ± 0.50	

[1] P-value has been calculated using Mann Whitney U test; [2] P-value has been calculated using Kruskal Wallis test; [3] Significant at $p < 0.05$ level.

between confidence and practice scores (r = 0.076; p = 0.183). Table VI describes the statistical association between confidence and practice scores in relation to the demographic characteristics of the participating healthcare providers. We found that being a male (T = 2.825; p = 0.008), being a non-physician (T = -2.120; p = 0.014) and an being allied medical professional (F = 5.379; p = 0.003) had significantly higher correlation with higher confidence level. On the other hand, being a consultant had significantly lower correlation with better practice scores (F = 4.774; p = 0.008) (Tab. VI).

Discussion

By the time the WHO declared COVID-19 a worldwide pandemic, healthcare systems have made many strategies to meet the challenges of COVID-19. Healthcare providers play an essential role at the front lines, providing care for patients. In this study, we aimed to evaluate the preparedness of our HCPs to maintain infection prevention and control measures as well as to emphasis the importance of following the recommended PPE usage guidelines. If not properly used, PPE could pose serious risk for self-contamination [14]. The CDC has published guidelines for HCPs to adhere to when they are dealing with confirmed or suspected COVID-19 cases [15]. Before providing care for these cases, HCPs must receive comprehensive training on which type and when PPE is needed, how to put on (donning) and take off (doffing) PPE, the limitations of PPE, and proper disposal of PPE. Face-to-face practice, video lectures, and computer simulation leads to fewer errors in comparison with traditional written protocols [14]. HCPs must demonstrate competency while performing these infection control policies [15, 16]. Donning and doffing the PPE must be practiced. More than one method might be acceptable. Following the health care institution's infection control policies is critical for the safety of oneself and others. The CDC has published a protocol for donning and doffing PPE [15]. Using this protocol has been reported to lead to a lower risk of infection when compared to no guidance [14]. Correct donning sequences are as follows: 1) gather required PPE items needed; 2) perform hand hygiene; 3) put on the isolation gown; 4) put on an N95 or higher fit-tested respirator; 5) put on the face shield or goggles; and 6) put on gloves. By following this protocol, the HCP is now ready to deal with the patient [15, 17]. Correct doffing sequences are as follows: 1) remove gloves; 2) remove gown; 3) exit the room; 4) perform hand hygiene; 5) remove the face shield or goggles; 6) remove and discard the respirator; 7) end with additional hand hygiene [15, 17].

According to the responses on our survey, more than half of the participants provided care to suspected or confirmed COVID-19 patients, and approximately one third were present during an aerosol generating procedure. These numbers indicate the risk of work-related exposure to the virus among these HCPs. To evaluate PPE knowledge, HCPs were asked the order in which they would don (put on) and doff (remove) PPE equipment. In our study, 231 participants (74%) assumed that they knew the correct sequence. A total of 295 participants (94.6%) showed confidence regarding following the right sequence of donning and doffing. However, only 43 participants (13.8%) demonstrated the right sequence of donning, while only 11 participants (3.5%) demonstrated the right sequence of doffing. These results raise concerns about the risk of COVID-19 nosocomial infection among HCPs. To the best of our knowledge, there is currently only one published study, conducted in Canada, where PPE donning and doffing sequences among HCPs during COVID-19 were evaluated. A total of 175 HCPs in Toronto, Canada completed a survey on knowledge and PPE usage. Only 86 participants (50%) put on (donned) the PPE in the correct order and only 60 participants (35%) took off (doffed) PPE in the correct order [18]. Comparing to our results, these percentages were higher, indicating better donning and doffing performance among those participants. This could be explained by the way those HCPs were trained before conducting their study. They had a mandatory COVID-19 PPE training, with a hands-on demonstration of PPE donning and doffing by an occupational health and safety team. In addition, a video of the proper PPE usage sequence and printed instructional materials were given to all HCPs. However, these findings raise concerns about PPE practice, especially the doffing technique.

Based on experiences from past infectious disease outbreaks, self-contamination rates can reach as high as 46-90% among HCPs during doffing [19, 20]. Occupational infection with COVID-19 has been investigated, and studies from China and Italy have shown that 3.8 and 11% of confirmed cases, respectively, were among healthcare providers [21, 22]. Even when HCPs presume that they are correctly trained on PPE usage, many factors might contribute to self-contamination during doffing. These include difficulty differentiating between dirty (outside) and clean (inside) surfaces, poorly fitting PPE, forceful movements, incorrect doffing sequences, and inconsistent PPE training [23]. In a study that focused on contamination of health care personnel during removal of PPE, 435 participants were observed during doffing of PPE. Skin and clothes contamination occurred in 200 participants (46%), which occurred most frequently during removal of gloves (52.9%) and gowns (37.8%) [24].

Adhering to infection and prevention control (IPC) guidelines, including the use of PPE, was studied by Houghton et al. [7]. They found that healthcare providers are more likely to adhere to the IPC guidelines when clearly communicated. PPE-trusted quality and usage training are critical in achieving HCP adherence [7]. In one Canadian study, adherence to the PPE protocol was found to be only 56% among physicians. To address these lapses in donning and doffing, a model was adopted in which two physicians were assigned to work together for patient care. One physician performed patient assessment, while the other acted as a spotter for donning and doffing [25].

Tong et al. assessed the risk of nosocomial infection of SARS-CoV-2 among frontline healthcare providers in a cohort study that was conducted on 222 frontline medical staff serving in Wuhan during the COVID-19 outbreak. None of the staff were infected. This could be explained by the extensive training and safety reviews provided to the staff. The authors suggest that preventing occupational infection is an achievable goal [26].

The National Institute of Safety and Health (NIOSH) in the United States demands an annual respirator fit test to ensure tight fitting and proper safety for the HCP before it

is used in the workplace [27]. NIOSH research confirms that there is a 10% chance of fit test failure after one year using the same respirator. A fit test must be repeated even before one year is past if there have been any physical changes that may affect the tight fitting of the respirator (e.g. significant weight loss of more than 20 Ibs, major dental work, facial scarring or cosmetic surgery) [27]. In our study, HCPs showed poor knowledge for the need of retest, as only 36.2% knew about it.

Based on our analysis, there were no significant correlations between the confidence and practice scores ($r = 0.076$; $p = 0.183$), despite inconsistent high confidence and poor practice. These results can help us to understand PPE practice issues among our HCPs and how to best direct attention to improve their practice. We found that 210 (67.30%) participants preferred tutorials and training monitored by infection control instructors, and 179 (56.41%) preferred onsite illustrated posters (patient room, ER, OR, etc.).

The demand for PPE is increasing worldwide, and it has become greater during the current pandemic. In a cross-sectional study by Suleiman et al., which included 308 physicians from different specialties, only 57 frontline doctors (18.5%) reported that all of the types of PPE were available to them. This lack of equipment increases risk of infection [28]. In our study sample, only 130 respondents (41.6%) reported that all of the PPE types were available. Powered Air-Purifying Respirators (PAPRs) were not always available according to 101 (32.3%) of respondents, and N95, FFP2, or FFP3 respirators were not always available according to 97 (31.0%) of the respondents. The CDC has published a PPE burn rate calculator in the form of a spread-sheet-based model. Each day, the number of confirmed and suspected COVID-19 cases can be added, along with the number of full boxes of PPE items in stock. This tool estimates PPE consumption (burn rate) [29], and can help health care institutions adjust for their future need of supplies.

Our study has several limitations. First, participants were enrolled using convenience and snowball sampling methods, which could have limited the external validity. Second, we were only able to nominally investigate HCP knowledge about PPE, using self-reported surveys within a limited time period. However, this investigation gives us a glance into current COVID-19 related PPE knowledge and practice among our HCPs. Our results reflect findings of previous studies on donning and doffing PPE practices, but, due to lack of standardized methodologies, comparison is limited. Piché-Renaud P-P, et al. investigated the use of personal protective equipment (PPE) among HCPs. Their cross-sectional survey also found deficiencies in reporting PPE doffing sequence. Therefore, they created an online module to reinforce and improve infection control and prevention measures learning and practices, with special focus on donning and doffing sequences [18]. In another study, a self-reported survey was used to assess knowledge, attitude, and practice of HCP toward Middle East Respiratory Syndrome (MERS) infection. They concluded that HCP showed good knowledge and positive attitude but low to average practice toward MERS [30]. Further investigations and researchs will be required to fill the knowledge gaps and to overcome the practice challenges. Our team suggests a multi-center study that recruits an appropriately sized sample with participants who work on the frontlines, as well as other HCPs. In addition, it will be important to modify and standardize the survey to more thoroughly investigate knowledge and practice.

Conclusions

Our study results demonstrate deficiencies among the participating healthcare providers in following the recommended practices for correctly using PPE during the early stages of the COVID-19 pandemic. Poor practice in PPE donning and doffing necessitates additional educational and training programs focused on infection control practices. Additionally, there must be further assessment of HCPs practices to achieve the improvement required to decrease the risk of infection transmission.

Institutional review board statement

The study was conducted according to the guidelines of the Declaration of Helsinki, and was approved by the Institutional Review Board (IRB) of Imam Abdulrahman Bin Faisal University (IRB - 2020 - 01 - 183).

Data availability

The dataset used in this research are available upon request from the corresponding author. The data are not publicly available due to restrictions i.e., privacy or ethical.

Supplementary materials

Questionnaire template for knowledge and practice of recommended (PPE) during COVID-19 pandemic.

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Conflict of interest statement

The authors declare no conflict of interest.

Authors' contributions

Conceptualization, MA; Methodology, SA and AA; Project administration, NA; Resources, ZA, AA and AA; Supervision, MA; Writing - original draft, SA and FA; Writing - review & editing, MA, SA and FA. All authors have read and agreed to the published version of the manuscript.

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COVID-19

Explaining the challenges of the Iranian Health System in fighting the COVID-19 pandemic: A Qualitative Study

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Keywords

Health system • Challenges • COVID-19 • Coronavirus • Pandemic

Summary

Introduction. *The COVID-19 pandemic has become a global threat for the general public and health care workers, and it has created major challenges for all healthcare sectors. The challenges created by this disease can vary in different countries depending on cultural, social, and economic factors. The purpose of this study was to explain the challenges of the Iranian health system in fighting the COVID-19 pandemic from the managers' and executive authorities' viewpoints.*

Methods. *The present study was a basic-applied research performed using a qualitative approach. It has studied 30 hospitals and medical centers' managers, deputies of the Ministry of Health, and the universities of medical sciences, which were selected by purposive and snowball sampling with the maximum variety in March-September 2020. Data collection was done through semi-structured interviews and content analysis was used to explain the challenges of the Iranian health system in fighting the COVID-19 pandemic (2020).*

Results. *Most of the interviewees (34%) had a Ph.D. degree, and 40% of the participants were graduated in management and health economy and policymaking fields. Analysis and synthesis of the data collected from the interviews led to the creation of 19 sub-themes and 12 main themes classified into four general scopes: organizational factors, resources, management factors, and other factors.*

Conclusion. *Identifying the mentioned challenges can provide helpful information for the managers and policy-makers to develop appropriate plans, take the necessary measures to resolve the challenges, and use the available resources to provide the most effective services.*

Introduction

Infectious diseases have constantly threatened human life and they can even ruin social stability. At the time of the spread of contagious diseases, especially when there is no specific prevention, people become scared. Therefore, infectious diseases are critical social problems that the government should control. Also, it is so essential for governments to suppress contagious diseases [1]. In fact, after an epidemic, delayed diagnosis and response will be a public challenge [2].

On December 31st, 2019, a group of patients with pneumonia were observed in Wuhan, Hubei, China. Further research revealed that this disease originated from the seafood market and is quite similar to viral pneumonia. This disease was different from severe acute respiratory syndrome coronavirus (SARS-COV) and Middle East respiratory syndrome coronavirus (MERS-COV); However, due to the structural similarities, the recent virus was considered as the first member of the coronavirus family that can transmit by humans [3-5]China, was caused by a novel betacoronavirus, the 2019 novel coronavirus (2019-nCoV. On February 11th, 2020, the World Health Organization (WHO) named this virus COVID-19, the short form of coronavirus disease 2019 [6]. This virus had a high dissemination speed, and on March 7th, 2020, after about two months of observing the first case, more than one hundred thousand people (101927) were infected by this virus in more than 90 countries [7]. On March 9th, 2020, the head of WHO mentioned the risk of the occurrence of this pandemic [8]. Finally, on March 11th, 2020, WHO declared this virus as a pandemia [9, 10]. So far, this virus has infected more than 139 million people and caused death to more than 3 million people worldwide. More than 2.1 million people have become infected by this virus in Iran, and more than 66 thousand people have died because of COVID-19 [11].

The high prevalence of this virus has caused fear, worry, health risks, and severe impacts on economic growth and social development [12]. In different societies, this virus has caused significant effects on the economic, banking, and insurance sectors, and the governments and financial markets [13]. The agriculture, petroleum, industry, and education sectors have also become affected by this pandemic, and it has caused the fear of economic crisis and recession. The emphasis on the observance of social distancing, quarantine, and traffic limitations has led to unemployment and serious damage to some jobs. Also, the demand for several goods has decreased and the need

for medical equipment has significantly increased [14]. COVID-19 pandemic has become a global threat for the general public and health care workers [15]; so that it has dramatically affected the provision of health services and telemedicine, the patients' expectations, the health care infrastructures, medical education, and research and publications in the scope of the of healthcare and medicine [16].

Meanwhile, the prevalence of this virus has led to significant challenges in the health economy, general health, and medical infrastructures [17]. The high costs of healthcare services, lack of personal protective equipment, lack of hospital beds and ventilators in intensive care unit (ICU) wards, and poor quality of patient care services are some of the challenges created by this disease [14]. On the other hand, this situation has created fear, concern, and anxiety for people [18].

The challenges created by this pandemic can vary in different countries depending on cultural, social, and economic factors. This study aims to explain the challenges of the Iranian health system in fighting the COVID-19 pandemic from the viewpoint of the managers and executive authorities working in the frontline of fighting with coronavirus, the managers and policy-makers of the Ministry of Health, and some of the Iranian medical sciences universities. Identifying these challenges can help the managers and policy-makers to make better decisions for fighting this pandemic.

Methods

This research was a basic-applied study performed using a qualitative approach [19] and content analysis [20, 21]. It aimed to explain the challenges of the Iranian health system in fighting COVID-19, 2020.

Selection of the participants

The participants' opinions were collected by purposive and snowball sampling with the maximum variety in this study. The participants were selected from all the managers and deputies of the Ministry of Health, the universities of medical sciences, and hospitals and medical centers' managers of Tehran, Iran, Shiraz, and Yazd Universities of Medical Sciences. The inclusion criteria included the participants' willingness to attend the study, at least one year of experience in management or specialized education in management and health policymaking, and also involvement in COVID-19 control or treatment issues in recent year. Data collection continued until reaching data saturation [22]. Finally, 30 people were interviewed, including ten hospital and medical centers' managers and 20 managers and deputies of the Ministry of Health and the mentioned universities of medical sciences.

Data collection

Data collection was done by an interview. First, an unstructured interview was done with three people in the frontline of pandemic management. They had comprehensive information about the challenges of the Iranian health system in managing and fighting COVID-19 by one of the researchers. Then, the main questions were designed about workforces, equipment, place and facilities, process, and internal and external communications. Finally, an open question was included to remind the interviewees about the probably missed issues. In the next step, to evaluate the validity of the questions, two experts were interviewed as a pilot stage. These interviews were included in the final analysis because of the similarities with the main phase of interviews. Before performing the main interviews, the interviewees were informed and received some explanations about the research goals and the interview schedule, its time, and place.

Due to the dispersion of the interviewees in this study and the limitations caused by COVID-19, the interviews were performed by four researchers. At the time of the interviews, the researchers explained the research goals again and ensured the participants about using their recorded voices privately without using their names. Also, they asked to fill a consent letter for participation in the study. To prevent possible problems, the contents of the interviews were recorded in addition to taking some notes. The interviews were continued until reaching data saturation (30 interviews) and they were performed in March-September 2020 in the participants' workplace. The researchers tried to conduct the interviews in an informal space, without any bias, and avoid expressing their ideas about the answers. The interviews lasted an average of 23 minutes. To reduce intervening factors, the specialists were asked to turn their cellphones off and prevent the entrance of anyone into their workplace, at the time of the interview.

After conducting the interviews, the researchers immediately wrote the recorded contents on the same day. In addition to the written contents, the interviewees' specialty and position, time and place of the interview, and other necessary information were also included in the documents. The interviews and the filled forms were assigned a specific code to facilitate the later reviews. Also, the participants were asked if they were willing to answer any further questions in the following. After writing the interview texts, the interviewees were called again and added the necessary information to the forms when there was any ambiguity.

Data analysis

After conducting the interviews and writing recorded contents, the collected data was analyzed and synthesized. Data analysis was done through qualitative content analysis. Many studies have used this method for subjective content interpretation of text data by systematic stratifying, coding, theme development, and designing common patterns processes [20, 21]. This analysis mainly aims to provide a precise and comprehensive description of the phenomenon and it results in the extraction of the concepts and categories that explain the phenomenon [23]. Before data analysis, one of the researchers reviewed all the recorded interviews to check their accuracy. Then, two researchers read the written texts of the interviews several

times to become familiar with the content of the data. After getting an insight into the collected data, they coded them by parallel coding. In this method, the researchers simultaneously code the written data by reading them. Based on the principles of parallel coding, it is probable that each of the meaningful coding units can be assigned to two different categories with different labels. So, at the end of coding, the researchers reviewed the items and assigned them to the more relevant codes to extract higher levels of subjective concepts such as the themes and sub-themes by inductive and implicit approaches. In the inductive method, since the researcher aimed to extract the underlying concepts of the data and higher levels of subjectivity, after reviewing the texts several times and parallel coding, the researchers defined the code labels. Then, the relevant codes were integrated and sub-themes were formed gradually. In the next step, the themes were generated by reviewing the concepts and their content relationship. Finally, to classify the explained themes, they were classified into four general scopes: organizational, resources, management, and other factors.

Trustworthiness and rigor of the study

Lincoln and Guba's (1994) index was used to ensure the trustworthiness and rigor of the collected data. This index includes credibility, transferability, dependability, and conformability [24]. The researchers used different methods such as taking notes, recording the interviews, long-term involvement, data immersion, co-researchers' revision, and the participants' revision to evaluate the data validity.

Regarding the transferability of the data, since the interviewees are the people who are directly involved in fighting this pandemic, the results of the research can be generalized to other studies performed in Iran or other similar regions. Also, the participants' demographic information is presented in Table I.

Considering the credibility of the data, the researchers have tried to clarify all the research stages, including the selection of participants, performing the interviews, and data analysis. Also, they attempted to include the participants' statements in their findings exactly. Meanwhile, all the recorded interviews, the written contents, data coding, and analysis were supervised by two co-researchers.

Regarding the conformability of the data, two experts out of the research team were asked to evaluate the research procedure and coding process.

Furthermore, all the interviews and the extracted codes were analyzed by two researchers. To approve the similar findings and decide about disagreements, they were compared again. Finally, all the members of the research team studied the themes and sub-themes in a meeting. It should be mentioned that the final synthesis was done by two research team members who did not have any conflict of interest and were qualified in this area. So, the issues related to the conflict of interests and reflexivity were observed.

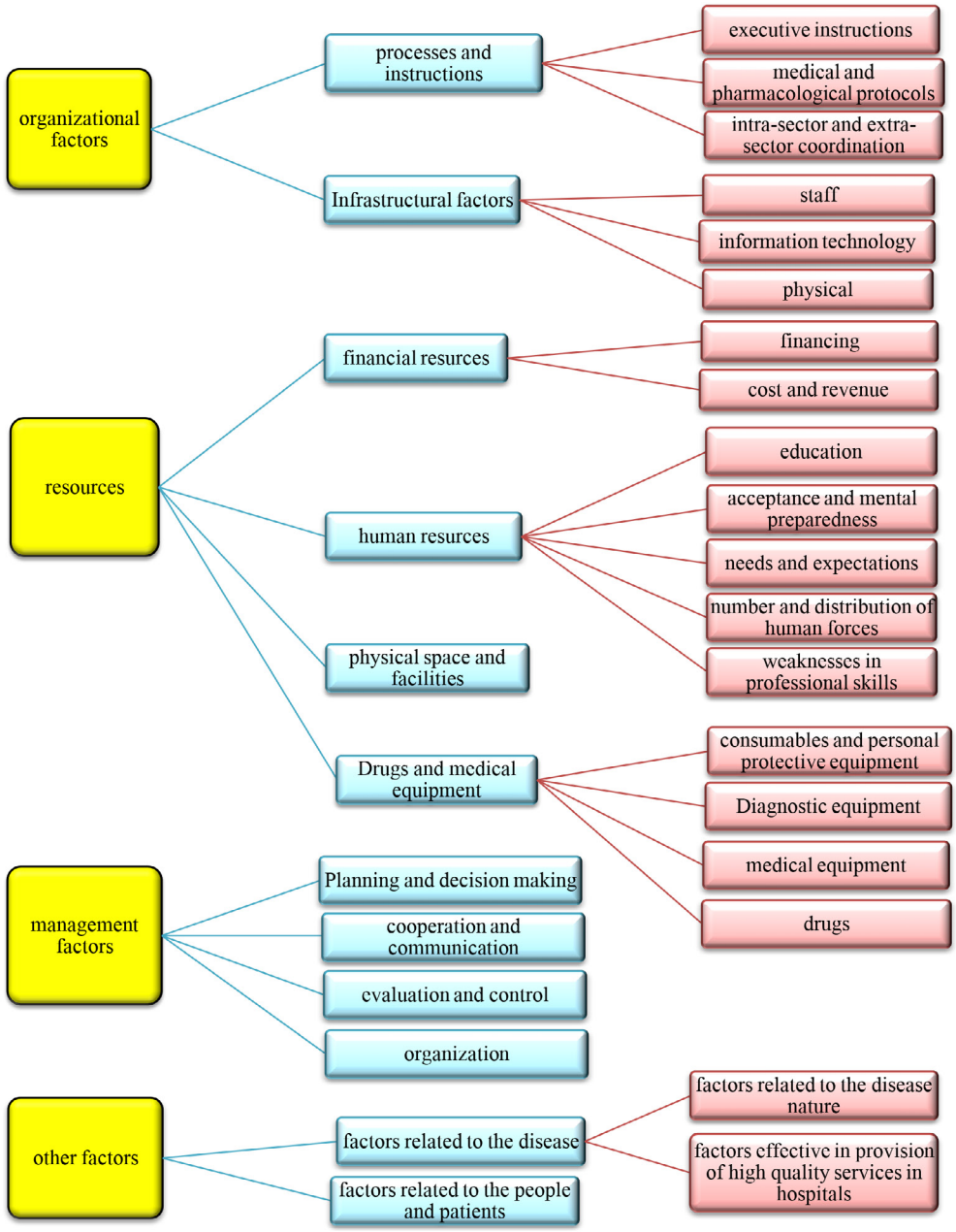
Results

In this study, 30 people were interviewed, including ten middle managers (the executive managers of hospitals and medical centers) and 20 top managers and policy-makers of the Ministry of Health and the Iranian universities of medical sciences. Most of the participants were male (87%) and had Ph.D. (34%) and MSc degrees (27%). Meanwhile, 40% of the participants were graduated in management and health economy and policymaking fields. The participants' average age was 48, and their average working experience was 20 years (Tab. I). Analysis of the data collected from the interviews and the extracted codes led to defining 19 sub-themes and 12 main themes classified into four general scopes: organizational factors, resources,

Tab. I. Characteristic of the study's interviewees.

Variables		Frequency (percent)	Mean ± SD
Experts' field of activity	Middle-level managers (Hospitals' executive)	10 (33)	-
	High-level managers & policy-makers	20 (67)	-
Gender	Male	26 (87)	-
	Female	4 (13)	-
Education degree	MD	3 (10)	-
	MSc	8 (27)	-
	MD, MPH	4 (13)	-
	Medical specialist	4 (13)	-
	MD, PhD	1 (3)	-
	PhD	10 (34)	-
Last field of education	General physician	7 (23)	-
	Special physician	4 (13)	-
	Management, health policy and health economic	12 (40)	-
	Others	7 (23)	-
Age		-	48 ± 7
Work experience (year)		-	20 ± 6
Duration of interviews (minutes)		-	23 ± 10

Fig. 1. The thematic framework of the challenges in front of Iran's health system in dealing with the COVID-19 pandemic.



management factors, and other factors. Figure 1 presents the thematic framework of the challenges of the Iranian health system in fighting the COVID-19 pandemic based on the four mentioned scopes. Also, Table II to V presents all the main themes, sub-themes, and their qualitative codes about the challenges of the Iranian health system confronting the COVID-19 pandemic.

Challenges related to the organizational factors

Challenges related to organizational factors consist of two major themes: "the processes and instructions" and "infrastructural factors".

The processes and instructions

This theme includes three sub-themes, i.e., "executive instructions", "medical and pharmacological protocols", and "intra-sector and extra-sector coordination". The factors related to executive instructions mentioned by the participants included the dispersion and lack of clarity or practicality of some of the Ministry of Health and WHO regulations and the repetitive changes in the protocols, especially in the early stages of the pandemic. One of the participants stated: "The regulations determined by Ministry of Health and WHO, even about some of the protective equipment, were unknown and the main items of personal protection were not specified. Our tasks were also unclear" (P25). Another participant stated:

Tab. II. The challenges of the Iranian health system in fighting COVID-19; organizational factors.

Themes	Line-managers	Staff-managers	Sub-themes and related codes	
Processes and instructions	✓	✓	Executive instructions	Dispersion, lack of transparency, and executive capacity of some of the laws and instructions proposed by the Ministry of Health and the World Organization
	✓	✓		Repetitive changes in the protocols especially in the early stage of the pandemic
		✓		Delay in sending instructions by the Ministry of Health
	✓	✓		Choosing a hospital as the referral hospital
	✓	✓	Medical and pharmacological protocols	Lack of treatment method or standard drug for the disease
	✓	✓		Repetitive changes in the treatment and medication protocols
	✓	✓	Intra-sector and extra-sector coordination	Lack of intra-sector and extra-sector coordination in the early stages of the pandemic
		✓		The time-consuming process of attracting new human forces
		✓		Lack of coordination and agreement among the different deputies of the university about human force attraction
Infrastructural factors		✓	Staff	Lack of experience in hospitals to fight with such prevalent respiratory diseases
		✓		The change in the human force structure in the area of treatment of (non-communicable diseases) compared to hygiene in the recent years
	✓	✓		Lack of specialist forces in some regions especially in the area of infectious diseases, ICU, pulmonary, and internal diseases
	✓	✓	Information technology	Lack of virtual education infrastructures
	✓	✓		Lack of a comprehensive centralized system for registering the positive cases of coronavirus and failure to analyze the data on time for proper decision making
		✓		Lack of electronic health records and previous records and information of the patients' underlying diseases
		✓	Physical	Lack of proper diagnostic infrastructures in the country
	✓	✓		Lack of the necessary infrastructure to prepare a large amount of the consumer and protective equipment
	✓			Lack of readiness of drug distribution network of Food and Drug Administration
	✓			Lack of protective equipment producing companies in the country

"Even supposing their accuracy, the instructions were frequently changing and the hospitals could not change their whole structure again to adjust that with the new protocols" (P8). The other challenge mentioned by some of the participants was choosing a hospital as the referral hospital. "Choosing the center of this disease was one of the challenges. After selecting our hospital as the coronavirus reference center, some disputes were raised about the reason for choosing an educational hospital as the corona disease reference center" (P25). In the sub-theme of intra-sector and extra-sector coordination, one of the issues mentioned by most of the middle and staff managers was the lack of intra-sector and extra-sector coordination in the early stages of the pandemic. This situation had led to the organizations' confusion about how to perform their tasks. "The university did not exclusively charge management. In most cases, we need to negotiate with the province attorney and the police. Although there was good cooperation in our province, it was impossible in many provinces and the order of upstream authorities was necessary" (P19). "Contradiction is the worst agent exacerbating the situation. The organizations were not coordinated at all and there was a weak agreement" (P8). Also, another interviewee (P21) explained: "The academic departments of the hospital did not cooperate in changing the application of the wards and canceling the operations to allocate the operating room to coronavirus patients and preventing the spread of the disease".

Infrastructural factors

These factors include three sub-themes of the staff, information technologies, and physical infrastructural elements. In the area of staff infrastructures, one of the challenges some interviewees mentioned was the lack of specialists in some regions, especially in the area of ICU, infectious, pulmonary, and internal diseases. "We did not educate the human forces to use the surplus forces in crises. So, in the case of a crisis, there will be more need for human forces depending on the specialties. In this pandemic, we faced the lack of specialists in infectious, pulmonary, and internal diseases fields" (P14). In the sub-theme of information technologies, most middle and staff managers mentioned the lack of virtual

education infrastructures. "We faced several problems in the area of educational infrastructures to provide the experimental and clinical education to the students. So, they had to attend the hospital wards to receive the necessary educations" (P25). Some participants mentioned the lack of a comprehensive centralized system for registering the positive cases of coronavirus and the failure to gather or analyze the on-time data for the proper decision-making process. "There should be a system for registering the positive cases of coronavirus so that the registered people could refer to the health system would be available to service providers under criteria of WHO and the Ministry of Health, Treatment, and Education" (P16). In the sub-theme of physical structures, most of the participants mentioned the lack of necessary infrastructures to prepare protective equipment. "One of our challenges was the need for products such as mask and glove in the society and the impossibility of supplying the whole demands at the time of the occurrence of this pandemic" (P17).

Challenges related to resources

These challenges refer to the lack of resources needed to fight this pandemic. They include four major themes: financial resources, human resources, drug and medical equipment, and physical spaces and facilities.

Financial resources

This theme includes two sub-themes of "financing" and "cost and revenue". Considering financing factors, the challenges mentioned by most of the interviewees were included insufficient staff payment benefits and support them. One of the interviewees stated that "the hospital's income had decreased during the pandemic and consequently the payment to the staff also decreased. Therefore, the Ministry of Health provided support to the personnel employed in the wards that involved with COVID-19 patients, but this support was not enough" (P25). In this regard, (P20) stated that: "One of the issues that was so important is that the corona had two important effects on the economy of hospitals, one was that the revenue of hospitals was sharply reduced and the other was that costs per patient increased due to the special needed medicine or equipment".

Human resources

This theme includes the five sub-themes of education, acceptance and mental preparedness, needs and expectations, number and distribution of human resources, and weaknesses in professional skills. Considering education, the challenges mentioned by most of the participants included the inefficiency of the education provided for the personnel to cope with the crises and emergencies, lack of updated and efficient education about infectious and respiratory diseases, and how to care for the patients. "Passive defense and crisis training have been provided for the personnel. However, this crisis showed the inefficiency of these educations" (P23). Also, another interviewee said that "Some of the death cases might be due to the inadequate educations provided for the personnel working in special care wards" (P25). In the sub-theme of acceptance and mental preparedness, some of the participants believed that one of the main challenges was the personnel's (the nurses and specialists) fear of getting infected by this virus and transmitting it to their family as one of the participants explained: "Some of the employees resigned not to be exposed to the risk of being infected by this virus" (P16). In the sub-theme of the needs and expectations, some of the middle managers mentioned the personnel's expectation for supplying personal protective equipment as one of the challenges. "The employees' expectation of receiving personal protective equipment was a challenge for the managers" (P25). In the sub-theme of the number and distribution of human resources, most participants, especially the staff managers, mentioned the lack of a trained and specialist workforce as the most critical challenge. "We had to exclude some of the employees who had an underlying disease and were not able to work in this pandemic" (P21). "Supplying specialized, skilled, and trained staff was also a challenge" (P7). "We faced the lack of experienced and skilled employees in the ICU ward" (P26). In the sub-theme of weaknesses in professional skills, a few numbers of the staff managers mentioned the challenges in the relationship between the personnel and patients, such as: "In the early stages, we did not know how to talk to the patients and what to do for them and what not to do" (P24).

Drugs and medical equipment

The four sub-themes included in this theme include consumables and personal protective equipment, Diagnostic equipment, medical equipment, and drugs. One of the main challenges in this sub-theme was the lack of personal protective equipment such as ordinary masks, N95 masks, gloves, clothes, shields, glasses, head cover, shoe cover, etc. It was mentioned by most of the interviewees. Since the middle and staff managers were responsible for supplying these items, most of them mentioned that as a key challenge. "In the early stages of this pandemic, we faced challenges to supply protective equipment such as mask, special clothing for protection (that was found to be unnecessary later), shield, glasses, head and shoe cover, and other protective equipment" (P25). In the sub-theme of diagnostic equipment, one of the challenges mentioned by some of the interviewees was inaccuracy of diagnostic tests. In this regard, one of the interviewees stated that "the results of some PCR tests performed in the early days of the pandemic were incorrect, which affected the functioning of the health system" (P14). In the sub-theme of medical equipment, most of the participants mentioned the lack of medical equipment (CT scan, oxygen generator, respiratory aids, laser thermometer, and pulse oximeter) and updated laboratory and diagnostic facilities as the other challenges. "In some of the hospitals, we had only one CT scan device. So, we faced challenges in using that

for both corona and other patients. Meanwhile, some of the oxygen generators in the hospitals were not working properly and there was a lack of ventilator in ICU wards" (P53). The other challenge mentioned by some of the staff managers was the lack of useful and effective drugs for the disease in the early stages of the pandemic. "The drugs suggested for the disease were not common drugs; i.e. they were not commonly used and so, they were not produced routinely. For example, one of them was malaria drug that is rare in Iran" (P13).

Physical spaces and facilities

Some of the participants mentioned the observance of infection control protocols in allocating physical spaces to coronavirus wards as one of the challenges of the Iranian health system. This challenge was related to both the hospitals covered by the Health Ministry and the medical sciences universities and the temporary treatment centers established by other institutions. "One of the necessary standards for fighting this disease in hospitals is to separate the corona-patients

Tab. III. The challenges of the Iranian health system in fighting COVID-19; resources.

Themes	Line-managers	Staff-managers	Sub-themes and related codes	
Financial resources		✓	Financing	Lack of finical support for research and hygiene
	✓	✓		Lack of necessary budget and credit
		✓		Lack of transparency in funding some of the actions taken and the problem of paying for them
		✓		Consequences of quarantine such as economic problems
	✓			Inadequacy payment benefits and support for medical staff
	✓	✓	Income and cost	Decreased revenue of hospitals and the consequent problems
	✓	✓		Increase costs per case
Human resources	✓	✓	Education	The problems in the area of education (training) or continuing it during the pandemic
		✓		The professors' unpreparedness for virtual education
	✓	✓		Inefficiency of the education provided for the personnel to fight the critical and emergency conditions
	✓	✓		Lack of up-to-dated and inadequate education about infectious and respiratory diseases and how to care for the patients
		✓	Acceptance and mental preparation	Lack of proper insight to the disease
	✓	✓		The personnel's (the nurses and specialists) fear and anxiety of being infected by this virus and transferring that to their family
	✓	✓		Lack of acceptance and willingness to face the disease in the personnel
	✓	✓		Inadequate mental preparedness in the personnel and the consequent mental problems
	✓	✓		Fatigue and burnout of medical staff / manpower
	✓		Needs and expectations	The personnel's expectation for supplying personal protective equipment
	✓			Providing proper welfare and nutrition facilities for the corona ward personnel
	✓		Number and distribution of human forces	The absence of some of the employees from their workplace
	✓	✓		Increased work load and numerous responsibilities of the personnel
	✓	✓		The employees' personal problems such as pregnancy, having underlying diseases, and high risk conditions
	✓	✓		Lack of manpower
	✓	✓		Lack of specialist and trained manpower
		✓		Inappropriate distribution of manpower and employing them in inappropriate positions
	✓	✓		Infection or death of health workers
		✓	Weaknesses in professional skills	The personnel's inability to management the disease load
		✓		Negligence and not taking seriously in infection control by some of the specialists
		✓		Challenges in the relationship between the personnel and patients

▶

Drugs and medical equipment	✓	✓	Consumables and personal protective equipment	Lack of personal protective equipment such as the ordinary masks, n95 masks, gloves, clothes, shield, glasses, head cover, shoe cover, etc.
	✓	✓		Low quality of some of the personal protective equipment
	✓	✓		Lack of disinfectants
	✓	✓		The need to supply a lot of personal protective equipment and disinfectant in the early stages of the pandemic
	✓	✓		High price and hoarding of the personal protective and consumables equipment
	✓	✓	Diagnostic equipment	Lack of kit and diagnostic equipment
		✓		High price of coronavirus diagnosis kits
	✓	✓		Low accuracy of the diagnosis kits
	✓			Time-consuming process of diagnosis
	✓	✓	Medical equipment	Lack of medical equipment (ct scan, oxygen generator, respiratory aids, laser thermometer, and pulse oximeter) and updated laboratory and diagnostic facilities
		✓		Shortage of hospital beds, especially icu beds
	✓	✓		Depreciated facilities and equipment
		✓		Lack of biobank
		✓		Impossibility of supplying medical equipment from foreign countries
		✓	Drugs	Shortage of useful and effective drug for the disease in the early stages of the pandemic
		✓		High price of drugs
Physical space and facilities	✓	✓	Shortage of physical space in hospitals for reception of respiratory patients such as coronavirus cases	
	✓		Observance of infection control protocols in allocation of physical space to coronavirus wards	
	✓		Inobservance of standards in temporary treatment centers and their low popularity	
		✓	Shortage of laboratory space	
	✓		Lack of infectious (biological) ward, negative pressure ventilation system, and standard isolation room in some of the hospitals	
	✓		Lack of specialized biological (infectious) hospital in the country	
		✓	Inappropriate ventilation in some units	
		✓	Density of personnel in some units	

emergency, triage, and hospitalization wards from the wards allocated to other patients. However, except for some specialized respiratory hospitals, others did not have the capacity of these measures" (P14). "Regarding physical space and the establishment of convalescent homes, our country showed that it has good capacities for fast and shocking actions. Still, the main problem was compliance with the standard. Here, this question is raised: Was it a right decision to establish temporary facilities and change the application of sports fields and parking spaces to the convalescent homes for hospitalization of corona-patients, in terms of the observance of standards?" (P16).

The challenges related to management factors

The main themes of this area are classified into four general categories: planning and decision-making, cooperation and communication, evaluation and control, and organizing.

Planning and decision-making

One of the challenges mentioned by most of the staff managers was the lack of proper plan and preparation in the early stages of the occurrence of this pandemic so that no measure could be taken for the situation. "The Ministry of Health, despite being informed about the disease in the world from a month before it occurred, had no specific and codified plan to deal with this crisis", (P7) interviewee said.

Cooperation and communication

Parallel actions of some of the institutions were other challenges some staff managers mentioned. "Unfortunately, there are many organizations in Iran that take similar measures without any coordination. These parallel decisions, parallel costs, and parallel human resources create serious problems for the health system" (P2).

Evaluation and control

One of the challenges mentioned by some of the interviewees was the lack of any reference to approve the validity of different information and instructions. "In the early stages of the pandemic, instructions were developed by different sectors and circulated to hospitals and other medical centers for implementation. There was no referral institution to evaluate the validity of

Tab. IV. The challenges of the Iranian health system in fighting COVID-19; management factors.

Themes	Line-managers	Staff-managers	Sub-themes and related codes
Planning and decision making	✓	✓	The authorities' negligence in the befor and early stages of the pandemic
	✓	✓	Failure to recognize and diagnose the disease and how to deal with it in the early stages of the pandemic
	✓	✓	Lack of planning and preparation before and in the early phases
	✓	✓	Surprise, the health system's confusion on how to deal with the disease
		✓	No need assessment and proper estimate before the measures and decisions
		✓	Poor crisis management and lack of plan before, during, and after the early crisis
	✓		Passive, reactive, and nonsystematic actions
		✓	Poor evidence-based policy making
Cooperation and communication		✓	Lack of on-time information and education for the general public
		✓	Poor performance of passive defense
	✓		Stopping the activity of medical equipment supplying companies in quarantine
		✓	Parallel actions in some of the organizations
		✓	Lack of coordination and organization of the facilities provided by charities
		✓	Delayed formation of the national headquarters of COVID-19 administration
		✓	Poor management of the media and virtual space
Evaluation and control	✓	✓	The large mass dispersed and invalid information and inadequacy of the reliable statistics and information
	✓		Lack of a reference for checking and approving the instructions
		✓	Lack of attention to the experiences of successful countries in fighting coronavirus and failing to use different post-crisis policy models
		✓	Irrational use of the drugs such as antibiotics
	✓		Lack of supervision of prices in the early phases of the pandemic
		✓	Lack of international control on the borders and openness of the country's entrances
Organization	✓	✓	More focus on treatment than prevention and less attention to care systems
	✓	✓	The unclear role of the temporary treatment centers and lack of proper management in them
	✓		Involvement of most of the hospitals in the diseases in some periods
	✓	✓	Lack of a trustee, management and command system in the beginning of the pandemic
		✓	Poor management of the available resources and waste of the resources
	✓	✓	Failing to use all the available capacities and institutions
	✓	✓	Improper allocation of financial supports among the personnel (inequity)

the instruction and circulate them. Different versions of instruction were contradictory and it was tried to execute them quickly" (P16).

Organizing

Another challenge some participants mentioned was the lack of trustee and a specific and clear management structure at the beginning of the pandemic that led to the confusion of the involved organization. "We did not have any proper and systematic structure in Ministry of Health, universities, province attorneys offices, and another institution in charge of coronavirus management. The previous structured proposed for crisis management were not efficient in this situation" (P6).

Other factors

Two categories of themes, including "the factors related to the people and patients" and "the factors related to the disease" were included in this area, besides the other mentioned challenges.

The factors related to the people and patients

One of the main challenges mentioned in this area is the people's fear of the disease. For example, one interviewee stated, "Most of the patients were somewhat frightened when they became informed of their disease and became quite frustrated after being transferred to the ICU" (P24).

The factors related to the disease

This theme includes the two sub-themes of "the factors related to the disease nature" and "the factors that are effective in the provision of high-quality services in hospitals". In the first sub-theme, most participants mentioned the new and unknown nature of the disease and its symptoms and complications. The interviewee

Tab. V. The challenges of the Iranian health system in fighting COVID-19; other factors.

Themes	Line-managers	Staff-managers	Sub-themes and related codes	
Factors related to the people and patients	✓	✓	Delayed treatment of patients with other diseases and the consequent complications due to not going to the hospital in pandemic condition	
	✓	✓	The people's fear of the disease	
	✓	✓	Inobservance of health protocols by some of the people and patients	
		✓	The people's tiredness of observing the protocols and the decreased social resilience	
Factors related to the disease	✓	✓	Factors related to the disease nature	New and unknown nature of the disease and its symptoms and complications
	✓	✓		The changed behavior of the virus and impossibility of predicting the disease
		✓		The high transmission rate of the disease
		✓		The long incubation period
		✓		Person-to-person transmission of the disease
	✓	✓	Factors that are effective in provision of high quality services in hospitals	Impossibility of providing face-to-face clinical education for the people and patients
	✓	✓		The coronavirus patients' referring to hospitals simultaneous with other diseases
	✓	✓		The large population of patients
	✓			The people's expectations from health workers for service provision
	✓			The impacts to other routine services
	✓	✓		Decreased quality of service provision
	✓			The increased workload in laundry and the volume of hospital waste
		✓		The limited time for preparing the personnel for reception of the patients

(P15) stated in this field, "The involved countries such as China did not provide adequate information about this disease, and the unknown nature of the disease and its complications was a major challenge because it created serious problems in decision making and planning" (P15). The decreased quality of service provision was another factor mentioned in the sub-theme of the factors effective in providing high-quality services in hospitals. For example, one of the interviewees stated that "The decreased quality of service provision due to the use of non-specialist forces in the new infectious wards was a significant challenge. For example, when we changed the surgical ward into an infectious ward, the surgical personnel had to work in an infectious ward, so they did not have enough skills and specialty. Someone who has been away from the infectious ward for years and only does dressing and injections is definitely not of the same quality as someone who has been in the infectious department" (P23).

Discussion

The spread of COVID-19 has created many challenges for all the health sectors [25]. The challenges created by this disease can vary in different countries depending on cultural, social, and economic factors. According to the findings of the present research, the challenges of the Iranian health system to deal with COVID-19 include 19 sub-themes and 12 themes classified in four general areas of organizational factors, resources, management factors, and other factors.

One of the challenges in the area of organizational factors mentioned by most of the participants was the lack of intra-sector and extra-sector coordination in the early stages of the pandemic. Tello-Leal has reported that to provide better services and achieve the system goals, and there should be more concentration on the inter-organizational processes and coordination [26]. Inter-sector coordination prevents surplus actions and increases efficiency. So, it can avoid the waste of resources and lead to proper use [27]. In the study of service provision challenges in the COVID-19 crisis, Ashrafi Rizi states that the nature of the crisis is the rapid creation of tension in societies. However, it seems that the authorities involved in crises have not adopted proper information policies and plans in this crisis. So, they have not predicted any coherent program and strategy for information management in the current crisis. Sometimes, procrastinating to provide the general public with the statistics leads to the increased concerns in the society and the creation of quasi-information and miss-information [28]. In the spread of coronavirus, there should be some plans to use the capacities for the realization of proper responsiveness. Extra-sector coordination among the province authorities, NGOs, charities, and public and private organizations and intra-sector coordination among the health system, Ministry of Health, universities, and hospitals to share the experiences and opinions could

lead to a better performance of the health system to deal with the virus. The organization is necessary for developing a proper management system to fight this virus. The Incident command system (ICS) has been circulated in different organizations since several years ago, and it has been operated in hospitals for various crises such as an earthquake. This structure should become activated for fighting the coronavirus spread, too. In the hospitals involved in this pandemic, this system should become activated and the employees' responsibilities should be circulated in the framework of the incident command system. Also, it is necessary to develop this system and circulate the employees' tasks in the hospitals that have not been involved in this pandemic yet. There should be continuous contact with the EOC of the universities for more coordination and the incident command system should monitoring the critical situation (the incidence and outbreak of the disease) in hospitals in order to take proper measures.

Workforce protection is one of the fundamental challenges mentioned by most of the participants. Caring for infected patients is a risk for the employees, particularly in special care wards. Caring for the infected patients increases the probability of infection of the health workers due to their continuous exposure to patients with severe conditions. Also, the experience of severe infection and death among the health workers in the spread of the previous epidemics such as SARS and MERS and also the current pandemic has created fear and stress in the employees. Health workers have described their concerns about their own and their families' health in the previous epidemics and their experience of fear, anxiety, social prejudice and stigma [29]. In the acute phase of the epidemics, stressor factors such as social distancing, the fear of COVID-19 infection, loss of the family members and friends, and reorganization of the family, academic, and professional life are prioritized [30]. When we feel a threat and we are not able to encounter that, it is common to feel concern, anxiety, and fear. In the current conditions, coronavirus is the worrying phenomenon and it requires care and attention. In this special situation, the fear and anxiety created by the unknown nature of the disease and its rapid transmission have a geart affected not only the patients but also the planners, policy makers, health worker and all people in general. The fear of being infected by this disease can disturb the health workers' performance. Health workers should have a high quality of work life to be able to provide favorable services for patients. Job stress in any group especially in health workers can negetively affect in the individuals' health status and it also leads to organizational consequences such as decreased productivity.

According to the findings, supplying protective equipment was a serious challenge for the people and health workers in the early stages of the pandemic. The consumption of medical equipment needed to control infection such as medical masks, N95 masks, hand disinfectants, etc. significantly increases in pandemic situations [31]. So, it is important to ensure the availability of a supply chain of the necessary items. To be informed of infection control strategies and acquire updated information and knowledge, the doctors of special care wards should contact healthcare authorities [29]. Regarding the reported challenge, the critical issue is to pay attention to "drug and equipment supply chain management" to adopt proper strategies for using the external capacity and supplying the necessary items. Also, it is necessary to provide a favorable situation for treatment centers and hospitals to supply the necessary equipment to provide efficient services.

According to the findings, one of the mentioned challenges was the lack of a comprehensive and centralized system for registration of the positive cases of coronavirus and on-time data analysis for proper decision making. Providing the necessary infrastructures for information registration and continuous reporting of performance and pandemic (COVID-19) information is a useful tool for realization of optimal performance among the health system and hospitals managers and authorities such as planning, organizational, resource allocation, coordination, decision making, and monitoring based on the available information and documents. Najafi et al. performed a study to investigate the experiences of hospital managers in coping with this virus in Iran. They reported that appropriate documentation and data collection increases the organization's ability to plan and survive in this crisis. An organization's ability to effectively perform its tasks depends on its decisions and the quality of decisions is a function of the quality of the information used as a basis of decision making [32].

Conclusions

The COVID-19 virus has created a global pandemic; Since COVID-19 has spread beyond the borders and is not considered a regional epidemic anymore (as stated by WHO), it can be mentioned as an almost novel crisis. This study explains the challenges of the Iranian health system in fighting the coronavirus pandemic from the viewpoint of the managers of different levels of the health system. Identifying the mentioned challenges can provide useful information for the managers and policy makers to develop appropriate plans, take the necessary measures to resolve the challenges, and use the available resources to provide the most effective services.

Also, health system policy-makers should be aware of the ethical principles observed in this area. On the other hand, the people should understand the health system's challenges and follow the suggestions emphasized by the health system.

Strengths and limitations

In this study, a qualitative interview with the managers and executive authorities working in the frontline of fighting coronavirus and also the senior policy-makers of the Ministry of Health and medical universities was

used to explain the challenges of the Iranian health system. This method provides an in-depth investigation of the unknown opinions and challenges that are almost novel. One of the research limitations was the absence of evaluation and weighting of the extracted challenges that require further studies.

Ethical approval

Ethics approval for this study was obtained from the Shahid Sadoughi University of medical sciences (the ethical code of the research project is IR.SSU.SPH.REC.1399.062). All methods were carried out under relevant guidelines and regulations.

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Conflict of interest statement

The authors declare no conflict of interest.

Authors' contributions

MK RZ and T Sh designed this study, developed the study methods, collected and analyzed the study data, and wrote the first draft of the manuscript. S M M, F E. M R, and R A also collected the data. All authors read and approved the final version of the manuscript.

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COVID-19

Epidemiological characteristics and outcomes of COVID-19 in asymptomatic versus symptomatic patients

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Keywords:

COVID-19 • Asymptomatic infection • Patients with clinical symptoms

Summary

Background. *The clinical manifestations of COVID-19 are different, which can be attributed to asymptomatic carriers, acute respiratory disease and pneumonia with different severities. The aim of this study was to compare the epidemiological characteristics and outcomes of COVID-19 in patients with clinical symptoms versus asymptomatic patients.*

Methods. *In this retrospective cohort study, the epidemiological characteristics of two groups of patients, with clinical symptoms (n = 38,630) and without clinical symptoms who were definitive cases of COVID-19 (n = 2,327) were investigated in the southwestern of Iran. Chi-square test was used to evaluate the differences between qualitative variables in the two study groups.*

Results. *Of 40,957 patients with COVID-19, 2,327 (5.68%) were asymptomatic, of whom 1391 (59.77%) were males, 1841 patients (79.11%) had a history of contact with definite or suspected cases of COVID-19. Asymptomatic patients were older than symptomatic cases. Patients with clinical symptoms had higher mortality rate than asymptomatic patients (2.68% in symptomatic patients vs 0% in asymptomatic patients).*

Conclusion. *According to the results of our study, the detected viral load in asymptomatic individuals was similar to that of symptomatic patients, indicating that asymptomatic infections can potentially transmit the disease. Therefore, screening and detection of asymptomatic cases is an important and key measure in prevention and early control of COVID-19 worldwide.*

Introduction

Coronaviruses are a large family of viruses that may cause respiratory infections ranging from colds to more severe conditions, such as MERS and SARS [1]. A type of the virus called coronavirus 2019 also known as COVID-19 has spread rapidly around the world, and has been declared as pandemic by the world health organization [2-5].

In late December 2019, a series of unexplained cases of pneumonia were reported in Wuhan, China, and the government and health researchers in China took swift measures to control the epidemic and began etiological research. On January 12, 2020, the World Health Organization (WHO) temporarily named the new virus the novel coronavirus 2019 (2019-nCoV). On January 30, 2020, the WHO declared the 2019-nCoV outbreak as a public health emergency of international concern. On February 11, 2020, the WHO officially named the disease caused by the 2019-nCoV as coronavirus disease 2019 (COVID-19) [6-9].

On February 23, 2020, 77,041 cases of COVID-19 infection were confirmed in China [10].To date, COVID-19 has affected people in all countries/regions and has become a global threat to the general population [11]. COVID-19 has also spread rapidly in Iran and threatened the mental and physical health of Iranian people [12]. Recent clinical observations have shown that patient's age, male gender, and certain and chronic medical conditions, such as diabetes, cardiovascular disease, and chronic obstructive pulmonary disease appeared to increase the risk of COVID-19 infection as well as the severity of the disease [2].

The clinical manifestations of COVID-19 are significantly different, which can be due to asymptomatic carriers, acute respiratory disease and pneumonia with various degrees of severity [13]. As the COVID-19 has become pandemic, more evidence has emerged that many COVID-19 infections are asymptomatic while can still transmit the virus to the others [14]. In addition, there is growing evidence that asymptomatic cases may accelerate the spread of SARS-COV-2 from person to person [13]. Asymptomatic patients with COVID-19 are those who carry the virus but display no symptoms, including fever, gastrointestinal or respiratory symptoms, and reported no magnificent radiograph abnormalities in laboratory chest radiographs [15].

Identification and isolation of asymptomatic carriers and patients with mild COVID-19 is very important in preventing the disease spread in the later stages.

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Therefore, we carried out this study to determine the prevalence of asymptomatic cases of COVID-19 and symptoms of patients with mild COVID-19.

Methods

Study design and data collection

This retrospective cohort study examined 40,957 patients with COVID-19 who were admitted to hospitals under the auspices of Abadan University of Medical Sciences in the southwest of Khuzestan province. The total population of this region regarding the annual growth, was estimated 627,970 using the databases of the health centers and the national census in 2020.

All COVID-19 patients who were hospitalized from February, 2020 to February, 2021 were recruited into this study. Confirmation of the definite COVID-19 infection was done by real-time polymeraze chain reaction (RT-PCR) using nasal and throat swab samples or CT scan imaging. Duplicate items have been identified and excluded based on the national identity code. Subjects were divided into two groups: patients with clinical symptoms (n = 38,630) and patients without clinical symptoms (n = 2,327). Patients without clinical symptoms were identified and selected through the screening plan performed on office personnel, people who tended to settle in/out the country, people with a history of contact with positive cases, people who referred to health centers, the elderly, people who were referred for surgery and pregnant women. Then, demographic characteristics and other comorbidities were compared between the two groups of symptomatic patients and asymptomatic patients. The variables used in this study include: age, gender, occupation, final outcome (e.g. death and recovery), comorbid diseases, such as diabetes, cardiovascular disease, kidney disease, liver disease, immune deficiency and chronic lung disease and thyroid disease, history of contact with infected cases and ICU stay.

Statistical analysis

Quantitative variables were descriptively expressed as median and qualitative variables as percentage and frequency. Chi-square test and Fisher's exact test were also used to evaluate the differences between qualitative variables in the two study groups. A significance level of 0.05 was considered as statistically significant. Data analysis was performed using SPSS software 20.0 and Excel 2010.

Results

During the study period, a total of 40957 new cases of COVID-19 occurred in the cities under the auspices of Abadan University of Medical Sciences. The median age of patients was 45.73 years (IQR 29-50), and 57.4% of subjects were males, of whom 2,327 (5.68%) were asymptomatic, and 1391 (59.77%) of the participants were males, 1841 patients (79.11%) had a history of contact with definite or suspected cases of COVID-19. Also, 2.53% of all COVID-19 patients (n = 1,038) died, none of whom were asymptomatic (Table I).

Asymptomatic patients were older than symptomatic cases. The median age of asymptomatic and symptomatic patients was 51.70 years (IQR: 29-52) and 45.37 years (IQR: 29-50), respectively. However, this difference was not statistically significant (p = 0.537). In both groups of patients, symptomatic and asymptomatic, the disease was more prevalent in age group of 20-34 years (34.60% of patients with symptoms and 34.90% of patients without symptoms) and the lowest frequency in both groups was observed in patients aged < 5 years (0.80% of symptomatic and 0.70% of asymptomatic patients).

Besides, comorbidities, such as heart disease, diabetes, hypertension, chronic lung and kidney disease, liver disease, thyroid and immunodeficiency, and occupation, ICU stay and history of contact with definite or suspected cases of COVID-19 were not significantly different between the study groups (Tab. I). Patients with clinical symptoms had also higher mortality rate than asymptomatic patients (2.68% in symptomatic patients *vs* 0% in asymptomatic patients).

Discussion

The present study, was a retrospective observational study that examined the epidemiological characteristics of asymptomatic patients with COVID-19 compared with symptomatic patients. Of 40957 cases of COVID-19 in the cities under the auspices of Abadan University of Medical Sciences, 2327 (5.68%) were asymptomatic, and 1391 subjects (59.77%) were asymptomatic males. Also, 2.53% of the patients (1038) died, none of whom were asymptomatic.

In addition, comorbidities, such as heart disease, diabetes, hypertension, chronic lung and kidney disease, liver disease, thyroid and immunodeficiency, and occupation, ICU stay and history of contact with definite or suspected cases of COVID-19 were not significantly different between the study groups. Patients with symptoms displayed higher mortality rate than asymptomatic patients (2.68% in symptomatic patients *vs* 0% in asymptomatic patients).

In our study, 5.68% of patients were asymptomatic. A wide range of proportion of asymptomatic patients has been reported in various studies. For example, Kimball and colleagues reported the prevalence of asymptomatic patients as 34.8% [16], Kim and colleagues investigated 72314 patients in China and reported this proportion as 1% [17], Lai and colleagues as 1.95% [11], Bai et al. as 12.9% [18], Tong and colleagues as 51.7% [19], Wei and colleagues as 4.12% [20]. Liu and colleagues as 15.8% [15], Qian and colleagues as 43% [21], Luo and colleagues as 65.9% [22], Mizumoto et al. as 87.9%[23], Zou and colleagues as 56.5% [24], and Gao reported this prevalence as 1.6% in China [14], 30.8% in Japan [25], and 10.7% in Korea [26]. Each person may display

Tab. I. Demographic and Clinical Characteristics of asymptomatic and symptomatic patients with COVID-19.

Variable Number (%)		**Total (n = 40957)**	**Asymptomatic patients (n = 2327)**	**symptomatic patients (n = 38630)**	**P-value**
		Number (%)	Number (%)		
Age, median (IQR)		45.73(29-50)	51.70 (29-52)	45.37 (29-50)	0.570
Gender	Male	23521 (57.42)	1391 (59.77)	22130 (57.28)	0.018
	Female	17436 (42.58)	936 (40.23)	16500 (42.78)	
Occupation	Worker	831 (2.02)	41 (1.76)	790 (2.04)	0.404
	Healthcare worker	2692 (6.57)	177 (7.60)	2515 (6.51)	
	Employee	7263 (17.73)	428 (18.39)	6835 (17.69)	
	Freelance job	6154 (15.02)	407 (17.49)	5747 (14.87)	
	Student	1736 (4.23)	91 (3.91)	1645 (4.25)	
	Elderly	1121 (2.73)	69 (2.96)	1052 (2.72)	
	housekeeper	7622 (18.60)	449 (19.29)	7173 (18.56)	
	Children	186 (0.45)	11 (0.47)	175 (0.45)	
	Retired	705 (1.72)	44 (1.89)	661 (1.71)	
	Unemployed	1229 (3.00)	67 (2.87)	1162 (3.00)	
	Farmer	217 (0.52)	11 (0.47)	206 (0.53)	
	unknown	11201 (27.34)	532 (22.86)	10669 (27.61)	
Comorbidities	Cardiovascular	1998 (4.87)	100 (4.29)	1898 (4.91)	0.365
	Diabetes mellitus	2842 (6.93)	141 (6.05)	2701 (6.99)	0.229
	Hypertension	1927 (4.70)	94 (4.03)	1833 (4.74)	0.254
	Immunodeficiency	389 (0.94)	23 (0.98)	366 (0.94)	0.686
	Chronic liver disease	101 (0.24)	8 (0.34)	93 (0.24)	0.533
	Thyroid disease	140 (0.34)	9 (0.38)	131 (0.33)	0.609
	Chronic kidney disease	588 (1.43)	34 (1.24)	554 (1.43)	0.720
	Chronic pulmonary disease	988 (2.41)	55 (2.36)	933 (2.42)	0.870
	History of ICU stay	148 (0.36)	7 (0.30)	141 (0.37)	0.611
	Exposure to disease	32858 (80.22)	1841 (79.11)	31017 (80.29)	0.186
	Mortality	1038 (2.53)	0 (0.00)	1038 (2.68)	<0.001

different clinical symptoms, and the results of previous studies have shown that asymptomatic infections are more common in young and middle-aged populations and those without comorbid diseases [14]. In this disease, the window period lasts about 7 days. Detection of viral nucleic acids by RT-PCR is the standard method for detecting coronavirus infection. Although, this screening method has high specificity, its low sensitivity may lead to a number of false negatives and the method is time consuming [27]. The presence of negative results led to the conclusion that the combined use of CT imaging of clinical signs plus laboratory tests can be the initial diagnosis of pneumonia caused by COVID-19. Antibody-based immunoassay techniques are complemented by molecular techniques as complementary tools. These techniques are fast and inexpensive, but have low sensitivity and are the best tools in epidemiological studies and diagnosis of asymptomatic patients. For molecular detection, the WHO recommends screening samples with E Envelope corona gene and then confirming with the RNA-dependent RNA polymerase (RdRP, RDR). In the United States, the two proteins, nucleocapsid N1 and N2 genes of coronavirus are tested. Immunoassay for detection of anti-N protein antibody, which is an immunodominant antigen, is used for early detection of COVID-19 [28]. Sample size of studies, age groups of under study patients, individuals with different comorbid diseases, access to diagnostic tests and time of referrals to be associated with this difference.

In our study, asymptomatic patients were older than symptomatic patients. The median age of asymptomatic and symptomatic patients were 51.70, and 45.37 years, respectively. In asymptomatic patients, the highest frequency was observed in the age group of 20-34 years (34.60% of symptomatic patients *vs* 34.90% of asymptomatic patients), and the lowest frequency belonged to those younger than 5 years (0.80% of symptomatic patients *vs* 0.70% of asymptomatic patients). According to the results stated by Gau and colleagues, asymptomatic infection was more prevalent in people under 15 years of age [14]. Wang and colleagues also reported that the median age of asymptomatic patients was 49 years and was more prevalent at age group of 30-49 years [27]. It is assumed to be lower in children than in the general population, which can be due to the specific immune response and ACE2 levels in children [28], and the cellular immune system, which is the most important part of the immune system against viral infections, is weakened in the elderly [29]. The spread of the disease depends on

the interaction between the virus and the individual's immune system. Factors associated with the pathogen also include type of virus, mutation, and the number of viruses. A person's immune system is influenced by genetics, such as the HLA gene, age, gender, nutritional status, homeostasis between the immune, nervous and endocrine systems, and physical condition. All of these factors play a key role in the onset, duration and severity and recurrence of the disease [27, 30].

In our study, 1841 (79.11%) of the patients had a history of contact with definite or suspected cases of COVID-19. Hu and colleagues [31], reported that 33.3% of asymptomatic patients had a history of travel to high-risk areas [2]. The patient's age and physical status may be major determinants of COVID-19 severity, which can be related to the state of the patient's immune response to coronavirus [14]. Due to the lack of knowledge about asymptomatic infections and the limited ability to detect the disease in these patients, the frequency of asymptomatic patients in this study was estimated as 5.6% which may be underestimated. Also, lack of published similar studies has made it difficult to compare the results of our study with other studies.

Conclusion

According to the results of this study, the viral load detected in asymptomatic individuals was similar to that of symptomatic patients, indicating that asymptomatic infections can potentially transmit COVID-19, and may occur more frequently at early stages of the disease [24], and is considered as a challenge in disease prevention and control. Therefore, screening and detection of asymptomatic cases is a key measure in prevention and early control of COVID-19 worldwide.

We recommend that the necessary measures should be taken to identify asymptomatic cases of COVID-19, such as seriously screening those in contact with the COVID-19 positive cases, people who intend to enter the area, screening elderly and high risk individuals, as well as staff of the health system and other departments.

Abbreviations

WHO: World Health Organization; RT-PCR: Real-time Polymeraze Chain Reaction

Availability of data and material

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Ethical statement

Ethics approval and consent to participate: the analysis data file did not contain the name of the participants. The study was reviewed and approved by Medical Ethics Committee of Abadan University of Medical Sciences (Code: IR.ABADANUMS.REC.1399.051).

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Conflict of interest statement

The authors declare no conflict of interest.

Authors' contributions

All authors contributed to the study conception and design. HA participated in the design of the study. MD, AV, and AJ performed data collection and wrote the manuscript. MGG and EP helped with statistical analysis and prepared the illustrations. EP edited the manuscript. All authors read and approved the final manuscript.

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COVID-19

Lessons learnt from alcoholism and substance use disorders (SUDs) during the COVID-19 pandemic in India

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Keywords

Drug Abuse • Substance Use • Drug Dependence • Alcohol Abuse • Alcoholism

Summary

SUD is a widespread non-communicable disease (NCD) with biological, social, or psychological foundations which policymakers have given less attention during the COVID-19 pandemic. People with alcohol dependence went into withdrawal as a result of the lockdown and acute lack of alcohol availability, which led to black marketing and, in extreme cases, suicide. On the other hand, De-addiction services in India were not adequately equipped for the SUD pandemic, and as a result, most services could not cope with lockdown problems. To generate revenue and to get out of this Catch-22 situation, the Government opened liquor shops and sold alcohol while people purchased it as usual because of excess stress, lack of social contact, loneliness and boredom. We recommend that during COVID-19 pandemic, national, state, and local governments, as along with organisations such as Alcoholics Anonymous, develop and support networks to address the needs of patients with SUD.

Introduction

The inability to manage the use of legal or illegal drugs or substances is referred to as substance use disorder (SUD) [1]. In India, according to the National Mental Health Survey conducted in 2015-2016, the prevalence of tobacco use disorder was 20.9 per cent, alcohol use disorder was 4.7 per cent, and drug use disorder was 0.6 per cent among the population respectively [2]. In the current scenario, COVID-19 infection and accompanying consequences are more likely in people with SUD [3, 4]. Drug abuse is included under the phrase "substance use disorder". Any substance abuse can result in chemical changes in the brain, which can lead to addiction. The words "drug abuse" and "substance abuse" are frequently interchanged [5]. Although SUD is a widespread non-communicable disease (NCD) with biological, social, or psychological foundations which policymakers, stakeholders, and doctors have given it less attention during the COVID-19 pandemic than any other physical or mental health problem [6]. Non-consideration could be because of stigma, negative attitudes, and a lack of knowledge regarding SUD.

While the whole world has been enduring the pandemic for a few years now, many people have been going through the ongoing pandemics and post pandemic effects, although the pandemic is not yet over. In India, alcohol consumption and mental health problems are two major illnesses that have a significant impact on people, individually. When both come together, it adds to the burden of disease and creates a vicious cycle involving healthcare providers, consumers, and the patient itself. Consumption of alcohol has been identified as an important risk factor for the development of diseases, morbidity, and mortality [7]. The abuse of alcohol is a well-recognized health problem in our country and globally as well, resulting in economic loss and more hospital admissions [8]. Approximately 3.2% of deaths worldwide are caused because of alcohol each year and as per the estimates of the World Health Organization, 1/3rd of Indian males consume alcohol while the consumption of alcohol among females is increasing with the latest societal trends [9]. As per the estimates from India, Alcohol use is common both in rural and urban areas with prevalence rates ranging from 23% to 74% among males while the prevalence among females was a little lesser at 24% to 48% in a certain section and communities [9].

Alcohol acts as a small molecule, which crosses the membrane barrier and reaches different parts of the body, quickly reaching the equilibrium concentration in different cellular compartments [8]. Chronic consumption of alcohol over a period causes serious health and mental health issues involving cognition and memory problems [10]. Post alcohol dependency for any reason, it also continues to impair the decision-making capabilities. The mind keeps craving for this substance, and that is how the addiction usually start. In the long run, this hampers mental health. It can lead to various problems, such as stress, anxiety, and depression among many others.

The worrisome fact is that those facing the alcohol use disorder often have a co-occurrence of a psychiatric disorder, but they never receive regular treatment for

both the conditions that address their concerns, are some worrisome findings received from the studies [11]. The correlation between alcohol and drug dependence with mental health and its associated illnesses is difficult to conclude and establish, making it even difficult to provide effective treatment options. We recommend that a combination of psychosocial as well as pharmacological approaches be integrated to treat such patients and further research to guide the best viable treatment is warranted for this cohort [12-14]. Although alcohol consumption and mental health might be interdependent on each other, there are various other factors that are necessary for observation and need to be investigated in order to arrive at a suitable correlation between the two.

To halt the spread of the COVID-19 disease, the Indian government had announced a countrywide lockdown on March 24, 2020, for three weeks at first, and then for another four and a half weeks [15]. The abrupt surge in patients with SUD (primarily alcohol) related disorders (e.g., withdrawal) was noticed because of the sudden non-availability of alcohol or opioid distribution. It resembled a pandemic's emotional epidemic curve [16]. Around 40 people have died because of SUD-related withdrawal and suicide [17], as per the media reporting's. People with alcohol dependence went into withdrawal as a result of the lockdown and acute lack of alcohol availability, which led to black marketing and, in extreme cases, suicide due to reported anger at not having access to alcohol [18]. Methanol intoxication has been reported in several parts of the country. Similar to Indian trends, 700 people reportedly died because of methanol intoxication in Iran [19]. Because of the lack of alcohol and bogus statements or misinformation extolling the good effects of alcohol on Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2) on social media, methanol poisoning occurred because of ingesting methanol tainted alcohol [20]. Methanol poisoning is a widespread poisoning outbreak in India, affecting mostly the poor and uneducated. Methanol is a low-cost replacement that's been added to local liquor as an adulterant. And, people believed that alcohol would protect them against the virus during the COVID-19 epidemic [21, 22].

Unfortunately, de-addiction services in India were not adequately equipped for the SUD pandemic, and as a result, most services could not cope with lockdown problems [23]. To our surprise, some jurisdictions have opted to make alcohol available to those who cannot live without it regularly, in order to treat alcohol withdrawal [24]. Though this method may be effective in the short term or in delaying the SUD epidemic, it will have a long-term impact on de-addiction efforts and treatments delivered in hospitals or community settings [25]. Most patients with SUD are unaware of the withdrawal symptoms of substances (e.g., alcohol, opioids) and have only a rudimentary understanding of the tremors [26].

Impact of the imposing COVID-19 lockdowns

The recent alterations brought about by the COVID-19 outbreak are unprecedented compared to previous crises [27]. Many countries have made valiant attempts, and lockdown being one of them is highly efficient in halting the spread of the coronavirus. During the lockdown, the international community was concerned about the rise of mental and psychosocial disorders among families and communities. A surge in substance misuse, alcoholism, and addiction has also been recorded [28]. If we dive deep to find the answer to these questions, we can easily determine many factors responsible, especially the socio-economic crisis which led to the job loss, closure of small businesses, factory units, etc. The loss was suffered by the governments, autonomous establishments, and the people. The government had to ensure supplies of essential drugs and other amenities to the people for free of cost while the people had to sit back at home to help the government prevent the spread of the Infection. People back home, are left without any job or other means of income and had to suffer from the socioeconomic crunch, eventually leading to mental health trauma [29]. In a hope that every next day the lockdown will ease out and they may return to their job, people lost all their savings on food and other activities, including paying loans/ EMIs, electricity bills etc and finally fall prey to their own deeds. Not only this, but the developing tension within homes also gave rise to the battlefield between couples and doubled the rates of domestic violence and/or divorces which is already a grave social problem in India and saw an alarming increase during the lockdown period as reported by a study [30]. To generate revenue and to get out of this Catch-22 situation, the Government opened liquor shops and sold alcohol while people purchased it as usual because of excess stress, lack of social contact, loneliness and boredom. Here the situation is tricky. Before the pandemic, the people used to work in offices, with no mental stress and there was no hue and cry situation at all. But nowadays, people work from home, and with many having no jobs, they have little money left and that too they spend on alcohol making them vulnerable for basic amenities. More social interaction is observed of such people with their family members leading to domestic violence, mental health issues, conflicts, and fights.

From the very beginning, the pandemic of COVID-19 gave multiple hard blows to every single economy in the world. It gave birth to another different pandemic-*Global Unemployment*. The International labour organization (ILO) recently reported unprecedented job losses [31] and according to ILO, 114 million jobs were lost globally in 2020. The global labour income saw an 8.3 per cent loss, which translates to 3.7 trillion USD [31]. Added to loss of employment opportunities, businesses of all sizes suffered huge losses owing to pandemic related closures, and many falling enterprises stated that the efforts of years/decades were ruined during the first quarter itself.

While the big fishes survived the pandemic, many small businesses did not make it in through. In another report, ILO estimated 75 per cent of small-scale businesses to suffer unprecedented losses while 33 per cent are expected to lose half of their revenue in near future [32]. Conditions in India look no better and a leading business daily reported 27.11 per cent unemployment rate in May 2020, which is an unprecedented low [33]. The daily in its recent survey found that a loss of 1 crore jobs was seen in the month of May 2021 owing to the second wave of COVID-19 hitting India. The survey further reported that 97 per cent of households across the country have witnessed significant financial losses since the beginning of the pandemic in India, i.e., March 2020 [34]. A study conducted by Dun and Bradstreet, reported by another leading daily shows 82 per cent of small businesses have suffered huge losses in the pandemic during 2020 across the country. Out of those, 70 per cent of them are expected to take more than a year to return to pre-COVID status [35]. While the economy plunges lower with each new wave of COVID, the alcohol industry is among the few industries that can still generate a good amount of capital for the governments of various states and countries. Alcohol contributes to 15-25 per cent of revenues in most of the Indian states and this industry saw losses of only about 11 per cent since March 2020
Some of the major mental health issues in India amidst this pandemic are depression, insomnia, denial, anger and fear. A study by Salari et al. [36] reported that 18-80 per cent of people in the study experienced anxiety and depression as a common reaction to the pandemic. Another survey reported over 80 per cent of participants experienced anxiety and preoccupation on contracting COVID-19, 12.5 per cent had sleep issues and 34.6 per cent had distress related to social media [37]. Similarly, another study conducted during the pandemic in India revealed an increase of 67.7 per cent in suicide when compared to the year 2019 [38]. While pondering at the global scenario, some of the mental health issues faced in the pandemic were anxiety, depression, sleeping difficulties (36 per cent) or eating disorders (32 per cent), worsening of chronic disorders (12 per cent) and an increase in alcohol use and substance abuse (12 per cent) [36].

Recommendation

Based on our experience, we would advise concerned stakeholders, and physicians to raise awareness of substance withdrawal symptoms, treatment options and policy makers to register this issue for a policy on awareness and/or sensitization of general public. It looks like the only practicable and logical alternative and solution to this alarming issue. Efforts should be made to identify people with SUD quickly, assessment of the risk of early withdrawal/ intoxications, provide treatment via mobile teams or inpatient care (depending on severity), and track patients with SUD in various vulnerable or otherwise groups (e.g., suspected or diagnosed COVID-19, quarantined people).

To increase access to care for people with SUD, we advocate the introduction of tele psychiatry services, hotlines, specific cells or clinics, and a mental health surveillance system [6, 39]. Tele psychiatry may be a viable solution for people suffering from mild-to-moderate SUD withdrawal symptoms. Recently, the Board of Governors in supersession of the Medical Council of India took a significant step by issuing guidelines for telemedicine in India allowing registered medical practitioners (RMP) to consult patients/caregivers or another RMP through audio, video, text messages, email and other virtual means. This recommendation was eventually amended to allow for the prescription of clonazepam, clobazam, and phenobarbitone [40]. This strategy may be viable and safe; nevertheless, in present Indian settings, it is accompanied by scarcity of data and huge research gap. We recommend that during COVID-19 pandemic, national, state, and local governments, as along with organisations such as Alcoholics Anonymous (AA), develop and support networks to address the needs of patients with SUD and service providers in the community and hospital settings. These methods or suggestions may aid in flattening the emotional epidemic curve and improving the mental health care system's capabilities [39].

Conclusion

The use of Alcoholism and substance use disorders (SUDs) during COVID-19 pandemic has seen sudden rise alongside mental health issues. Efforts made to identify people with SUD are very important to assess the risk of withdrawal/ intoxications quickly, provide counselling and/or treatment, depending on severity after tracking the patients with SUD. Moreover, sensitisation of policymakers on this concern is a must and foremost thing we need to do at this hour.

Ethical statement

Ethics approval and consent to participate: not required**.**

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Conflict of interest statement

The authors declare no conflict of interest.

Authors' contribution

SMS: Conceptualization, Formal analysis, Methodology, writing – original draft, Data curation, Validation,

Visualization, Investigation, Project administration, Resources, Supervision, Writing – review & editing. SS & RD: Conceptualization, Formal analysis, Methodology, Writing – original draft, Data curation, Validation, Visualization. HMG & IZ: Conceptualization, Data curation, Formal analysis, Methodology, Writing – review & editing.

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COVID-19

Weight of risk factors for mortality and short-term mortality displacement during the COVID-19 pandemic

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Keywords

COVID-19 • SARS-CoV-2 • Harvesting effect • Mortality displacement • Comorbidities • Risk factor

Summary

Background. *We conducted a population-based cohort study to estimate mortality before, during and after the COVID-19 peak and to compare mortality in 2020 with rates reported in previous years, with a view to helping decision makers to apply containment measures for high-risk groups.*
Methods. *All deaths were collected between 2015 and 2020 from municipal registry database. In 2020, weeks 1-26 were stratified in three periods: before, during and after the COVID mortality peak. The Poisson Generalized Linear regression Model showed the "harvesting effect". Three logistic regressions for 8 dependent variables (age and comorbidities) and a t-test of differences described all-cause mortality risk factors in 2019 and 2020 and differences between COVID and non-COVID patients.*
Results. *A total of 47,876 deaths were collected. All-cause deaths increased by 38.5% during the COVID peak and decreased by 18% during the post-peak period in comparison with the average registered during the control period (2015-19), with significant mortality displacement in 2020. Except for chronic renal injuries in subjects aged 45-64 years, diabetes and chronic cardiovascular diseases in those aged 65-84 years, and neuropathies in those aged > 84 years, the weight of comorbidities in deaths was similar or lower in COVID subjects than in non-COVID subjects.*
Discussions. *Surprisingly, the weight of comorbidities in death, compared to weight in non-COVID subjects allows you to highlight some surprising results such as COPD, IBD and Cancer. The excess mortality that we observed in the entire period were modest in comparison with initial estimates during the peak, owing to the mild influenza season and the harvesting effect starting from the second half of May.*

Introduction

The harvesting effect is the compensatory reduction in mortality following a temporary increase in the number of deaths of older individuals, frail subjects and patients with comorbidities. This effect is usually observed after environmental phenomena, such as heat waves or cold spells, but is sometimes seen after epidemics and pandemics, such as unusually virulent seasonal influenza pandemics [1-3]. Mortality displacement was first described as a short-term effect within days or weeks after heat waves [4]. Subsequent studies reported major long-term mortality displacement, showing, for example, that the winter mortality rate significantly modified the estimated effect of temperature on mortality in the following summer [5, 8].
Mortality displacement due to the COVID-19 pandemic, and the weight of factors potentially related to death, i.e. underlying health conditions, have been scantly investigated, despite their importance in delineating the epidemiological picture and in guiding public health measures to reduce the impact of the disease.
From the start of the pandemic to 5th July 2020, almost 35,000 deaths due to SARS-CoV-2 were recorded in Italy, the third highest mortality rate, behind Belgium and Spain. The estimated case-fatality rate was 14%, which peaked at 20% among people aged 80 years and older [9].
In Liguria, a region of North-Western Italy with 1,550,640 inhabitants, the impact of COVID-19 was heavy, with cumulative incidences above 6 cases and 1 death per 1,000 residents. SARS-CoV-2 circulated intensely between weeks 11 and 18 and the epidemic curve reached its peak in week 14 [10]. The demographic structure of the region affected COVID-19-related mortality, as Liguria is the Italian region with the oldest population, with 28.5% (442,279) of residents aged ≥64 years and 5.1% (80,229) aged ≥ 84 years [11].
In order to estimate mortality before, during and after the COVID-19 peak, and to compare mortality in 2020 with the rates reported in previous years, we carried out a population-based cohort study of the Ligurian population. Our objective was to provide relevant parameters, such as COVID-19-related excess mortality and risks according to underlying health conditions at different ages [12]. These parameters constitute valuable aids to understanding the real burden of disease and assisting decision-makers in applying and prioritizing the most appropriate physical distancing and other strategies focused on high-risk groups [13].

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Materials and methods

Raw data on deaths and demographic information, such as age and municipality of residence, were obtained from municipal registry databases. These data were subsequently linked to and integrated with the central platform of electronic health records of the Ligurian Health System, which includes data on primary care and hospital care; comorbidities were estimated through the chronic condition data warehouse by using validated and standardized definitions of several hundred underlying conditions [14-16].

Confirmed cases were diagnosed on nasopharyngeal swabs, by means of real-time polymerase chain reaction testing and applying the World Health Organization (WHO) case definition.

The study population consisted of a dynamic cohort of about 940,000 > 44-year-old residents in the Liguria region, from 2015 to 2020. The analysis considered the total number of deaths during weeks 1-26 each year from 2015 to 2020 among residents in cities with more than 10,000 inhabitants; this was done in order to avoid the possibility of delayed notification by the regional registry office. The study population included patients who had received a diagnosis of COVID-19 from February 26th (first case in Liguria) to June 14th and who had died up to July 5th 2020. Excess mortality was calculated as the difference between the mortality rates observed and the all-cause mortality rates registered in the last five years. We considered three different periods according to the pattern of SARS-CoV-2 circulation: weeks 1-10 (Pre-COVID), weeks 11-18 (COVID peak), weeks 19-26 (Post-peak). Poisson time-series Generalized Linear regression Model (GLM) analysis was used to assess the difference between years, and a value of $p < 0.05$ was taken to indicate statistical significance[17-19]. To estimate the weight of underlying health conditions, multiple logistic regressions were used to assess associations between death and comorbidities, i.e. chronic cardiovascular disease, chronic obstructive pulmonary disease (COPD), chronic renal injuries (CRI), diabetes, neoplasia, chronic inflammatory bowel disease (IBD) and neuropathies, in 3 age-groups (45-64, 65-84, > 84 years) and in COVID-19 patients and non-COVID-19 patients in 2019 and 2020. Odds ratios (ORs) were used to assess the magnitude of associations, and 95% confidence intervals (95% CI) are reported. To compare the impact that risk factors had on death in COVID-19 patients and in non-COVID-19 patients in 2019 and 2020, the ratio between Odds Ratios was used.

Statistical significance in this case was obtained from the standard normal distribution of z-value, for the ratio $z = \frac{\delta}{SE(\delta)}$ with $\delta = logOR_1 - logOR_2$ with the standard error pooled *SE (δ)* resulting from *SE (δ)*= $\sqrt{SE_1^2 + SE_2^2}$ [18]. Statistical analyses were conducted by means of JMP v.15 software.

Results

A total of 47,876 deaths were registered from 2015 to 2020 during weeks 1-26 in cities of Liguria with 10,000 inhabitants or more, accounting for more than 70% of all deaths in the Region. In the first 26 weeks of each year from 2015 to 2019, the number of deaths ranged between 7,330 and 8,146, while during the same period in 2020, 8,371 deaths were recorded; 1,070 (12.8%) were in individuals positive for SARS-Cov2. In this last group, the M:F ratio was 1.42:1 and the median age was 82 years (IQR 76-88; min 35; max 102).

In the first 26 weeks of 2020, cumulative mortality due to COVID-19 increased with age from 1.9 deaths/10,000 in the 45-64-year age-group to 21.2/10,000 and 80.3/10,000 in the 65-84-year and > 84-year classes, respectively. Cumulative non-COVID-19-related mortality increased with age from 14.2 deaths/10,000 in the 45-64-year age-group to 113.7/10,000 and 675.1/10,000 in the 65-84-year and > 84-year age-classes, respectively.

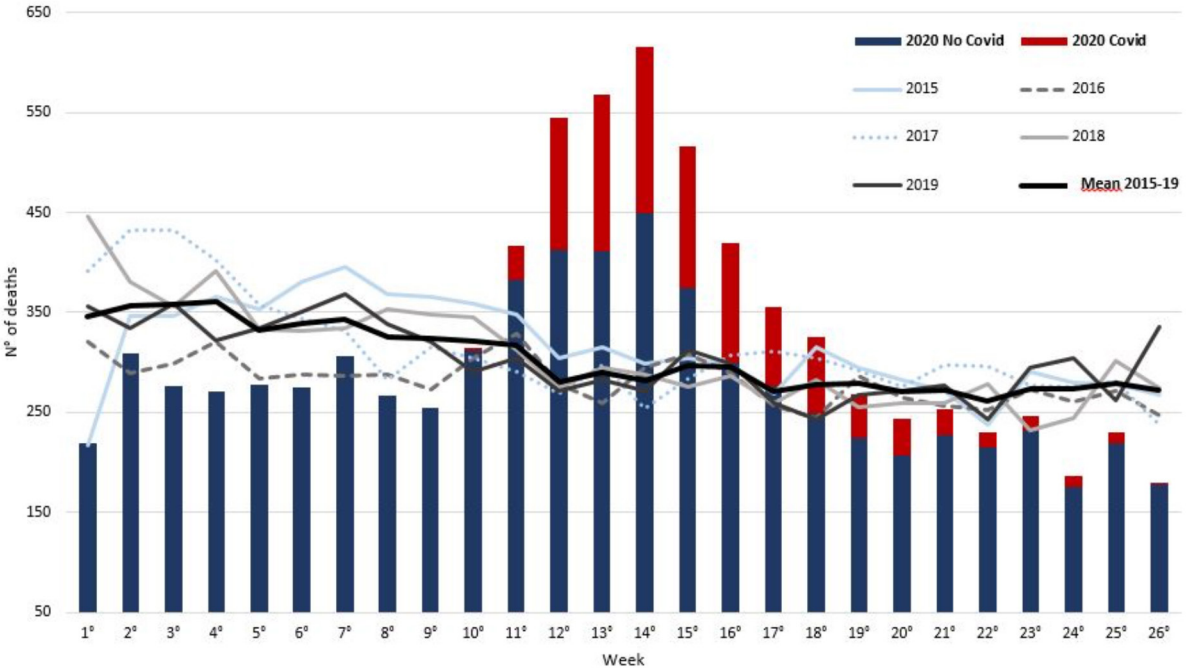
In the 2015-19 period, the M:F ratio was 0.86:1 and the median age was 85 years (IQR 77-90). Yearly cumulative mortality increased with age from 17.7 deaths/10,000 in the 45-64-year age-group to 125.9/10,000 and 727.7/10,000 in the 65-84-year and > 84-year age-classes, respectively.

Figure 1 illustrates the number of deaths in each week of the first semester from 2015 to 2020. During the 2015-19 period, the number of weekly deaths ranged between 217 and 446 (mean 338.6, median 338, IQR 309-359) in weeks 1-10, between 243 and 348 (mean 288.9, median 290, IQR 271.8-305) in weeks 11-18, and between 232 and 335 (mean 272.8, median 274, IQR 259-283) in weeks 19-26. In 2020, the number of weakly deaths ranged between 219 and 315 (mean 277.2, median 276, IQR 268-299.7) in the pre-COVID period, between 325 and 615 (mean 470.1, median 468, IQR 401.5-550.8) during the COVID-19 peak and between 179 and 268 (mean 229.8, median 237, IQR 219.3-248.5) in the post-peak period. In comparison with the average number of all-cause deaths registered during the control period (2015-19), an increase of 63.3% (+ 1449.6, 95% CI 55.5-72.5%) during the COVID peak and a decrease of 14% (- 314.6, 95% CI 8.5-19.2) during the post-peak period were observed. Deaths in SARS-CoV-2-positive patients accounted for 31% (n. 908) and 13% (n. 160) of all deaths in the peak and post-peak periods, respectively.

Table I shows the mean number of weekly deaths, the regression coefficient and intercept estimates over the 6 years considered, as calculated by means of Poisson distributed time-series regression GLM.

During the 2015-19 period, weeks 1-10 showed a high variation of regression coefficients, ranging between -34.9 and 31.7, while during weeks 11-18 and weeks 19-26 the coefficients displayed lower ranges (between -38.4 and -29.3 and between -2.5 and 16.3). In 2020, 151 (95% CI 137.8-164.4) excess deaths per week were registered during the COVID-19 peak, and a significant mortality displacement occurred in the following weeks (-35.9, 95% CI -45.5 -26.0).

Fig. 1. Deaths in the Liguria region in 2015-2020 in cities with > 10,000 inhabitants, from week 1 to 26.



Age, COPD, CRI, diabetes, chronic cardiovascular disease, neoplasia (except in those aged > 84 years), and neurological syndromes were significantly related to increased mortality in both COVID-19 patients and non-COVID-19 patients who died in 2019 and 2020; IBD was a significant risk factor in non-COVID-19 patients who died in 2019 and 2020.

The probability of dying of COVID-19 per year of age (Y.O.A.) in people aged > 44 yrs increased by 8.2% (OR 1.082, 95%CI 1.077-1.088), with values not statistically different from the OR in non-COVID patients in the same period and in 2019 (1.11, 95% CI 1.107-1.113 and 1.106, 95% CI 1.102-1.108, respectively).

Multivariate logistic regressions of comorbidities associated to all-cause deaths in 2019, and COVID-19 and non-COVID-19 deaths in 2020, in the 3 age-classes, are shown in Table II.

The ORs for underlying conditions according to age-group were not significantly different between COVID-19 patients and non-COVID-19 patients who died in 2019 and 2020, with some exceptions. Patients with CRI in the 45-64-year age-group (OR_1/OR_2 of 2.32 in 2020 and 3.02 in 2019), and patients aged 65-84 years with diabetes (OR_1/OR_2 of 1.11 in 2020 and 1.11 in 2019) and chronic cardiovascular disease (OR_1/OR_2 of 1.22 in 2020 and 1.28 in 2019) showed a higher risk of dying of COVID-19 than of dying of other causes in 2019 and 2020). Neurological syndromes showed higher OR in patients who died with COVID-19 in 45-64 years age group (OR_1/OR_2 of 2.04) compared with patients died in 2019 and in > 84 year adults compared with non-COVID-19 patient died in 2019 and 2020 (OR_1/OR_2 of 1.18 in 2020 and 1.37 in 2019).

Tab. I. Analysis of yearly variation of mean number of weekly deaths, by Poisson distributed time-series regression of generalized linear model (GLM).

	N° weekly deaths	95% CI	Regression coefficients	95% CI	P value
WEEKS 1-10 (mild seasons in 2016 and 2020)					
Intercept	330.15	325.6-334.8	-	-	<.0001*
2020	**277.2**	**266.9-287.5**	**-52.9**	-62.5; -43.3	**<.0001***
2019	337.3	325.9-348.7	7.15	-3.13-17.6	0.1741
2018	361.8	350-373.6	31.7	21.1-42.2	<.0001*
2017	359.5	347.8-371.3	29.4	18.8-40.1	<.0001*
2016	295.3	284.7-305.9	-34.9	-44.6; -24.9	<.0001*
2015	349.8	338.2-361.4	-	-	-
WEEKS 11-18 (excess mortality in 2020)					
Intercept	319.12	314.1-324.2	-	-	<.0001*
2020	**470.1**	**455.1-485.2**	**151.0**	137.8-164.4	**<.0001***
2019	280.8	269.1-292.4	-38.4	-49.01; -27.5	<.0001*
2018	284.6	272.9-296.3	-34.5	-45.2; -23.6	<.0001*
2017	289.9	278.1-301.7	-29.3	-40.0; -18.3	<.0001*
2016	282.8	271.1-294.4	-36.4	-47.1; -25.5	<.0001*
2015	306.6	294.7-319	-	-	-
WEEKS 19-26 (mortality displacement in 2020)					
Intercept	265.60	261-270.2	-	-	<.0001*
2020	**229.8**	**219.3-240.3**	**-35.9**	-45.5; -26.0	**<.0001***
2019	281.9	270.2-293.5	16.3	5.8-26.9	0.0021*
2018	263.1	251.9-274.4	-2.5	-12.6-7.9	0.637
2017	279.1	267.6-290.7	13.5	3.1-24.1	0.0107*
2016	264.4	253.1-275.6	-1.2	-11.4-9.2	0.8151
2015	275.4	263.9-286.9	-	-	-

Tab. II. Impact of age and risk factors on death in COVID-19 patients and non-COVID-19 patients in 2019 and 2020 in adults aged > 44 years.

	Age class	COVID-19 deaths			non-COVID-19 deaths 2020			COVID / non-COVID	Z value	P value	All-cause deaths in 2019			COVID / 2019	Z value	P value
		OR 2020	p	IC95%	OR 2020	p	95% CI				OR 2019	p	95% CI			
Each Y.O.A.	>44	1.082	***	1.077-1.088	1.110	***	1.107-1.113	0.998	-0.56	0.575	1.106	***	1.102-1.108	1.002	0.693	0.488
COPD	45-64	2.52	**	1.34-4.75	1.90	**	1.34-2.67	1.33	1.49	0.136	2.95	***	2.23-3.91	0.85	-0.89	0.373
	65-84	1.92	***	1.59-2.32	1.84	***	1.65-2.06	1.04	0.71	0.476	2.07	***	1.87-2.29	0.93	-1.35	0.178
	>84	1.42	**	1.13-1.79	1.32	***	1.19-1.48	1.07	1.10	0.271	1.55	***	1.4-1.72	0.92	-1.37	0.170
CRI	45-64	5.47	***	2.72-10.99	2.35	***	1.56-3.55	2.32	3.90	***	1.81	**	1.17-2.8	3.02	5.22	***
	65-84	2.08	***	1.67-2.6	2.23	***	1.96-2.53	0.93	-1.02	0.307	1.96	***	1.74-2.22	1.06	0.91	0.361
	>84	1.65	***	1.31-2.08	1.48	***	1.33-1.66	1.11	1.59	0.111	1.54	***	1.38-1.71	1.07	1.06	0.287
Diabetes	45-64	2.62	**	1.53-4.48	2.49	***	1.88-3.3	1.05	0.31	0.753	2.14	***	1.65-2.79	1.22	1.30	0.192
	65-84	1.77	***	1.5-2.08	1.59	***	1.45-1.76	1.11	2.10	*	1.59	***	1.46-1.74	1.11	2.16	*
	>84	1.33	**	1.08-1.64	1.31	***	1.19-1.45	1.01	0.18	0.856	1.20	**	1.09-1.33	1.10	1.65	0.098
Inflammatory Bowel Diseases	45-64	0.83	0.73	0.29-2.36	2.70	***	1.93-3.78	0.31	-4.18	***	2.06	***	1.45-2.92	0.40	-3.24	**
	65-84	1.34	0.15	0.9-1.97	1.92	***	1.6-2.29	0.70	-3.19	**	1.47	**	1.2-1.8	0.91	-0.83	0.404
	>84	1.17	0.61	0.64-2.14	1.50	**	1.16-1.94	0.78	-1.49	0.137	1.36	*	1.05-1.78	0.86	-0.92	0.358
Chronic Cardiovascular Diseases	45-64	2.20	***	1.87-2.58	2.66	***	2.04-3.47	0.83	-1.25	0.213	2.58	***	2.03-3.27	0.85	-1.06	0.291
	65-84	2.44	**	1.42-4.2	2.01	***	1.83-2.2	1.22	4.19	***	1.91	***	1.75-2.07	1.28	5.39	***
	>84	1.57	***	1.32-1.87	1.59	***	1.47-1.72	0.99	-0.18	0.854	1.56	***	1.45-1.69	1.01	0.14	0.887
Neoplasia	45-64	3.13	***	1.94-5.06	8.22	***	6.7-10.08	0.38	-7.24	***	8.31	***	6.89-10.04	0.38	-7.43	***
	65-84	1.61	***	1.37-1.89	2.65	***	2.44-2.88	0.61	-10.73	***	2.82	***	2.6-3.05	0.57	-12.20	***
	>84	1.04	0.69	0.85-1.29	1.24	***	1.13-1.36	0.84	-2.91	**	1.43	***	1.31-1.56	0.73	-5.39	***
Neurological sindromes	45-64	6.44	***	3.37-12.29	4.62	***	3.27-6.53	1.39	1.71	0.087	3.15	***	2.16-4.6	2.04	3.73	***
	65-84	2.71	***	2.22-3.31	4.30	***	3.87-4.77	0.63	-7.99	***	2.88	***	2.58-3.2	0.94	-1.04	0.297
	>84	2.45	***	2.03-2.95	2.07	***	1.89-2.27	1.18	3.15	**	1.78	***	1.62-1.96	1.37	5.96	***

***p-value < 0.001 **p-value < 0.01 *p-value <0.05

IBD displayed a lower OR in COVID-19 patients aged 45-64 years who died than in non-COVID-19 patients who died in 2019 and 2020 (OR_1/OR_2 of 0.31 in 2020 and 0.40 in 2019); neoplasia showed a lower OR in all age-groups (OR_1/OR_2 ranged from 0.84 to 0.38 in 2020, and from 0.73 to 0.38, in 2019, see table 2 for further details).

Discussion and conclusion

Estimating mortality attributable to the COVID-19 epidemic and the role played by risk factors for mortality are fundamental to understanding the real burden of the disease and to identifying risk-based preventive strategies. The present population-based study provided an estimate of excess COVID-19-related mortality in Liguria during the epidemic peak; it also estimated the short-term mortality displacement and calculated the weight of risk factors for mortality in COVID-19 patients and non-COVID-19 patients in 2019 and 2020 in different age-groups.

During the epidemic peak, a 63.3% increase in all-cause deaths was observed in comparison with the average registered during the control period (2015-19); however, the decrease in mortality observed in the following 8 weeks softened this impact by 22%. Indeed, Poisson GNL indicated a short-term mortality displacement equal to 24% of the amount of excess mortality observed during the peak. The harvesting effect can reasonably be entirely ascribed to the extra mortality due to COVID-19, as the 2019-20 influenza season was extraordinarily mild, being globally similar in terms of mortality to the 2015-2016 seasons (WHO, EUROMOMO, Italian Ministry of Health) [20-23].

The global effect of the mild influenza season in January and February, the vigorous circulation of SARS-CoV-2 in March and April and the harvesting effect starting from the second half of May determined a mild/reduced increase in mortality in the first 26 weeks of 2020, amounting to 7% of expected deaths.

Since the start of the pandemic, age has been indicated as the key determinant of prognosis in COVID-19 patients. In our study, age was identified as an independent predictor of mortality in patients with COVID-19, and the magnitude of the odds ratio per year of increase was similar in SARS-CoV-2-positive patients and non-COVID-19 patients who died in 2019 and 2020. We observed an increased risk with an OR of 1.08 per year of age in COVID-19 patients; this largely overlaps with the ORs registered in other populations with different characteristics during the pandemic [24].

Our study confirmed that COVID-19 patients with various comorbidities, including chronic lung disease, CRI, neoplasia, chronic cardiovascular disease, neurological syndromes and diabetes, have a higher likelihood of complications and death [25-30]. The weight of these underlying conditions in COVID-19 patients in comparison with non-COVID patients, both during and before the spread of SARS-CoV-2, showed different patterns; for the majority of comorbidities, however, the risk proved comparable in COVID-19 and non-COVID-19 patients.

In the literature, the reported effect of comorbidities on the outcomes of patients with COVID-19 are conflicting. In our study, CRI in COVID-19 patients aged 44-64 years, diabetes and chronic cardiovascular disease in those aged 65-84 years and neurological syndromes in those aged > 84 years were found to exert more influence than in non- COVID individuals.

Several studies have found that CRI, diabetes, chronic cardiovascular disease and neurological syndromes are associated with severe outcomes. However, the present study is the first to compare these independent predictors of death in SARS-CoV-2-positive and -negative patients during the pandemic and in previous years. Various immunological and molecular mechanisms, including chronic inflammation, proinflammatory cytokine storms, increased coagulation activity, impaired immune response, elevated expression of ACE-2 and potential direct pancreatic damage by SARS-CoV-2, may explain these associations. These effects are counterbalanced or increased by the asymmetric distribution of some underlying diseases, of social mixing behaviour, of compliance with social isolation or of living in high-risk settings (e.g. nursing homes), etc. The role played by each single immunological, molecular or behavioural factor is difficult to estimate.

Surprisingly, the weight of cancer in influencing death in COVID subjects proved minimal in those aged > 84 years; moreover, it was much lower than in non-COVID patients in 2020 and 2019 in all age-groups. The results of a recent meta-analysis by Vassilis G. et al. showed that all-cause mortality in the elderly (aged 64 years) was comparable between individuals with cancer and those without (RR, 1.06; 95%CI, 0.79 to 1.41; P = .71), as found in our study in individuals aged > 84 years. The absence of an increased mortality risk in older individuals implies that the presence of cancer does not further affect the already burdened prognosis among older individuals [31]. In cancer patients, immunosuppression may dampen the so-called "cytokine storm", the most dangerous and potentially life-threatening event related to COVID-19, because of their down-regulated immune response. Furthermore, cancer patients are more likely to implement self-isolation, social and physical distancing and personal health measures, which may explain the lower incidence of COVID-19 [32-34]. The reduced weight of neoplasia in COVID-19 patients during the first wave is only the short-term effect of the pandemic, but substantial increases in the number of avoidable cancer deaths are to be expected in the near future as a result of diagnostic delays due to the COVID-19 pandemic [35]

IBD seems not to influence the likelihood of death in COVID-19 patients; the ORs were significantly lower in this group than in non-COVID patients in 2020 and 2019. These results could suggest a protective role of immunosuppressive drugs; indeed, some therapies that are frequently administered in patients with IBD, such as anti-TNFα, anti-IL-6 and JAK inhibitors, may have a beneficial role in attenuating severe COVID-19 disease, although more evidence is needed [36, 37]. In our population, about 10% of patients with IBD were on immunosuppressive drugs.

This study has some limitations. The analysis considered the total number of deaths in residents in cities with more than 10,000 inhabitants (above 70% of the total population) to avoid the possibility of delayed notification by the regional registry office. This sample was therefore not exactly representative of the total population; this may have introduced the bias of the possible different access to treatment in small towns or the different spread of the virus in less populated areas. However, as we compared different outcomes and risk factors in infected and non-infected residents in cities with > 10,000 inhabitants in different periods of time, this bias does not affect, or only minimally affects, the results.

To compare the impact of risk factors on death in COVID-19 patients and non-COVID-19 patients in 2019 and 2020, we used the ratio between Odds Ratios, evaluated by the difference between logOR and pooled SE, by means of Student's T test. Some epidemiologists argue that, in order to compare two odds ratios, it is enough that the OR confidence intervals overlap. However, we needed a finer method in order to obtain an indicator of results that was comparable between the various categories.

In conclusion, the evaluation of the weight of comorbidities in COVID-19 patients yielded some surprising results, such as the low/minimal weight of cancer in influencing death in older COVID-19 patients and the comparable weight of COPD and chronic cardiovascular disease (except in the 65-84-year age-group) in COVID-19 and non-COVID subjects. The excess mortality that we observed in the first semester of 2020 was modest, in comparison with the initial estimate during the peak, owing to the mild influenza season and the harvesting effect starting from the second half of May.

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Conflict of interest statement

The authors declare no conflict of interest.

Authors' contributions

FA, GI and MA conceived the study. MA, FT, CP and FA verified the analytical methods. SS and DG provided informatics data. All authors contributed to data acquisition and data quality control. MA, FT, CP, DA, MFA, AO, GI, DP, IA and MP contributed to the interpretation of the results. MA, FA and FT wrote the manuscript, with input from all authors. All authors have read and agreed to the published version of the manuscript.

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ENVIRONMENTAL HYGIENE

Airborne chemical pollution and children's asthma incidence rate in Minsk

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Key words:

Air pollution • Children's health • Asthma incidence rate

Summary

Introduction. *Asthma manifestations are closely connected with air pollution. Discovering interconnection between concentrations of air pollutants and asthma incidence rate among children provides information for developing effective measures to reduce air pollution and improve population health. Study purpose was to carry out hygienic analysis of the influence of atmospheric air quality on the incidence rate of bronchial asthma of children in Minsk in 2009-2018.*
Methods. *During 2019 retrospective health cohort study was conducted, data from stationary air quality monitoring posts were collected. Correlation analysis was conducted by determining the Pearson coefficient.*
Results. *Ten-year levels of asthma incidence rate had a moderate downward trend; the highest levels were registered among 5-9-year-old children. 74.7% of all cases of asthma were registered among children under 10 years: 33,61% among 1-4-year-old and 41.09% – among 5-9-year-old. Results of the study showed that concentrations of ammonia, particulate matter (dust/aerosol undifferentiated in composition) and lead in Minsk were characterized by downward trend, carbon oxide and nitrogen dioxide concentrations remained unstable, elevated levels of formaldehyde remained near highways with heavy traffic. Strong evidence was found for concentrations of particulate matter (dust/aerosol undifferentiated in composition) ($R = 0.76\text{-}0.85$, $p < 0.05$), lead ($R = 0.69\text{-}0.97$, $p < 0.05$), ammonia ($R = 0.64\text{-}0.72$, $p < 0.05$) nitrogen dioxide ($R = 0.63\text{-}0.8$, $p < 0.05$) and children's asthma incidence rate.*
Conclusions. *Obtained results indicate that particulate matter, lead, ammonia and nitrogen dioxide concentrations hesitation causes changes in children's asthma incidence levels. Not being the initial cause of the disease, they influence epidemic process and can be the target for preventive measures.*

Introduction

Air pollution is on the second place among reasons of economic losses of the gross domestic product of developing countries from mortality and morbidity associated with the negative impact of environmental factors at the population level [1] and the most important environmental risk factor for human health in the European Region [2]. Many studies prove that air pollution makes a significant contribution to the formation of disorders of the cardiovascular and respiratory systems, causing an increase in morbidity and mortality levels from diseases of the circulatory and respiratory systems [3-7]. Improving air quality can reduce the burden of diseases such as stroke, heart disease and lung cancer, as well as chronic and acute respiratory diseases, including asthma. Asthma is one of the most common chronic diseases in the world. It is estimated that around 300 million people in the world currently have asthma [8]. It is a leading chronic illness among children and adolescents in the United States. Asthma is also one of the leading causes of school absenteeism [9].
Previous studies discovered that air pollution levels in big cities contribute greatly into developing asthma in children [10-13] and air pollution control can be one of the effective preventive measures to reduce asthma manifestations. Yet, studies on determination of air pollution effects on asthma manifestations in Minsk, 10th most populated city in Europe, hasn't been conducted.
Study objective was to explore the effect of air pollution on the levels of asthma incidence among children in Minsk. It would help in understanding the degree of environmental conditioning of children's asthma in Minsk, in comparing obtained results with global trends and determining the direction of preventive measures within the framework of reducing ambient air pollution.

Methods

Research design

The research design was retrospective health cohort study. Data were collected in 2019, study period – 2009-2018.

Data collection

Air quality data: system of monitoring air quality in Minsk is represented by 12 stationary and 40 route posts [14, 15]. In 2019 during the research was

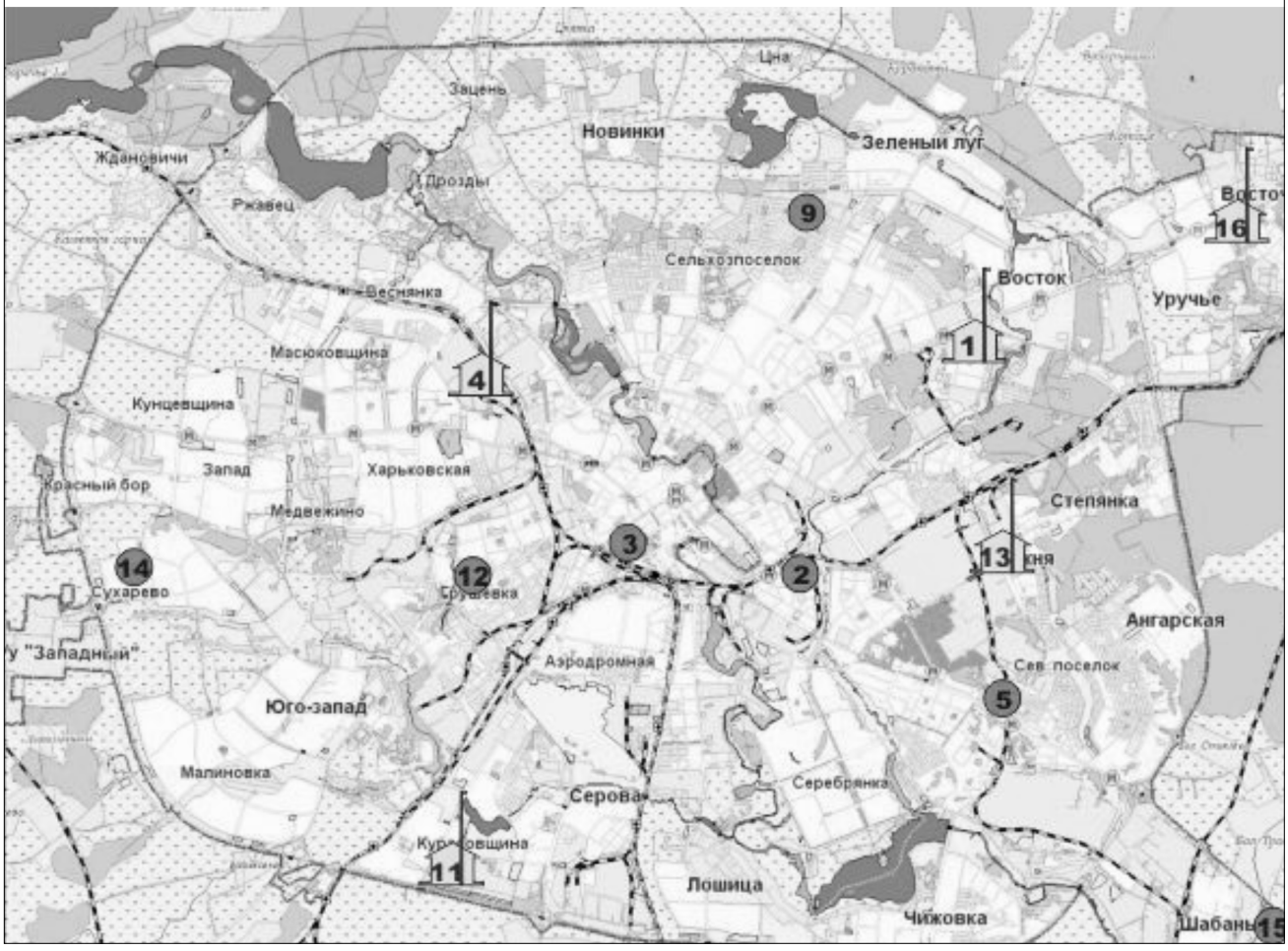
collected chemical annual concentration data from 12 stationary posts in 2009-2018. 12 stationary posts included 7 discrete monitoring posts and 5 automatic posts (Fig. 1). Monitoring technology at discrete posts included: air sampling by a chemical technician, their delivery to the laboratory and subsequent chemical analysis. Air samples were taken in absorption devices or aerosol filters within 20 minutes. Observations of pollutant concentrations were carried out daily 3 times a day (except Sundays and holidays). Automatic posts measured concentrations of pollutants automatically each hour. Annual concentrations were determined as average from several thousand measurements per year. Automatic posts controlled concentrations of particulate matter (fractions up to 10 microns), sulfur dioxide, nitrogen oxide, nitrogen dioxide, benzene, carbon oxide and ground-level ozone. Discrete posts measured concentrations of particulate matter (dust/aerosol undifferentiated in composition), carbon oxide, nitrogen dioxide, formaldehyde, ammonia, phenol, hydrogen sulfide, carbon disulfide. The inclusion criteria for pollutants in study were: the duration of pollutant concentration control in the atmospheric air at the post for 5 years or more; the percentage of samples with the result "below the sensitivity level of the method" less than 30%. In the study concentrations of following pollutants were analyzed in the atmosphere of Minsk: particulate matter (dust/aerosol undifferentiated in composition), nitrogen dioxide, ammonia, carbon oxide, formaldehyde and lead.

Health status data: Medical data concerning number of registered cases of asthma and asthmatic status (J45, J46) was collected from all Minsk children clinics (15 clinics), using annual governmental statistical reports. Population under study ranged from 311735 children in 2009 to 376,500 in 2018. Disease cases were structured by age groups: children under one year, 1-4 years, 5-9 years, 10-14 years and 15-17 years. Children under one year old were excluded from the study, as in 83% of the analyzed years 0 cases of asthma were registered in this group.

Population research

Retrospective study of asthma and asthmatic status incidence rate among children (0-17 years) living in Minsk was conducted in 2019, period of study included ten years (2009-2018). Asthma incidence rate was calculated to characterize morbidity as number of new cases of asthma or asthmatic status during a year divided by average children population during this year [16]

Fig. 1. Location of air monitoring quality posts in Minsk, Belarus, as of 2019 year. Circles mark discrete posts, home-formed figures – automatic posts. Posts numeration was saved and used in further study.



expressed in units per hundred thousand people. Obtained values of incidence rate were analyzed for 9 administrative districts of Minsk.

Statistical analysis

Descriptive statistical analysis was made for pollutant concentrations and incidence rate of asthma and asthmatic status: growth rate, average values, age-specific rates, long term trend (linear and polynomial) and prognosed levels were calculated. One sample Kolmogorov-Smirnov test showed normal distribution in asthma cases (0.47, p = 0.979) and in concentrations of particulate matter (dust/aerosol undifferentiated in composition) (0.9, p = 0.698), nitrogen dioxide (0.91, p = 0.585), ammonia (0.85, p = 0.63), carbon oxide (0.51, p = 0.957), formaldehyde (0.47, p = 0.941) and lead (0.6, p = 0.835). Correlation analysis was carried out by calculating Pearson's correlation coefficient between annual concentrations of main pollutants in the air and incidence rates of asthma and asthmatic status among children, the critical level of significance *p* when testing statistical hypotheses was taken equal to 0,05. T-test was used to determine differences between mean values.

Results

Air quality in Minsk

Concentrations of analyzed pollutants in ambient air in Minsk mostly didn't exceed national normative levels. Concentrations of nitrogen dioxide had slight downward trend in the atmosphere of the city, still maintained heterogeneity in different districts and average ten-year concentrations ranged from 26.9 μg/m^3 to 40.6 μg/m^3 (annual normative level in Belarus is 40 μg/m^3). Carbon oxide concentrations did not have expressed trend and varied diversely during analyzed period. Annual ten-year concentrations ranged from 320.53 μg/m^3 to 519.96 μg/m^3 (annual normative is 500 μg/m^3). (Fig. 2). Increased level of formaldehyde concentrations near highways with heavy traffic remained a characteristic feature of air pollution in Minsk. The maximum concentration of formaldehyde reached 12.3 μg/m^3 (annual normative is 3 μg/m^3) in 2014. Concentrations of particulate matter (dust/aerosol undifferentiated in composition), ammonia and lead were characterized by downward trend, the highest average ten-year concentration of ammonia was 14.9 μg/m^3. The maximum average ten-year concentration of lead reached 0.032 μg/m^3 (annual normative is 0.1 μg/m^3), maximum average five-year concentration of particulate matter (dust/aerosol undifferentiated in composition) reached 19.75 μg/m^3 (annual normative is 100 μg/m^3). Concentrations of the analyzed pollutants in administrative districts of Minsk did not have significant differences.

Children asthma incidence rate

The ten-year levels of incidence rate of asthma and asthmatic status among children in Minsk had a moderate downward trend, the growth rate was -1.51%, the highest levels were noted in 2011 and 2012 (182.9 and 188.7 per 100 thousand of the population, respectively). The minimum incidence rate was established in 2010 (128.9 per 100 thousand people). Regression analysis showed that model $y = -21{,}313x^2 + 55{,}881x + 172{,}49$ (polynomial trend, $R^2 = 0.9029$) was describing changes of incidence rate levels changes.

Analysis by age groups showed that 74.7% of all cases of asthma were registered among children under 10 years: 33,61% among 1-4-year-old children and 41.09% - among 5-9-year-old. Analysis of the dynamics of incidence rates showed an upward trend among children 15-17 years, a moderate tendency to decrease among children under 4 years and relatively stable trends among children 5-9 and 10-14 years. The highest level of incidence was found in 5-9 years old group (Fig. 3).

Over 10 years of observation, the maximum level of incidence rate of asthma was recorded in *Oktyabr'skiy* district (190.67 ± 7.6 per 100 thousand people), minimum – in *Partizanskiy* district (82.9 ± 7.21 per 100 thousand people). Analysis revealed a significant increase of incidence rate levels in *Oktyabr'skiy* (t = 3.7, p = 0.02) and *Frunzenskiy* (t = 3.3, p = 0.03) districts comparing with the average city levels. In the remaining districts, levels of asthma incidence rate did not exceed average city levels significantly.

Correlation analysis results

The correlation analysis, by means of the Pearson's correlation coefficient (R), highlighted strong positive and moderate positive correlation between asthma incidence rate among children of different age groups and concentrations of studied pollutants (Tab. I).

In 82.14% cases among discovered correlations were determined high positive correlations, in 17.86% - moderate positive. 43.48% of high positive correlation were noted for lead. In 35% of cases, a correlation was established for the age groups 1-4 years and 10-14 years, in 20% - for 5-9 years. Thus, the age group of children under 10 years old accounted for 55% of all correlations. When analyzing the distribution of the obtained correlations in the city districts, it was noted that more often than others, correlation between atmospheric air pollution and asthma incidence levels was found in *Zavodskoy* district (35,7% of all positive correlations).

Among polluting chemicals, whose concentration in the atmospheric air influenced asthma incidence levels among children, the most significant were: lead (39.3% of cases), nitrogen dioxide (21.4% of cases), and particulate matter (dust/aerosol undifferentiated in composition) (17.9% of cases).

Discussion

Results from this study showed that concentrations of analyzed pollutants mostly didn't exceed national standard levels. The most unfavorable situation was noted for formaldehyde, this is due to the fact that elevated levels of formaldehyde were formed due to oxidation of

Fig. 2. Annual concentrations of pollutants (μg/m3) at air monitoring quality posts in Minsk.

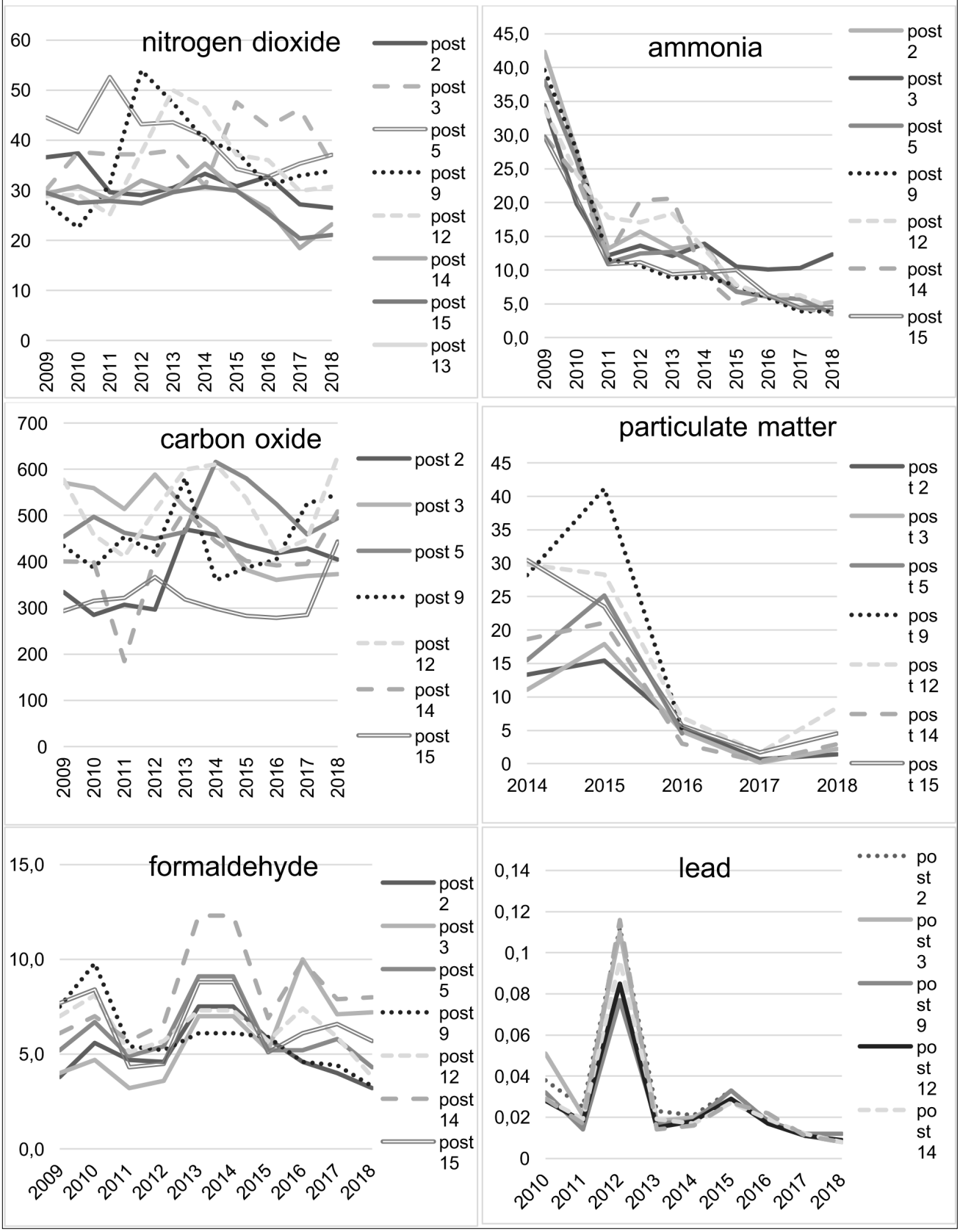
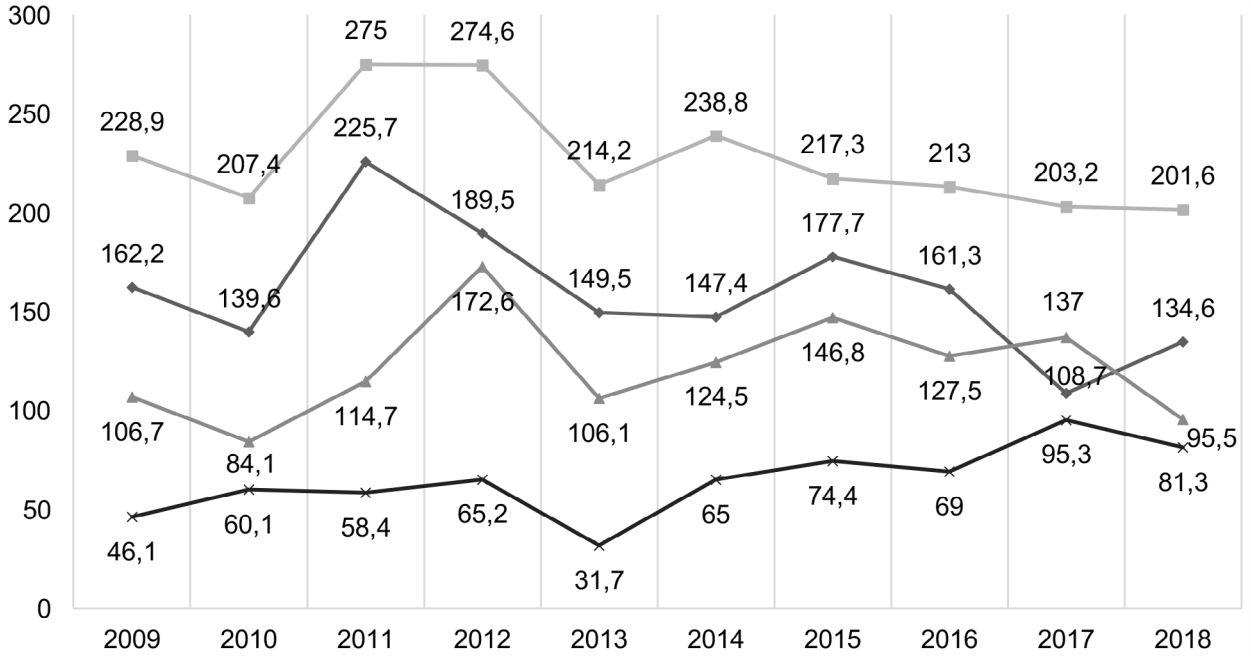


Fig. 3. Levels of asthma incidence rate (per hundred thousand people) in different age groups of children in Minsk in 2009-2018. Rhombus-marked line represents incidence rate for children under 4 years old, square-marked – 5-9 years old children, triangle-marked – 10-14 years old and cross-marked – 15-17 years.



Tab. I. Correlation analysis results between children asthma incidence rate and concentrations of pollutants, Minsk, 2009-2018.

District	Pollutant	Age group	R	p
Pervomayskiy	Nitrogen dioxide	5-9	0.683	0.043
		10-14	0.802	0.009
	Ammonia	1-4	0.722	0.018
		0-17	0.7	0.049
	Particulate matter (dust/aerosol undifferentiated in composition)	0-17	0.775	0.041
	Lead	5-9	0.705	0.034
		10-14	0.921	0.0009
		0-17	0.925	0.0009
Oktyabr'skiy	Carbon oxide	1-4	0.727	0.017
	Particulate matter (dust/aerosol undifferentiated in composition)	1-4	0.854	0.007
	Lead	10-14	0.909	0.001
		0-17	0.859	0.003
Moskovskiy	Lead	10-14	0.832	0.001
		0-17	0.685	0.042
Frunzenskiy	Carbon oxide	1-4	0.998	0.041
	Lead	15-17	0.93	0.0009
Zavodskoy	Nitrogen dioxide	1-4	0.721	0.019
		5-9	0.634	0.049
		0-17	0.721	0.049
	Ammonia	1-4	0.642	0.045
	Particulate matter (dust/aerosol undifferentiated in composition)	1-4	0.763	0.028
		5-9	0.846	0.016
		0-17	0.806	0.029
	Carbon oxide	15-17	0.72	0.019
	Lead	10-14	0.967	0.0009
		0-17	0.883	0.002
Sovetskiy	Nitrogen dioxide	10-14	0.66	0.035
	Lead	10-14	0.91	0.001

hydrocarbons [17, 18]. Therefore, formaldehyde content was formed not only by emissions of this substance, but also by the presence of other polluting chemicals and solar radiation. Formaldehyde can be irritating to the upper respiratory tract and eyes with inhalation exposure and play a significant role in the development of acute reflex reactions, including asthma among children [17, 19]. Concentrations of the analyzed pollutants in administrative districts of Minsk did not have significant differences, which is due to the fact that the layout of stationary posts is aimed at determining background concentrations in the city and excludes the influence of local especially large sources of atmospheric pollution.

Ten-year levels of asthma incidence rate in Minsk had a moderate downward trend for all children and moderate upward trend for 15-17-year-old children, the highest incidence levels were registered among 5-9-year-old children, absolute number prevailed in 1-4 and 5-9-year-old groups. Results of epidemiological analyses were similar with world trends: study of children asthma in USA showed that children who were 4 years-old or younger were less likely to have asthma, but the children in this age range with asthma were more likely to have asthma attacks (62.4%), emergency department or urgent care center visits (31.1%) and hospitalizations (10.4%) compared to older children who were 12 to 17 years-old [20]. Still global trend of asthma shows increase of asthma symptoms in children and adolescents, particularly in Low-Middle Income Countries [21]. The global epidemic of asthma that has been observed in both children and adults is still continuing especially in low to middle income countries, although some evidence suggests it has subsided in some high-income countries [22].

The correlation analysis highlighted positive correlation between asthma incidence rate and concentrations of particulate matter (dust/aerosol undifferentiated in composition), lead, ammonia and nitrogen dioxide. These interconnections have already been described in other studies. Study of Taiwan children health showed that lead exposure was associated with IgE and might increase the risk of asthma in children [23]. Ammonia exposure on children in literature shows controversial results on asthma morbidity. 13 months study in the Yakima Valley of Washington State showed no relationship between reported asthma symptoms and the weekly ammonia exposure estimated for the week before the interview date [24]. Still toxicological findings report that histopathologic examination of lung tissue after acute exposure to ammonia demonstrates acute pulmonary congestion and edema and desquamation of the bronchial epithelium [25, 26]. Professional exposure to ammonia in adults is associated with significant chronic irreversible and acute reversible decrements in the lungs' functional capacity [27]. Nitrogen dioxide and particulate matter (PM_{10} and $PM_{2.5}$) shows significant association with asthma exacerbations in children and adults [28]. In addition, many authors who have studied the effect of vehicle emissions on the asthma exacerbations in children, discovered a positive relationship between asthma incidence and the content of nitrogen, sulfur, and carbon oxides [11, 29, 30], $PM_{2.5}$ and black carbon [12], PM_{10} and nitrogen oxides [31-33].

We find results of this research important because of the fact that such studies in Minsk have not been carried out before. In this regard, on the one hand, the results obtained confirm the fact that the formation of asthma manifestations in Minsk is similar to global trends and is not strongly influenced by special local factors. On the other hand, the established fact of changes in the incidence of asthma in response to changes in the concentration of certain polluting chemicals in the atmosphere makes it possible to develop measures to reduce air pollution in such a way as not only to improve air quality, but also to reduce the incidence of asthma.

Possible limitations of our study may be connected with uneven location of air quality monitoring stationary posts, as well as with differences in the list of controlled pollutants. Thus, at the moment of research it did not seem possible to study the effect of the content of ultrafine particulate matter on the asthma incidence rate in whole Minsk, since the monitoring of ultrafine particles in Belarus has been carried out for less than 5 years and only at few posts. In addition, the study of the incidence rate by administrative district may somewhat distort the real picture, as some children may attend preschool and school institutions in other districts. However, children are less likely undergo intra-urban migration, they are more closely tied to the territory in which they live and do not experience the direct influence of professional factors, bad habits. In addition, due to the anatomical and physiological characteristics, children are more sensitive to the quality of their environment, increases the reliability of medical and statistical studies [34]. We suppose our incidence data was not subject to underdiagnosis [35], as Minsk city has highest in Belarus density and breadth of medical coverage for children.

Conclusions

In conclusion, findings suggest that Minsk outdoor air pollution in concentrations that mostly do not exceed national standards influences epidemic process of the development of asthma incidence and may be the goal for developing preventive measures. The results obtained by the authors were used by the sanitary service of Minsk in the development of preventive measures in a perspective five-year plan of Minsk development.

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Declarations of interest

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Authors contribution

ND: data analysis and interpretation, drafting the article
AH: conception or the work, revision of the article
LH: data analysis and interpretation, drafting the article
IS: conception or the work, revision of the article
DK: data collection, data analysis and interpretation
UU: data collection, data analysis and interpretation
NC: data collection, data analysis and interpretation
AV: data collection, data analysis and interpretation
EM: data collection, data analysis and interpretation
SE: conception or the work, revision of the article
NH: conception or the work, revision of the article

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ENVIRONMENTAL HYGIENE

Fungal contamination of indoor public swimming pools and their dominant physical and chemical properties

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Keyword

Disinfection systems • Iran • Parasitic and fungal contamination • Physical and chemical characteristics • Swimming pool.

Summary

Introduction. *Considering the existence of both parasitic and fungal pathogens in the indoor public swimming pools and non-utilization of suitable filtration and disinfection systems in these places, this research aimed to determine the relationship between the indoor public swimming pools and possible pollution with parasitic and fungal agents, as well as physical and chemical characteristics of these pools and compare the results with national standards.*

Methods. *In this study, 11 active indoor swimming pools of Zahedan city were sampled, using plastic pump techniques, from the middle of winter to the late summer season. A total of 88 water samples (eight water samples from each pool) were examined to determine the residual chlorine, contamination with parasitic and fungal agents, using culture media and slide culture techniques. Results were analyzed with SPSS software (V16) and, Microsoft Excel (V2010).*

Results. *The findings revealed fungal contamination with Cladosporium, Penicillium, Aspergillus flavus and Aspergillus fumigatus, etc. and the physicochemical factors comply with the minimum standards, which indicates the need for continuous monitoring and control of water filtration and disinfection of water in the pools.*

Conclusion. *The results show reasonable derangement of physicochemical and microbial factors of the evaluated pools. Efforts shall be made by the concerned authorities to provide health education to users, quality water at the pools and to maintain the safety and quality of the water through proper and adequate chlorination.*

Introduction

Swimming pools are among the recreation and most attractive sport fields. Swimming has beneficial effects on human physical and mental health. Maintaining the quality and hygiene of the pools' water helps to protect swimmers from acquisition and dissemination of transmittable diseases, such as eye and skin diseases [1]. Water in recreation centers and public swimming pools are, therefore, a potential source of biological contamination, transmission and outbreaks of diseases if not properly treated [2, 3]. The study of opportunistic fungal pathogens found in these places and the establishment of their sources can effectively help to reduce contamination of swimming pools [4-6]. Pools and other water pollutions can result from non-compliance with health policies, leading to the development of skin, aural, and ocular diseases particular fungal, viral, and parasitic infections among swimmers [7-9]. Water disinfection affects biological factors such as skin and fat deposits, ammonia, urine, sweat, dirt, gum, and participatory food; environmental factors such as acid rain, air pollution, algae, fungi, gas, air moisture content, sunlight, ambient temperature, and evaporation [10]. The quality of pool's water depends on the number of swimmers per unit of time and the effect of disinfectants [11]. The study of potential pathogens and their survival in this environment can be very effective in developing control methods to eliminate contamination. And thus prevent possible infections [12, 13]. Today, swimming pools have been proven to be agents of transmission of infectious diseases in the world [14]. Considering the beneficial effects of swimming on human physical and mental health, disease treatment and personal hygiene, establishing and maintaining standards in swimming pools is important, and microbiological tests to determine the quality of water in swimming pools becomes essential [1]. It is known that the water quality depends on the type of pool (men's, women's and men's, or women's only), and therefore, the water treatment and

disinfection system is different. The optimal parameters for residual chlorine, temperature, and microbial load of the pool water must be under routine monitoring in order to meet minimum standards. Specifically, the undesirable levels of physico-chemical parameters including water temperature, pH, turbidity, T- sulfate, and residual chlorine, and biological parameters such as microbial fungi, parasites, and *Pseudomonas aeruginosa* results from an inability to meet up to the standards, and this leads to various diseases among swimmers. In connection with the evaluation of microbiological and chlorination of swimming pools, numerous studies have been conducted in other parts of the world [15, 16]. However, such studies have not been conducted in Zahedan. This study aimed to determine the types of parasitic and fungal contamination, as well as chemical and physical characteristics of most indoor public swimming pools in the city of Zahedan in 2017, with a view to healthcare, disease prevention, and control.

Materials and Methods

Study area and sample collection

This cross-sectional study was conducted at the Department of Medical Parasitology, Zahedan University of Medical Sciences, Iran. In this study 11, indoor pools (7 public and 4 private) were selected and sampled under practically the same condition. Due to the small number of swimming pools in Zahedan city and also according to similar studies [17], a convenient sampling was done and the sample size was determined to be 88 water samples.

Sampling strategy

A total of 88 water samples (eight water samples from each pool) were examined to determine the residual chlorine, contamination with parasitic and fungal agents, using culture media and slide culture techniques. Sampling was done during the middle of winter to the late summer season period. Generally, utilization of indoor swimming pools is throughout the year, however, utilization is at peak during summer and therefore sampling was done more during the summer in order not to miss the important aspects of parameters. Standard procedure was followed for collecting samples using a manual plastic pump, in a 500 mL sterilized bottle. Eight water samples were collected from each pool. During each sampling, 500 ml of water was collected at a different depth from the floor of the pool to a depth of 1.5 m, and between 2.5 m and 5 m (twice for each depth), in sterile glass bottles. Thus, total of 8 samples were taken from each pool. The samples were transferred to the laboratory within 2 hours in ice [17, 18].

Chemical and Microbiological tools and techniques

The residual chlorine, pH, and temperature were examined on site and then the samples were transported to the laboratory in a cool box and turbidity was measured. A thermometer was used to measure the temperature and turbidity was determined by (HACH Co, 2100 P turbidimeter; USA). The pH was assessed using a DPD kit (N, N-Diethyl-p-Phenylenediamine kit) and phenol red. To measure residual chlorine level in this study, Palin kit manufactured by US DPD was used. According to authorities, 1-3 ppm is considered as the acceptable level of residual chlorine in swimming pools. The standards of the physicochemical parameters of water in Iran are; turbidity less than 0.5 nephelometric turbidity units (N.T.U) and residual chlorine 1-3 ppm, pH 7.2-8, temperature 27-29°C [13, 19, 20]. For the purposes of diagnosing parasite cysts or eggs, and fungi spores, 150 mL of the samples were filtrated through Millipore filters with a pore size of 0.45 micrometers. Then, the filter paper was washed with 2 mL of sterile physiological serum and the residual water was centrifuged at 3000 rpm for 8 minutes. Immediately after that, the sediment was examined to see whether there were any trophozoites, protozoa cysts, or worm eggs [21]. Another 100 mL of the swimming pool water was passed through this filter. This filter was inoculated upside down over the Bactoagar medium enrichment with *E-coli*. Following the closing of the plates with Parafilm, they were kept in an incubator at 30°C for one week [22]. Then the plates were examined under the microscope to check for the presence of free-living ameba colonies and the results were recorded in a checklist. Fungal identification were based on macroscopic, microscopic characteristic and complementary tests when necessary. To detect fungal contamination, the sterile swabs were placed in the residual filtrated water; surface and deep samples, were then cultured in Sabouraud dextrose agar (S) and Sabouraud dextrose agar + chloramphenicol + cycloheximide (SCC). The plates were incubated at room temperature for two weeks and then the level of fungal growth was determined by routine laboratory methods. Dermatophyte confirmation was done using complementary tests such as hair penetration, corn meal agar medium containing 2% dextrose (CMA), and urea medium where necessary. In cases where there were signs of colonial fungal growth it was designated positive, and then it was examined by the teased mount method or slide culture [23].

Statistical analysis

Finally, one-way ANOVA test to examine the relationship between parasitic and fungal contamination in indoor public swimming pools along their physical and chemical properties were performed using the software SPSS 16. P-value of less than 0.05 was considered to be statistically significant. This study was approved by the Ethics committee at the Zahedan University of Medical Science [24].

Results

The results of one-way ANOVA showed no significant relationship between the components of fungal

Tab. I. One-way ANOVA test result of the relationship between the fungal contaminants and physicochemical parameters of the pools water.

Variable	Sig. p- value
Depth	1.000
	Not significant
T- sulfate	1.000
	Not significant
pH	0.000
	Significant
In terms of turbidity ntu	0.000
	Significant
Residual chlorine in ppm	0.000
	Significant
Temperatures in ° C	0.000
	Significant

contamination and physicochemical factors of swimming pools, such as depth and t-solfate and showed a significant relationship with pH, turbidity, residual chlorine, temperature, and communication (Tab. I).

Mean physicochemical properties of the pool's water studied were shown in Table II.

The results showed a total of 34 water samples were contaminated with fungal elements. The prevalence of fungal contamination was 38.7 %. Out of 11 swimming pools, 7 were old and crowded. The prevalence of fungal contamination in old and newer pools were 76.5 % and 23.5 %, respectively. The findings of this study indicated that the water of the pools had a relatively little amount of fungal contamination. In terms of the residual chlorine content, which is about 3 ppm, and within the standard range. Parasitic elements such as eggs of worms, trophozoites or intestinal cysts of pathogenic and non-pathogenic parasites were not seen in this study. Table III, showed the average residual chlorine component in pools' water that did not have fungal contamination was about 2.6852.

The level of fungal contamination in surface and deep water of the pools were, 48% and 29%, respectively. In this study, different types of saprophytic opportunistic fungi were isolated from 88 samples of surface and deep pools.

The most common isolated fungi belong to *Aspergillus* genus (35.3%) especially, *Aspergillus flavus, Aspergillus fumigatus,* and *Aspergillus Niger*. These fungi were most often isolated during the summer in the pool water. Only one case of *Trichophyton* spp was seen in the studied water sample (Tab. IV), (Fig. 1).

Discussion

Several studies were conducted to investigate the physical, chemical and microbiological elements of the pools' water in the world. The results indicate the presence of various chemical and infectious agents in these pools, which may under certain circumstances pose a serious health threat to those coming in contact with the pools' water. Since the indoor pool attracts people all year round, the safety and hygiene of the water are of particular importance [5, 21, 25-31]. We used Palin UDP kit (USA) to measure residual chlorine level in this study. According to authorities, 1-3 ppm is considered as the acceptable level of residual chlorine in swimming pools [32, 33]. In our results (Figure 2) approximately 12 samples studied, the residual chlorine level in the

Tab. II. Mean physicochemical properties of the pool's water studied.

Variable Swimming pool	Mean pH	The average in terms of turbidity ntu	Mean residual chlorine in ppm	Average temperatures in ° C
A	7.6500	0.2275	0.0500	29.5000
B	7.7700	0.2400	1.5000	28.5000
C	7.8500	0.1725	0.0375	30.0000
D	7.8000	0.3650	1.7000	29.0000
E	8.2000	0.4050	2.5000	30.5250
F	8.2000	0.3325	3.0000	29.0000
G	8.2000	0.4300	3.0000	26.5000
H	7.6000	0.3150	2.2500	29.5000
J	7.8000	0.3250	3.0000	28.0000
K	7.8000	0.3625	0.0000	30.5000
L	8.2000	0.4125	5.0000	29.5000
Sum	7.9155	0.3261	2.0034	29.1386

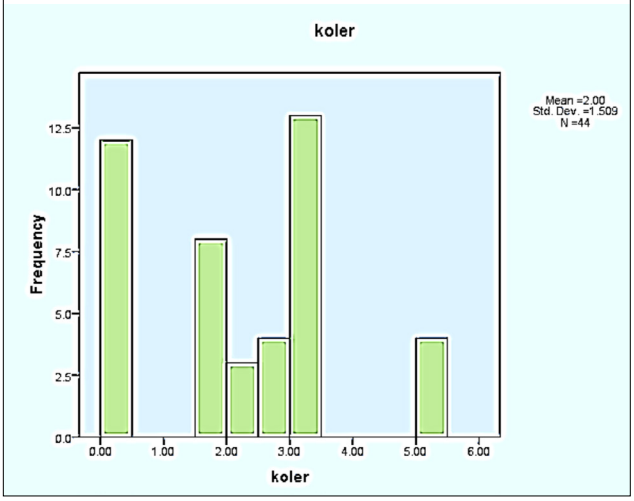
Tab. III. Comparison of mean and standard deviation for evaluation of fungal contamination and residual chlorine component, water-based milligrams per liter.

Variable	Fungal contamination	Number	Mean	Standard deviation	Deviation, Standard Error
Chlorine, water	had not	54	2.6852	1.42874	0.27496
	has it	34	0.9206	0.88106	0.21369

Tab. IV. Frequency of fungal contamination in eleven pool.

	Type of Fungi			
Valid	Frequency	Percent	Valid Percent	Cumulative Percent
	54	61.3	61.3	61.3
Alternaria spp	2	2.28	2.28	63.58
Aspergillus Flavus	7	7.96	7.96	71.54
Aspergillus Fumigatus	4	4.55	4.55	76.09
Aspergillus Niger	1	1.14	1.14	77.23
Cladosporium spp	4	4.55	4.55	81.78
Geotrichum	2	2.28	2.28	84.06
Mucor spp	1	1.14	1.14	85.2
Rhizopus spp	3	3.41	3.41	88.61
Phialophora spp	3	3.41	3.41	92.02
Trichophyton spp	1	1.14	1.14	93.16
Sterile mycelium	3	3.41	3.41	96.57
Penicillium spp	1	1.14	1.14	97.71
Unknown	2	2.28	2.28	100.0
Total	88	100.0	100.0	

Fig. 1. Frequency of residual chlorine levels in milligrams per liter in eleven indoor pool.



studied pools' water was within the acceptable standard range. Only 3 of the studied pools had a residual chlorine level (about 5 ppm) above the acceptable standard range. The level of physical, chemical, and microbial quality of chlorinated pools can be influenced by several factors. In the first place, the level of knowledge, experience, and understanding of the importance of water quality and the efforts to improve and maintain the quality of the water (including proper chlorination) by the administrative staff and the overseers of the swimming pool facilities are very essential. Secondly, the stringency of quality control and environmental health officials, including several other stakeholders can be a crucial factor that influences the microbial quality of the pool water. In addition, personal hygiene (e.g. shower before swimming) and health status of the swimmers can greatly affect the water quality of the swimming pools [3, 7, 34]. Human skin infections have dramatically increased in recent years and one of the reasons is the rise in recreational facilities and frequent contact among people polluted indoor water environments [35, 36]. Fungal skin infection is found worldwide, irrespective of age or sex. According to the results of the study, the frequency of fungal contamination of indoor swimming pools in Zahedan was found to be higher in the locker room showers than in other pools. Higher frequency of contamination was seen more in highly crowded pools and also in old pools that lack modern construction design. While the newer pool with modern construction that comply with minimal international standards showed the least pollution. Therefore, the less number of people who use pool facilities and the better design of pool building, the lower the level of pools' contamination. Maghazy et al. have studied two swimming pools in Assiut, Egypt and demonstrated contamination of the pools with various types of fungi including three dermatophyte species [37]. Another study conducted by Kraus et al, succeeded in getting a number of pathogens including *T. verrucosum* from pool's water with a free chlorine content of less than 0.35 mg/l (DPD 1) [38].

Conclusion

Based on our findings we can recommend authorities concerned with the pool management to be giving special health education to people attending and using facilities especially those identified with skin infection, tinea infections or vaginal infections. Water disinfectants shall be added and replaced regularly. After each use of the pool, dressing room environment shall be cleaned with disinfectants. If the aforementioned recommendation shall be observed fungal and microbial contamination of the water and environment around it will be a significantly decreased [39]. It is hoped that a way to solve such problems in order to improve the situation

arise. It is also suggested that future studies shall engage the proper and effective methods for the treatment and disinfection of swimming pool water [20].

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Conflict of interest

Authors and coauthors declare that they have no conflict of interest that affects this study.

Author's contribution

Study concept and design: NR, MJM, SD. Collecting samples and preparing for experiment: ED, NR and FP. Analysis and interpretation of data: SD, MJM, MY, AS, VR. Drafting of the manuscript: OR, MG, VR, BA. Critical revision of the manuscript for important intellectual content: OR, MG, S SH, SA. Statistical analysis: MJM, SD, OR.

Ethical statement

The study was approved by the joint Ethical Committees of Zahedan University of Medical Sciences ethic no. ir.zaums.rec.1395. 75.

Availability of data and materials

In this study, all data and materials are included. If more information is needed, please contact the author for data requests.

Consent for publication

Not applicable because this manuscript does not contain any individual personal data.

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HEALTH PROMOTION

Prevalence of gestational diabetes and its association with stillbirth, preterm birth, macrosomia, abortion and cesarean delivery: a national prevalence study of 11 provinces in Iran

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Keywords

Gestational diabetes mellitus • Macrosomia • Stillbirth • Abortion

Summary

Background. *Gestational diabetes mellitus (GDM) is one of the most common metabolic disorders during pregnancy that significantly affects perinatal outcomes.*
Objective. *The aim of this study was to determine the prevalence of GDM and its relation with the incidence of stillbirth, preterm birth, macrosomia, abortion and cesarean section (C-section) delivery in pregnant women.*
Methods. *This cross-sectional study was conducted on 3675 pregnant women in 11 provinces across Iran. Cluster sampling was used to select samples from mothers covered by health plans in 11 provinces of Iran. Prevalence of adverse pregnancy outcomes, including preterm delivery, type of delivery, macrosomic preterm birth, miscarriage, stillbirth, infant death, and birth weight were measured, using family record and face-to-face interviews. Data were analyzed by logistic regression, using STATA14.2 software.*
Results. *About four percent of Iranian pregnant women had GDM during pregnancy. Prevalence of C-section was significantly higher in diabetic women than in the non-diabetic ones (53.19 vs 46.81, respectively, P < 0.001). Abortion in diabetic mothers was more than twice that of the non-diabetic mothers (P < 0.001). In the adjusted logistic regression model, the odds of stillbirth in mothers with GDM were 1.8 (95% CI: 1.11, 2.91, P = 0.018) times higher than that of the non-diabetics. The odds of macrosomia in diabetic women was about 7 times higher than the non-diabetic women (95% CI: 2.81, 17.14, P < 0.001). The odds of GDM had an increasing trend according to the BMI (p < 0.001). The risk of GDM were significantly lower, according to the daily physical activity (PA) (p < 0.001).*
Conclusion. *The GDM prevalence has a decreasing trend in Iran. It increases the adverse pregnancy outcomes such as stillbirth, neonatal deaths, macrosomia, preterm birth, abortion and C-section delivery. As, some of these consequences like macrosomia are not treatable, thus early prevention is very crucial.*

Background

Gestational diabetes mellitus (GDM) is one of the most common metabolic disorders during pregnancy that significantly affects perinatal outcomes [1]. The prevalence of GDM is different in recent studies, worldwide. The prevalence of GDM is reported to be 5.4% in Europe, 14% in Africa and 0.7 to 51% in Asia [2-6]. Timely diagnosis and appropriate treatment of GDM are very vital in preventing maternal and fetal complications [7]. GDM occurs in approximately 2-5% of pregnancies and has short- and long-term consequences for the mother, infant, and fetus [8, 9].
Preterm delivery, macrosomia, abortion, respiratory distress, stillbirth, neonatal deaths, and increased caesarean section (C-section) delivery are among the outcomes of GDM. In addition, GDM not only increases the risk of type 2 diabetes and hypertension disorders in mothers [10, 11] but also increases the risk of congenital malformations, especially obstructive urinary tract disorders, renal agenesis, and cardiovascular disorders by 1.2 times in fetus [12].
Preterm labor and increased cesarean delivery are other major complications of GDM that can lead to stillbirth and infant mortality. For example, a case-control study reported that the risks of C-section delivery in diabetic pregnant women were twice that of non-diabetic mothers [13]. In addition, in a cohort study, the

relative risk of C-section delivery for diabetic mothers was 1.4 times (95% CI: 1.04-2.02) more than the non-diabetic mothers [10].

Furthermore, a study on the consequences of GDM has shown that perinatal events are higher in diabetic mothers than in the non-diabetic patients. The results of this study reported a 3-fold higher prenatal mortality in neonates born in diabetic mothers, 9-fold higher rates of first-year mortality, 3-fold more congenital anomalies, and 3.6-fold higher incidence of large for gestational age birth (LGA) in neonates of diabetic mothers compared to the non-diabetic mothers [11]. Another study has shown that pregnant women with a higher glucose challenge test (GCT) have a significantly higher chance of preterm delivery and perinatal events [14]. Another adverse of GDM is the increased risk of diabetes type 1 in children. Despite therapeutic advances such as stem cell therapies for the treatment of diabetes type 1, a feasible and safe clinical approach still remain for this purpose [15, 16].

Given that the consequences of GDM can endanger the health of the mother and baby and even some of these consequences like macrosomia are not treatable, therefore, comprehensive research is needed on this area, involving different population. Understanding the adverse consequences of GDM can help us to better plan for the prevention and control of GDM. So far, several studies individually have investigated the prevalence and complications of GDM in several cities of Iran, but the present study was conducted in a more comprehensive way, at the national level in 11 provinces of Iran. The aim of this study was to determine the prevalence of GDM and its relationship with the occurrence of stillbirth, preterm birth, macrosomia, abortion and C-section in pregnant women.

Materials and methods

Study design and population

This cross-sectional study was performed on 3,675 pregnant mothers in 11 provinces of Iran in 2019. The present study was conducted, using data from a population-based national case-control study conducted in the year 2018 to determine the factors associated with stillbirth and neonatal death. At the beginning of the study, participants were provided with comprehensive information on the study objectives, and questionnaires were filled with informed consent. In Iran, health centers provide primary health cares and general medical services to the residences who are living in their defined geographical areas. Mother and child's health cares are among the most important health services, which are provided by the health centers under the supervision of the Iranian ministry of health. The services include maternity and pregnancy cares, vaccination and monitoring child's growth and development [17].

Samples were selected by cluster random sampling from different regions of Iran, so that from all health centers in Fars, Golestan, Kohkiluyeh and Boyer Ahmad, Yazd, Kermanshah, Hamadan, Hormozgan, Chaharmahal and Bakhtiari and South Khorasan provinces, as well as health centers in Mashhad and Zahedan cities. Four cities in each province were selected by cluster sampling from different geographic regions of the North, South, East and West, and in each of these areas, two health centers, one urban and one rural, were randomly selected. Pregnant women with a history of pre-gestational diabetes, use of drugs that affect glucose metabolism, such as steroids and chronic liver disease, endocrine disorders and connective tissue disorders were excluded from the study.

Diagnosis of GDM is based on the latest nationwide guidelines on GDM screening and diagnosis. Women with GDM were identified by a GCT test by taking 50 g of glucose and the blood glucose was measured one hour later. The test result, as low as 130 mg/dL were considered negative and disease free, but equal to or greater than 130 mg/dLwere deemed to be positive in this program, and OGTT testing with 100 g of glucose was performed for those subjects. Finally, the diagnosis was based on Carpenter's criteria [17], so that if at least two of the glucose tests were positive, the GDM was confirmed.

Outcomes of pregnancy

Adverse pregnancy outcomes: Maternal and neonatal outcomes included preterm delivery, type of delivery (vaginal or C-section), and neonatal preterm birth. Fetal/neonatal outcomes included macrosomia, abortion, stillbirth, neonatal death, and low birth weight. Preterm delivery and preterm birth were defined as delivery, or birth before 37 weeks of gestation. Stillbirth was defined as infant death at 22 weeks of gestation or after, and abortion was defined as neonatal birth before 22 weeks of gestation. Weight less than 2500 grams at birth, was defined as low birth weight (LBW). Birth weight of 4000 g or more was considered as macrosomia of the newborn [4].

Data collection

Required data were collected based on the family records of pregnant women in health centers, and by in-person interviews to complete the questionnaires, using trained individuals in health centers in the designated provinces. The questionnaire included demographic characteristics such as maternal age, place of residence, education, ethnic, domestic violence during pregnancy and the information on the outcomes of GDM, including type of delivery, preterm birth, macrosomia, abortion, stillbirth, neonatal death, and infant birth weight.

Weight gain during pregnancy was defined according to the recommended weight gain by the World Health Organization (WHO) guidelines and it was adjusted by BMI categories [18]. We used five questions regarding domestic violence during pregnancy to determine the experience of it during pregnancy. It was defined as a binary variable for analysis.

Statistical analysis

Statistical analysis of data was performed at 95% CI, using STATA 14.2 software (StataCorp, College Station, TX, USA). Descriptive statistics were reported in

frequency and percentage. Chi-square test was used to compare the frequency of pregnancy outcomes between diabetic and non-diabetic pregnant mothers. Univariate and multiple logistic regression analysis was used to evaluate the relationship between variables and GDM.

Results

In this study, 3,675 pregnant mothers from 11 provinces of Iran with mean age of 27.2 ± 6.0 years were participated. Overall, four percent of Iranian pregnant women had GDM during pregnancy. Most pregnancies were in the age group of 26-35 years (46.78%) and the highest prevalence of GDM was in the age group of 26-35 years (50.71%). The proportion of GDM was higher in urban mothers compared to the rural mothers. The prevalence of C-section was significantly higher in diabetic patients than in the non-diabetic women (53.19 *vs* 46.81, P < 0.001). Abortion in diabetic mothers was more than twice that of the non-diabetic mothers (P < 0.001) (Tab. I).

Table II presents the association between gestational diabetes and adverse pregnancy outcomes. The independent variable is GDM that was included into the logistic regression model with adverse pregnancy outcomes. The variables of age, education, place of residence, ethnicity and physical violence were considered as confounding factors in the logistic regression analysis. GDM increases the adverse outcomes of pregnancy, with a 63% higher risk of neonatal death in diabetic mothers than the non-diabetic mothers (95% CI: 1.01, 2.63, P = 0.044). Abortion in pregnant women with GDM was 2.86 times more than the non-diabetic mothers (95% CI: 1.96, 4.17, P < 0.001).

Tab. I. Descriptive characteristics of participants by gestational diabetes.

Variables	Categories	Total	Gestational diabetes	
			Yes	No
			No. (%)	No. (%)
Mother's age	< 20	469 (13.19)	9 (6.43)	460 (13.46)
	21-25	1,090 (30.64)	19 (13.57)	1,071 (31.34)
	26-35	1,664 (46.78)	71 (50.71)	1,593 (46.62)
	36-40	253 (7.11)	30 (21.43)	223 (6.53)
	> 41	81 (2.28)	11 (7.86)	70 (2.05)
	P-value*		< 0.001	
Living location	Urban	1,528 (45.34)	71 (51.82)	1,599 (45.59)
	Rural	1,842 (54.66)	66 (48.18)	1,908 (54.41)
	P-value		0.135	
Education	Illiterate	192 (5.560	12 (8.51)	204 (5.67)
	Under diploma	1,676 (48.51)	69 (48.94)	1,745 (48.53)
	Diploma	1,251 (36.21)	38 (26.95)	1,289 (35.85)
	Academic	336 (9/73)	22 (15.60)	358 (9.96)
	P-value		0.018	
Type of delivery	Vaginal	2,340 (68.18)	75 (53.19)	2,415 (67.59)
	Cesarean	1,092 (31.82)	66 (46.81)	1,158 (32.41)
	P value		< 0.001	
Birth weight	< 2,500	1,336 (63.30)	33 (47.83)	1,303 (66.96)
	2,500-4,000	637 (31.61)	30 (43.48)	607 (31.19)
	> 4,000	42 (2.08)	6 (8.70)	36 (1.85)
	P-value		< 0.001	
Weight gain during pregnancy	0-11.5 kg	332 (10.61)	9 (7.89)	323 (10.72)
	12-14 kg	1,447 (46.26)	64 (56.14)	1,383 (45.89)
	> 14 kg	1,349 (43.13)	41 (35.96)	1,308 (43.40)
	P-value		0.094	
Gestational age	> 37 week	1,174 (60.64)	27 (42.19)	1,147 (61.27)
	< 37 week	762 (39.36)	37 (57.81)	725 (38.73)
	P-value		0.002	
Abortion	Yes	475 (13.18)	41 (29.08)	434 (12.54)
	No	3,128 (86.82)	100 (70.92)	3,028 (87.46)
	P-value		< 0.001	
Birth outcome	Live birth	1,016 (28.20)	27 (10.15)	989 (28.57)
	Stillbirth	1,438 (39.91)	65 (46.10)	1,373 (39.66)
	Infant death	1,149 (31.89)	49 (34.75)	1,100 (31.77)
	P-value		0.049	

* P value < 0.05, using the Chi-squared test.

Tab. II. Crude and adjusted odds ratios (95% CI) of the association between gestational diabetes and adverse pregnancy outcomes.

Variables	Categories	Unavailable Odds Ratio (95% CI)	P-value	Adjusted Odds Ratio (95% CI)	P-value
Birth outcome	Live birth	Ref.	-	Ref.	-
	Stillbirth	1.73 (1.09, 2.73)	0.018	1.80 (1.11, 2.91)	0.018
	Infant's death	1.63 (1.01, 2.63)	0.044	1.72 (1.03, 2.85)	0.036
Type delivery	Vaginal	Ref.	-	Ref.	-
	Cesarean	1.88 (1.34, 2.64)	< 0.001	1.53 (1.07, 2.19)	0.02
Birth weight	Normal	Ref.	-	Ref.	-
	Macrosomia (> 4,000 gr)	6.58 (2.59, 16.69)	< 0.001	6.94 (2.81, 17.14)	< 0.001
Weight gain during pregnancy	12-14 kg	Ref.	-	Ref.	-
	> 14 kg	1.66 (0.81, 3.37)	0.160	1.20 (0.57, 2.53)	0.636
Preterm birth	No	Ref.	-	Ref.	-
	Yes (< 37 weeks)	2.16 (1.30, 3.59)	0.003	1.82 (1.07, 3.09)	0.028
Abortion History	No	Ref.	-	Ref.	
	Yes	2.86 (1.96, 4.17)	< 0.001	1.84 (1.21, 2.78)	0.004

* Adjusted for age, place of residency, ethnic, physical activity.

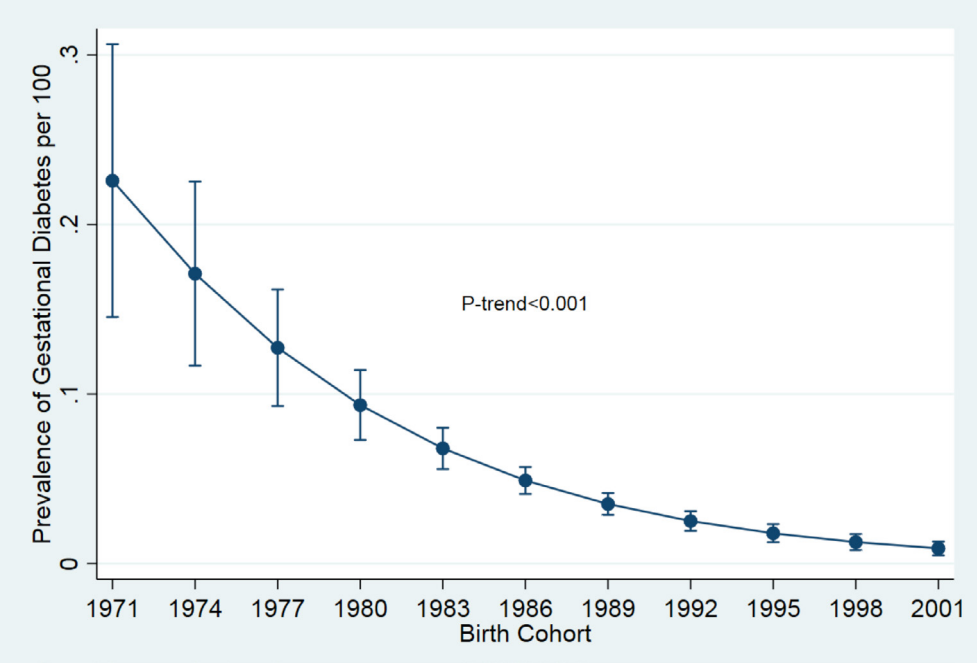
Adjusted logistic regression model showed that the chance of stillbirth in women with GDM was 80% higher than in the non-diabetic women (95% CI: 1.11, 2.91, P = 0.018). The chance of macrosomia in diabetic women was about 7 times higher, compared to the non-diabetic women (95% CI: 2.81, 17.14, P < 0.001). The chances of preterm birth were about two times higher in women with GDM than in women without GDM. GDM in women with history of C-section had a higher chance of 50% than women who did not have C-section (95% CI: 1.07, 2.19, P = 0.02).

The chance of overweight pregnancy (over 14 kg) were about 20% higher in women with GDM than in the non-diabetic women. A significant increasing trend was found in the odds of having GDM in terms of body mass index (P < 0.001). There was also a significant decrease in the odds of GDM, according to the daily physical activity (PA) (P < 0.001) (Fig. 1).

Discussion

The findings of the present study, conducted in 11 provinces of Iran, showed that GDM increased the adverse outcomes of pregnancy such as stillbirth, neonatal death, macrosomia, preterm birth, abortion, and cesarean delivery. A significant decreasing trend in the GDM was found by birth cohort in the pregnant Iranian women. In diabetic mothers, the odds of macrosomia, miscarriage, and preterm birth were 6.9, 1.84 and

Fig. 1. Prevalence trend of GDM during pregnancy in Iran from 1971 to 2001.



1.82 times of the non-diabetic mothers, respectively. These consequences can decrease the quality of life of the mother and infant in the short term or until the end of life. Some of these outcomes like macrosomia are not treatable, so early prevention is very important.

However, multifactorial congenital anomalies and their causes are largely unknown, but meanwhile, several non-hereditary factors including maternal age, pre- and intra-pregnancy diabetes, maternal obesity, and folic acid deficiency play an important role in their development [19, 20]. The findings of this study indicate that GDM is one of the important and changeable factors that increases the chance of congenital anomalies. The macrosomia was 7 times higher in mothers with GDM than the non-diabetic mothers. The results of a study conducted in Canada during the years 2002–2012 is consistent with the results of the present study, and shows an increasing trend of macrosomia in diabetic mothers.

The percentage of population attributable risk (PAR%) of congenital malformations associated with diabetes mellitus increased from 0.6 to 1.2% in pregnant women. PAR% was increased from 2.3 to 4.2 and 0.8 to 1.4, in congenital cardiovascular malformations and gastrointestinal deficiency, respectively [21]. Numerous studies have reported a considerable high incidence of congenital malformations in diabetic mothers than the non-diabetic mothers [12, 19]. The study of Nelson *et al*. has also shown that GDM increases the risk of congenital malformations by 1.2 times, especially obstructive urinary tract disorders, renal agenesis, cardiovascular disorders, and multiple congenital abnormalities [12]. The cost of treatment of these outcomes is very high and on the other hand, complete improvement is often not feasible and may affect on quality of life. Accordingly, there is a necessity for better implementation of primary care and screening before pregnancy.

We found that the chance of stillbirth and neonatal death in women with GDM was about 80% higher than that of the non-diabetics. Previous studies have also reported that GDM is associated with stillbirth and neonatal death. In a study, the infant mortality rate (death rate per 1,000 or relative risk) in diabetic mothers was 15.5 *vs* 2.8, stillbirths in diabetic mothers, 9.7 *vs* 4, compared to the non-diabetic women, and both outcomes were significantly greater in the diabetic mothers. Perinatal deaths in diabetic mothers were more than 3 times higher than in the non-diabetic mothers [11]. Given the adverse physical and psychological effects of this outcome for mothers, it is recommended that pre-pregnancy health care be provided at counseling clinics to reduce these unpleasant outcomes. Control and regulation of blood sugar before pregnancy can reduce the neonatal deaths from GDM.

Having a body mass index (BMI) less than or above the normal range is considered as a high-risk pregnancy [22]. Maternal obesity during pregnancy increases premature birth and the risk of C-section delivery which is associated with GDM, preeclampsia, intrauterine growth restriction (IUGR) and thromboembolic events [23]. Numerous studies have reported a relationship between high BMI during pregnancy and increased risk of GDM and insulin resistance [24, 25]. In the present study, the chance of weight gain (over 14 kg) in mothers with GDM was about 20% higher, compared to the non-diabetic mothers.

A significant increasing trend in the odds of GDM was found in terms of BMI in the results. Since there is a non-linear dose-response relationship between concomitant increases in gestational BMI and GDM [25, 26], the incidence of GDM also increases with increasing BMI levels, such as in those with low birth weight is 5.5% and in obese individuals is 14.6% [25]. Therefore, high BMI at the beginning of pregnancy is a serious alarm for GDM that should be considered in prenatal care. In fact, GDM increases the risk of type 2 diabetes, but the results of various previous studies have shown that the risk of type 2 diabetes decreases with weight loss, and increased by PA during pregnancy and postpartum as well [27]. Based on the similar results of various studies and the importance of weight gain during pregnancy, it can be said that BMI can predict the occurrence of GDM in subsequent pregnancy [25].

In the present study, the chance of GDM in women with a history of C- section was about 50% higher, compared to women without a history of C- section. The association between GDM and increased risk of cesarean delivery has been reported in numerous studies [10, 13]. C-section in mothers with diabetes is approximately twice than that of the non-diabetic mothers [13]. Gorgal et al. in a study to determine whether GDM is associated with non-elective cesarean sectionshowed that the rate of non-selective C-section in diabetic mothers was 19.5% and in non-diabetic mothers 13.5% with a relative risk of 1.4 [10]. In another study, cesarean delivery was also significantly higher in diabetic mothers than in the non-diabetic mothers (50.8 *vs* 31.8%) [13]. Therefore, GDM is a risk factor for C-section and its associated complications, and timely diagnosis and control can reduce cesarean delivery and its complications.

The present study also revealed that the chance of preterm birth in mothers with GDM is about twice as high as those of the non-diabetic mothers. Other similar studies have also reported an increased chance of preterm delivery and preterm birth in diabetic mothers [28]. Another study has shown that preterm labor in diabetic mothers is not different from the non-diabetic mothers, but controlling blood glucose and bringing glucose levels to a normal level, reduce preterm birth rates in diabetic mothers [29].

Our study showed that the risk of GDM in mothers with a history of abortion was about 80% higher than women who had no history of abortion. The results of national and international studies are in line with our findings [30]. In the study of Jiang et al. the history of abortion in mothers with GDM was significantly higher than in the non-diabetic mothers (39.8 *vs* 30.5%) [31]. A study by Feleke et alalso showed the association of GDM with a history of abortion, and reported that abortion increases the risk of GDM in the future pregnancies. In his study, the chances of GDM in women with a history

of abortion were 5 times higher [32], which may be due to the effect of abortion on impaired normal insulin metabolism in women [33].
Previous epidemiological studies have reported an inverse relationship between the amount of PA during pregnancy and GDM, and women with high levels of PA were significantly less likely to develop GDM [5]. The results of the present study also show a significant decrease in the chance of GDM in terms of daily PA. Increasing PA levels can reduce the risk of GDM in various approaches. First, PA can compensate for the defect in the insulin signaling pathway [34]. Second, PA may alter adipokine profile levels, including adiponectin, leptin, resistin, and Visfatin, which may lead to a decreased insulin resistance [35]. Third, PA by controlling the secretion and activity of inflammatory markers such as TNF-α and IL-6 can decrease the level of inflammation and insulin resistance inhibiting factor [36]. Fourth, PA can decrease insulin resistance in GDM by increasing levels of antioxidants such as superoxide dismutase, catalase and glutathione peroxidase, oxidative stress and the pathogenesis of insulin resistance in GDM [37]. Therefore, the importance of adequate PA during pregnancy is clearly understood.
Geographical extent and large sample size are the strengths of the present study. One of the limitations of the study is its cross-sectional design that does not indicate any causal relationships. Future cohort studies and clinical trials can provide more definitive conclusions by better controlling the confounding factors.

Conclusions

The results revealed that GDM could be considered as a predictive factor which increases the adverse pregnancy outcomes such as stillbirth, neonatal deaths, macrosomia, preterm birth, abortion and C-section delivery which are related with both maternal and fetus. Given that these adverse consequences are preventable and treatable, hence, early diagnosis of pregnant women at high-risk for GDM is suggested to implementation the educational program and to better prevent of the adverse pregnancy outcomes.

Ethical approval

This study was approved by the Ethics Committee of Kermanshah University of Medical Sciences (IR.KUMS.REC.1400.385).

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Conflict of interest statement

The authors declare no conflict of interest.

Authors' contributions

Conception and design was done by MH, SRe, and TV; collection and assembly of data was done by HY, MS, MH, NT, and TV; data analysis and interpretation was done by SRe, MDa, KE and MDi; manuscript writing was done by SRe, MDa, and MDi; final approval of manuscript was done by all authors.

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HEALTH PROMOTION

Validation of Gender Friendly Breastfeeding Knowledge scale among young adults

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Keywords

Breastfeeding • Knowledge • Scale • Behaviour • Practice • Youth

Summary

Introduction. *Breastfeeding is the most effective intervention to improve child health. Young adults, both genders play an important role in society supporting breastfeeding as they will be stepping towards parenthood in the near future. Bringing awareness and busting the myths among them is essential. This study aimed to develop a Gender Friendly Breastfeeding Knowledge scale based on a conceptual framework that reflected the knowledge of young adults and evaluates its validity and reliability.*

Methodology. *Development of the questionnaire for Conceptual framework and item generation was done using PubMed, Google Scholar, other sources and expert opinion. The type of measurement was structured as a 5-point Likert scale. The Lawshe technique to assess the content validity ratio. A cross-sectional survey in graduation colleges situated in Mangalagiri or within the radius of 30 km of Mangalagiri, Andhra Pradesh, India was conducted in 2020. 1400 Adult males and females aged 20-25 years and perusing full-time graduation course were recruited. For each item in the Gender Friendly Breastfeeding Awareness scale, we assessed individual item characteristics and item-test correlation. To check to construct validity, we performed exploratory factor analysis and confirmatory factor analysis.*

Results. *Expert panel retained 23 items from initially 30 items. The content validity index score for the each of 23-items in the scale was more than 0.80. A four-factor structure perfectly fitted the data and illustrated 54% of the variation in knowledge of breastfeeding. 4 stages of CFA were completed. The chi-square = 860.534 was significantly above the 0.01 level. Cronbach's alpha = 0.787 based on standardized items reflected the overall internal consistency of the Gender Friendly Breastfeeding Awareness scale.*

Conclusion. *Gender Friendly Breastfeeding Knowledge scale is a valid and reliable tool, it is recommended that this scale be used in communities, educational institutions, and in relevant research to assess Breastfeeding knowledge among young adults of both genders, thereby promoting breastfeeding practices in the future.*

Introduction

Breastfeeding is the most effective intervention to improve child health. In 2018, stunting affected an estimated 21.9% (14.9 crores) of children under five and wasting continued to threaten the lives of an estimated 7.3% (4.9 crores) of children under-five globally [1]. Under-nutrition is associated with at least 45% of child deaths [2]. In 2011 it is estimated that suboptimal breastfeeding, especially non-exclusive breastfeeding contributes to 11.6% of mortality in children under five years of age [3].

Breastfeeding not only helps in bonding and development of the infant but also delays a new pregnancy thus protecting the mothers' health against ovarian and breast cancers [4]. Breastfeeding is an unbeaten way of providing ideal food for the healthy growth and development of infants. It is a global public health recommendation as per Innocent Declaration that infants should be exclusively breastfed for the first six months of life to achieve optimal growth, development, and health. Exclusive breastfeeding is defined as "giving a baby only breast milk, and no other liquids or solids, not even water. Drops or syrups consisting of vitamins, mineral supplements or medicines as permitted" [4]. The World Health Organization also recommends exclusive breastfeeding in the first six months of life and supplemented breastfeeding up to two years or more [4]. It is found that only 40% of children younger than six months are exclusively breastfed worldwide among 194 countries as evaluated using the global breastfeeding scorecard in 2017 [5]. Most breastfeeding difficulties are a relatively normal experience; however, due to the wide range of severity, they can be very stressful and have been a risk factor for breastfeeding discontinuation in different studies [6-8].

To improve this situation, mothers and families require support to initiate and continue appropriate breastfeeding practices in the first six months of life. Mother's Absolute Affection is a nationwide program of the Ministry of Health and Family Welfare, Government of India to build an enabling environment for breastfeeding through

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awareness generation activities, targeting pregnant and lactating mothers, family members, and society to promote optimal breastfeeding practices [9]. As a major population of young adults, both genders play an important role in society supporting breastfeeding as they will be stepping towards parenthood in the near future. Bringing awareness and busting the myths among this population would bring a lot of change in improving breastfeeding.

On an extensive review of literature, to the best of authors' knowledge, there are tools to assess knowledge of health personnel and maternal perception for breastfeeding [10-15]. However, there is no validated tool for non-healthcare young adults, addressing both genders, which has to be studied. Hence this study was conceived by the authors to perform the construct validation and evaluate the internal consistency of a gender friendly questionnaire to develop an understanding of breastfeeding among young adults and aiming at its application in the Indian population of young adulthood.

Breastfeeding is a complex phenomenon that can undergo biological, psychological, cultural, social, economic, and political influences. Several global tools have been developed and tested to assess some aspects of the breastfeeding process. These instruments involve elements such as maternal confidence, newborn's behavior, mother's behavior, positioning, holding, effective milk extraction, breast aspects, maternal satisfaction, mother's perception, maternal experience, among others [16]. A series of measurable scales of the most diverse aspects are available; however, they are old and not updated. Young adulthood is not included in many breastfeeding evaluation studies. A validated gender friendly questionnaire for breastfeeding among young adults, who are future parents, is not available in the literature. People are attending colleges to attain higher education. The literacy rate among youth (ages 15-24) has improved in India. In 2018, the youth literacy rate was 92% which was 86.1% in 2015 [17]. However, there is no proper education regarding breastfeeding. So, young adults are the ideal population to create awareness and bust their myths about breastfeeding. This study aimed to develop a Gender Friendly Breastfeeding Knowledge scale based on a conceptual framework that reflected the knowledge of young adults and evaluates its validity and reliability.

Community is the perfect setting and is often preferred to validate any questionnaire however due to reticent behaviour of young adults in the community, logistic reasons, availability of good sample, and availability of peers to share their thoughts, the college setting is selected for the present study.

Methods

Design

This validation study developed and evaluated the Gender Friendly Breastfeeding Knowledge scale.

Development of the questionnaire

Conceptual framework and item generation

Using PubMed, Google Scholar, and other sources, we carried out a literature review relating to knowledge of breastfeeding. We coded the results into themes reflecting particular areas of breastfeeding awareness among young adults. Through a review of the literature, we found that knowledge on breastfeeding includes general knowledge, colostrum, benefits to mothers and babies, effective feeding method, duration of feeding, expressed breast milk, storage of EBM, complementary feeding, and problems with breastfeeding. Knowledge related to breastfeeding positioning and attachment was not included in this scale to ensure a shy free environment for young adults. The benefit of breastfeeding to the baby such as provides immunity to the child, good for digestion of the child, hygienic for a child, and Improve the IQ of the child. The benefit to mothers such as weight loss/decreased risk of osteoporosis for mothers prevents breast and ovarian cancer for the mother helps in the involution of uterus/lactation amenorrhea of mother and promotes bonding for mother and baby. Benefits to family, such as lower medical expenses for everyone in the family, ensure few sick days of mother and baby, and increases work productivity. Exclusive breastfeeding is the child is fed by only breast milk, without any other food in the first six months irrespective of prelacteal feed. Role of family and particularly fathers in breastfeeding practices [10, 18-21]. The conceptual framework of the current study, based on the aforementioned literature review included multidimensional facets for promoting breastfeeding among young adults, consisting of first general awareness of breastfeeding, storage of BM, Frequency like colostrum, duration of exclusive feeding, expressed breast milk, Exclusive breastfeeding complementary feeding, second benefits to babies, third benefits to mothers, and last role of father, family, and society.

We generated 30 items based on the conceptual framework. The type of measurement was structured as a 5-point Likert scale to measure the degree of breastfeeding knowledge of young adults (1 = false, 2 = may be false, 3 = don't know, 4 = may be true, 5 = true). The statement was framed both positively and negatively to add variety and limit respondent reporting bias. May option was included to identify the grey areas of knowledge. The positive items were scored 1, 2, 3, 4, 5. Then the negative items were rescored as 5, 4, 3, 2, 1.

Content validity testing

The content validity of the scale was based on the experts' assessment that items and questions in an instrument were critical, important, and applicable to the young adults. The purpose of this was, therefore, to ensure that the scale of Gender Friendly Breastfeeding Awareness is relevant, clear, concise, consistent, and culturally appropriate. Qualitative and quantitative approaches had also been applied. In the qualitative phase, a panel consisted of 14 specialists of paediatrics,

gynaecologists, community medicine, master of public health, personnel from National Health Program like ICDS, medical officer, nursing officer, ANM/ASHA, Female nursing orderly, and undergraduate teacher who were in promoting breastfeeding and analyzed the questionnaire's pronunciation, evaluated grammar, wording, and scaling of the questionnaire. We choose the Lawshe technique to assess the content validity ratio (CVR). The substantiveness of each object was analyzed by experts. Using a three-point rating scale, they measured the necessity of the items: a) not necessary; b) useful, but not essential; and c) essential. The CVR was determined using the formula for each item (N = the total number of experts and n = the number of experts who have selected the c) option for each item) [22]. Through these processes, a preliminary questionnaire of 23 items consisting of 8 general, 4 benefits of breastfeeding to the child, 4 benefits of breastfeeding to mother, and 7 breastfeeding frequency and was composed. We performed 50 pre-test interviews on the 23 items on the scale. The participants were MBBS College undergraduate students. We performed individual 10-minute interviews in which respondents determined if each sentence was false, may be false, don't know, may be true, true, recognizing ambiguous terms or phrases, and explaining where was it difficult to answer the question. Interviews were conducted through google forms and phone. The scale was further revised for grammar, language as required after pilot testing.

Validity and reliability assessments

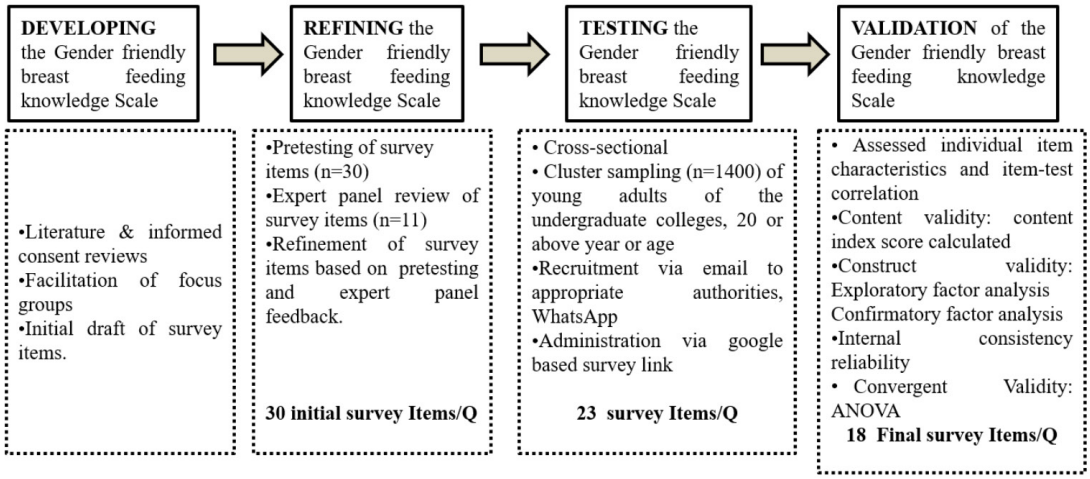
A third revision produced the final version of Gender Friendly Breastfeeding Knowledge scale. We conducted a cross-sectional in graduation colleges situated in Mangalagiri or within the radius of 30 km of Mangalagiri, Andhra Pradesh, India in 2020. Adult males and females aged 20-25 years and perusing full-time graduation course were recruited. The sample size was calculated based on the prevalence of knowledge of breastfeeding among students in a college is 55% [23]. Level of the confidence interval was kept at 95%, i.e. Z = 1.96. Cluster random sampling was used. To overcome the impact of study design on sampling variability, the design effect is used to estimate the sample size. The design effect of three was taken for calculating the sample size for this study. With absolute precision of 5%, the sample size was estimated to be 1,188. Assuming a non-response rate of 15% the final sample size was 1,366 students. Therefore, a sample of 1,400 students was studied. Kaiser-Meyer-Olkin Measure of Sampling Adequacy 0.6 to 0.9 was considered appropriate. All graduation colleges in the target area, having official websites were enumerated using google. Each graduation college was equivalent to one cluster. 14 clusters were randomly selected. One undergraduate college was considered equivalent to one cluster. The colleges differ in size, academics, demographics, and cultural diversity, which offered a diverse study population. From each cluster minimum of the first 100 students were enrolled for the study. Principals of the colleges were approached to discuss the need and purpose of research. A participant information sheet copy was shared with the principals. The anonymity of the school and student was ensured. After receiving permission from the concerned authority. The questionnaire link was sent electronically via google and WhatsApp to the college authority or representatives. Students were asked to fill the Google form from their email id. The first question of the Google form was the consent form with the answer "I accept to participate" to access subsequent questions. Clicking "I accept to participate" was considered equal to informed consent. Gender Friendly Breastfeeding Knowledge scale with demographic details was administered to the students.

The data collected were analyzed with the assistance of SPSS 20 and AMOS (IBM Inc., Armonk, NY). The characteristics of the participants were analyzed using descriptive statistics. For each item in the Gender Friendly Breastfeeding Awareness scale, we assessed individual item characteristics and item-test correlation. We reviewed missing items and summarised the mean, SD, and item-test correlation. The removal of items in this step was based on a low correlation of item-tests ($r < 0.40$). Second, to check to construct validity, we performed exploratory factor analysis. We constructed exploratory models with strong item-test correlation values, including all remaining variables. To simplify the analysis of loadings, models were rotated using varimax rotation. We evaluated the exploratory factor loadings for each item and classified factors from those with a correlation $r > 0.40$ per the respective loadings. We assessed whether items cross-loaded on multiple variables and whether it made logical sense to group individual items loaded onto variables. The Keizer-Meyer-Olkin (KMO) sampling adequacy measure and the Bartlett sphere test were performed to verify that the data were acceptable for EFA. The reliability was measured by the alpha coefficient of Cronbach. Cronbach Alpha values > 0.6, object-total correlation coefficients > 0.20, and interitem correlation coefficients < 0.80 and higher than zero are considered appropriate. If its item-total correlation coefficient is less than 0.2, the item was considered for deletion, given that its deletion resulted in an increase of more than 0.1 in the alpha coefficient of Cronbach. Using principal component analysis with varimax rotation, exploratory factor analysis (EFA) was performed (Fig. 1). This study was approved by the Institutional Ethics Committee.

Results

The demographic characteristics of the 1400 young adults who completed the 23-item Gender Friendly Breastfeeding Knowledge scale are presented in Table I. Their mean age was 21.1 ± 1.35 years, and 21.7% were males.

Fig. 1. Gender Friendly Breastfeeding Knowledge scale development and analysis process.



Tab. I. Demographics of participants from depicting age groups and major breakdown (n = 1,400).

Variable	Category	Gender n (%)		Total n (%)	Chi	P-value
		Female	Male			
Age (years)	20	493 (83.4)	98 (16.6)	591 (100.0)	73.1	< 0.001
	21	374 (77.3)	110 (22.7)	484 (100.0)		
	22	104 (81.3)	24 (18.8)	128 (100.0)		
	23	73 (83.0)	15 (17.0)	88 (100.0)		
	24	18 (56.3)	14 (43.8)	32 (100.0)		
	25	34 (44.2)	43 (55.8)	77 (100.0)		
Residence	Rural	418 (77.1)	124 (22.9)	542 (100.0)	3.6	< 0.001
	Urban	673 (79.3)	176 (20.7)	849 (100.0)		
	Tribal	5 (55.6)	4 (44.4)	9 (100.0)		
Marital status	Unmarried	1,047 (79.7)	267 (20.3)	1,314 (100.0)	24.47	< 0.001
	Married	49 (57.0)	37 (43.0)	86 (100.0)		
Mother literacy status	Less than 5 standard	155 (70.8)	64 (29.2)	219 (100.0)	24.68	< 0.001
	5 standard to 9 standard	212 (71.4)	85 (28.6)	297 (100.0)		
	10 standard or more	729 (82.5)	155 (17.5)	884 (100.0)		
Father literacy status	Less than 5 standard	147 (73.1)	54 (26.9)	201 (100.0)	8.43	< 0.001
	5 standard to 9 standard	139 (73.2)	51 (26.8)	190 (100.0)		
	10 standard or more	810 (80.3)	199 (19.7)	1,009 (100.0)		
Mother occupation	Agriculture	54 (57.4)	40 (42.6)	94 (100.0)	30.66	< 0.001
	Labour	34 (91.9)	3 (8.1)	37 (100.0)		
	House wife	810 (78.7)	219 (21.3)	1,029 (100.0)		
	Other	198 (82.5)	42 (17.5)	240 (100.0)		
Father occupation	Agriculture	262 (70.2)	111 (29.8)	373 (100.0)	43.33	< 0.001
	Labour	126 (85.7)	21 (14.3)	147 (100.0)		
	Not working	1 (12.5)	7 (87.5)	8 (100.0)		
	Other	707 (81.1)	165 (18.9)	872 (100.0)		
Socioeconomic status as per BJ Prasad 2020 (Missing 287)	INR 7533 and above (upper)	348 (77.2)	103 (22.8)	451 (100.0)	4.99	< 0.001
	INR 3766-7532 (upper middle)	176 (74.3)	61 (25.7)	237 (100.0)		
	INR 2260-3765 (middle)	233 (82.0)	51 (18.0)	284 (100.0)		
	INR 1130-2259 (lower middle)	112 (79.4)	29 (20.6)	141 (100.0)		
Study field	MBBS, nursing	329 (82.3)	71 (17.8)	400 (100.0)	14.7	< 0.001
	Pharmacy, Pharmaceutical, Physiotherapy	480 (80.0)	120 (20.0)	600 (100.0)		
	Other like Engineering MBA, B.com, B.Sc.	287 (71.8)	113 (28.3)	400 (100.0)		
Total	1,096 (78.3)	304 (21.7)	1,400 (100.0)			

Tab. II. Summary statistics for 23 Items Included in the Gender Friendly Breastfeeding knowledge scale: item means, SDs.

Item No./ Question No.	Questions in Gender Friendly Breastfeeding Knowledge scale	Mean	Std. deviation
1	Mother milk is best for the baby	4.95	0.354
2	Mother milk is not easily digested by the child	3.52	1.583
3	Breastfeeding causes breast and ovarian cancer to mother	3.86	1.501
4	Child should be breastfed as early as possible soon after birth	4.74	0.727
5	Colostrum (breast milk secreted immediately after delivery) should not be discarded	4.40	1.132
6	Breastfeeding improves immunity of the child	4.90	0.460
7	Breastfeeding has no role in lactational amenorrhea/ family planning/ avoiding immediate pregnancy for 6 months after delivery	2.96	1.693
8	Child needs water along with Mother milk up to first 6 months of life	2.91	1.690
9	Mother milk improves the intelligence (IQ) of child	4.34	1.075
10	Breastfeeding promotes bonding between mother and baby	4.75	0.687
11	Breastfeeding reduces sickness in mother and baby	4.49	1.071
12	Father should not support the mother in breastfeeding	3.64	1.555
13	Breastfeeding decreases work productivity/ earnings/ working days of family	3.41	1.560
14	Breast milk cannot be stored in refrigerator	2.24	1.518
15	Exclusive breastfeeding is giving only breast milk for first 6 months of life/ child/ baby/ age	4.22	1.323
16	Child can be breastfed up to 2 years	4.26	1.188
17	Mother cannot continue breastfeeding after starting the supportive/complementary feeding from 6 months of life	3.28	1.563
18	Breastfeeding increases health related expenses of the family	3.21	1.713
19	Breastfeeding should be given only when child cries	3.47	1.595
20	Breast milk banks similar to blood banks are available in hospitals	3.01	1.554
21	Breastfeeding increases the satisfaction of the mother and family	4.52	0.950
22	As a future parent you are decision maker in facilitating breastfeeding	4.72	0.737
23	You are a motivator in facilitating breastfeeding	4.50	1.021

Table II shows the mean and SD for each item. Most items demonstrated variability in response. Items with the highest mean of 4.95 were #1 (Mother milk is best for the baby) and #10 (breastfeeding promotes bonding between mother and baby).

Face/content validity

The cumulative face/content validity of the scale was verified by expert panel assessments and pre-testing interviews. At this point, all 23 items were retained from initially 30 items, and no new items were produced. Pretesting interview participants indicated the importance of adding a "may be true" or "may be false" response option to the true/ false/ don't know format. We refined the Gender Friendly Breastfeeding Knowledge scale to reflect this feedback. The content validity index score for the each of 23-items in the scale was more than 0.80.

Construct validity

Exploratory factor analysis has been undertaken. The KMO value was 0.868, and the result of Bartlett's test of sphericity was $\chi 2 = 7{,}235.58$ ($p < 0.001$); therefore, the sample was suitable for conducting EFA. Using eigenvalues > 1 and evaluation of the scree plots, factor structures were explored. The factor extraction parameters have been set at 0.30 for communality and 0.40 for factor loading. Furthermore, products with a cross-load of 0.30 or greater and a gap of less than 0.20 have been excluded. The EFA process was repeated six times and deleted five items/questions. Item 8 (child needs water along with mother milk up to first 6 months of life), 14 (breast milk cannot be stored in the refrigerator), 20 (breast milk banks similar to blood banks are available in hospitals), 21 (21 breastfeeding increases the satisfaction of the mother and family), 23 (you are a motivator in facilitating breastfeeding) were removed due to numerous cross-loadings, low factor loadings, or poor logical fit. A four-factor structure perfectly fitted the data and illustrated 54 percent of the variation in knowledge of breastfeeding. To represent the logical context concerning breastfeeding, each factor was named as Mother and family role and benefits, breastfeeding frequency and duration, benefits to the child, and others (Tab. III). Factor 4 had only one item # 5 (Colostrum breast milk secreted immediately after delivery should not be discarded). Considering this an important question it was consider in factor second to model under CFA. This consideration led to a total variance of 53.4%.

The CFA was carried out to explore the dimensionality of Gender Friendly Breastfeeding Knowledge scale derived from the EFA. 4 stages of CFA were completed. The chi-square = 860.534 was significantly above the 0.01 level (Fig. 2). Root mean square residual (RMR) = 0.101; root mean square error of approximation (RMSEA) = 0.06; Tucker Lewis index (TLI) = 0.88; comparative fit index (CFI) = 0.89; Goodness of Fit Index (GFI) = 0.93; and Adjusted Goodness of Fit Index (AGFI) = 0.91 appear good.

Tab. III. External validity using principal component analysis with varimax rotation Gender Friendly Breastfeeding Knowledge scale.

Item No./ Question No.	Questions in Gender Friendly Breast-feeding Knowledge Scale	Mother and family role and benefits	Frequency	Benefits to child	Other
Eigenvalue		4.58	2.85	1.23	1.07
% of variance		25.4	15.8	6.8	5.9
3	Breastfeeding cause breast and ovarian cancer to mother	0.830			
12	Father should not support the mother in Breastfeeding	0.789			
19	Breastfeeding should be given only when child cries	0.755			
2	Mother milk is not easily digested by the child	0.751			
13	Breastfeeding decreases work productivity/ earnings/ working days of family	0.740			
18	Breastfeeding increases health related expenses of the family	0.732			
17	Mother cannot continue Breastfeeding after starting the supportive/ complementary feeding from 6 months of life	0.718			
7	Breastfeeding has no role in lactational amenorrhea/ family planning/ avoiding immediate pregnancy for 6 months after delivery	0.621			
4	Child should be breastfed as early as possible soon after birth		0.690		
1	Mother milk is best for the baby		0.661		
22	As a future parent you are decision maker in facilitating Breastfeeding		0.659		
16	Child can be breastfed up to 2 years		0.557		
11	Breastfeeding reduces sickness in mother and baby			0.736	0.336
9	Mother milk improves the Intelligence (IQ) of child			0.676	
10	Breastfeeding promotes bonding between mother and baby		0.312	0.665	
6	Breastfeeding improves immunity of the child			0.586	
5	Colostrum (breast milk secreted immediately after delivery) should not be discarded		0.347		0.667
15	Exclusive Breastfeeding is giving only breast milk for first 6 months of life/ child/ baby/ age		0.334		-0.560

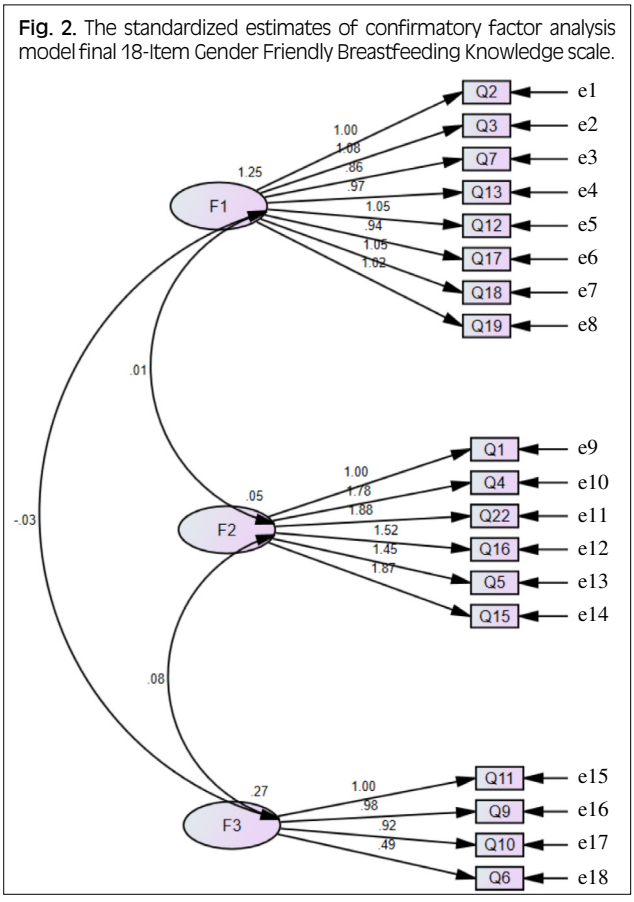


Fig. 2. The standardized estimates of confirmatory factor analysis model final 18-Item Gender Friendly Breastfeeding Knowledge scale.

Convergent validity

Demographic differences in Gender Friendly Breastfeeding Knowledge scale are detailed in Table IV. There were statistically significant differences in mean scores by age, residence, mother's education, father's education. Mother's occupation, father's occupation, socioeconomic class, and study field. Young adults from urban areas, with mother and father, educated more than 10th standard, and upper socioeconomic class had higher mean Gender Friendly Breastfeeding Knowledge scale scores ($p < 0.01$). No sex differences were observed.

Reliability

Cronbach's alpha was used to test the internal consistency and scale reliability of the questionnaire. Also, Cronbach's alpha was used to investigate the probability of shortening the questionnaire without sacrificing its properties and reducing its materials. The correlation values for each item were compared to all the other items. Cronbach's alpha = 0.787 based on standardized items reflected the overall internal consistency of the Gender Friendly Breastfeeding Awareness scale. To check the reliability of the subscales, the ICC was also measured. ICC values varied between 0.693 and 0.736, indicating adequate reliability for the Gender Friendly Breastfeeding Knowledge scale (Tab. V).

Tab. IV. Analysis of Variance (ANOVA) of Final 18-Item Gender Friendly Breastfeeding Knowledge scale.

Variable	Category	Mean	SD	P value
Gender	Female	73.10	9.94	0.827
	Male	73.24	10.23	
Age (years)	20	72.62	10.03	0.003
	21	73.01	10.31	
	22	74.23	9.50	
	23	74.86	9.13	
	24	78.84	7.39	
	25	71.56	9.62	
Residence	Rural	71.98	9.69	0.003
	Urban	73.87	10.15	
	Tribal	72.67	8.79	
Marital status	Unmarried	73.11	9.97	0.773
	Married	73.43	10.48	
Mother literacy status	Less than 5 standard	69.43	9.79	< 0.001
	5 standard to 9 standard	72.33	10.19	
	10 standard or more	74.31	9.75	
Father literacy status	Less than 5 standard	69.80	9.72	< 0.001
	5 standard to 9 standard	69.85	9.63	
	10 standard or more	74.41	9.84	
Mother occupation	Agriculture	72.68	9.57	< 0.001
	Labour	65.46	10.00	
	House wife	73.14	10.09	
	Other	74.42	9.28	
Father occupation	Agriculture	71.60	9.57	< 0.001
	Labour	69.07	10.51	
	Not working	64.75	10.73	
	Other	74.54	9.78	
Socioeconomic status as per BJ Prasad 2020 (Missing 287)	INR 7533 and above (upper)	74.16	9.67	< 0.001
	INR 3766-7532 (upper middle)	73.03	10.61	
	INR 2260-3765 (middle)	71.84	9.65	
	INR 1130-2259 (lower middle)	69.67	9.45	
Study field	MBBS, Nursing	74.95	11.21	< 0.001
	Pharmacy, Pharmaceutical, Physiotherapy	72.91	8.95	
	Other like Engineering MBA, B.com, B.Sc.	71.64	9.96	
Total	73.13	10.00		

Tab. V. Internal validity and reliability of Gender Friendly Breast-Feeding Knowledge scale.

Item No./ Question No.	Gender Friendly Breastfeeding Knowledge scale	Inter Item Correlation Coefficient	ICC	95% CI	Cronbach's alpha based on standardized items	Cronbach's alpha if item deleted
			0.715**	0.693 to 0.736	0.787	
1	Mother milk is best for the baby	0.279**	-	-	-	0.714
2	Mother milk is not easily digested by the child	0.666**	-	-	-	0.687
3	Breastfeeding cause breast and ovarian cancer to mother	0.721**	-	-	-	0.685
4	Child should be breastfed as early as possible soon after birth	0.259**	-	-	-	0.713
5	Colostrum (breast milk secreted immediately after delivery) should not be discarded	0.194**	-	-	-	0.714
6	Breastfeeding improves immunity of the child	0.285**	-	-	-	0.714

Item No./ Question No.	Gender Friendly Breastfeeding Knowledge scale	Inter Item Correlation coefficient	ICC	95% CI	Cronbach's Alpha based on standardized items	Cronbach's Alpha if item deleted
			0.715**	0.693 to 0.736	0.787	
7	Breastfeeding has no role in lactational amenorrhea/ family planning/ avoiding immediate pregnancy for 6 months after delivery	0.565**	-	-	-	0.692
9	Mother milk improves the intelligence (IQ) of child	0.031	-	-	-	0.720
10	Breastfeeding promotes bonding between mother and baby	0.268**	-	-	-	0.713
11	Breastfeeding reduces sickness in mother and baby	0.196**	-	-	-	0.714
12	Father should not support the mother in breastfeeding	0.706**	-	-	-	0.685
13	Breastfeeding decreases work productivity/ earnings/working days of family	0.649**	-	-	-	0.689
15	Exclusive breastfeeding is giving only breast milk for first 6 months of life/ child/ baby/ age	0.076**	-	-	-	0.720
16	Child can be breastfed up to 2 years	0.095**	-	-	-	0.718
17	Mother cannot continue breastfeeding after starting the supportive/ complementary feeding from 6 months of life	0.676**	-	-	-	0.687
18	Breastfeeding increases health related expenses of the family	0.682**	-	-	-	0.684
19	Breastfeeding should be given only when child cries	0.674**	-	-	-	0.686
22	As a future parent you are decision maker in facilitating breastfeeding	0.296**	-	-	-	0.712

ICC: Intraclass Correlation Coefficient; CI: Confidence interval; ** $p < 0.001$ (2-tailed); Item 2, 3, 7, 12, 13, 17 were reverse coded.

Final questionnaire

The final Gender Friendly Breastfeeding Knowledge scale included three factors: Factor I (Mother and family role and benefits), Factor II (breastfeeding frequency and duration), and Factor III (Benefits to the child) areas. The total number of items was 18, with eight items for factor I, six items for factor II and 4 items for factor III (Tab. VI).

Tab. VI. Final 18 item Gender Friendly Breastfeeding Knowledge scale.

Item No.	Gender Friendly Breast-Feeding Knowledge scale	Tick any one				
		True	May be true	Don't know	May be false	False
1	Mother milk is best for the baby					
2	Mother milk is not easily digested by the child					
3	Breastfeeding cause breast and ovarian cancer to mother					
4	Child should be breastfed as early as possible soon after birth					
5	Colostrum (breast milk secreted immediately after delivery) should not be discarded					
6	Breastfeeding improves immunity of the child					
7	Breastfeeding has no role in lactational amenorrhea/ family planning/ avoiding immediate pregnancy for 6 months after delivery					

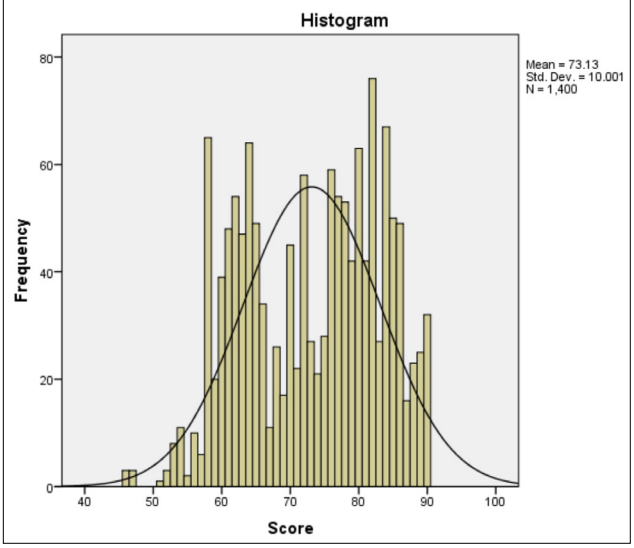
▶

Item No.	Gender Friendly Breast-Feeding Knowledge scale	Tick any one				
		True	May be true	Don't know	May be false	False
8	Mother milk improves the intelligence (IQ) of child					
9	Breastfeeding promotes bonding between mother and baby					
10	Breastfeeding reduces sickness in mother and baby					
11	Father should not support the mother in breastfeeding					
12	Breastfeeding decreases work productivity/ earnings/ working days of family					
13	Exclusive breastfeeding is giving only breast milk for first 6 months of life/ child/ baby/ age					
14	Child can be breastfed up to 2 years					
15	Mother cannot continue breastfeeding after starting the supportive/ complementary feeding from 6 months of life					
16	Breastfeeding increases health related expenses of the family					
17	Breastfeeding should be given only when child cries					
18	As a future parent you are decision maker in facilitating breastfeeding					

* Score for positively worded items: 1, 4, 5, 6, 8, 9, 10, 13, 14, 18 (1 = false, 2 = may be false, 3 = don't know, 4 = may be true, 5 = true); **score for negatively worded items: 2, 3, 7, 8, 11, 12,15, 16, 17 (5 = false, 4 = may be false, 3 = don't know, 2 = may be true, 1 = true).

The responses to each item are either 1 = false, 2 = may be false, 3 = don't know, 4 = may be true, 5 = true. The total Gender Friendly Breastfeeding Knowledge scale score can be between 18 and 90 (Fig. 3). Based on the normal distribution we divide GFBFKS scores into four categories; 80 and above = good, 65-80 = average, 50-65 = poor, and < 50 = no knowledge of breastfeeding, the Gender Friendly Breastfeeding Knowledge scale score of the 1,400 participants in the current study was 73.1 ± 10.0.

Fig. 3. Distribution of final 18-Item Gender Friendly Breastfeeding Knowledge scale scores.



Discussion

Mother's Absolute Affection is a national initiative of the Government of India's Ministry of Health and Family Welfare to build an enabling atmosphere for breastfeeding by awareness-raising campaigns, target pregnant and lactating women, family members, and community to encourage optimum breastfeeding practices [9]. To plan activities regarding breastfeeding promotion and facilitate male gender involvement in supporting breastfeeding, it is essential to have an objective, reliable, valid, and sensitive questionnaire to assess knowledge of breastfeeding among young adults of both genders and intervene accordingly. Some validated instruments are available to test awareness, attitude, trust, self-efficacy, or experience with breastfeeding [10-15].

To analyze some aspects of the breastfeeding process, there is a range of instruments that have been developed and evaluated. Few of them are Modified Breastfeeding Evaluation Scale [24], Breastfeeding Self-Efficacy Scale [15], the Breastfeeding Attrition Prediction Tool [22], Australian Breastfeeding Knowledge and Attitude Questionnaire [25], Preterm Infant Feeding Survey [26], Breast Milk Expression Experience [27], Breastfeeding Attrition Prediction Tool [28], Breastfeeding Knowledge, Attitude, and Confidence Scale [29], and Supportive Needs of Adolescents

Breastfeeding Scale [30]. However, young adults of both genders are not included in any breastfeeding evaluation studies. The goal of this research was to create a brief, accurate, and consistent questionnaire on the assessment of breastfeeding knowledge, which fills a void in the literature. The utility of the short, succinct, and shy free breastfeeding knowledge scale among young adults is in future parenthood breastfeeding rates would improve. Gender Friendly Breastfeeding Knowledge scale could easily be either self- or in-person administered. It includes major breastfeeding aspects. The 18-item GFBFKS is a valid instrument for assessing breastfeeding knowledge in the context of benefits to the child, mother, and family, role of the family in supporting breastfeeding, and recommended frequency and duration. Since this research used items to structure a scale, internal consistency was required. Acceptable internal consistency and reliability have been achieved. Three sub-scales created by PCA for construct validity, represented internal accuracy (Cronbach's alpha > 0.70) and internal reliability (ICC ranged from 0.693 to 0.736; $p < 0.01$; CI: 95%). This analysis showed that the Cronbach's alpha for the GFBFKS was above 0.7; thus, the objects were measured and compared with the same parameters. A minimum Cronbach's alpha value of 0.60 is considered ideal in research studies, thus this questionnaire is accurate for evaluating breastfeeding knowledge among young adults. GFBFKS was validated using wide-ranging samples which confirms its external validity. Our validity and reliability measures were equivalent to other tools for assessing breastfeeding knowledge [30]. The GFBFKS validation encourages its potential application in public health, clinical, and scientific contexts.

This research used factor analysis to assess the validity of questionnaire item ideas to decide how items could be divided into subscales and to pick and exclude some of the items from the tool. Three domains of breastfeeding awareness were built in this research through exploratory factor analysis. For each domain, it can provide the rationale for evaluating overview scales. This offers insight about which aspects of knowledge are missing for the studied participants and it can be directly geared at that factor and further action. Based on factor analysis, we omitted 5 things below 0.2 with factor loading. Based on factor analysis findings, it is normal to remove certain items from a scale.

Using the GFBFKS, we assessed breastfeeding knowledge among young adult female and male undergraduate college students. The mean score of breastfeeding knowledge was 73.13 (SD 10.0). Study participants had average knowledge of breastfeeding. The gender friendly initiative is a new and dynamic notion that takes into account how the person perceives and recognizes the importance of breastfeeding for making an informed decision about advocating breastfeeding in families and communities and practicing the same in their parenthood. In a society still breastfeeding is considered to be the mother's primary duty and female voice interaction [31]. Exclusive breastfeeding is vital to provide both mothers and children with immediate and long-term benefits [32]. It has been found that both professional and common man advocacy help decreases the likelihood of suboptimal breastfeeding practices [33, 34]. However effective methods and techniques help to build basic breastfeeding knowledge among young minds. This approach is relevant to future parenthood.

Lack of awareness among new mothers and support from household members who exercise authority over many household activities, including breastfeeding decisions, especially mothers-in-law, and grandmothers, is a key constraint. There have been several attempts to include men in the reproductive health program [35]. Lack of validated tools to assess breastfeeding knowledge of both genders possess a serious challenge to public health to plan, do, check and act.

GFBFKS can encourage openness towards discussions on the importance of breastfeeding and anticipate long-term changes in young adults' behaviours and practices. To discover other realms and components of the young adult sensitization regarding breastfeeding, our research could provoke continued inquiry. To further refine the scale, future prospective studies should investigate GFBFKS modeling, whether impacting breastfeeding knowledge in young adult brains are correlated with practice in their parenthood, and whether it contributed positively to the improvement of breastfeeding rates in the communities.

Strengths and limitations

The current research is important in that a reliable and relevant tool has been developed to assess breastfeeding knowledge among young adults of both genders. It is expected for future research and service planning, the Gender Friendly Breastfeeding Knowledge scale will be used to measure breastfeeding knowledge among young adults of both sexes. However, this research has a limitation. We cannot be certain of the relationship between knowledge of breastfeeding and practice of breastfeeding a child in the family because we conducted a cross-sectional survey. To more reliably estimate the predictive validity of the Gender Friendly Breastfeeding Knowledge scale, prospective studies are needed.

Conclusions

The Gender Friendly Breastfeeding Awareness scale is the first of its kind which addresses breastfeeding knowledge assessment for both genders. The final validated Gender Friendly Breastfeeding Awareness scale with three criteria and 18 items, a preliminary tool was built by a literature review, pre-testing, and expert content validity analysis, accompanied by a survey of 1,400 young adults and factor analysis. The internal consistency of the Gender Friendly Breastfeeding Knowledge scale was satisfactory. The criteria were met by construct validity and convergent validity, calculated by CFA. Because Gender Friendly Breastfeeding Knowledge scale is a

valid and reliable tool, it is recommended that this scale be used in communities, educational institutions, and in relevant research to assess breastfeeding knowledge among young adults of both genders, thereby promoting breastfeeding practices in the future.

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Conflict of interest statement

The Authors Declare there is no conflict of interest.

Authors' contributions

AG conceived the study design; AG wrote the manuscript draft. SS, NK, KS assisted in collection and synthesis of Data. RA & RK critically reviewed and revised the manuscript. RK approved the final draft. Authors declare the manuscript has been read and approved by all the authors, that the requirements for authorship have been met, and that each author believes that the manuscript represents honest work, and that information is not provided in another form.

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HEALTH PROMOTION

The relationship between demographic factors and levels of self-care against coronavirus in pregnant women referred to maternity wards

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Keywords

Coronavirus • Pregnant women • Self-care

Summary

Background. *The adverse effects of coronavirus infection on pregnant women and their infants are not apparent. The best strategies to deal with this disease is avoiding the infection and preventing its transmission.*
Purpose. *the present study aimed to investigate the relationship between demographic factors and levels of self-care against coronavirus in pregnant women referred to maternity wards of Kerman, southeast Iran.*
Method. *The present descriptive study was conducted on 200 pregnant women who referred to maternity wards in Kerman in 2020 and met the inclusion criteria. The required information was collected using demographic and obstetric questionnaires and a self-care checklist.*
Findings. *The mean age of the participants was 28.89 ± 7.07. Iranian and Afghan citizens comprised 82 and 18% of the participants, respectively. The highest level of self-care measures against coronavirus in pregnant women was attributed to the use of face masks (74%), and the lowest was warning the personnel to wear masks (28%). There was a statistically significant relationship between the nationality of the participants and warning the personnel to wear facemasks (r = 0.183; p = 0.02), having a sick spouse (r=0.149;P = 0.039), and having a sick child (r = 0.191; p = 0.043), and between the husbands' job and the patients' demand for a private room (r = 0.173; p = 0.013). There was an inverse relationship between mothers' age and warning the personnel about paying attention to their hygiene (r = -0.145; p = 0.04).*
Conclusions. *The results indicated that most pregnant women in the present study were active in self-care against coronavirus. Using face masks was more widely followed than other self-care measures; moreover, there was a relationship between personal characteristics and self-care levels.*

Introduction

Due to the high prevalence of coronavirus infection, substantial measures should be taken to prevent its transmission and reduce mortality and associated complications. Since one of the best strategies to deal with this disease is to avoid infection and prevent its transmission, most countries recommend guidelines such as home quarantine, social distancing, frequent hand washing, and the use of hand sanitizer gels [1].
Preventing coronavirus transmission must be considered, specifically in high-risk groups, including the elderly, people with underlying diseases such as diabetes, renal diseases, immunodeficiency, and pregnancy [2]. With the prevalence of coronavirus, the number of pregnant women infected with the virus is on the increase. Therefore, preventing and controlling the disease in pregnant women have become major concerns [3].
There is very little information about the effects of this newly emerging virus on pregnancy and delivery and its impact on the fetus. Currently, there is no evidence of COVID-19 transmission from mothers to their fetuses. Although the overall effect of MERS-CoV, a member of the coronavirus family, on mothers and delivery consequences needs further evaluation, research indicated that MERS-CoV may pose serious health risks to both mother and baby [4] and can cause sudden bleeding with rupture of membranes (ROM), mild to moderate fluctuation of fetal heart rate, and placental abruption leading to an emergency C-section [5]. Studies conducted during the outbreak of severe acute respiratory syndrome coronavirus (SARS-CoV) on pregnancy have shown spontaneous abortion, preterm birth (PTB), intrauterine growth restriction (IUGR), intensive care unit admission, renal failure, and maternal coagulation disorder [6, 7].
Prevalent manifestations of COVID-19 in pregnant women included fever, cough, and muscle aches. Lab results most commonly show decreased lymphocytes and increased CRP. Recent studies indicated an increased C-section rate and preterm birth in pregnant women with COVID-19 [8, 9]. Therefore, using self-care programs to prevent coronavirus infection reduces the prevalence of the disease, decreases C-section rates, and increases natural childbirth.
Self-care is an essential aspect of a health-oriented lifestyle, improving the quality of life and reducing costs. With self-care, acute or chronic complications of diseases can be prevented or delayed [10].

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Self-care in the coronavirus pandemic is the most crucial factor in controlling the disease. Principles of self-care behaviors such as using face masks, social distancing, and regular hand washing are observed by some people but not followed by others, and adherence to recommended guidelines for controlling the disease varies among individuals. Self-care measures that the pregnant woman consciously takes during pregnancy can also lead to her and the fetus's health during pregnancy, childbirth, and afterwards. The adverse effects of coronavirus infection in pregnant women and their infants are unclear [11]. Due to limited information, the fact that pregnant women are among high-risk groups during the COVID-19 pandemic, and the limited number of studies on various aspects of pregnancy and the emerging coronavirus infection, the present study was conducted aiming to investigate the relationship between demographic factors and levels of self-care against coronavirus in pregnant women referred to maternity hospitals.

Methods

Type of study

The present research was a descriptive-analytical study aiming to assess the relationship between demographic factors and self-care among pregnant women.

Sample and statistical population

Participates were eligible pregnant women hospitalized in maternity hospitals in Kerman, south of Iran, during the coronavirus pandemic in 2020. Sampling carried out from April to June.

Inclusion criteria

Inclusion criteria involved being hospitalized to terminate a pregnancy, and willingness to participate in the study.

Sample size and sampling

The sample size was calculated 195 people, by considering the ratio of pregnant women with appropriate self-care 15% (in the pilot study), 95 confidence level, 80% test power and 5% accuracy.

After receiving ethical code (IR KMU REC. 1399.131), eligible pregnant women who referred to maternity ward to terminate their pregnancy because of abortion, Ep, IUFD, preterm, term, and post-term labor, were invited to participate in study. Informed consents was obtained and participants were selected through convenience sampling. Demographic and obstetric part of questionnaire was completed with interview and the third part of questionnaire was fulfilled with observation by researcher. Data collection was continued until reaching specified sample size.

Measuring tools

Data collection tools included three parts: first part demographic questions, second part obstetrics information and third part a researcher-made checklist for pregnant women's self-care measures. The checklist was designed based on books, articles, and experts' opinions in this field and consisted of ten questions. It should be responded by yes, no and sometimes. In order to obtain scientific validity for the checklist, content validity was used. To this end, the checklist was given to ten faculty members of the obstetrics and health schools and was assessed in terms of content. Afterwards, the opinions were applied to the checklist. To check the reliability of the checklist, the concurrent reliability test was used. To this end, the researcher and a colleague with the same academic level completed the checklists of 10 samples simultaneously.

Data analysis

After completing the questionnaires and collecting the data, the collected information was analyzed using SPSS V21. In this study, descriptive statistical tests such as simple frequency distribution, central tendency and dispersion measures, standard deviation, Pearson correlation test, and multiple regression were used. The significance level was set at 0.05.

Results

Two hundred pregnant women with the mean age of 28.89 ± 7.07 participated in this study. One hundred and sixty-two of these women (82%) were Iranian, and 36 (18%) were Afghan. In terms of education level, 33.5% did not have a high-school diploma, 47.5% had a high-school diploma, and 19% had a university education (Tab. I).

Tab. I. Study population's demographic information.

Variable			Frequency (percentage)
Women's education level	No diploma		53 (26.30%)
	Diploma		83 (41.5%)
	University		64 (32%)
Husbands' education level	No diploma		67 (33.5%)
	Diploma		95 (47.5%)
	University		38 (19%)
Women's occupation	Housewife		111 (55.5%)
	Working	Self-employed	32 (16%)
		Governmental	57 (28.5%)
Husbands' occupation	Unemployed		20 (10%)
	Working	Self-employed	73 (36.5%)
		Governmental	107 (53.5%)
Socioeconomic status	Low		108 (54%)
	Average		72 (36%)
	High		20 (10%)
Women's addiction	No addiction		170 (85%)
	Cigarette		10 (5%)
	Narcotics		20 (10%)
Husbands' addiction	No addiction		147 (73.5%)
	Cigarette		23 (11.5%)
	Narcotics		30(15%)

Tab. II. Frequency and percentage of self-care in pregnant women against coronavirus.

Questions	Yes	No	Sometimes
Does the patient wash their hand with water and soap or use hand sanitizers regularly after touching different surfaces or eating and drinking?	128 (64%)	72 (36%)	
Does the patient wear a face mask?	148 (74%)	51 (25.5%)	1 (0.5%)
Does the patient use a cap or scarf in labor?	147 (73.5%)	53 (26.5%)	
Does the patient keep a proper distance from the personnel when giving history?	104 (52%)	53 (26.5%)	
Does the patient keep a proper distance from other patients?	90 (45%)	110 (55%)	
Does the patient warn the personnel to wear masks talking to them?	56 (28%)	144 (72%)	
Does the patient warn the personnel to wash their hands before doing anything?	71 (35%)	129 (64.5%)	
Does the patient ask for a private room or the minimum number of patients in the room?	87 (43.5%)	112 (56%)	
Does the patient ask for proper ventilation in the room?	87 (43.5%)	113 (56.5%)	
Does the patient take care not to touch their eyes, nose, and mouth?	87 (43.5%)	113 (56.5%)	

26 (13%) of the participants had a history of physical diseases, and 15 (7.5%) a history of mental disease. In terms of prenatal care, 10 (5%) of the participants had not done any prenatal care, 150 (75%) had done it regularly, and 30 (15%) irregularly. The results of the present study showed that among the sources of coronavirus information, TV (95%) had the highest frequency, followed by friends and relatives (89.5%), social media (86%), radio (19.5%), and newspapers and magazines (10.5%). The assessment of self-care measures taken by pregnant women in the study showed that the most significant self-care measure was using face masks (74%), followed by using a cap or scarf in labor (73.5%), using hand sanitizers after touching different surfaces or eating and drinking, and handwashing with water and soap (64%). The least significant self-care measure was warning the personnel to wear a mask (28%) (Tab. II).

The results of the present study regarding the relationship between self-care against coronavirus among pregnant women showed a statistically significant relationship between participants' nationality and warning the personnel to wear a mask ($r = 0.183$; $p = 0.02$). In fact, Iranian women warned the personnel more than non-Iranians.

The mother's body mass index had a significant relationship with keeping a proper distance from personnel ($r = 0.192$; $p = 0.016$). There was a significant relationship between having a sick husband ($r = 0.149$; $p = 0.039$) or child ($r = 0.191$; $p = 0.043$) and wearing a scarf or cap in labor. Moreover, there was a significant relationship between having a sick child and washing hands after touching different surfaces or before eating and drinking or using hand sanitizers ($r = 0.152$; $p = 0.020$).

Husbands' occupation had a significant relationship with asking for a private room or a room with the minimum number of patients ($r = 0.137$; $p = 0.013$). This relationship is even more significant in women whose husbands had nongovernmental jobs.

Patients' socioeconomic status showed a significant relationship with warning the personnel to wash their hands before doing anything ($r = 0.147$; $p = 0.011$).

There was also a significant relationship between women's occupation and warning the personnel to wear a face mask ($r = 0.176$; $p = 0.016$) and warning them to wash their hands before doing anything ($r = 0.147$; $p = 0.001$), with working mothers paying more attention to this issue.

Moreover, mothers' attention to wearing a scarf or cap in labor had a significant relationship with their occupation ($r = 0.192$; $p = 0.006$), and working mothers paid more attention to wearing a scarf or cap during labor.

There was an inverse relationship between mothers' age and warning the personnel about paying attention to their hygiene ($r = -0.145$; $p = 0.04$). However, there was a significant positive relationship between the mother's parity and keeping a proper distance from other patients ($r = -0.147$; $p = 0.03$) and touching the eyes, nose, and mouth ($r = 0.152$; $p = 0.03$).

Discussion

In the present study, the relationship between demographic factors and the levels of self-care against coronavirus in pregnant women was investigated. The pandemic has spread worldwide, and due to its high transmission, most countries recommend protocols such as using face masks, frequent hand washing and sanitizing, and social distancing in order to control the disease and reduce its transmission.

Self-care can be defined as leading a healthy lifestyle to help prevent diseases and injuries; it plays a vital role in reducing the use of health services [12].

The findings of the present study indicated that the most frequent self-care measure taken by the participants was attributed to the use of facemasks, and the least frequent was warning the personnel to wear masks. Using facemasks is one of the strategies to prevent the spread of coronavirus. In the study conducted by MacIntyre et al., using face masks was recommended as a valuable strategy to prevent the transmission of the diseases transmitted through respiratory droplets and to reduce infection transmission rates [13].

Moreover, the results of the study conducted by Brandt et al. on the role of wearing face masks in controlling coronavirus indicated the role of face masks in reducing the spread of respiratory droplets from asymptomatic individuals and those with mild COVID-19 [14].

The results of the present study showed a statistically

significant relationship between the nationality of the participants and warning the personnel to wear masks ($p = 0.02$). In fact, non-Iranians who consisted of Afghan women did not warn the personnel about personal hygiene, which could be due to feelings of lack of belonging to the environment and the country, resulting in decreased self-confidence. According to Bustani, immigrants suffer from relative deprivation and social phobia, which includes decreased power, respect, affection, and increased anxiety [15].

There was a significant relationship between the degrees of the pregnant mothers' attention to wearing a scarf or cap in labor and the variables of the mother's occupation ($p = 0.006$), having a sick husband ($p = 0.039$), and a sick child ($p = 0.043$). Having sick relatives can cause worry and anxiety in a pregnant woman. If she feels that her condition might worsen theirs and sometimes even lead to their loss, worry and anxiety will especially increase in her, motivating her to pay more attention to her personal hygiene and even to warn others about it. The study results conducted by Jafari Manesh indicated that the parents of sick children suffer from different degrees of anxiety and depression [16].

There was a significant relationship between the occupation of the patient's husband and the patient's demand for a private room or a room with the minimum number of hospitalized patients ($p = 0.013$). The husband's occupation can represent the family's economic status, and people with higher economic status are more likely to ask for a private room both during an outbreak of a disease and in normal circumstances. According to Ameri, economic factors and individuals' income are influential factors in choosing private hospitals for treatment [17].

The patients' socioeconomic status had a significant relationship with warning the personnel to wash their hands before doing anything ($p = 0.011$). This could be due to greater attention to hygiene in individuals with higher socioeconomic status. Studies have shown that individuals with a better socioeconomic status have higher self-confidence compared to those from lower-income classes. Having high self-confidence is one factor required for communicating with others, especially for having a decisive and critical attitude [18].

There was a statistically significant relationship between the participants' occupation and warning the personnel to wear facemasks ($p = 0.016$) and to wash their hands before doing anything ($p = 0.001$). Due to their presence in society and communication with various people other than their family members, workingwomen possess higher communication skills. Therefore, they can criticize and warn others because people are likely to be criticized, blamed, reprimanded, and sometimes punished due to work-related issues in the workplace. As a result, employed people are more capable than the un-employed in this matter. According to the study conducted by Nayebpour, workingwomen have higher communication skills than unemployed women [19].

There was a significant inverse relationship between mothers' age and warning about personal hygiene ($r = -0.145$; $p = 0.04$). According to previous studies, age is a factor influencing the level of self-care ability, and younger study units had higher self-care ability. Orem argues that self-care abilities and requirements in a healthy individual vary according to the level of growth determined by age [20].

There was a significant positive relationship between the patient's parity and keeping a proper distance from other patients and touching the eyes, nose, and mouth. In other words, the more pregnancies a woman had experienced, the more sensitive she had become about personal hygiene [21]. According to the study conducted by Hakan, there was a significant relationship between parity and communication skills and health responsibility [22].

Conclusions

The findings of the present study indicated that the majority of pregnant women studied were active in self-care, and the use of facial masks received more attention than other self-care measures. According to the present study, it is recommended that individuals' awareness be increased in order to improve self-care performance. Moreover, according to the results of the present study, it is recommended that pregnant women's attitude toward self-care behaviors during pregnancy be improved by removing barriers to self-care behaviors during pregnancy and increasing perceived sensitivity to consequences of ignoring self-care during this period. Moreover, we should raise their knowledge about the benefits of such behaviors and improve their health belief model constructs.

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Conflict of interest statement

The authors declare no conflict of interest.

Authors' contributions

FM and KA designed the work and drafted the manuscript. AH and KA prepared questionnaire. FM and AH had full access to all of the data and take responsibility for the integrity of the data. MG takes responsibility for accuracy of the data analysis. All authors read and approved the final manuscript.

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HEALTH PROMOTION

A study on parental awareness of feeding practices in children in the age-group 12-24 months

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Keywords

Breastfeeding • Colostrum • Complementary feeding • Malnutrition

Summary

Introduction. *Nutrition plays an integral part in growth and development of a child. Age-appropriate feeding is known to improve the child's well-being and reduce the risk of specific diseases. The present study aimed to assess the awareness of parents regarding breastfeeding and complementary feeding practices.*
Methodology. *This health-based prospective observational study was conducted in a tertiary care hospital enrolling 95 parents with children in the age group 1-2 years. The data was analyzed using SPSS version 26 and Microsoft excel.*
Results. *In the present study, the prevalence of exclusive breastfeeding was 73.68%. Eighty-six (90.53%) parents initiated complementary feeds at 6 months. However, only 45.26% of children were consuming adequate quantity of complementary foods. The association of child's calorie consumption with maternal age and occupation was found to be statistically significant.*
Conclusion. *Adequate nutrition during childhood and infancy is a key factor influencing growth and development. In the present study, the overall breastfeeding and complimentary feeding practices were satisfactory. However, the quantity of complementary feeding was inadequate. Counselling the mothers on appropriate breastfeeding and complementary feeding practices during antenatal and postnatal visits may have a positive impact on infant feeding practices.*

Introduction

At the fundamental level for supporting health and development, the right balance of nutrients along with taste and texture are necessary in appropriate quantities to cater the needs of the growing infant. Adequate nutrition is essential during infancy and early childhood to ensure optimal health, growth and development [1]. Across the developing countries with high population growth rate and low per capita income, triple burden of malnutrition (undernutrition, micronutrient deficiency and overnutrition) is becoming a major issue of concern [2]. The triple burden of malnutrition is a great threat for the development of the economy and nation [3]. The World Health Organization (WHO) and United Nations Children's Fund (UNICEF) jointly developed the global strategy for infant and young child feeding practices (IYCF). This strategy recommends initiation of breastfeeding within 1 hour of birth, exclusive breastfeeding for the first 6 months of life, with the addition of nutritiously appropriate complementary feeds at 6 months with continued breastfeeding at least until 2 years of age. Adherence to these recommended practices has proven to reduce the risk of undernutrition and overnutrition with added long-term physical and psychological health benefits [4].
According to National Family Health Survey 4 (NFHS 4), only 42% of Indian newborns are fed with breastmilk within 1 hour of birth and only 55% of children under 6 months of age are exclusively breastfed, as recommended [5]. Infants and young children are at increased risk of malnutrition during the period of changeover of baby's diet from breastmilk to solid food, i.e,6 months to 2 years of age. Introducing complementary feeds earlier or later than recommended can lead to malnutrition. Almost, 2 in 3 children between 6 months and 2 years of age across the globe are not fed food that supports their rapidly growing brain and body [6]. Inadequate complementary feeding practices drive malnutrition in early childhood leading to weight loss, muscle wasting, stunting, difficulty concentration in the initial phase, which gradually progresses to kwashiorkor, marasmus, poor brain development, reduced learning ability, increased risk of infections due to poor immunity and in many cases death. Studies and reported evidences have shown that meticulous compliance to the recommended feeding practices (IYCF) can reduce infant mortalities up to 19% in developing countries like India [7-9]. Therefore, optimal IYCF practices can have the most significant impact on child mortality among all preventive interventions.
In India, food consumption patterns reveal that child diets are largely starved of proteins and essential micronutrients, and are influenced by adult (family) food choices. Around 38% and 21% of children under the age of 5 still suffer from stunting and wasting, respectively [6]. This is attributed mainly to inadequate knowledge about appropriate feeding practices among parents rather than the lack of food due to poverty [9-12].

The co-occurrence of undernutrition and obesity is often perceived as paradoxical, but there are a few elucidations for this paradox. Due to existence of household food insecurities, children tend to consume unhealthy and highly energy-dense foods, such choices lead to the coexistence of overweight and undernutrition at the same time. Overnutrition is also a form of malnutrition arising from excessive intake of imbalanced nutrients leading to impairment of physical and psychosocial functioning of the child. Overweight and obesity can cause long-term health consequences such as diabetes mellitus, hypertension, fatty liver disease, kidney disease, cardiovascular diseases, stroke and orthopedic morbidities. India has the second highest number of obese children in the world, translating to 14.4 million in the year 2015 [13].

There are only a few studies in South India to assess the feeding practices of young children. It is necessary that parents are aware of the proper feeding practices for the benefit of their child's heath status and immunity. Thus, time to time assessment should be done to find out the awareness of the parents at the given time and scenario so that necessary interventions can be carried out to educate the parents regarding healthy feeding practices. The present study aims to gain information about the feeding practices currently undertaken by the parents of children aged 12 to 24 months and therefore help health professionals gain an understanding of the child's food habits and any related risk factors to suggest modifications to the parents in their feeding practices.

Malnutrition is a multi-dimensional problem encompassing social, cultural, economic, educational and nutritional aspects, in India. Children and adolescents form the backbone of the nation's future, and their nutrition and health play a critical role in human resource development of the country. Thus, meeting the nutritional needs of the younger generations is essential to bridge the gap in the nation's growth milestones.

Aims and objectives

- To find out the feeding practices undertaken by the parents with children in the age group 12 to 24 months, taking into consideration the breastfeeding and complementary feedings.
- To find out the relationship between the feeding habits of the child and the sociodemographic characteristics of the family.

Materials and methods

This is a prospective health-based observational study. It was conducted in an urban based tertiary care hospital in South India. The study was carried out after approval from Institutional Ethics Committee (CSP/20/FEB/84/88). Parents of children in the age group of 12 - 24 months attending out-patient pediatric department or admitted in this center were the participants of this study.

This study was conducted over a period of 2 months (1st October 2020-30th November 2020) with the study population of 95 parents. The simple random sampling technique was adopted to determine the participants of the study. Questionnaires were employed to collect information from the participants. The questionnaire has been validated by three expert Pediatricians to enhance its clarity and comprehension. Questionnaire was translated into the regional language which was reviewed and back translated by Pediatrician to check the accuracy of the terms used. Any discrepancies in the translated version were resolved. Final version was prepared after a pilot study. Written informed consent form was obtained from the parents who gave consent to participate after explaining to them the objectives of this study in the participant's own language. Parents who did not give consent to participate and parents of children with co-morbidities such as congenital abnormalities, metabolic and endocrine disorders and chronic disease involving cardiac, kidney, gastro-intestinal, neurological and blood related disorders were excluded from the study. Predesigned and pretested questionnaires were used to collect the data on socio-demographic profile (age, residence, educational qualification, occupation and income) and initiation of breastfeeding, exclusive breastfeeding and complementary feeding practices.

Data entry and statistical analysis was carried out using SPSS software version 26 and Microsoft excel. Descriptive statistics like mean, standard deviation and frequency were calculated, where necessary. In addition, bivariate and multivariate logistic regression along with chi-square test was also carried out to see the associations. Crude and Adjusted Odds ratios (COR, AOR) were computed for each explanatory variable to determine the degree of association and to control the confounders. Statistical test of significance is defined as confidence interval of 95% and p value less than 0.05. All results were expressed as percentage and numbers.

According to WHO, the following terms were used in this study to describe infant feeding practices [1]:

Early initiation of breastfeeding: infants should be breastfed within the first hour of birth

Exclusive breastfeeding: breastfeeding the infant for first 6 months of life – meaning no other foods or liquids are provided, including water

Optimal complementary feeding: complementary food should be introduced at six months of age (180 days) while continuing to breastfeed up to 2 years. The food should contain all macronutrients and micronutrients in the right proportion

Minimum meal frequency: feeding solid/semisolid foods 2 times per day for breastfed infants aged 6–8 months, 3 times per day for breastfed children aged 9–24 months and 4 times per day for non-breastfed children aged 6-24 months

Minimum dietary diversity: dietary diversity is present when the diet contains four or more of the following seven food groups - grains, roots and tubers, legumes and nuts, dairy products, flesh foods, eggs, vitamin A-rich fruits and vegetables, other fruits and vegetables

Results

Among 95 participants, the mean age of children, mothers and fathers were 17.90 (± 3.10 Standard Deviation [SD]) months, 27.88 (± 4.19 SD) years and 33.09 (± 4.98 SD) years, respectively. Of the 95 children, 55 (57.89%) were males and 40 (42.12%) were females. More than half, 68 (71.58%) children lived in urban households. Most of the mothers, i.e, 84 (88.42%) were housewives. Majority of the fathers (95.79%) were employed, among which 67.37% were professional workers. Table I shows the socio-demographic characteristics of the study population.

Tab. I. Socio-demographic characteristics of participants of the study (N = 95).

Variable	Frequency (N = 95)	Percentage (%)
Characteristics of the child		
Age of child (mean ± SD)	17.903 ± 3.100	
Gender of the child		
Female	55	57.89%
Male	40	42.12%
Birth weight		
Low birth weight (< 2.5 kg)	23	24.21%
Normal weight (≥2.5 kg)	72	75.78%
Period of gestation		
Preterm	16	16.84%
Term	79	83.16%
Birth defects		
Yes	13	13.68%
No	82	86.32%
Sibling		
Yes	46	48.42%
No	54	51.58%
Characteristics of the family		
Residence		
Urban	68	71.58%
Rural	32	28.42%
Age of mother (mean ± SD)	27.88421 ± 4.187	
Maternal education		
Primary	4	4.21%
Secondary	26	27.36%
Graduate	65	68.42%
Maternal occupation		
Housewife	84	88.42%
Employed	11	11.58%
Age of father (mean ± SD)	33.094 ± 4.976	
Paternal education		
Primary	14	14.74%
Secondary	19	20%
Graduate	62	65.26%
Paternal occupation		
Unskilled	4	4.21%
Skilled	27	28.42%
Professional	64	67.37%
Type of family		
Nuclear	47	49.47%
Joint	48	50.53%
Socio-economic class		
Upper	20	21.05%
Upper-middle	45	47.37%
Lower-middle	22	23.16%
Upper-lower	8	8.42%
Lower-lower	0	0%

Breastfeeding practices

From the total of 95 children, 64 (67.37%) were initiated on breastfeeding within 1 hour of birth, 70 (73.68%) were exclusively breastfed until 6 months of age and 70 (73.68%) had continued breastfeeding until 1 year of age (Tab. II). At the time of interview, 42 (44.21%) mothers were breastfeeding their children, among which 35 (59.32%) children were in the age group 12-18 months and 7 (19.44%) children were in the age group 18-24 months. The most common reasons given by mothers for stopping breastfeeding were "trouble in milk flow to start" in 31 (60.78%) and "mother became pregnant" in 11 (21.57%). Other reasons for stoppage of breastfeeding are mentioned in Table III.

The timely initiation of breastfeeding significantly correlated to maternal age at marriage ($p = 0.048$), birth weight of the child ($p = 0.046$), mode of delivery ($p = 0.04$), birth defects ($p = 0.0002$) and period of gestation (0.027), but not with maternal education, maternal occupation and socioeconomic status of the family. Common birth defects observed in this study population were cleft lip/palate (6 out of 13 children) and imperforate anus (4 out of 13 children). Univariate analysis using chi square also revealed that practice of exclusive breastfeeding feeding did not vary significantly with residence, type of family, educational status, occupation and age of parents, birth order or weight of the child ($p > 0.05$) (Tab. IV). Using fisher's exact test, the practice of expressed breastmilk was found to have a significant association with birth weight of the child ($p = 0.019$), period of gestation ($p = 0.045$) and birth defects ($p = 0.034$).

Tab. II. Breastfeeding and complementary feeding practices of participants (N = 95).

Variable	Frequency (N = 95)	Percentage (%)
Initiation of breastfeeding within 1 hour		
Yes	64	67.37%
No	31	32.63%
Exclusive breastfeeding for 6 months		
Yes	70	73.68%
No	25	26.32%
Continued breastfeeding at 1 year		
Yes	70	73.68%
No	25	26.32%
Initiation of complementary feed at 6 months		
Yes	86	90.53%
No	9	9.47%
Supplements		
Yes	29	30.53%
No	66	69.47%
Salt in complementary feeds		
Yes	89	93.68%
No	6	6.32%
Sugar in complementary feeds		
Yes	77	81.05%
No	18	18.95%
Expressed breast milk		
Yes	11	11.58%
No	84	88.42%
Formula feeding		
Yes	26	27.37%
No	69	72.63%
Cow milk		
Yes	68	71.58%
No	27	28.42%

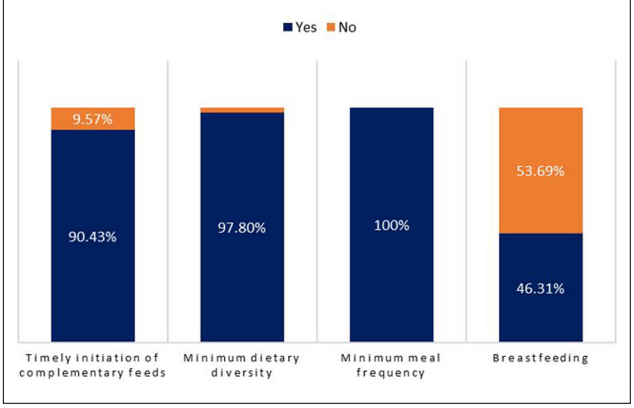
Tab. III. Reasons for stopping breastfeeding.

Reasons for stopping breastfeeding	Response (N = 51)
Trouble in milk flow to start	60.78% (31)
Breastfeeding was painful	9.80% (5)
Mother was sick	5.88% (3)
Mother had to leave the baby for long hours	13.73% (7)
Mother wanted to go back to her usual diet	0% (0)
Mother did not want to breastfeed in public	0% (0)
Mother became pregnant	21.57% (11)

Complementary feeding practices

Overall, 86 (90.43%) mothers had initiated timely complementary feeds as per the pediatrician's advice (Tabs. II, V). In addition, all children received the minimum meal frequency and the majority (97.8%) met the criteria of minimum dietary diversity (Fig. 1). However, only 43 (45.26%) children consumed adequate quantity of complementary feeds (Fig 2). The bivariate logistic regression analysis showed that present weight of the child, birth order, type of family and socioeconomic status were statistically associated with appropriate complementary feeding practice. In the multivariate logistic regression analysis, present weight of the child, educational status of the mother and father, type of family and socioeconomic status were independent predictors for appropriate complementary feeding practice. Univariate analysis using chi square found that the optimal complementary feeding was significantly associated with maternal age ($p = 0.029$) and maternal employment status ($p = 0.049$) but not with gender of

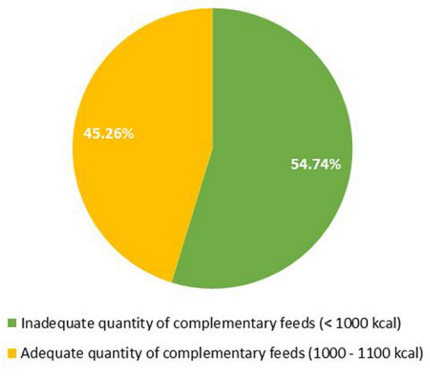
Fig. 1. Feeding characteristics of the children (N = 95).



Tab. IV. Bivariate and multivariate logistic regression for the predictors associated with exclusive breastfeeding (N = 95).

Population characteristics		Exclusively breastfed (N = 70)	Not exclusively breastfed (N = 25)	Crude odds ratio	Adjusted odds ratio	95% CI	p-value
Age	< 18 months	14 (93.33%)	1 (6.67%)	1.022	0.891	0.293 – 3.559	**0.047**
	≥18 months	56 (70%)	24 (30%)				
Gender	Female	27 (67.50%)	13 (32.50%)	0.889	1.013	0.351 – 2.252	0.243
	Male	43 (78.18%)	12 (21.82%)				
Place	Urban	51 (75%)	17 (25%)	1.833	2.360	0.609 – 5.520	0.644
	Rural	19 (70.37%)	8 (29.63%)				
Sibling	Yes	33 (71.74%)	13 (28.26%)	0.958	0.414	0.346 – 2.656	0.677
	No	37 (75.51%)	12 (24.49%)				
Present weight	Normal	52 (75.36%)	17 (24.64%)	0.630	1.158	0.249 – 1.592	0.366
	Underweight	18 (69.23%)	8 (30.77%)				
Mother's age	< 30 years	50 (78.13%)	14 (21.88%)	4.889	4.471	1.336 – 17.896	0.158
	≥30 years	20 (64.52%)	11 (35.48%)				
Mother's education	Primary	3 (75%)	1 (25%)	0.845	1.501	0.364 – 1.960	0.528
	Secondary	17 (65.38%)	9 (34.62%)				
	Graduate	50 (76.92%)	15 (23.08%)				
Mother's occupation	Housewife	62 (75.61%)	20 (24.39%)	0.516	0.452	0.152 – 1.758	0.284
	Employed	8 (61.54%)	5 (38.46%)				
Father's age	< 35 years	48 (76.19%)	15 (23.81%)	3.5	1.359	1.085 – 11.292	0.436
	≥35 years	22 (68.75%)	10 (31.25%)				
Father's education	Primary	9 (64.29%)	5 (35.71%)	0.611	0.542	0.300 – 1.246	0.508
	Secondary	13 (68.42%)	6 (31.58%)				
	Graduate	48 (77.42%)	14 (22.58%)				
Father's occupation	Unskilled	2 (50%)	2 (50%)	0.664	1.470	0.274 – 1.607	0.287
	Skilled	18 (66.67%)	9 (33.33%)				
	Professional	50 (78.13%)	14 (21.88%)				
Type of family	Nuclear	32 (68.09%)	15 (31.91%)	0.473	0.380	0.185 – 1.215	0.220
	Joint	38 (79.17%)	10 (20.83%)				
Socioeconomic class	Upper	12 (60%)	8 (40%)	1.562	1.596	0..882 – 2.766	0.588
	Upper-middle	21 (46.67%)	24 (53.33%)				
	Lower-middle	6 (27.27%)	16 (72.73%)				
	Upper-lower	4 (50%)	4 (50%)				
	Lower-lower	0 (0%)	0 (0%)				

Fig. 2. Quantity of complementary feeds among the children (N = 95).



Tab. V. Reasons for starting complementary feeds.

Reasons for starting complementary feeds	Response
Baby started consuming too much milk	16.48% (16)
Baby was hungry most of the time	38.94% (37)
Mother did not have enough milk	37.89% (36)
Baby not gaining weight	23.16% (22)
Mother wanted to feed something in addition to milk	63.16% (60)
Baby sleeps well at night	44.21% (42)
Baby was old enough to take solid food	72.63% (69)
Doctor recommended to give	78.95% (75)
Family members asked to give	72.63% (69)

the child, birth order, residence, maternal education, socioeconomic status, type of family, paternal age, paternal education and paternal occupation (Tab. VI).

Discussion

Breastmilk is the most nutrient-rich and safest food for infants up to 6 months of age. It is easily digested and thereby reducing the risk of constipation, upset stomach or diarrhea. Optimal feeding practices during the first 24 months of life is of utmost importance, as this time-period is the "critical window" for the promotion of good growth, health, cognitive and behavioral development. In addition, breastfeeding protects the neonate from common childhood illnesses like pneumonia, and also offers long-term health benefits, such as minimizing the risk of obesity in childhood and adolescence [14]. Feeding the mother's breastmilk to infants within 1 hour of birth is termed as "early initiation of breastfeeding" and this ensures that the baby receives the colostrum, which is abundant in protective factors. In the present study, 64 (67.37%) mothers had initiated breastfeeding within 1 hour of birth. A similar finding was found in the study conducted by Liaquathali et al. in which only 44% infants were initiated breastfeeding within 1 hour of birth [15]. Reddy et al. and Asare et al. reported that 59% and 60.5% of children were initiated breastfeeding within 1 hour of birth, respectively which were coherent with the present study [16, 17]. In our study, we were able to find significant association between timely initiation of breastfeeding and birth weight of the child ($p = 0.046$), mode of delivery ($p = 0.04$), period of gestation ($p = 0.027$) and birth defects ($p = 0.0002$). Data from this study showed that rates of timely initiation of breastfeeding were lower among babies delivered through caesarean section. Similar findings were highlighted in a systematic review and meta-analysis, which showed that rates of early initiation of breastfeeding following caesarean deliveries were significantly lower compared to vaginal deliveries [18]. In addition, pre-mature infants with low birth weight and children with birth defects

Tab. VI. Bivariate and multivariate logistic regression for the predictors associated with calorie consumption (N = 95).

Population characteristics		Sufficient calories (N = 43)	Deficient calories (N = 52)	Crude odds ratio	Adjusted odds ratio	95% Confidence Interval	p-value
Child's age	< 18 months	5 (33.33%)	10 (66.67%)	0.553	0.445	0.173 -1.762	0.312
	≥18 months	38 (47.50%)	42 (52.50%)				
Gender of the child	Female	16 (40%)	24 (60%)	0.691	0.730	0.303 -1.577	0.379
	Male	27 (49.09%)	28 (50.91%)				
Residence	Urban	30 (44.12%)	38 (55.88%)	0.850	0.643	0.348 -2.078	0.722
	Rural	13 (48.15%)	14 (51.85%)				
Present weight	Normal	32 (46.38%)	37 (53.62%)	1.179	1.333	0.474 -2.932	0.722
	Malnourished	11 (42.31%)	15 (57.69%)				
Sibling	Yes	21 (45.65%)	25 (54.35%)	1.031	0.944	0.459 -2.314	0.941
	No	22 (44.90%)	27 (55.10%)				
Mother's age	< 30 years	24 (37.50%)	40 (62.50%)	0.379	0.389	0.157 -0.916	**0.029**
	≥30 years	19 (61.29%)	12 (38.71%)				
Mother's education	Primary	1 (25%)	3 (75%)	0.827	1.735	0.399 -1.715	0.707
	Secondary	12 (46.15%)	14 (53.85%)				
	Graduate	30 (46.15%)	35 (53.85%)				
Mother's occupation	Housewife	34 (41.46%)	48 (58.54%)	0.315	0.298	0.090 -1.107	**0.049**
	Employed	9 (69.23%)	4 (30.77%)				
Father's age	< 35 years	25 (39.68%)	38 (60.32%)	0.512	0.710	0.216 -1.211	0.125
	≥35 years	18 (56.25%)	14 (43.75%)				
Father's education	Primary	6 (42.86%)	8 (57.14%)	0.771	1.115	0.440 -1.350	0.362
	Secondary	6 (31.58%)	13 (68.42%)				
	Graduate	31 (50%)	31 (50%)				
Father's occupation	Unskilled	2 (50%)	2 (50%)	0.676	0.619	0.322 -1.420	0.338
	Skilled	9 (33.33%)	18 (66.67%)				
	Professional	32 (50%)	32 (50%)				
Type of family	Nuclear	25 (53.19%)	22 (46.81%)	1.894	1.454	0.836 -4.293	0.124
	Joint	18 (37.50%)	30 (62.50%)				
Socioeconomic class	Upper	12 (60%)	8 (40%)	1.434	1.356	0.882 -2.332	0.192
	Upper-middle	21 (46.67%)	24 (53.33%)				
	Lower-middle	6 (27.27%)	16 (72.73%)				
	Upper-lower	4 (50%)	4 (50%)				
	Lower-lower	0 (0%)	0 (0%)				

also had delayed initiation of breastfeeding which can be attributed to the need for Neonatal Intensive Care Unit (NICU) admission and/or difficulty breastfeeding in these children.

Seventy (73.68%) mothers continued to exclusively breastfeed their children until 6 months of age, which was comparable to 70.2% reported in the study by Kulkarni et al. [19]. However, in the study conducted by Karmee et al. only 44.35% infants were exclusively breastfed until 6 months of age. Continuance of breastfeeding among children (12-24 months) were seen in 44.21%, which was lower compared to 72.36% reported by Karmee et al. [14]. This variance in breastfeeding practices among young infants may be explained by the literacy rate of the respondents, and diverse cultural and traditional practices prevalent in different topographical areas. In our study population, expressed breastmilk (EBM) was given only to 11 (11.58%) children, which was markedly lower compared to studies from developed countries [20]. There was a significant relationship ($p < 0.05$) between EBM and the period of gestation, birth weight, and birth defects of the child in the present study. Five out of 13 working mothers were not able to exclusively breastfeed their children for 6 months. If the duration of exclusive breastfeeding is to be extended among working women in the era of increasing employment of mothers, practice of expressed breastmilk has a crucial role to play [21]. In our study, duration of breastfeeding had a positive impact on the nutritional status of the child (Figs. 3, 4)

When exclusive breastfeeding is no longer adequate to meet the nutritional needs of the growing infant, complementary foods must be added to the diet of the child. Complementary feeding ought to be timely, meaning that all children should be initiated on solid/semi-solid foods in addition to breastmilk from 6 months of age. It should also be adequate, meaning that the weaning foods must be given in recommended frequency, quantity and consistency to meet the nutritional needs of the growing infant while continuing breastfeeding [1, 9]. Eighty-six (90.53%) children were introduced complementary feeds at 6 months of age, which was comparable to the results of a study conducted in Ethiopia [22]. Studies conducted by Sethi et al. and Aggarwal et al. reported that only 16.5% and 17.5% children were initiated on timely complementary feeds, which were significantly lower compared to the present study [23, 24]. In the present study, almost all (100%) children consumed cereal-based foods, 94.74% children consumed fruits and vegetables, and 90.53% children consumed dairy products as a part of their daily diet. However, percentage of children consuming nuts, and flesh foods like meat, fish and eggs were comparatively lower in our study population (Fig. 5). Overall, all children received minimum meal frequency and majority (97.8%) satisfied the criteria of minimum dietary diversity. High rates of timely initiation of complementary feeds and optimal complementary feeding practices may be attributed to high maternal literacy rates and better socioeconomic status of the study population (Fig. 6). Although most of the children satisfied minimum meal frequency and minimum dietary diversity, only 43 (45.26%) consumed adequate quantity of complementary feeds (i.e, 1000-1100 kcal). This was similar to the finding of Rao et al, where only 32% mothers fed their children with adequate quantity of complementary feeds (8). In the present study, the quantity of complementary feeds significantly correlated with the maternal age ($p = 0.029$) and maternal occupation ($p = 0.049$). Higher knowledge

Fig. 3. Relationship between duration of breastfeeding and nourishment of the child (N = 95).

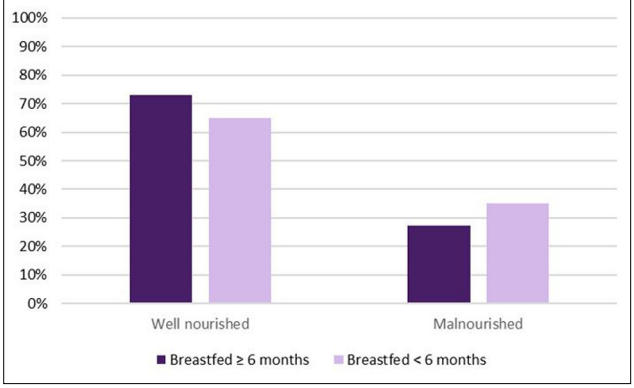


Fig. 4. Relationship between breastfeeding and nutritional status of the child (N = 95).

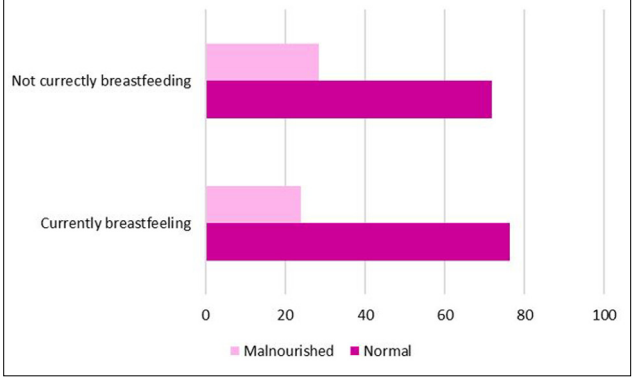
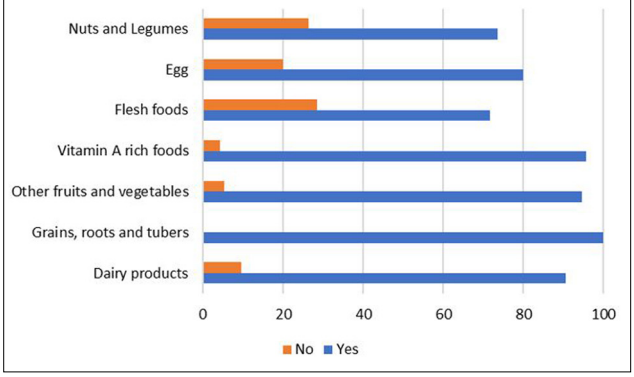


Fig. 5. Consumption of different food groups among the children (N = 95).



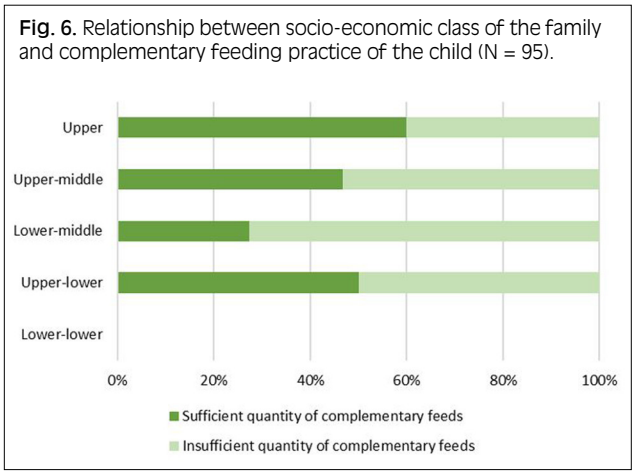


Fig. 6. Relationship between socio-economic class of the family and complementary feeding practice of the child (N = 95).

on adequate feeding was seen in older mothers, this may be ascribed to the fact that most of these children were 2nd born. Higher proportion of children (69.23%) of working mothers consumed adequate quantity of complementary feeds which could be explained by the financial self-reliance of the mother.

Using validated questionnaires and direct interview of the caregivers by the investigators could be stated as the strengths; however, the recall method could result in overestimation or underestimation of the measure of the child's dietary consumption due to recall and social desirability biases, which may be the limitations of this study. As this was a hospital-based prospective study, selection bias might have also affected the result. Community-based studies are required to represent the values in the general population. Another limitation of this study was the short timescale over which the study was undertaken.

Conclusion

Age-appropriate complementary feeding ensuring growing infants are fed nutritionally rich complementary foods is a major challenge in developing countries like India. Studies conducted in India have shown that proper utilization of existing health services can bring about drastic improvements in infant and young child feeding practices. Attention should be directed towards socio-economic empowerment especially education of female children, regular health-care visits and access to a community-based IYCF counselling support system to implement knowledge about optimal feeding practices. It is also imperative to create public awareness to stop the spread of misconceptions and to provide authentic information about appropriate infant feeding practices.

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Conflict of interest statement

The authors declare no conflict of interest.

Authors' contributions

Study concept and design: SG, JJ, SG and MR. Analysis and interpretation of data SG, JJ, SG: drafting the manuscript: SG, JJ and SG; critical revision of the manuscript for important intellectual content: SG and SG.

Patient consent for publication

Parental/guardian consent obtained.

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HEALTH PROMOTION

Knowledge and attitudes on smoking cessation of e-cigarettes: a mixed-methods study of pharmacy students in Surabaya, Indonesia

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Keywords

Attitude • E-cigarettes • Knowledge • Pharmacist students • Smoking cessation

Summary

Background. *Pharmacy students as candidates for health workers who will take part in smoking cessation. Knowledge and attitudes of smoking cessation can help map the behavior of pharmacists in the future. This study aimed to explore knowledge and attitudes on smoking cessation of e-cigarettes with the mixed methods study of pharmacist students.*

Method. *This research was conducted in Januari-Juni 2021 in Surabaya. The research design was mix-method with sequential explanatory strategy. The variables were knowledge and attitudes on smoking cessation of e-cigarettes. The sample in this qualitative approach was derived from a sample of quantitative data. Respondents were interviewed in depth until the data reached the saturation level in order to obtain good and usable qualitative data.*

Results. *This study involved 31 respondents. The highest level of knowledge about dangers of e-cigarettes, especially related to nicotine (100% of respondents answered correctly). The highest positive level of attitude about dangers of e-cigarettes, especially e-cigarettes harmful to passive smokers (27% of respondents had positive attitude). Cigarettes were harmful to lung and cardiovascular health, regarding the dangers of passive smoking, some agree and disagree. Non-smokers didn't need to be recommended for e-cigarettes, e-cigarettes can be recommended for tobacco smokers, e-cigarettes cause addiction, and e-cigarettes can be a good recommendation for those who want to carry out smoking cessation. Regulation of e-cigarettes in Indonesia was considered to be lacking and needs to be improved.*

Conclusions. *Pharmacist students have a high level of knowledge and a positive attitude towards smoking cessation.*

Introduction

Smoking is a public health threat in the world that causes death. Indonesia is the fifth largest producer of tobacco leaf and also the largest producer and exporter of cigarettes in the world. In fact, Indonesia is also the third largest cigarette consumer in the world [1]. Indonesia is one of the countries with the largest smoking prevalence in the world. In 2012 the prevalence percentage of male smokers, which was 67%, was much higher than female smokers, which was 2.7% [2]. The government has tried to limit the number of smokers, one of which is by restricting cigarette advertising in Government Regulation No. 109/2012 article 39 [3], but the number of smokers is still large. Several types of diseases that can be triggered by smoking include cardiovascular disease, chronic respiratory disease, digestive disorders, which can cause death [4-6].

The losses due to smoking in terms of health and economy make the smoking cessation program the main choice of treatment for smokers. Although many pharmaceutical products have been used to stop smoking, they are only able to make smokers stop temporarily [7, 8]. This is because the nicotine in cigarettes causes dependence. Nicotine stimulates acetylcholine receptors on dopamine-containing neurons, thereby causing an increase in dopamine in the central brain reward system. Nicotine peaks, a temporary activation of the brain reward system, followed by a gradual decrease in nicotine levels, to a point of withdrawal that can only be relieved by smoking a cigarette. Nicotine causes a pleasant feeling that makes smokers addicted to continue smoking. When smokers try to reduce or try to quit smoking, it can cause symptoms of anxiety and restlessness. The longer the nicotine content in the body, the stronger the smoking behavior, so that smokers are increasingly difficult to leave cigarettes [9]. Research by Lorensia et al. [10], shows that quitting smoking is complex and not easy. All of the study respondents who failed to quit smoking had known the dangers of smoking, and had tried to quit smoking because smoking affects health and economic factors.

Now many smokers are switching to using e-cigarettes, which are increasing rapidly. E-cigarette users report buying e-cigarettes to help quit smoking, reduce cigarette consumption, and continue to want to 'smoking', but with a reduced risk of health hazards. Other surveys also show that many smokers try e-cigarettes for reasons that e-cigarettes can deliver nicotine into the bloodstream and reduce tobacco use [11-14]. In addition to providing

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nicotine, e-cigarettes are believed to be able to change the habits of someone who is used to holding the cigarette to be smoked. E-cigarettes can help smokers to continue to consume cigarettes but without going through the burning process [15]. However, the use of e-cigarettes is still controversial.

However, there was not enough evidence to claim e-cigarettes can help a person to quit smoking and it was not recommended to recommend e-cigarettes because they can cause nicotine addiction problems and can increase the risk of chronic disease and other health problems. E-cigarette users have reason to use e-cigarettes as a smoking cessation therapy [12, 16]. In previous research on knowledge and attitudes as a predisposition to smoking behavior in the vapor community or e-cigarette users [17, 18]. There was a relationship between knowledge, attitudes, and perception of e-cigarette users [19-22]. In another study conducted by Aghar et al. [22], which was conducted on 3,652 respondents aged 18 to 24 years. The results showed that 63.3% of respondents had low or less knowledge of the use of e-cigarettes, but more than 50% of respondents had a positive attitude or supported the use of e-cigarettes. This study aimed to explore knowledge and attitudes on smoking cessation of e-cigarettes with the mixed methods study of pharmacist students. Pharmacists as one of the health workers play an important role in the smoking cessation program. University of Surabaya pharmacy students who are prospective pharmacists are required to carry out the role of pharmacy listed in the Good Pharmacy Practice guidelines which include four main activities, namely: promotive, preventive, curative and rehabilitative [23]. Activities that have been determined, promotive or preventive activities can be carried out in order to create vigilance for e-cigarette users [24].

Method

Research design

This study used mixed-method research method by combining two data, namely: quantitative data and qualitative data so as to produce a more comprehensive explanation. The design strategy was sequential explanatory strategy, so that quantitative data obtained in the form of the level of knowledge and attitudes of subjects who use e-cigarettes then the data was re-analyzed and used to obtain qualitative data with a sequential explanatory strategy design. Data collection was carried out from Januari-Juni 2021 in Surabaya, East Java, Indonesia, through filling out questionnaires. The ethics committee of the Stikes Harapan Bangsa approved the study protocols (No. 055/C/I/SHB/2021).

Research variable

The variables were knowledge and attitudes on smoking cessation of e-cigarettes. Knowledge was divided into 2 groups, namely high (if the respondent answers the questionnaire with a correct value of > 60% of the total knowledge questions) and low (if the respondent answers the questionnaire with a correct value of 60% of the total knowledge question). Attitudes were divided into 2 groups, namely positive and negative. The attitude level was good if the individual answers the attitude statement with a total score of more than 66.7% of the maximum score and the less attitude level when the individual answers the attitude statement with a total score of more than 66.7% of the maximum score.

Population and sample research

The population was male students at a private university in Rungkut sub-district, Surabaya. The criteria of this research subjects were: > 18 years old and no other respiratory or cardiovascular disease which can affect the measurement of lung function. The sampling method used was purposive and snowball sampling method. Respondents were recruited consecutively until data saturation. The respondents were encountered in several public places on campus where students commonly smoked. The smokers who were participants in this study were asked to introduce the authors to their friends/relatives who were then approached as participants.

Method of collecting data in statistics and data analysis method

The questionnaires containing questions and statements aimed at determining the level of knowledge and attitudes towards the use of e-cigarettes. This instrument was designed from various research articles that have been traced and then validated and to determine whether an instrument is valid or not by looking at the r_{count} value. The value of r_{count} must be greater than the value of r_{table} so that the questionnaire was declared valid. The instrument reliability test was carried out by testing its reliability with SPSS 25 software using the Cronbach's method. The questionnaire was declared reliable if the Cronbach's alpha value was greater than 0.6.

The sample in this qualitative approach was derived from a sample of quantitative data that has been previously collected and each question point in the quantitative data was analyzed again. Respondents were interviewed in depth until the data reached the saturation level in order to obtain good and usable qualitative data. In collecting qualitative data this will be done by interviewing the respondents. The data from the interviews were analyzed in an early stage, namely transcribing the results of the coding interviews with the following coding stages: (1) Open coding by simplifying the results of interview transcripts with respondents. The results of the interviews were simplified according to the answers given by the respondents in order to represent the themes studied; (2) Axial coding which aims to organize various categories, link between these categories and find core categories; (3) Selective coding was the last stage, which was choosing the core category and connecting it with other categories to get the main theme in the research.

Result

The research had been done, 31 respondents had been successfully obtained to fill out the questionnaire and continued with in-depth interviews. The characteristics of respondents were age, medical history, and profile history of using e-cigarettes (Tab. I). Most of respondents were in the age of 20-21 years (15 of 31) and had no comorbidities (18 of 31) (Tab. I).

Table II described the history of smoking e-cigarettes from the respondents. Most respondents use e-cigarettes for < 1 year (18 of 31) and use it every day (23 of 31). The biggest reason for using e-cigarettes was wanting to quit smoking or as a switch from tobacco cigarettes (26 of 31).

The level of knowledge of respondents about e-cigarettes related to smoking cessation can be seen in Table III. There were 5 topics observed, namely dangers of e-cigarettes, their effects on health, the flow of e-cigarettes with smoking cessation, smoking cessation programs, and their relation to regulation. The highest level of knowledge about dangers of e-cigarettes, especially related to nicotine (100% of respondents answered correctly). The lowest average score on the topic of the

Tab. I. Frequency distribution of characteristics.

Respondent characteristics		Frequency (n: 31)	Percentage (%)
Age (years)	18-19	14	45.16
	20-21	15	48.39
	22-23	2	6.45
Disease history	Dyspepsia	10	32.36
	Hipertensi	3	9.68
	Tidak ada penyakit penyerta	18	58.06

Tab. II. Frequency distribution of e-cigarette use history.

Frequency distribution of e-cigarette use history		Frequency (n: 31)	Percentage (%)
Long time using e-cigarettes	1 year	13	41.96
	< 1 year	18	58.06
Frequency of using e-cigarettes	Every day	23	74.19
	Often (> 3x a week)	5	16.13
	Sometimes (1-3x a week)	3	9.68
Reasons for using e-cigarettes	Want to quit smoking (previously/currently using cigarettes)	26	83.87
	Just want to try	5	16.13
For those who want to quit smoking with e-cigarettes (n: 26). The desire to do smoking cessation before	Ever	28	90.32
	Economic factor	***8***	***25.81***
	Health factor	***13***	***41.94***
	Environmental factor	***5***	***16.13***
	Self factor	***2***	***6.45***
	Never	3	9.68
Reasons for failure to quit smoking that have been done before	Discomfort in the mouth	12	38.71
	Restlessness and headache	10	32.26
	The feeling of wanting to smoke again due to environmental factors	6	19.35
	Never tried to quit smoking	3	9.68
Reasons for smoking using e-cigarettes	Nicotine reduction can be self-regulated	20	64.52
	Cheaper than tobacco cigarettes	6	19.35
	Does not cause bad breath	4	12.90
	Does not cause smoke	1	3.23
The benefits that have been obtained in the use of e-cigarettes on the frequency of smoking	Quit smoking tobacco	5	16.13
	Frequency is decreasing	16	51.61
	Permanent	7	22.58
	The frequency of smoking actually increases	3	9.68
Benefits of using e-cigarettes on health	Breath feels easier	11	35.48
	Weight begins to increase/appetite increases	8	25.81
	Reduced bad breath	5	16.13
	Permanent	7	22.58

Tab. III. Knowledge of e-cigarette smoker related to smoking cessation.

Knowledge of e-cigarette smoker related to smoking cessation		Respondents who answered correctly	
		Frequency	Percentage (%)
Knowledge about the dangers of e-cigarettes	Nicotine content	31	100
	Propylene glycol content	28	90.32
	Flavoring content	25	80.65
The dangers of e-cigarettes for health	Dangers for lung and cardiovascular function	27	87.10
	Relationship with nutritional intake due to decreased appetite	23	74.19
	The risk of drug abuse	24	77.42
The role of e-cigarettes in smoking cessation	Use of e-cigarettes with gradual reduction in nicotine (reduces addiction)	30	96.77
	The use of e-cigarettes in reducing the risk of disease	27	87.10
	The difference between e-cigarettes and tobacco cigarettes is related to health	17	54.84
Smoking cessation program	Relation to medicine	30	96.77
	Relation to physical activity	17	54.84
	Relation to healthy diet	17	54.84
	Relation to comorbidities	29	93.55
E-cigarette regulations and smoking cessation programs	E-cigarette regulations in Indonesia	17	54.84
	Regulation of smoking cessation program in Indonesia	19	61.29

role of e-cigarettes related to smoking cessation, which is related to the difference between e-cigarettes and tobacco cigarettes (54.84% of respondents answered correctly); and smoking cessation program in relation to physical activity (54.84% of respondents answered correctly) and relation to a healthy diet (54.84% of respondents answered correctly); and regulation of e-cigarettes in Indonesia (54.84% of respondents answered correctly) (Tab. III).

The level of attitude of respondents about e-cigarettes related to smoking cessation can be seen in Table IV. There were 3 topics observed, namely the dangers of e-cigarettes, role e-cigarettes in smoking cessation, and their relation to regulation. The highest positive level of attitude topic about dangers of e-cigarettes, especially e-cigarettes harmful to passive smokers and used of e-cigarettes the best choice in smoking cessation (27 of respondents had positive attitude). The lowest average score on regulation of e-cigarettes in Indonesia (5 of respondents had positive attitude) (Tab. IV). Table V showed the results of the classification of knowledge and attitudes of e-cigarette smokers related to smoking cessation, indicating that most respondents had high level of knowledge (921 of 31) and most respondents also had positive attitude level (18 of 31). The results of in-depth interviews with several snippets of respondents' answers can be seen in Table VI.

Discussion

Most respondents were between 20-21 years old (Tab. I), which was young age. Age can affect a person's knowledge and attitudes. Aging is associated with two areas of change that may increase the importance of knowledge in later life. First, aging is associated with declines in efficiency of cognitive processes. Second, knowledge, representing the long-term products of

Tab. IV. Attitude of e-cigarette smoker related to smoking cessation.

Attitude of e-cigarette Smoker related to Smoking Cessation		Respondent's answer (n: 31)	
		Positive	Negative
The dangers of e-cigarettes for health	Are e-cigarettes harmful to lung and cardiovascular health?	21	10
	Are e-cigarettes harmful to passive smokers?	27	4
The role of e-cigarettes in smoking cessation	Should e-cigarettes be recommended to non-smokers?	6	25
	Should e-cigarettes be recommended for tobacco smokers?	11	20
	Do e-cigarettes cause dependence/addiction?	17	14
	Is the use of e-cigarettes the best choice in smoking cessation?	27	4
E-cigarette regulations and smoking cessation programs	Is there a need for special regulations for e-cigarettes?	5	26
	Is smoking regulation in Indonesia correct?	13	18

Tab. V. Classification of knowledge and attitude of e-cigarette smoker related to smoking cessation.

	Classification	Frequency (n: 31)	Percentage (%)
Knowledge	High	21	67.74
	Low	10	32.26
Attitude	Positive	18	58.06
	Negative	13	41.93

Tab. VI. In-depth interview findings.

Topics	Question	Quote respondents answer
The dangers of e-cigarettes for health	Are e-cigarettes harmful to lung and cardiovascular health?	*"I think smoking is harmful to health, but health factors are also influenced by genetics and heredity"*
		"Smoking is dangerous because it can cause chronic lung disease, lung cancer, or complications of heart disease. Especially when it comes to old age"
		"I don't think it's dangerous, because nicotine levels are low"
	Are e-cigarettes harmful to passive smokers?	*"E-cigarettes tend to be safer for passive smokers than tobacco cigarettes, because e-cigarette smoke does not contain harmful substances"*
		"Probably not dangerous, because it doesn't burn tobacco like tobacco cigarettes"
The role of e-cigarettes in smoking cessation	Should e-cigarettes be recommended to non-smokers?	*"no need, because it can cause addiction due to nicotine"*
	Should e-cigarettes be recommended for tobacco smokers?	*"Yes, because quitting smoking can use e-cigarettes by reducing nicotine levels gradually"*
		"No, because in Indonesia, e-cigarettes have not officially become part of the smoking cessation program"
	Do e-cigarettes cause dependence/addiction?	*"Yes, of course because it contains nicotine"*
	Is the use of e-cigarettes the best choice in smoking cessation?	*"No, because it is at risk of drug abuse. The use of e-cigarettes must be able to control oneself so that efforts to stop smoking are successful"*
		"I can, when I use vapor I can not smoke for 6 months but after I don't use vapor anymore, I will go back to smoking"
E-cigarette regulations and smoking cessation programs	Is there a need for special regulations for e-cigarettes?	*"E-cigarette regulations must be clear, because there are many sales in online shops but no one is supervising them"*
		"There needs to be a standard for e-cigarettes, to be able to protect the safety of the user community"
		"If the regulation is e-cigarettes are legalized, then pharmacists must play a role in providing them in a standard manner and providing special counseling"
	Is smoking regulation in Indonesia correct?	*"I think it's still not enough, because the warning in the form of a picture of the condition when you are sick on cigarette packaging still can't reduce the desire of smokers to quit."*
		"It is necessary to clarify the sanctions for smokers who smoke in public places"
		"The smoking cessation program in Indonesia is still not widely known by the public and health workers themselves"

processing, is relatively well-preserved in later life as reflected in stable levels of crystallized ability [25]. Possible predictors of factors associated with smoking cessation included age, socioeconomic status, health conditions, and severity of nicotine dependence [26]. Comorbidities that the respondent has are dyspenia and hypertension (Tab. I). Gastroesophageal reflux disease (GERD), functional dyspepsia (FD), and irritable bowel syndrome (IBS) are common gastrointestinal diseases. Several studies have shown a significant occurrence of overlap among these 3 diseases, and cigarette smoking was significantly associated with overlaps among GERD, FD, and IBS in Japanese adults [27]. Tobacco smoking is regarded as an aetiological factor of GERD, by reducing the lower oesophageal sphincter pressure, facilitating reflux. Tobacco smoking reduces the production of saliva rich in bicarbonate, which is important for buffering and clearance of acid in the oesophagus [28].

Based on in-depth interview data, there are 3 topics discussed, namely:

a. The dangers of e-cigarete for health.

"I think smoking is harmful to health, but health factors are also influenced by genetics and heredity".

"Smoking is dangerous because it can cause chronic lung disease, lung cancer, or complications of heart disease. Especially when it comes to old age".

Previous studies have identified variants in genes encoding proteins associated with the degree of addiction, smoking onset, and cessation. There were differences in the genotype frequencies of SNPs in genes related to nicotine metabolism and nicotine dependence. Slow metabolizers smoked more cigarettes per day than intermediate and normal metabolizers [29].

"E-cigarettes tend to be safer for passive smokers than tobacco cigarettes, because e-cigarette smoke does not contain harmful substances".

E-cigarette liquid was a solution that usually contains nicotine, glycerol, propylene glycol and various flavour additives. When thermally treated, it emits what was commonly referred to as a 'vapour', which is in fact a fine aerosol consisting of liquid and solid particles, dispersed in a gas. Following inhalation using the e-cigarette, the aerosol is delivered into the user's lungs, while during expiration the remaining aerosol is exhaled into the environment, forming an unintentional pollution source of particulate matter (second-hand aerosol or SHA) to which bystanders are potentially exposed. 30-minute passive exposure to e-cigarette emissions revealed immediate alterations in respiratory mechanics and exhaled biomarkers, expressed as increased fres and reduced FeNO [30].

b. The role of e-cigarettes in quitting smoking

"Yes, because quitting smoking can use e-cigarettes by reducing nicotine levels gradually"

"Yes, of course because it contains nicotine".

"No, because it is at risk of drug abuse. The use of e-cigarettes must be able to control oneself so that efforts to stop smoking are successful".

The benefits of e-cigarettes in smoking cessation show that previous studies by Malas et al. [31] showed that more people probably stop smoking for at least six months using nicotine e-cigarettes than using nicotine replacement therapy (3 studies, 1498 people), or nicotine-free e-cigarettes (4 studies, 1057 people). Nicotine e-cigarettes may help more people to stop smoking than no support or behavioral support only (5 studies, 2561 people). For every 100 people using nicotine e-cigarettes to stop smoking, 10 or 11 might successfully stop, compared with only six of 100 people using nicotine-replacement therapy or nicotine-free e-cigarettes, or four of 100 people having no support or behavioral support only [31]. Other research showed that as consumer products, in observational studies, e-cigarettes were not associated with increased smoking cessation in the adult population. In RCTs, provision of free e-cigarettes as a therapeutic intervention was associated with increased smoking cessation. E-cigarettes should not be approved as consumer products but may warrant consideration as a prescription therapy [32].

c. E-cigarette regulations and smoking cessation programs

"E-cigarette regulations must be clear, because there are many sales in online shops but no one is supervising them".

"There needs to be a standard for e-cigarettes, to be able to protect the safety of the user community"

"If the regulation is e-cigarettes are legalized, then pharmacists must play a role in providing them in a standard manner and providing special counseling".

"The smoking cessation program in Indonesia is still not widely known by the public and health workers themselves".

Discussions related to e-cigarettes have actually been going on since 2014. There are many obstacles, one of which is because e-cigarettes have not been included in health products. For (conventional) cigarettes, there are clearly rules in PP 109 [3], while at this time (e-cigarettes) only public goods are sold without permission from the Ministry of Health. E-cigarettes circulating in Indonesia are included in electronic goods. So there is no regulation whether it is prohibited or restricted. In Brunei Darussalam, Malaysia, Singapore and Vietnam, e-cigarettes are equated with tobacco cigarettes, so they use the existing regulations in terms of importation, sales, and so on. Meanwhile in Cambodia, there is a new regulation at the level of a Ministry Circular which regulates the import, sale, and places that are not allowed to consume e-cigarettes. Thailand chose to combine existing regulations and issue new regulations related to e-cigarettes. Indonesia itself is a country that is very slow in responding to e-cigarettes, as evidenced by the recently released regulations regarding e-cigarettes where the regulation only states that liquids sold on the market must include customs duties which will then be taxed at 57%. The existence of regulations regarding e-cigarettes in several Southeast Asian countries should be a consideration for the State of Indonesia in making regulations regarding e-cigarettes, especially those related to the health of their users [33].

Pharmacy as one of the health workers must play a role in the smoking cessation program. Skill-based training for pharmacists and pharmacy assistants, ongoing practical support, investment in electronic resources and the promotion of pharmacy-based smoking cessation to GPs were found to be crucial for the improvement of smoking cessation services provided by community pharmacists [34]. Community pharmacists could provide effective smoking cessation treatment because they offer easy access to members of the community. They were well placed to provide both advice on the correct use of smoking cessation products and behavioral support to aid smoking cessation. Community pharmacists can provide effective behavioral support to people trying to stop smoking. However, this conclusion was based on low-certainty evidence, limited by risk of bias and imprecision [35].

The sample size was pooled until the collected data reached saturation, and no additional data were found. Although the saturation parameter was still determinant,

how the saturation parameter found in previous methodological studies and the community norm sample size may best inform [36].

Conclusions

The highest level of knowledge about dangers of e-cigarettes, especially related to nicotine (all respondents answered correctly). Meanwhile, all knowledge topics showed > 50% of respondents who answered correctly. The highest positive level of attitude about dangers of e-cigarettes, especially e-cigarettes harmful to passive smokers. Regulation of e-cigarettes in Indonesia was considered to be lacking and needs to be improved.

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HEALTH PROMOTION

The methodology of the Italian Health Behaviour in School-aged Children (HBSC) 2018 study and its development for the next round

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Keywords

Healthy behavior • Epidemiological surveillance • Adolescents • Italy

Summary

Introduction. *The Italian "Health Behaviour in School-aged Children" (HBSC) is a national surveillance system that collects data on health and well-being among adolescents aged 11, 13 and 15 years attending school. It is part of the HBSC Research Network, an international alliance of researchers from 45 European and North American countries and regions started in 1982.*

Methods. *All countries and regions participating in HBSC must adhere to a common international standard protocol developed and systematically updated by the entire HBSC Network. Data collection occurs every four years. Italy joined the international Network in 2000 and, to date, five waves (in 2002, 2006, 2010, 2014 and 2018) have been carried out. From 2010 the Italian HBSC is representative at regional level and in 2017 the base of the "Surveillance system for risk behaviours in 11-17 year-olds" became part of the Prime Ministerial Decree "Identification of surveillance systems and registries of mortality, tumours and other diseases". Cluster sampling is used, with school class as primary sampling unit, and two validated questionnaires are used to collect the information.*

Results. *In 2018, the Italian HBSC involved 3,608 classes and 58,976 students. The average response rates were 86% of sampled classes and 97% of students achieving a national and regional representative sample for youths of all age groups (19,504 eleven-year-old, 20,554 thirteen-year-old and 18,918 fifteen-year-old). The national coordination group prepared a standardized format for disseminating the results locally and indicating areas for intervention A national report and some articles have been published. The next round, which will take place in the 2021-2022 school year, will also involve a representative sample of students of grade four of secondary schools (adolescents aged 17 years) and use on line questionnaires.*

Conclusions. *Over 3 decades at international and 2 decades at national level 35 years have demonstrated that HBSC methodology and its results are useful for monitoring and deepening the knowledge on the most critical issues of adolescents' well-being.*

Introduction

All over the world there are about 1.2 billion adolescents (10-19 years), who represent the 16% of the world's population [1]. Investing in children's health and well-being is a priority public health strategy; adolescence is a formative phase of life during which models of growth, development and behavior lay the foundation for health in the adult stage and in subsequent generations [2]. Adolescents experience rapid physical, cognitive and psychosocial growth. This affects how they feel, think, make decisions, and interact with the world around them. At this age, children also gradually acquire decision-making autonomy about important behaviours and lifestyles that may affect their present and future health, such as eating habits, physical activity, alcohol and tobacco consumption, and use of drugs [3-7]. Several studies have used national health surveys and multicenter studies to estimate children's and adolescents' behaviour trends worldwide and in specific regions, or to carry out cross-country comparative analyses [8-10]. In addition, cross-country analyses enable to observe disparities between the states with the lowest and highest rates of health inequalities and to detect policy differences [11], to assess the effectiveness of interventions that have already been implemented, and to plan priorities for health care resource allocation. In order to investigate and monitor the behaviour and health choices of teenagers aged 11, 13 and 15 years and to provide information to support education and health promotion policies, researchers from England, Finland and Norway launched the Health Behaviour in School-aged Children (HBSC) study in 1982 [12, 13]. The HBSC was among the first international surveys on adolescent health.

Since then, the study participation has grown and in 2018, 50 countries and regions took part. At first, producing valid and reliable data was challenging, due to the range of structural and practical factors such as different school systems in which fieldwork was conducted, the compliance with a common research protocol, the

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issues around language and translation, and the different research capabilities of the participating countries. In the last 35 years, these challenges have been faced and overcome.

The increased focus on the HBSC study has resulted in greater methodological scrutiny and the need for a sharper focus on continuous improvement.

Italy joined the HBSC international network in 2000 and five data collections have been carried out since then (2002, 2006, 2010, 2014, 2018). The first two surveys were coordinated by the Universities of Turin, Padua and Siena, with the support of the Ministry of Education, and carried out on a sample of about 5000 children, with a national representativeness [14, 15].

From 2010, the HBSC survey was promoted and funded by the Ministry of Health and the Istituto Superiore di Sanità (ISS) (Italian National Institute of Health) which joined the three Universities (Padua, Siena and Turin) in its coordination in the 2010 and 2018 waves. HBSC became the first Italian population-based, national and regional representative surveillance system with the aim to acquire knowledge of well-being, health behaviours and social environments in early adolescence through the involvement of more than 65,000 students aged 11, 13 and 15 years [16-18].

The Prime Ministerial Decree (DPCM) of 3 March 2017, "Identification of surveillance systems and registries of mortality, tumours and other diseases, implementing Decree-Law n. 179 of 2012", included the "Surveillance system for risk behaviours in 11-17 year-olds" among those of national and regional significance, and identified the Italian National Institute of Health as its national reference body. This paper provides an overview of the methods employed in 2018 and the developments for the next data collection which will be carried out in 2022.

Materials and methods

The Italian 2018 HBSC survey mostly followed the international HBSC protocol 2017-2018 [19-21]. The main differences lay in the representativeness and the sample size involved in the Italian surveillance. In fact, as all the 20 Italian Regions demanded a representativeness for their territory, the sample size was much larger than the one requested by HBSC protocol. The target population consisted of boys and girls aged 11, 13 and 15 years enrolled in the first and third grades of lower secondary school and the second grade of upper secondary school.

The Italian HBSC 2018 survey represents a success of the collaboration between school and health systems. Many professionals were involved in the HBSC national network and contributed to its activities. School head teachers, class teachers and other school staff together with health workers were involved. Regional and Local Health Unit (LHU) coordinators were nominated for each Region in order to carry out and support activities at regional level. The national coordination HBSC 2018 Group, consisting of the National Institute of Health and the Universities of Turin, Siena and Padua, coordinated the activities and performed training sessions on 2018 survey methods for the health workers. In addition, the school's personnel involved in HBSC 2018 survey was informed on data collection procedures by the Provincial School Offices.

Sampling

The sampling procedures adopted in 2018 in Italy followed the rules agreed internationally. Cluster sampling was used, with school class as primary sampling unit [21]. More details about this type of sampling method and the main disadvantages are described elsewhere [22]. From the complete list of public and private schools and classes of each Region, provided by the Ministry of Education, the team of the Italian National Institute of Health extracted a representative sample of classes at national and regional level for each age group (11, 13 and 15 years-old). As in the last 2 surveys, the sample size for each Region was about 1,200 children for each age group. This sample size was corrected for the general population of students, in order to achieve a precision of ± 3.5% (95% confidence interval, 7% between the minimum and maximum limits for a binomial proportion 50%). Over-sampling of 5% for third grade of lower secondary school and of 15% for the second grade of upper secondary school was applied in order to compensate for students that repeated the class; additional over-sampling of 10% was considered for those expected to refuse to participate. From the Italian national sample, a sub-sample of 1,500 students of each age group (proportional to the Italian regional populations) was randomly extracted to be the Italian contribution to the international HBSC study [19].

The Ethics Committee of the Italian National Institute of Health approved the 2018 protocol, including the use of an opt-out consent form, in which parents deny the consent for the participation of their son and the lack of a returned form was considered to imply consent to adolescents' participation. For the protection of privacy, as indicated by the international protocol, procedures have been adopted to avoid the possible identification of single individuals according to the European laws [23].

Instruments used for data collection, procedures and analysis

Data were collected using two questionnaires prepared by the international and national HBSC networks: one aimed at adolescents aged 11, 13 and 15 years and the other at school head teachers (which was optional but was adopted by all Italian Regions). Both questionnaires contained a "core" section of common questions (mandatory); "optional" packages concerning questions on specific topic areas which countries could choose either to include or not in their questionnaires; "country-specific" questions related to issues of national importance.

Survey questions covered a range of health indicators and health-related behaviours as well as the life circumstances of adolescents. Questions are subjected to validation studies and piloting at national and

international levels and the outcomes of these studies are often published [17, 19, 20]. Questions about the use of drugs (cannabis), gambling and sexual behaviour were addressed only to 15 year olds.

In the 2018 round, the Italian national coordination group decided to add some questions about sexual behaviour, social media and nutrients intake, and to modify some questions on smoking and alcohol in the adolescent questionnaire. For dietary habits, the weekly consumption of cereals (e.g. cornflakes, muesli, bread, pasta and rice), legumes (e.g. peas, beans and chickpeas) and savoury snacks was added to mandatory information on fruit, vegetables, sweets and soft drinks containing sugar; furthermore, a question on the frequency of family meals was included in the questionnaire. Additionally, given the growing importance of the phenomenon, students were asked if they had participated in or suffered cyberbullying actions in the last 2 months. A focus on social media regarding contacts and online communications with friends, parents, brothers/sisters, classmates and teachers was introduced. Through a set of 9 questions on the use of social networks (for example Facebook, Twitter, Instagram, Ask and You-tube) and instant messages (for example, WhatsApp, Facebook Messenger), an internationally validated scale with a synthetic indicator that identifies the "problematic" use of these social tools was also created.

The topics of mandatory and optional sections, and the packages included in the questionnaire specifically addressed to Italian adolescents are reported in Table I. The questionnaires were self-completed, anonymous and administered in the classroom during school hours. As per protocol, questionnaires, once completed, were collected and immediately placed in an envelope sealed by health workers. Demographic information collected (gender, year and month of birth, class frequency,

Tab. I. List of sections in the 2017-2018 international HBSC protocol, for the adolescents' questionnaire; main section (mandatory) and "optional" section.

Sections	Mandatory Packages [a]
Social context	School, peers, family, social inequality, migration, electronic media communication (special topic)
Health outcomes,	Body image, body mass index, injuries, positive health
Health behaviours	Eating habits (breakfast consumption, food frequency consumption, family meals), toothbrushing, MVPA/VPA
Risk behaviours	Alcohol use, tobacco use, cannabis use, sexual health, bullying, fighting
Sections	**Optional Packages** [b]
Chronic conditions	Disability and chronic conditions
Eating and dieting	**Food frequency questionnaire** [b], **weight reduction behaviour** [b], food related lifestyle aspects, body image
Electronic media mommunication	Fear of missing out, **Internet gaming disorder** [b]
Family culture	Current family situation, quality of family communication, school related parental support, young carers, parental monitoring, family activities
Gender	Gender norms
Health literacy	Health literacy for school aged children
Leisure	Leisure activities (organised and unstructured)
Migration	Attitudes to migrants, feelings toward immigrants, perception of unequal treatment
Neighbourhood	Neighbourhood social features, neighbourhood structural features
Peer culture	Generalized trust and empathy
Physical activity	**Screen time related sitting** [b], active travel to school, environmental factors, motivations
Positive health	Short depression scale (Center for Epidemiologic Studies Short Depression Scale (CES-D-R 10)), sleep and chronotype, sleep quality, medicine use, Strengths and Difficulties Questionnaire (SDQ), Cohen Perceived Stress Scale, WHO (Five) Well-Being Index, positive youth development, positive mental health through active engagement, Positive mental health through sense of unity, positive mental health through social self-efficacy
Puberty	**Pubertal status and timing** [b]
Risk behaviour	Smoking at present, number of cigarettes smoked in last 30 days, **beverage-specific frequency of alcohol use,** drinking motives, use of electronic cigarettes, use of waterpipe, frequency of substance use in last 12 months, **illicit drug use in lifetime, peer substance use, adolescent gambling** [b]
School	School related competence/autonomy, school related reward, **participation/theory of organised participation** [b]
Sexual health	Romantic experiences, **first sexual intercourse** [b]
Social inequalities	**Parental education** [b], perceived family wealth
Spiritual health	Spiritual health measure
Violence & injuries	**Serious injuries (past 12 months)** [b], **specific forms of bullying perpetration and victimisation** [b], suicidal ideation and behaviour, violence (physical fighting and weapon carrying), child abuse and maltreatment

[a] The sections dealing with cannabis use and sexual habits are present only in the questionnaires addressed to 15-year-olds; [b] In bold the optional topics included in the 2017-2018 questionnaire administered in Italy.

nationality, nationality of parents) can never be traced back to the individual student.
The main aspects investigated by the questionnaire were detailed in a previous publication [22].
A single alpha-numeric code was adopted to link the students' questionnaires of a specific class with that compiled by the head teacher so as to obtain detailed analyses of young people habits possibly depending on school environment and policies.
A "class form" to be filled during the day of the survey was also prepared. It provided more detailed information on present or absent students on the day in which the survey was performed.
In total, 70,000 copies of the questionnaires for the adolescents were printed on special paper suitable for optical data reading. Similarly to the last two Italian HBSC surveys, in 2018 the lists of selected classes and schools, together with the questionnaires, were sent to the regional coordinators. They shared all the materials with the health workers involved in the data collection in each LHU.
The LHU informed teachers of the objectives and the methods of the survey and described the teachers' responsibilities.
The teachers were provided with:

- a descriptive presentation of the project;
- a letter/guide including all procedures;
- a letter from the head teacher to the parents containing a form to be returned in case the parents refused the consent for their child's participation.

The questionnaire for head teachers was transmitted to the LHU personnel on the day the questionnaire was administered to adolescents. On the day of data collection, teachers gave the health workers information on adolescents not participating in the survey and the questionnaire which had been completed by the head teachers. After the teachers and the health workers had distributed the questionnaires to the students and given them all the instructions, they filled out the class form.
The regional coordinators were responsible for gathering all questionnaires in their Regions and delivering them to the company which had been contracted to create a data-file by optical data reading. The data-file of each Region was sent to the Italian National Institute of Health which was responsible for checking the data, creating a national database and analyzing the data. According to the international protocol, data on young people outside the target age groups were removed. Stata software version 16.1 was used for all statistical analyses.

Results

Data collection began in late March 2018 and lasted until the end of June 2018. Overall, the Italian HBSC 2018 survey consisted in 65,358 questionnaires addressed to adolescents. The records were cleaned and compiled following the study protocol. The final sample included 3,608 classes and 58,976 students: 19,504 11 year-olds, 20,554 13 year-olds and 18,918 15 year-olds. All Italian Regions (N = 21) were involved. In 2018, the response rate was 86.3% among the sampled classes (in comparison to 90% in 2014, 96% in 2010, 66% in 2006 and 77% in 2002). Table II shows the percentages of classes' participation in the Italian Regions: in 14 (66.7%) the participation was above 94%, in 3 (14.3%) between 81 and 83%, in 2 (9.5%) between 50 and 60% and in 2 (9.5%) below 50%.
The national coordination group prepared a standardized format for reporting the obtained results, and regional coordinators were able to download it from a reserved area of the website of the national survey. The format of the regional report complied with the technical report prepared by the international coordination group. The regional reports enabled health workers to locally disseminate the results and indicate areas for intervention [24].
In October 2018, a national congress was organized to disseminate the 2018 Italian HBSC results. Representatives from all Italian Regions took part in this event. The main results were relaunched by the national and local press. In October 2020, the national report was published, focusing on regional and gender differences in adolescents' health behaviours [18]. In addition, the results of the Italian HBSC 2018 survey on adolescents' eating habits [25], sexual behaviours [26], alcohol use [27] and problematic social media use (PSMU) [28] were published in a monographic section of the "Annali dell'Istituto Superiore di Sanità". A comparison between Italian and international HBSC results was also reported in the same issue [29].

Discussion and conclusions

Adolescence is a window of opportunity, given its critical developmental timing in terms of identity, age, and vulnerability. During adolescence, an individual acquires the physical, cognitive, emotional, social, and economic resources that are the foundation for health and wellbeing in later life [2]. Adolescence is an ideal time for health promotion on nutrition, exercise, mental health, relationships, drug use – such as smoking, vaping, and alcohol consumption – domestic and gang violence, positive sexuality, and active political citizenship [30 32].
For all these reasons, there is a need for public health surveillance systems to monitor countries and regional variations and temporal trends of health behaviours and health outcomes among adolescents. The HBSC study is an efficient way to collect data on adolescents' health and health-related behaviours. In the last 3 decades, the use of a common protocol has enabled the collection of comparative cross-national data in the HBSC participating countries, providing a platform for systematic data collection at the country level.
Since 2010, the methodology of both national and international HBSC study protocols was adopted by all the Italian Regions making it possible to collect information on well-being and health-related behaviours

Tab. II. Classes' participation in the 20 Italian regions in the 2017-2018 HBSC.

	First grade of middle school		Third grade of middle school		Second grade of secondary school		Total N. sampled classes	Total N. enrolled classes	% of classes' participation
	N. sampled classes	N. enrolled classes	N. sampled classes	N. enrolled classes	N. sampled classes	N. enrolled classes			
Piemonte	58	58	62	62	66	65	186	185	99.5
Valle d'Aosta	60	34	60	34	61	23	181	91	50.3
Lombardia	60	58	65	63	68	67	193	188	97.4
Provincia autonoma Bolzano	61	51	64	56	76	56	201	163	81.1
Provincia autonoma Trento	55	53	60	55	71	67	186	175	94.1
Veneto	134	111	132	110	133	110	399	331	83.0
Friuli V.G.	58	58	63	62	73	72	194	192	99.0
Liguria	58	56	60	57	65	59	183	172	94.0
Emilia Romagna	54	53	56	55	64	62	174	170	97.7
Toscana	58	58	60	60	68	67	186	185	99.5
Umbria	58	22	65	27	65	35	188	84	44.7
Marche	54	54	58	58	64	63	176	175	99.4
Lazio	58	57	62	62	68	68	188	187	99.5
Abruzzo	59	58	60	57	67	67	186	182	97.8
Molise	62	49	69	56	68	57	199	162	81.4
Campania	60	60	61	61	67	64	188	185	98.4
Puglia	55	55	58	56	64	61	177	172	97.2
Basilicata	64	34	65	35	71	28	200	97	48.5
Calabria	65	65	69	69	69	69	203	203	100.0
Sicilia	58	58	61	59	71	71	190	188	98.9
Sardegna	64	39	69	40	72	42	205	121	59.0
Tot	1313	1141	1379	1194	1491	1273	4183	3608	86.3

on representative samples of 11, 13 and 15 year-olds in each Region. This allowed researchers to monitor trends in the following 8 years, to compare regional data and provide a guidance to policy-makers to define strategies and interventions aimed at improving adolescent's health and decreasing inequalities. The results of the 2018 survey show a high level of participation of schools and students, proving the feasibility of the survey and its methodology. The success of the survey has been achieved thanks to the contribution, participation and professionalism of the network of health workers and teachers.

One limitation of the HBSC study is that the information collected is self-reported rather than measured or observed. For example, it is well-known that Body Mass Index calculations based on self-reported height and weight are underestimates, but they are widely used in cross-sectional studies [33-35]. However, in order to improve the quality of collected data, the international Research Protocol was updated based on the scientific evidence at each survey [19, 20, 30].

The cross-sectional design of the surveillance has another limitation: if it is well suited for estimating prevalence and studying trends, it doesn't allow researchers to infer causalities. Nevertheless, cross-sectional studies enable the investigation of several age groups and are less time-consuming and costly than longitudinal studies [36]. In these studies, analyses of variables in participant groups are performed for the same moment in time and causal associations among variables cannot be assessed [37]. The limitation of cross-sectional studies is called a 'cohort issue' [36]. The absence of a time dimension (as opposed to longitudinal studies) hinders the interpretation of the findings [38]. Moreover, the results obtained by cross-sectional studies are prone to selection bias [36] and might erroneously report on changes in a given variable depending on the respondents' age, while it might be caused by differences between cohorts. Longitudinal studies, on the other hand, might incorrectly observe changes in a given variable as depending on the respondents' age, while actually the changes are rather attributable to the specific or historical period in which the repeated measurements were conducted [39]. Moreover, studies observing trends are essential for monitoring the variables investigated, checking the efficiency of interventions, both during an intervention itself and in the follow-up after its end, and providing data for future studies or interventions.

As such, these trend studies have an essential role in research and in putting research findings into practice.

Moreover, the strength of the HBSC study lies in its long history (over 30 years for the international study and about 20 in Italy), continual development, and ability to compare data at international and national level, as well as analyzing the changes in various areas of adolescents' lives in relation to their health and well-being. This enables the monitoring of trends in, for instance, physical activity, sedentary behaviour, and overweight/obesity [40-42], but also in other health indicators in school-aged children [36-39].

The next round of HBSC will take place in the 2021-2022 school year. The Italian national coordinating group, in agreement with the Ministry of Health, the Ministry of Education and the Regions, decided to include also a representative sample of students of grade four of the upper secondary school (adolescents aged 17 years). The adolescents and head teachers will fill in the questionnaires on line and, only in case of particular need (e.g. unavailability of digital devices, lack of Internet access), a paper version will be used. An optional package of questions about COVID-19 will be introduced in Italy, as well as in the majority of the participating countries.

In conclusion, the results over 35 years have demonstrated that the HBSC methodology and its findings are useful for both monitoring and for research on the most critical issues currently characterizing adolescents' lives, their health and health behaviours.

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Conflicts of interest

None declared.

Ethics approval

The Italian HBSC study protocol and questionnaire were formally approved by the Ethics Committee of the Italian National Institute of Health (PROT-PRE876/17, 20 November 2017).

Authors' Contributions

GL, PN: conceptualized and drafted the manuscript, contributed to interpretation of data and wrote the paper.
AS, PD, SC: contributed to the analysis and interpretation of data for the manuscript execution; wrote the paper.
LC, AV, DG: critically reviewed the manuscript
All Authors revised the manuscript and gave their contributions to improve the paper. All authors read and approved the final manuscript.

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HEALTH PROMOTION

Prevention of cardiovascular diseases and diabetes: importance of a screening program for the early detection of risk conditions in a target population

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Keywords

Screening • Prevention • Cardiovascular diseases • Diabetes

Summary

Introduction. *Cardiovascular diseases and diabetes are two of the main causes of morbidity and mortality worldwide. In their genesis, an important role is played by some behavioural risk factors that may induce the onset of further risk factors represented by hypertension, prediabetes, overweight and obesity. This study aimed to show the importance of the screening methodology for early detection of these risk conditions in order to reduce the burden of cardiovascular diseases and diabetes complications.*
Methods. *We carried out a screening programme involving a cohort of people aged 45-60 in which risk factors for cardiovascular diseases and diabetes were evaluated. The subjects were then classified into four groups according to the risk conditions.*
Results. *A high percentage (27.0%) of the sample had some alteration in the detected anthropometric and/or clinical-laboratory parameters but were unaware of this condition and, consequently, not under therapeutic treatment.*
Conclusions. *The screening programme allowed the early detection of hypertension and prediabetes or full-blown diabetes conditions in subjects who were unaware they had a pathological condition, and consequently to proceed with adequate investigations and start healthy lifestyles/pharmacological therapies. Overall, the results highlight the need to anticipate these screening campaigns, especially in men, to increase the effectiveness of the prevention programmes.*

Introduction

Cardiovascular diseases (CVDs) and diabetes represent the leading causes of disability and mortality worldwide and result in remarkable social and economic costs [1]. An estimated 17.9 million people died from CVDs in 2016 (31% of all global deaths), of which 85% were caused by heart attack and stroke [2, 3]. In Italy, CVDs are responsible for 44% of all deaths [4]. Moreover, according to the World Health Organization (WHO), from 1980 to 2014 the global prevalence of diabetes among those > 18 years old has risen from 4.7 to 8.5% [5].
In the onset of CVDs and diabetes, an important role is played by some behavioural risk factors such as an unhealthy diet, physical inactivity, tobacco use and harmful use of alcohol [6-10]. Particularly, the important role of healthy nutrition in the prevention of these diseases has been stressed, especially for fighting oxidative stress [11-16]. Stopping tobacco use, reducing salt intake, a healthy diet rich in fruits and vegetables, regular physical activity and restraint in the use of alcohol reduce the risk of these diseases [17-19]. Therefore, people at high risk for the onset of CVDs and diabetes need early detection and management and behavioural/pharmacological treatment [20].
Unlike many cancer types, for CVDs and diabetes there are no consolidated screening programmes to contain the disease burden. Because this public health approach needs to be expanded, we performed a screening intervention in a target population, aimed to make an early identification and treatment of possible pathological conditions and to prevent the onset of complications.

Methods

In the period January-December 2019, in a cohort of people aged 45-60 years resident in Messina, Italy, we assessed unhealthy lifestyles (smoking habits, alcohol consumption, unhealthy diet and sedentary life) and/or the presence of clinical and laboratory conditions (hypertension, hyperglycaemia, overweight/obesity). According to the plans, the programme should have lasted 3 years but, due to the COVID-19 pandemic outbreak, only the first year was carried out. A flowchart of the programme, consisting of several steps, is provided in Figure 1.

Sample enrolment

The participants were extracted from the list of the Messina Health Agency's assisted registry office and enrolled through written invitation sent to their domicile. People aged 45-60 years were invited.

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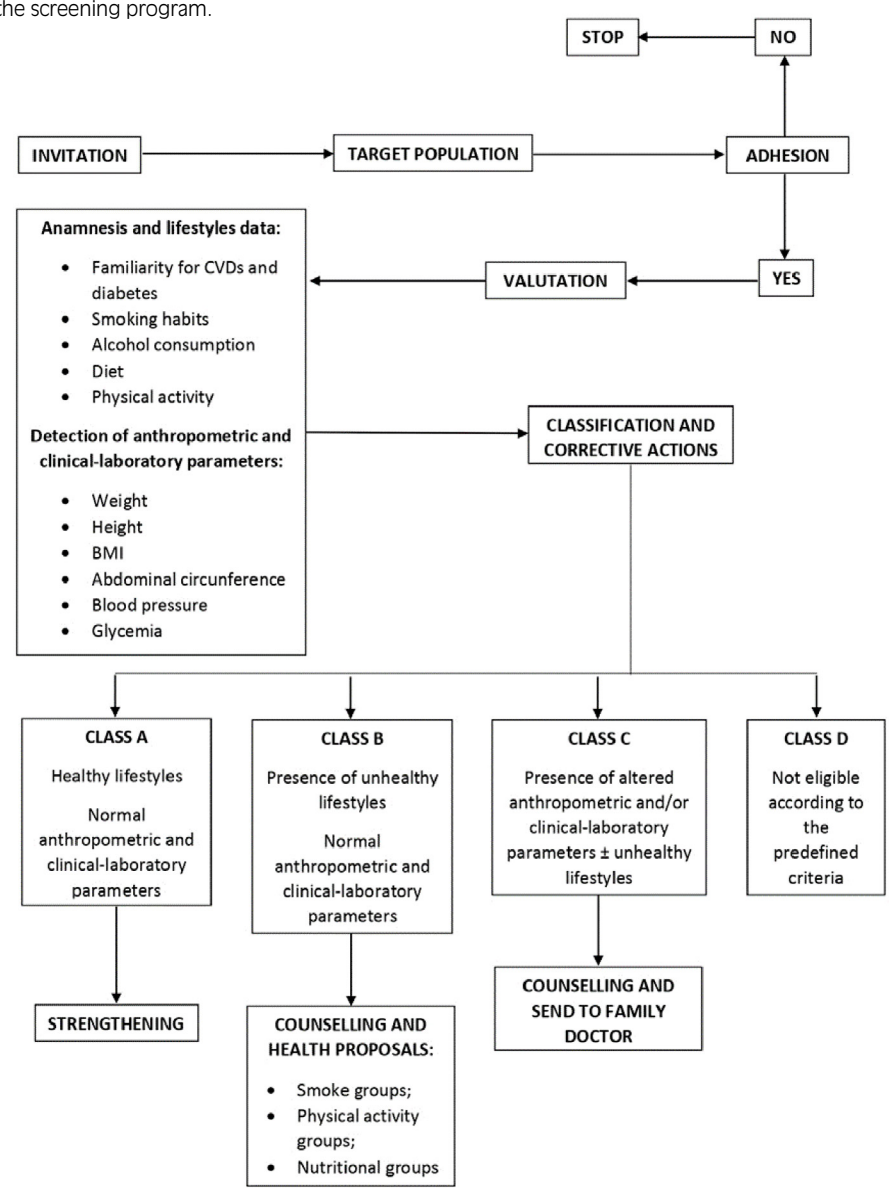
Fig. 1. Flow-chart of the screening program.



Selection of eligible subjects

Specifically trained physicians carried out a direct interview to obtain anamnesis and lifestyle variables and measure some parameters (weight, height, body mass index (BMI), abdominal circumference, blood pressure and blood glucose) in subjects who joined the programme. For the evaluation of lifestyle, we referred to the guidelines of the Italian PASSI (Progress of Healthcare Companies in Italy) Surveillance of the Istituto Superiore di Sanità (ISS) [21].

Concerning the smoking habit, we divided subjects into non-smokers (who had never smoked or had smoked fewer than 100 cigarettes in their whole life and currently do not smoke), former smokers (who currently do not smoke and who had quit smoking for at least 6 months), occasional smokers (smokers who do not smoke every day) and daily smokers (who smoke at least one cigarette every day).

The alcohol-related risk was based, for each sex, on the amount of alcohol usually ingested and the modality of alcohol consumption, which was measured in alcoholic units (AU). One AU corresponds to 12 grams of ethanol, an amount approximately contained in a can of beer (330 ml), a glass of wine (125 ml) or a small glass of liqueur (40 ml). Considering as moderate consumption the ingestion of two AUs and one AU on average per day for men and women, respectively, levels above these thresholds were classified as 'at risk'.

Since a daily intake of 400 grams of fruit or vegetables, equivalent to five portions of 80 grams, is recommended, on this basis we discriminated between a healthy and an unhealthy diet.

Concerning physical activity, we distinguished the subjects as active, partially active or sedentary. Physically active people do a heavy job with considerable physical effort and/or do moderate activity for 30 minutes at least 5 days/week and/or intense activity for more than 20 minutes, at least 3 days a week. Partially active persons

do not work physically hard but do some physical activity in their leisure time, without reaching the levels recommended by the guidelines. Sedentary persons do neither a heavy job nor perform physical activity in their leisure time.

Regarding the anthropometric parameters, we considered for both sexes a BMI value < 25 as normal, 26-30 as overweight, 31-35 as moderately obese, 36-40 as obese and > 40 as severely obese. Concerning abdominal circumference, we considered as normal a value as < 88 cm for women and < 102 cm for men.

Finally, we evaluated the blood pressure and blood glucose levels as clinical-laboratory parameters. For the methodology to correctly measure the blood pressure values, we followed the American Heart Association guidelines for the prevention, detection, evaluation and management of high blood pressure in adults [22]. We considered as normal blood pressure values < 140 mmHg for systolic and < 90 mmHg for diastolic. Considering as normal values of glycaemia < 100 mg/dl under fasting conditions and < 140 mg/dl 2 hours after a meal, values of 101-125 mg/dl under fasting conditions and 140–199 mg/dl 2 hours after a meal indicate a reduced glucose tolerance (prediabetes condition) while values ≥ 126 mg/dl under fasting conditions and ≥ 200 mg/dl were considered as full-blown diabetes.

Unfortunately, during the outpatient visit we had no possibility of performing blood collections for the evaluation of cholesterolaemia.

Sample classification

After the counselling and the physical and clinical examination, the subjects were classified into four groups, named:

- subjects with a healthy lifestyle and without any alteration in the anthropometric and clinical-laboratory parameters;
- subjects with some lifestyle risk but without alteration in the anthropometric and clinical-laboratory parameters;
- subjects with some alteration in the anthropometric and/or clinical-laboratory parameters, whether or not accompanied by unhealthy lifestyle variables, and not under therapeutic treatment as they were unaware of their unhealthy condition;
- ineligible subjects already under therapeutic treatment for hypertension and/or diabetes.

Statistical analysis

Using the Statistica program (version 10), Lilliefors and Shapiro–Wilk normality tests were used to assess data distribution patterns of continuous variables, which were expressed either as mean ± standard deviation (SD) or as median and interquartile intervals. The impact of the independent variables was evaluated using chi-square and non-parametric Mann–Whitney tests. The relationship between clinical and anthropometric parameters and independent variables was evaluated by Spearman test. Multivariate regression analysis using a priori models was performed to assess in both sexes the role of the same covariates in the variability of clinical-laboratory parameters. These included age, educational level, familiarity for hypertension and diabetes, BMI and all the behavioural variables.

Results

In the period considered, we sent 12,000 written invitations to the target population, of which 9,000 were actually delivered. Of the latter, 873 people (9.7%) joined the programme, of which 583 (66.8%) were women and 290 (33.2%) were men, with a mean age of 54.0 ± 4.1 and 54.1 ± 4.2 years, respectively (P ns). Only 1.6% were of foreign nationality.

Table I shows the socio-demographic characteristics and the anamnesis results of the entire sample.

Following anamnestic evaluation, 224 (25.7%) subjects, of which 89 were men and 135 women, were already being treated for hypertension and/or diabetes (not eligible for the screening programme: class D); 29.0 and 21.1% of the men and women were hypertensive while 5.5 and 3.8% were diabetic, respectively. Although a high percentage of the entire sample had a family predisposition to hypertension, diabetes and/or both pathologies, the percentages were higher in ineligible subjects (P < 0.01; data not shown).

Table I also reports the anthropometric and clinical parameters of the eligible subjects. BMI was lower in women (P < 0.05) and 45.5% of them were within the normal value (< 25). Gender differences were confirmed, stratifying the sample into five classes (Tab. I). In men, the mean abdominal circumference was 96.8 ± 11.2 cm (min-max: 71-150 cm) while in women it was 87.6 ± 11.1 cm (min-max: 61-126 cm). Considering as normal values of abdominal circumference of ≤ 102 and ≤ 88 cm in men and women, respectively, a not significant higher percentage of women showed values above this limit. As expected, in both genders higher values were observed for the all anthropometric parameters in the not eligible subjects compared to the health ones, with mean BMI and abdominal circumferences equal to 29.4 ± 4.6 (P < 0.001) and 102.1 cm ± 10.9 (P < 0.001) in men and 29.5 ± 5.3 cm (P < 0.001) and 95.8 ± 13.8 cm (P < 0.001) in women.

Among lifestyle variables, differences between genders were observed in the eligible subjects for smoking and alcohol use (P = 0.01 and P < 0.001 respectively). With regard to smoking habits, 55.2% of men and 67.4% of women were non-smokers while 18.4 and 10.3%, respectively, were former smokers. The percentages of daily smokers were comparable (19.4 and 17.0% in men and women, respectively) while the significant inter-gender differences were due to higher and lower percentages of women recorded in the non- and former smoker groups, respectively. The percentages of regular drinkers were 33.0% in men and 14.5% in women and almost all were moderate drinkers in both genders. Only a very low fraction of subjects (2.1%) had an alcohol consumption above the threshold value. A difference

Tab. I. Socio-demographic characteristics of the tested sample and anthroprometric and clinical parameters of the eligible subjects (* percentages of subjects with values above the limit, fixed to 102 and 88 cm in men and women respectively).

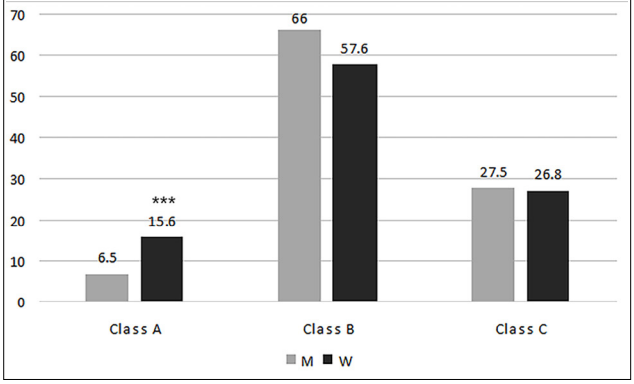
Percentages of socio-demographic characteristics and anamnestic results in the tested sample			
	Men (290)	Women (583)	P value
Age	53.6 ± 4.5	53.4 ± 4.3	ns
Educational level Lower school diploma Higher school diploma University degree	 33.7 45.8 20.5	 30.6 47.0 22.4	 ns
Workers	83.5	55.7	< 0.01
Not eligible (class D)	31.3	23.5	ns
Familiarity for hypertension	57.7	66.2	< 0.05
Familiarity for diabetes	44.0	54.2	< 0.01
Familiarity for both the conditions	26.2	36.1	< 0.01
Anthroprometric and clinical-laboratory parameters in the eligible subjects			
	Men (202)	Women (448)	P value
BMI < 25 (normal weight) % 26-30 (overweight) 31-35 (moderately obese) 36-40 (obese) > 40 (hyper obese)	27.1 ± 4.4 35.0 47.0 13.0 3.0 2.0	26.2 ± 4.6 45.5% 36.2 11.9 5.4 1	< 0.05 < 0.05
Abdominal circumference %	33.8	42.3	ns
Blood pressure (mmHg) Diastolic Systolic	 81 (80-90) 130 (120-140)	 80 (75-90) 120 (115-135)	 < 0.001 < 0.001
Fasting blood glucose (mg/dL)	102 (94-112)	98 (92-106)	ns
Post-prandial blood glucose (mg/dL)	102 (97-113)	102 (94-110)	< 0.05

was observed in dietary habits since a higher percentage of men (55.7 *vs* 45.8% of women) do not regularly eat the advised five portions/day of fruits and vegetables ($P < 0.05$). No differences were observed between genders for physical activity. Stratifying the sample into three classes, 34.3 and 30.8% were physically active, 36.8 and 32.6% were partially active and 28.9 and 36.6% were sedentary, among men and women, respectively. No differences were observed for lifestyle variables between eligible and ineligible men while, in women, the two groups differed for smoking habits and physical activity. In fact, while 67.4% of eligible women had never smoked, this percentage dropped to 47.1% in those not eligible ($P < 0.01$). The opposite was observed for sedentary lifestyle, more frequent in ineligible women (48.9 *vs* 36.6; $P < 0.01$).

Both diastolic and systolic pressure were higher in men ($P < 0.001$) and in 23.9% of them the values of at least one of the two parameters exceeded normal values of 90 and 140 mmHg, respectively. Instead, only 15.7% of the women showed a similar pathological condition (Tab. I). Similarly, to the blood pressure values, fasting and post-prandial blood glucose allowed us to identify, in this cohort of apparently healthy subjects, a fraction of new hyperglycaemic subjects (23.9% of men and 4.7% of women; $P < 0.001$). Although in hyperglycaemic subjects we observed mainly a prediabetes condition, 2.5% of the men and 0.7% of the women had full-blown diabetes. It should be added that in 8.6% of men, both hypertension and hyperglycaemia were observed, while in women only 3.4% had a similar pathological condition.

Figure 2 shows the classification of the eligible subjects according to the detected clinical-laboratory and anthropometric parameters.

Fig. 2. Classification of the eligible subjects according to the detected clinical-laboratory and anthropometric parameters.



Similarly to ineligible subjects, a higher familiarity for both hyperglycaemia and hypertension was observed in the subjects in class C, in comparison to classes A and B ($P < 0.01$). Only 12.7% of men and 20.8% of women in class C had no family history of either of the two pathological conditions and their inclusion in class C was mainly due to a slight alteration of diastolic and/or systolic pressure for men and high or very high anthropometric parameters for women.

Clinical and anthropometric parameters were related to lifestyle variables, socio-demographic characteristics and anamnestic data in a much-diversified manner in the two sexes (Tab. II).

Tab. II. Spearmann test performed to evaluate the role of independent variables on the clinical-laboratory and anthropometric parameters.

	Diastolic blood pressure		Sistolic blood pressure		Fasting blood glucose		Post-prandial glucose		BMI		Abdominal circumference	
	M	W	M	W	M	W	M	W	M	W	M	W
	R (p)	R (p)	R (p)	R (p)	R (p)	R (p)	R (p)	R (p)	R (p)	R (p)	R (p)	R (p)
Age		0.167 (0.0004)		0.214 (< 0.0001)								
Educational Level								-0.124 (0.0222)		-0.217 (< 0.0001)		-0.175 (0.0002)
Working Activity	0.163 (0.021)		0.163 (0.021)				-0.185 (0.045)	0.124 (0.0225)				-0.096 (0.0434)
Familiarity for hypertension												
Familiarity for diabetes	0.166 (0.018)		0.166 (0.018)							0.150 (0.0015)		0.134 (0.0047)
Familiarity for both	0.174 (0.013)		0.174 (0.013)							0.138 (0.0034)		0.138 (0.0034)
Diastolic pressure						0.318 (0.0009)			0.365 (< 0.0001)	0.361 (< 0.0001)	0.331 (< 0.0001)	0.316 (< 0.0001)
Sistolic pressure									0.289 (< 0.0001)	0.265 (< 0.0001)	0.345 (< 0.0001)	0.194 (< 0.0001)
BMI	0.289 (< 0.0001)	0.361 (< 0.0001)	0.289 (< 0.0001)	0.265 (< 0.0001)		0.316 (0.0010)	0.190 (0.037)	0.181 (0.0007)			0.849 (< 0.0001)	0.819 (< 0.0001)
Abdominal circumfe-rence	0.345 (< 0.0001)	0.316 (< 0.0001)	0.345 (< 0.0001)	0.194 (< 0.0001)		0.255 (0.0086)		0.107 (0.0473)	0.849 (< 0.0001)	0.819 (< 0.0001)		
Fasting glucose		0.318 (0.0009)										0.255 (0.0086)
Post-prandial glucose									0.190 (0.0375)	0.181 (0.0007)		0.176 (0.0011)
Smoking habit												
Physical activity		-0.118 (0.013)		-0.136 (0.004)			-0.236 (0.010)			-0.236 (< 0.0001)		-0.289 (< 0.0001)
Alchol Intake									0.306 (0.0055)		0.153 (0.03)	
Dietary habit		-0.144 (0.002)		-0.161 (0.0007)						-0.130 (0.0058)		-0.103 (0.0292)

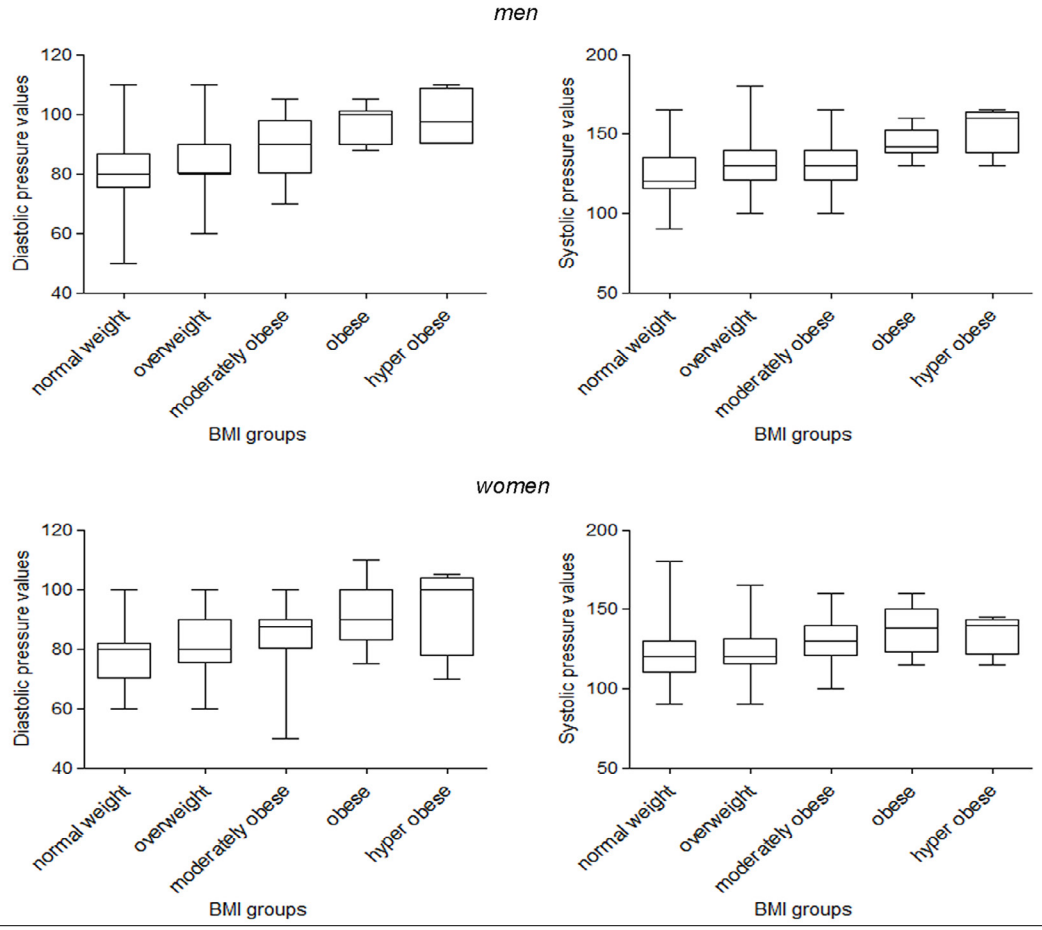
M: men; W: women.

Anthropometric parameters were an exception because in both sexes they were significantly and directly related to blood pressure values (Fig. 3).

Moreover, in men diastolic and systolic values were higher in the workers and in the presence of familiarity both for diabetes and for both pathological conditions. As expected, and surprisingly not observed in men, the blood pressure in women was related to their age in addition to familiarity for hypertension while it was negatively related to physical activity and dietary habit. In men, fasting and post-prandial blood glucose were poorly correlated with the examined variables and, limited to post-prandial glycaemia, the levels were directly related to BMI and inversely related to working and physical activity. In women, both glycaemic values were strongly related to the anthropometric parameters; in addition, fasting blood glucose was related to diastolic values while the post-prandial one was directly related to working activity and inversely related to educational level. Some anthropometric parameters were related to behavioural variables, such as alcohol consumption in men, while in women they were inversely related to physical activity and dietary habit. In the latter, a protective role was also shown by educational level and working activity.

The multivariate analysis (Tab. III) confirmed these data, highlighting in men the effect of hypertension and diabetes familiarity for the respective pathological conditions. Instead, in women, blood pressure values were mainly influenced by age and BMI, while a protective role was played by dietary habit and no variable was related to blood glucose values. Only in women, the analysis underlined the effect of biological, socio-demographic and lifestyle variables and familiarity on anthropometric parameters. Diabetes familiarity was directly related, while age and educational level were inversely related, to BMI (P = 1.192, −0.066 and −0.438, respectively). Instead, abdominal circumference was directly related to age and inversely related to physical activity (P = 0.112 and −0.515, respectively),

Fig. 3. Box-plots showing the correlation between BMI groups and blood pressures values in eligible men and women.



Tab. III. Multiple regression analysis in eligible subjects.

	Men			Women	
Covariates	Diastolic	Sistolic	Fasting blood glucose	Diastolic	Sistolic
R^2 adjusted	0.272 (<0.0003)	0.312 (<0.0001)	0.158 (n.s)	0.196 (<0.0001)	0.165 (<0.0001)
Age				0,274 (0.0003)	0,180 (<0.0001)
Educational level					
Familiarity for hypertension	4.94 (0.03)	6.35 (0.005)			
Familiarity for diabetes			15.89 (0.03)		
Familiarity for both					
BMI	0,561 (0.02)	0.753 (0.002)		0,385 (<0.0001)	0.467 (<0.0001)
Smoking habits					
Alchol intake			-18.23 (0.047)		
Physical activity					
Dietary habit				-1.105 (0.010)	-1.217 (0.006)

For each covariate are reported p value and, in the bracket, p value. In the women both fasting and post-prandial blood glucose were not related to any of the examined covariates while in men this was observed for post-prandial only.

emphasizing the appropriateness of the latter in women over 40 for whom BMI can be paradoxically normal, due to the depletion of bone tissue and muscle mass.

Discussion

Because of their heavy impact on the general population worldwide in terms of burden, mortality, disability and costs, it is necessary to diagnose CVDs and diabetes and their risk factors as early as possible in order to modify unhealthy lifestyles and to treat affected people. Cancer screening programmes have been active in several countries but similar programmes for preventing the other most common chronic diseases have not yet been routinely used. Our screening programme to detect unhealthy lifestyles and/or the presence of altered clinical-laboratory conditions (principal risk factors for the onset of these diseases) highlights this deficiency. This was the first initiative in our territory about this

kind of disease and it allowed us to widen the concept of screening to a large part of the population flanking the already existing oncologic screening programmes. The combination of these two fundamental prevention practices will allow a very large part of the population to be reached and the burden of chronic diseases to be reduced.

The response rate was quite low, probably because it was the first project in our territory regarding these diseases and people are only familiar with oncological screening. This result, in association with the prevalence of women in our sample, shows that awareness of this issue needs to be improved and highlights that the consolidated habit of being screened for breast and cervical cancers makes women more aware of the importance of prevention. Targeted studies should identify the reasons for not joining, considering that risk habits and unrecognized altered parameters may be present in the unresponsive subjects, to whom the percentages in classes C and D can be hypothesized as relevant by inferring our results. Moreover, it should be underlined that our results have arisen from only the first planned year of the programme. We can certainly state that the COVID-19 pandemic determined a loss of opportunity for a certain number of subjects to be diagnosed early and consequently treated with an appropriate therapeutic regimen, if the programme had been continued according to the expected times.

Female gender and a medium–high social and cultural status were the most important variables that pushed subjects to join the programme, further underlying the low awareness of poorly educated people to be responsible for their own health. An informative health campaign must increase knowledge on this topic, improving the response rate of the unresponsive subjects.

The results for men were significantly worse than for women and 30.7% of them were ineligible. Regarding behavioural risk factors, gender differences were observed between non-smokers and former smokers, of which there was a higher and a lower percentage, respectively, of women than men. The number consuming alcohol above the recommended level was low, with no gender difference, underlining the low propensity of the Italian southern population of this age group to abuse alcohol, limiting consumption to during meals [23]. Conversely, half of the sample had an unhealthy dietary habit and more than two-thirds of the sample was sedentary or partially active. An opposite situation between sexes was observed for eating habits and physical activity, which were better and worse, respectively, in women in comparison to men.

The screening programme allowed the early detection of hypertension and prediabetes or full-blown diabetes conditions in subjects who were unaware of their condition. On the basis of the results, the physicians proposed some corrective actions. These included advice to keep a healthy lifestyle for group A, initiatives to correct the wrong lifestyle habits through participation in smoking cessation, gym and/or walking groups, and providing nutritional advice for group B, and sending to the family doctor to set up therapy for group C.

Overall, the results highlight the need to anticipate screening campaigns, especially in men, to increase the effectiveness of prevention programmes. This seems confirmed by the absence in men of age-related effects of blood pressure, underlining the earliest onset of hypertension in the men of our sample.

A further motivation to implement and anticipate prevention is the leading role of hypertension and diabetes familiarity, highly frequent in our area, which can be mitigated by a careful and constant adherence to a healthy lifestyle, started as early as possible [24, 25]. Since, surprisingly, we observed a significant inter-gender difference for these variables, data regarding this information could be affected by a recall bias. However, both bivariate and multivariate analysis highlighted that hypertension and diabetes familiarity are strongly related to risk condition, which was assessed by both early predictors as the anthropometric measures in women and later ones as higher values of diastolic and systolic pressure in men.

The high percentages of subjects with an unhealthy lifestyle, regardless of whether or not there is hypertension and/or diabetes familiarity, stressed the need to plan and frequently re-propose health education campaigns aimed to change risky behaviour and to tailor them, at least by gender, considering the inter-gender differences that can induce a lasting change in behaviour. As expected, our study confirmed that subjects, especially women, with a higher cultural level have a greater tendency to care for themselves as well as being more aware of the importance of healthier behaviours, and in the women in our cohort this independent variable was inversely related to both anthropometric measures and to post-prandial blood glucose level.

A limit of this study was that it did not assess an important and well-known risk factor for CVDs – hypercholesterolaemia – but we think that, despite this limit, the study has an important impact on the epidemiology and prevention of the chronic diseases considered.

Conclusions

Our study confirms the importance of the presence, in national prevention plans, of screening programmes for early detection of the risk factors for CVDs and diabetes and to act promptly in their diagnosis and treatment. However, the non-negligible number of subjects in whom there was early recognition of hypertension and/or diabetes and that ignored their conditions highlights the need to target screening programmes on a younger population, i.e. under the age of 50, especially for men. Due to the COVID-19 pandemic, our programme was stopped but, according to the results of the first year of the project, it is crucial to resume it as soon as possible in order to reduce the burden of these important public health concerns. We can assume that the blockade or in any case the remarkable slowdown in screening

campaigns, such as the one discussed here, is a further damage in terms of health that humanity has suffered from the COVID-19 pandemic.
Our Provincial Health Agency has already performed some investigations to evaluate the spread of infectious diseases in our territory [26-28] and to determine the attitudes and spread the culture of prevention regarding sexually transmitted infections and vaccine prevention [29-31]. Following these results, we intend to extend our field of action by including chronic diseases.

Ethics declarations

The study protocol was promoted and approved by the Sicily Region as part of the 2014-2018 Regional Prevention Plan and by the Messina Provincial Health Agency as part of the 2014-2018 Prevention Plan in the project 2.1-Objectives 1.2.1. All humans research procedures were in accordance with the standards set forth in the Declaration of Helsinki principles of 1975, as revised in 2013. An informed consent was priority obtained by the subjects enrolled in the research. No animals were used in this research.

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Conflict of interest statement

The authors declare no conflict of interest.

Authors' contributions

Conceptualization: ADP, GDA and RC. Methodology: MV and GS. Formal analysis, data curation and writing - original draft: GV and AF. All Authors revised the manuscript and gave their contribution to improve the paper. All authors read and approved the final manuscript.

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NOSOCOMIAL INFECTIONS

Health care-associated infections, including device-associated infections, and antimicrobial resistance in Iran: The national update for 2018

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Key words

Nosocomial infections • Resistance • Surveillance • Mortality • Infection Control

Summary

Introduction. *Surveillance of health care-associated infections (HAIs) is an essential part of an efficient healthcare system. This study is an update on incidence and mortality rates of HAIs in Iran in 2018.*
Methods. *Almost all hospitals across the country (940 hospitals) entered the data of HAIs and denominators to the Iranian Nosocomial Infections Surveillance (INIS) software. Statistics were derived from INIS.*
Results. *From 9,607,213 hospitalized patients, 127,953 suffered from HAI, 15.65% of whom died. The incidence rate of HAI was calculated as 4.2 per 1000 patient-days. Considering relative frequencies among HAIs, Pneumonia (29.1%) and UTIs (25.6%) were the most common types of infection. Ventilator-associated pneumonia (VAP) was the most frequent device-associated infection (DAI) 25.66 per 1000 ventilator-days, and had the highest mortality rate (43.08%). Incidence density of other DAIs was 5.43 for catheter-associated UTI and 2.86 for catheter-associated BSI per 1000 device-days. Medical ICUs had the highest incidence and percentage of deaths (15.35% and 37.63%, respectively). The most causative organisms were Escherichia coli, Acinetobacter baumannii, and Klebsiella pneumonia. The rate of methicillin-resistance Staphylococcus aureus (MRSA), vancomycin-resistant Enterococcus (VRE), and Klebsiella pneumoniae carbapenemase (KPC)-producing bacteria was about 49%, 57%, and 58% respectively.*
Conclusion. *This study provided an overview of HAIs in Iran and indicated that HAIs required special attention both in detection/reporting and in infection control measures. Future studies could be done on adherence rate of DAIs' preventive bundles, interventions via multimodal strategies, evaluating the effect of training, and effect of antibiotic stewardship programs.*

Introduction

Health care-associated infections (HAIs) are amongst the major patient safety problems, which cause significant morbidity, mortality, prolonged hospitalization, and increased health care costs [1]. HAIs are infections that are acquired after admission to a hospital or during the process of care in a health care facility [2]. The prevalence of HAIs varies from 5-7% in Europe and North America to 6-20% in Sub-Saharan Africa, Latin America and parts of Asia [3-10]. Among HAIs, the upmost important and problematic ones are device-associated infections (DAIs) including ventilator-associated pneumonia (VAP), central-line bloodstream infection (CLA-BSI), and catheter-associated urinary tract infection (CA-UTI). Statistics of these infections shows an incidence density of about 5 VAPs, less than 1 CLA-BSI, and 0.5-5 CA-UTI per 1000 device-days in well controlled ICUs of developed countries vs. 20-50 VAPs, 4-12 CLA-BSIs, and about 3-8 CA-UTIs per 1000 device-days in ICUs of some developing countries [7-10].
HAIs' causative organisms vary in different infection types and in different locations (wards, hospitals, states, and countries). Overall, the most important gram negative bacilli are *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, *Acinetobacter baumannii*, *Escherichia coli*, and other Enterobacteriaceae; among gram positive cocci the most prevalent ones are *Staphylococcus aureus*, *Staphylococcus epidermidis*, and Enterococcus Spp. and at the top of fungi list are *Candida albicans* and non-albicans Candida (NAC) species. Antimicrobial resistance has been developed and increased gradually in these organisms during recent years and lead to a global threat [4, 5, 8-11].
Due to the complicated and multifactorial nature of HAIs, without information about the incidence of HAIs and causative organisms, effective programming for infection prevention and control (IPC) is almost impossible. In March 2007, first national nosocomial surveillance guideline was specifically established by the Iranian Center for Communicable Disease Control (ICDC) to report and control HAIs and a software named Iranian Nosocomial Infection Surveillance (INIS) was designed to facilitate data registry and management [6, 12-15]. Under- and over-reporting of HAIs are main challenges in Iran. The results of a blinded retrospective

review of ICUs' medical records in Iran revealed 57.3%-82.2% under-reporting and 8%-15% over-reporting of four types of HAIs [14, 16].
In order to prevent HAIs, it is crucial that physicians, healthcare providers, scientists, and health care authorities have access to information on data at the country level, which can help to develop newer guidelines, make better decisions and necessary modifications. Therefore, we aimed to report the updated data on national surveillance of HAIs regarding the incidence and mortality in Iran.

Methods

Almost all hospitals in Iran (940 hospitals) participated in this study and entered the data of HAIs and denominators to the Iranian Nosocomial Infections Surveillance (INIS) software. This national software has been used by ICDC since the first year of implementation of the surveillance program in 2007 (last update: 2017). Registry is performed on a monthly basis upon completion of individual hospital forms. The forms are completed by a trained infection control nurse who has been assigned to the program in each hospital. The criteria for diagnosis of HAIs are per advice of the ICDC guidelines which are based on the CDC/NHSN case-definitions criteria.

Definitions

The HAIs' diagnostic criteria were as follows [12]. BSI was defined as having a positive blood culture of a known BSI pathogen in one or more blood samples such that the growing organism was not related to infection in another site; or at least one of the following signs or symptoms (fever, chills, or hypotension [Aged ≤1 year: fever, hypothermia, apnea, or bradycardia]). In addition, common commensals were cultured from two or more blood samples drawn on separate occasions.
Symptomatic UTI was defined as fever (T >38C), urgency, frequency, dysuria, suprapubic tenderness, or costovertebral angle pain/tenderness with a positive urine culture of $\geq 10^5$ CFU/mL of no more than two isolated species. Asymptomatic bacteremic UTI was defined as no urinary symptoms and both urine culture and blood culture were positive with an uropathogen.
SSI was defined as purulent discharge from the surgical incision, organisms isolated from an aseptically obtained culture, an abscess involving the deep incision which is found on direct examination, during reoperation, or by histopathologic or radiologic examination; or one of signs or symptoms of infection (pain or tenderness, swelling, redness, or heat), and diagnosis of SSI by the surgeon or attending physician within 30 days of the surgery, or within 90 days for some specific surgeries including ones involving implants.
For Clinically Defined Pneumonia, chest radiographs with one of the following findings (new or progressive and persistent infiltrates, consolidation, cavitation, or pneumatocele [Aged ≤1 year]) are needed plus one of the following (fever, leukopenia or leukocytosis, or altered mental status [Aged >70 years]) and at least two of the following: purulent sputum, or change in character of sputum, or increased respiratory secretions, cough, or dyspnea, or tachypnea, rales or bronchial breath sounds, or worsening gas exchange. Furthermore, for Pneumonia with Specific Laboratory Findings, there needed to be a positive culture (from respiratory secretions, pleural fluid, lung tissue, or blood) or histopathologic evidence of infection such as abscess formation or foci of consolidation with polymorphonuclear cell accumulation in bronchioles and alveoli. For Pneumonia in Immunocompromised Patients, in addition to the radiologic findings and signs/symptoms mentioned above, hemoptysis or pleuritic chest pain were also considered as symptoms; and additional criteria were matching positive blood and sputum cultures with *Candida* spp, or evidence of fungi or *Pneumocystis carinii* from pulmonary-derived specimen.
And finally, the Ventilator-Associated Event defined as at least 20% increase in the minFiO2 or a minimum increase of 3 cm-H_2O in the PEEP (positive end-expiratory pressure) to maintain oxygenation for a sustained period of more than 2 days (VAC: Ventilator-associated condition). And it happened in the setting of an infection (fever, leukocytosis, etc.) and antibiotics are instituted for a minimum of 4 days (IVAC: Infection related VAC). And the detection of respiratory pathogens on cultures or by equivalent techniques (PVAP: Possible VAP).

Data acquisition and statistical analysis

We obtained our data, including demographic features (such as age, gender, ward, date of admission, and date of discharge/death), diagnoses, devices data, microbiologic studies, by using the standard checklists which then entered to INIS system. We acquired items of interest that included the number of hospitalizations, diagnosed HAIs, and deaths. All retrieved forms were finally analyzed by the Iranian Center for Communicable Disease Control (ICDC).

Ethical considerations

This study was approved by the ICDC Research Council and all data were registered under the supervision of the Iran Ministry of Health and Medical Education.

Results

12-month HAIs surveillance reported from 940 hospitals (out of 999 hospitals in total [94% coverage]) were registered in the INIS system during the year 2018. From 9,607,213 hospitalized patients, 127,953 were diagnosed with HAI (cumulative incidence = 1.33%) which was 13.4% higher compared to 2017. This number varied amongst different medical universities (0.14%-3.41%), hospitals (0.01%-33.45%), and departments (0.15%-15.35%). In addition, 30,559,894 patient-days were registered and incidence rate of HAI was calculated as 4.2 per 1000 patient-days (Tab. I).
Considering relative frequencies among HAIs, the most common was pneumonia (29.1%) followed by UTIs

Tab. I. Summary of health care-associated infections (HAIs) in Iran, 2018.

	Pneumonia*	UTI	BSI	SSI	Others	Total
Frequency (Number)	37234	32756	14843	27894	15226	127953
Relative Frequency (% of total infections)	29.1	25.6	11.6	21.8	11.9	100
Incidence (% in 100 admissions)	0.38	0.34	0.15	0.29	0.16	1.33
Incidence (in 1000 patient-days)	1.2	1.1	0.5	0.9	0.5	4.2
Crude Mortality Rate (%)	28.6	12.7	20.5	3.6	8.0	15.65

* Pneumonia: including ventilator-associated pneumonia (VAP) and non-VAP pneumonia. UTI: Urinary Tract Infection; BSI: Blood stream infection; SSI: Surgical site infection; Others: Other than 4 major infections.

(25.6%), SSIs (21.8%), and BSIs (11.6%). Although pneumonia was the most frequent HAI, age-adjusted rates revealed that SSI was the most common HAI in ages 5-44. Among device-associated infections, 25.66 ventilator-associated pneumonias (VAPs), 5.43 catheter-associated urinary tract infections (CA-UTIs), and 2.86 catheter-associated bloodstream infections (CA-BSI) per 1000 device-days were identified. The highest incidence of HAI were reported from medical ICUs (15.35%) followed by burn units (11.98%), general ICUs (10.89%) and transplant units (8.85%). Additional information is shown in Figure 1.

In 28% of cases, infection-causing pathogen was not identified (Fig. 2). This number was 58% in SSIs. The most frequent microorganisms reported in cultures were *Escherichia coli, Acinetobacter baumannii* and *Klebsiella pneumonia* (15.29%, 9.47%, and 6.91%, respectively). The most common germs of the four main infections separately were: Pneumonia/VAP (*Acinetobacter baumannii*, *Klebsiella pneumonia*, and *Pseudomonas aeruginosa*), UTI (*Escherichia coli*, *Klebsiella pneumonia*, and Candida Spp.), BSI (*Staphylococcus epidermidis*, *Staphylococcus aureus*, and *Escherichia coli*), and SSI (*Escherichia coli*, *Staphylococcus aureus*, and *Acinetobacter baumannii*)

Antimicrobial resistance pattern was shown in Table II. The rate of methicillin-resistance S*taphylococcus aureus* (*MRSA*), vancomycin-resistant *Enterococcus* (*VRE*), and *Klebsiella pneumoniae* carbapenemase (*KPC*)-producing bacteria was about 49%, 57%, and 58% respectively. Extended spectrum beta-lactamase (ESBL)-producing gram negative bacilli were reported with a wide range of 35-95% from different centers.

Overall crude mortality rate due to HAIs was 15.65%. The highest percentage of deaths was reported from medical ICUs (37.63%), general ICU (31%) and Surgical ICUs (30%).

Discussion

The incidence of health care-associated infections was

Fig. 1. Incidence of health care-associated infections (HAIs) in different wards in Iran, 2018.

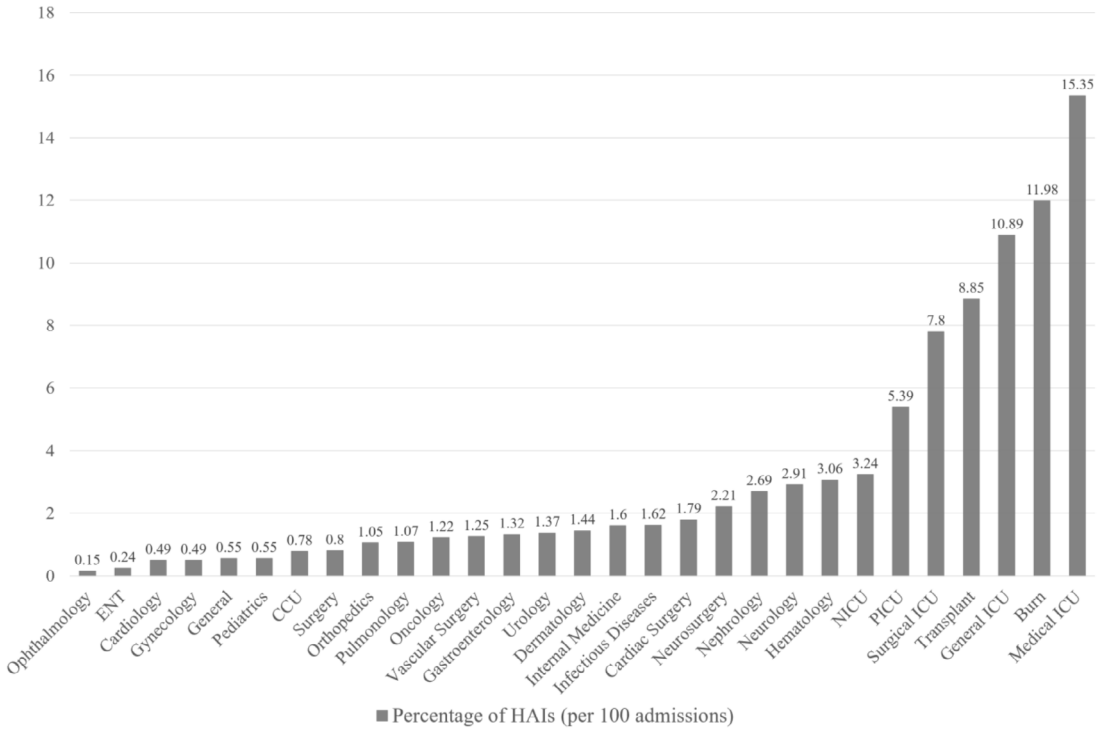
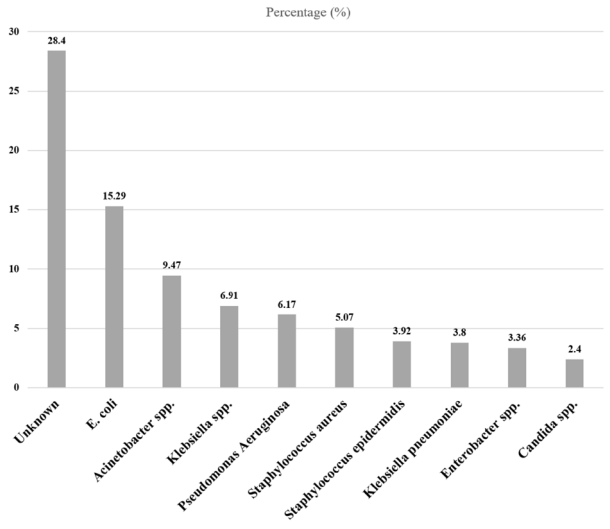


Fig. 2. Microorganisms in health care-associated infections (HAIs) in Iran, 2018.



measured at 940 hospitals in the Islamic Republic of Iran in 2018, with an average reported 1.33% nationwide. Calculation and evaluation the incidence density of HAIs per 1000 patient-days in Iran is also carried out following the recommendation of the WHO, which has been reported 4.2 per 1000 patient-days during the mentioned period of time. Although pneumonia was more common overall followed by UTIs, surveys of infections by age groups showed that SSI is the most prevalent infection at ages 5 to 44 years. In addition, the most common devices-related infections were ventilator and urinary catheter associated infections, respectively. *Escherichia coli, Acinetobacter baumannii* and *Klebsiella pneumonia* were known as the most common causative agents. As we expected, ICUs had the highest incidence of HAIs and the highest death rate.

HAI is one of the most important threatening factors to patient safety that lead to important complications, including increased mortality, delay in surgical wound healing, occupation of hospital beds, increased hospitalization time, increased costs, increased use of antibiotics, development of antimicrobial resistance, and adverse psychological effects on patients and their families [17].

According to the WHO report in 2011, the prevalence of nosocomial infections in Iran (1990-2010) expected to be 8.8% [18] that was confirmed by well-designed studies in the country [19-21]. In the Iranian CDC national report in 2015, the nationwide incidence rate was reported to be 1.18% [16], likewise 1.33% in the current report. According to the study conducted on the accuracy of the routine surveillance system in Iran, these low estimates may be due to the weakness of system in post-discharge surveillance, insufficient personnel training, misinterpretation of HAIs' definitions, high

Tab. II. Antimicrobial resistance pattern of main microorganisms in HAIs in Iran, 2018.

Microorganism	Antibiotic	Resistance (%)	Interpretation
Staphylococcus aureus	Oxacillin / Cefoxitin	**49.29**	**MRSA**
	Clindamycin	59.77	
	Vancomycin	0.04	
Enterococcus spp.	Ampicillin	55.88	
	Vancomycin	**56.56**	**VRE**
	Linezolid	0.76	
Klebsiella pneumonia	3rd or 4th generation cephalosporin	80.41	ESBL-producing
	Fluoroquinolone	68.19	
	Beta-lactamase inhibitor	71.63	
	Carbapenem	**57.83**	**KPC-producing**
Escherichia coli	3rd or 4th generation cephalosporin	70.16	ESBL
	Fluoroquinolone	62.69	
	Beta-lactamase inhibitor	33.96	
	Carbapenem	21.45	
Pseudomonas Aeruginosa	Ceftazidime	57.75	
	Fluoroquinolone	56.57	
	Aminoglycoside	54.97	
	Piperacillin/Tazobactam	54.55	
	Carbapenem	60.06	
Acinetobacter baumannii	Ceftazidime	93.76	
	Fluoroquinolone	92.82	
	Aminoglycoside	89.18	
	Ampicillin/Sulbactam	68.05	
	Carbapenem	93.02	
	Colistin	3.81	

HAI: Health care associated infection; MRSA: Methicillin-resistance Staphylococcus aureus; VRE: Vancomycin-resistant Enterococcus; ESBL: Extended spectrum beta-lactamase; KPC: Klebsiella pneumoniae carbapenemase.

Tab. III. Comparison of DAIs' Incidence density per 1000 device-days among this study, CDC/NHSN. ECDC, INICC, and TUMS multi-center study.

	This study 2018	CDC/NHSN 2019	ECDC 2017	INICC 2012-2017	TUMS 2014
CLA-BSI	2.86	0.84	3.7	5.05	10.20
VAP	25.66	4.49	9.5	14.1	21.08
CA-UTI	5.43	0.78	3.6	5.1	7.42

DAI: Device-associated Infection; CDC/NHSN: Centers for Disease Control and Prevention, National Healthcare Safety Network; ECDC: European Centre for Disease Prevention and Control; INICC: International Nosocomial Infection Control Consortium; TUMS: Tehran University of Medical Sciences; CLA-BSI: Central-line Bloodstream Infection; VAP: Ventilator-associated Pneumonia; CA-UTI: Catheter-associated Urinary Tract Infection.

workload of infection control nurses, and low-activity of infection control link-nurses in the wards [14].

Pneumonia in this study (accounted for 29.1% of HAIs) was the most common infection; a finding in contrast to previous national study and a number of other studies in Iran that represented UTI was the most prevalent [16, 20]. The reason for the increase in pneumonia rank in Iran can be the decrease in adherence to pneumonia/VAP preventive bundle in most hospitals (compared to urinary-catheter and CV-line) in recent years. Therefore, the evaluation of nationwide adherence to DAIs' preventive bundles can be a good topic for future research.

On device-associated infections (DAIs), Tab. III shows a comparison among this national study, CDC/NHSN [7], European CDC [8], International Nosocomial Infection Control Consortium (INICC) [10], and a multi-center study at Tehran University of Medical Sciences (TUMS) [21].

The first thing that comes to mind by the above table is that the rate of VAP was much higher in Iran than developed countries and even INICC report [7, 8, 10]. As mentioned earlier, the reason might be poor adherence to VAP preventive bundle in most hospitals; and it states that more attention should be paid to the implementation of the pneumonia preventive bundle by using multimodal strategies includes training ICUs' staff, supervising, and etc. About CA-UTI, the rate in Iran was like other developing countries as the summarized report of the INICC showed [10]; however, more than developed countries as expected [7, 8]. Although the rate of CLA-BSI seemed relatively low in Iran, the authors of this article believed that there was an under-detection of BSI across the country because of negative blood cultures in a significant number of patients despite clinical sepsis. This could be due to prescribing antibiotics before taking the blood sample, technical errors in sampling, or improper culture of blood samples. We know, according to CDC/NHSN case-definitions, BSI can only be reported when the blood culture is positive.

In microbiological study of this research, Enterobacteriaceae were the most common isolated pathogens. The frequency pattern of reported pathogens in the four major infections is different, as in VAPs, *Acinetobacter baumannii*; in UTIs and SSIs, *Escherichia coli*; and in BSIs, *Staphylococcus epidermidis* were the most abundant. Comparing this study with INICC, NHSN, and ECDC report for DAIs' causative agents, the organisms almost were the same with a bolder role of *Pseudomonas Aeruginosa* in these reports [7-10]. Antimicrobial resistance (AMR) patterns in HAIs-related organisms were less resistance in developed countries for gram negative bacilli e.g. NHSN reported resistance to carbapenems about 15%, 60%, and 25% for *Klebsiella pneumonia* (KP), *Acinetobacter baumannii* (AB), and *Pseudomonas Aeruginosa* (PA), respectively [9]; resistance to carbapenems was higher in INICC report: about 35%, 80%, and 40% for KP, AB, and PA respectively [10]; and in the current study, 58%, 93%, and 60% for KP, AB, and PA respectively. The rate of being methicillin-resistant (MRSA) among *staphylococcus aureus* isolates was almost similar in the above studies (about 50%) [8-10]. Our interpretation of increasing resistance rate in gram negative bacilli from developed countries to less-developed countries including Iran was overuse and inappropriate use of antibiotics. The solution is antibiotic stewardship program (ASP) and implementation of infection control principles.

In the current study, the causative agents of a significant number of infections (28.4%) were unknown (Fig. 2). The possible reasons were tendency to use the clinical criteria more than the culture-based criteria to diagnose some infections especially for surgical site infection, lack of appropriate access to the microbiology laboratory for some centers, and financial limitations to perform microbiological cultures for suspected patients at some hospitals.

The limitations of this survey are the inclusion of mostly four major HAIs (although some hospitals had a more partial categorization), relative failure to perform post-discharge surveillance, lack of documentation of imaging results, and low sensitivity of routine surveillance [8].

Conclusions

Despite the limitations mentioned earlier, this study provides a general overview of health care-associated infections in Iran, such as incidence percentage, incidence density per 1000 patient-days, device-associated infections rates (per 1000 device-days), rates in different wards, the pathogens and their epidemiology, and antimicrobial resistance patterns; which led health care authorities and practitioners to make better decisions. The findings also indicate that HAIs in Iran require special attention both in detection/reporting HAIs and in IPC measures. Future studies could be done on adherence rate of HAIs' preventive bundles, making interventions via multimodal strategies and assay their

efficacy on HAIs rates, evaluating the effect of training on more accurate detection of HAIs, design antibiotic stewardship programs and review the results on reducing antimicrobial resistance., and etc.

Funding

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Ethics

This study was approved by the ICDC Research Council and all data were registered under the supervision of the Iran Ministry of Health and Medical Education.

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Conflict of interest statement

None to declare.

Authors' contributions

MM and GMM: senior supervisors of the study from ICDC; PZ and EB: data extraction from INIS database and data analysis; ASH: preparing the manuscript draft and revising the paper; FMR: revising and confirming the microbiological data; SA: designing the study, final analysis and revising the paper.

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MOLECULAR EPIDEMIOLOGY

Pneumococcal infections and homelessness

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Keywords

Homelessness • Invasive pneumococcal diseases • *Streptococcus pneumoniae* • Pneumococcal vaccination • Real-time polymerase chain reaction

Summary

Objective. *To assess the prevalence of pneumococcal nasopharyngeal carriage, the role of potential risk factors, and the pneumococcal vaccination coverage among sheltered homeless people in Marseille, France.*

Methods. *During the winters 2015-2018, we enrolled 571 sheltered homeless males and 54 non-homeless controls. Streptococcus pneumoniae was directly searched from nasal/pharyngeal samples using real-time polymerase chain reaction.*

Results. *The homeless people were mostly migrants from African countries, with a mean age of 43 years. Pneumococcal vaccination coverage was low (3.1%). The overall pneumococcal carriage rate was 13.0% and was significantly higher in homeless people (15.3% in 2018) than in controls (3.7%), with p = 0.033. Among homeless people, being aged ≥ 65 years (1.97, 95% CI; 1.01-3.87), living in a specific shelter (OR = 1.80, 95% CI: 1.06-3.05), and having respiratory signs and symptoms at the time of enrolment (OR = 2.55, 95% CI: 1.54-4.21) were independently associated with pneumococcal carriage.*

Conclusion. *Pneumococcal nasopharyngeal carriage, which is a precursor for pneumococcal disease in at-risk individuals, is frequent among French homeless people. Studies conducted in other countries have also reported outbreaks of pneumococcal infections in homeless people. Pneumococcal vaccination should be systematically considered for sheltered homeless people in France, as is being done in Canada since 2008.*

Introduction

Invasive pneumococcal disease (IPD) is caused by *Streptococcus pneumoniae* and has been associated with several outbreaks among homeless people [1-4]. In several studies conducted in Canada between 2000 and 2016, many patients with IPD were homeless (7.4-18.8%) and experienced high mortality rates (6.9-15.6%) [1-4]. Serotype 4, 5, 8 and 12F IPD outbreaks were associated with homelessness in Canada [3, 5]. Serotype 4 outbreaks were also associated with homelessness in New Mexico, USA [6]. A study investigating the baseline risk of invasive streptococcal infections in Alaska, USA, estimated that the prevalence of IPD among homeless people between 2002 and 2015 was 8.7%, 36 times higher than the prevalence in non-homeless people [7]. A serotype 1 IPD outbreak was reported among sheltered homeless individuals in Paris, France in 1988 and 1989 [8].

Studies have found that homeless individuals with IDP were typically younger [1, 7], more often male [1], smokers [1, 9, 10], alcohol abusers [1, 7, 9], illegal drug users [1, 9], and had a primary diagnosis of pneumonia [1], HIV infection, or liver disease [10] compared to non-homeless individuals.

In this article, we share our research experience in Marseille, south of France, as part of a global surveillance and research project that started in 2000 on the diagnosis, prevention and treatment of infectious diseases among homeless people living in Marseille. We aimed to assess the prevalence of pneumococcal nasopharyngeal carriage and pneumococcal vaccination coverage among sheltered homeless people. We also investigated the role of potential risk factors on pneumococcal nasopharyngeal carriage.

Methods and materials

Ethics

Ethical approval was obtained from our institute's Institutional Review Board and Ethics Committee (2010-A01406-33). Informed consent was dated and signed by all individuals.

Setting, study design and population

Cross-sectional one-day surveys were conducted on February 17th 2015, March 7th and 10th 2016, February 6th and 8th 2017 and February 6th and 8th 2018, among adults living in two municipal emergency shelters for homeless men (A and B) in Marseille. The two shelters have a total capacity of 300 beds each and include emergency units (overnight stays) with a quick turnover (7-14 nights). Shelter A has a special unit (day-night) with a capacity of 35 beds, dedicated to high-risk sedentary homeless people (high level of poverty, poor hygiene, alcoholism, and mental illness). Rooms can accommodate 3-8 people for shelter A and 2-3 people for shelter B.

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Participants were asked to complete a questionnaire including information on their demographic characteristics, personal history, addictions, chronic disease status, respiratory signs and symptoms (including IPD symptoms), and fever at enrolment. In addition, information on personal hygiene habits and pneumococcal vaccination status that was not part of the standard questionnaire used in 2015-2017 was investigated during the 2018 survey. A pair of swabs (nasal and pharyngeal) was systematically collected from each participant on transport media using Sigma-Virocult® (Medical Wire, Corsham, United Kingdom), and stored at -80°C in our laboratory until processing. The homeless people who were screened were offered treatment, or further evaluation based on the assessment of their symptoms. Indeed, quantitative PCR results were obtained several weeks after the surveys were performed.

During the 2018 survey, a non-homeless group (controls) was also enrolled, including administrative staff, medical staff, medical students and PhD students from our research institute who agreed to provide nasal and pharyngeal samples. Data collected included demographic characteristics, chronic medical conditions, addictions, vaccination status, and respiratory signs and symptoms at enrolment. Age, gender and ethnic origin were considered as selection criteria for controls in order to avoid marked demographic differences between the two groups. Enrolment took place only five days after the recruitment of homeless people.

PCR assay for identification of *Streptococcus pneumoniae*

The automated DNA extraction was performed on 200 µL of each swab using a BioRobot® EZ1 Advanced XL instrument (QIAGEN, Hilden, Germany) and DNeasy® Blood & Tissue according to the manufacturer's instructions.

Real-time PCR based on *lytA* gene was carried out using in-house protocol. The amplification was performed in 20 µL volume including the 5 µL extracted DNA, 10 µL ready-to-use Hot Start reaction mix (Light-Cycler® 480 Probes Master kit, Roche Diagnostics, Meylan, France), 0.5 µL Uracil-DNA glycosylases (Thermo Fisher Scientific, Strasbourg, France), 0.5 µL sense primer (5′-ACGCAATCTAGCAGATGAAGCA-3′) at 20 µM, 0.5 µL antisense primer (5′-TCGTGCGTTTTAATTCCAGCT-3′) at 20 µM, 0.5 µL probe (6-FAM-TGCCGAAAACGCTTGATACAGGGAG-TAMRA) at 5 µM, and 3 µL distilled water. The PCR cycling conditions were 50°C for 2 min, 95°C for 5 min, followed by 39 cycles at 95°C for 5 sec, and 60°C for 30 sec. Results were considered positive when the cycle threshold value of the real-time PCR was ≤ 35. Individuals with at least a nasal or a pharyngeal positive sample were considered positive cases.

Statistical analysis

Statistical procedures were performed using Stata 11.1 software (StataCorp LLC, USA). We used Pearson's chi-square or Fisher's exact tests to compare percentage differences between the two groups of individuals, where appropriate. The theoretical normal distribution of quantitative data was assessed using Shapiro-Wilks test and means of quantitative data were compared using the Wilcoxon signed-rank test when samples were not normally distributed. A two-sided p-value of less than 0.05 was considered as statistically significant. A multivariate logistic regression analysis was applied to identify factors (demographic, chronic medical condition) associated with pneumococcal nasopharyngeal carriage in homeless people between 2015 and 2018. The results were presented as percentage and odds ratio (OR) with a 95% confidence interval (95% CI). Variables with p-values of < 0.2 in univariate analyses were included in the initial multivariate multinomial model. The stepwise regression procedure and likelihood-ratio tests were applied to determine the final model.

Results

Participant characteristics

During the 2015-2018 period, 571 subjects [265 from shelter A (46.4%), 306 from shelter B (53.5%)] volunteered to participate in this study, accounting for an estimated 40% of homeless people present in the shelters at the time of enrolment. The homeless individuals had a mean age ± SD (range) of 42.9 years ± 16.3 (18-83), and 62 of them (10.9%) were aged ≥ 65 years. They were mostly migrants from African countries who had settled in France approximately 10 years before the survey was performed (Tab. I). The mean duration of homelessness was about 2.6 years. Tobacco use and frequent alcohol consumption were reported by 244 (39.4%) and 64 (11.3%) individuals, respectively. Current cannabis use was reported by 100 individuals (17.6%). Drug addiction, defined as using injected or nasally inhaled illicit substances or being under opioid agonist treatments (methadone or buprenorphine), was uncommon, being reported by 26 individuals (4.6%). A proportion of 16.9% (n = 96) of homeless people had an indication for vaccination against IPD (chronic diseases) according to French guidelines [12]. 4.1% (n = 22) were underweight, 37.1% (n = 200) were overweight or obese. About 36.4% (n = 208) reported suffering from at least one respiratory symptom, notably a cough (n= 142, 24.8%) and expectoration (n = 69, 12.1%) at enrolment. About 2% (n = 13) were febrile (Tab. I).

In 2018, the pneumococcal vaccination coverage was less than 4% (3 of 98) among homeless individuals (Tab. II). More than a quarter reported taking a shower less than twice a week, more than a third reported changing their underwear less than twice a week, about a third reported brushing their teeth less than once a day. Compared to controls, homeless individuals were significantly more likely to report tobacco use and chronic diseases (Tab. II), and to present with respiratory signs and symptoms at enrolment (Fig. 1).

Tab. I. Characteristics and associations between multiple factors and pneumococcal nasopharyngeal carriage among 571 homeless individuals in a survey conducted between 2015 and 2018 (univariate and multivariate analysis).

Characteristics	Total	Positive	Negative	Univariate		Multivariate	
				OR (95%CI)	P-value	aOR (95%CI)	P-value
Total, n (%)	571 (100)	74 (13)	497 (87)				
Year of study[1] (571) [2]							
2015, n (%)	123 (21.5)	29 (23.6)	94 (76.4)				
2016, n (%)	154 (27.0)	9 (5.8)	145 (94.2)				
2017, n (%)	196 (34.3)	21 (10.7)	175 (89.3)				
2018, n (%)	98 (17.2)	15 (15.3)	83 (84.7)				
Housing facility (571)							
Shelter A, n (%)	306 (53.6)	49 (16.0)	257 (84.0)	**1.83 (1.09-3.05)**	**0.021**	**1.80 (1.06-3.05)**	**0.028**
Shelter B, n (%)	265 (46.4)	25 (9.4)	240 (90.6)	Ref		Ref	
Age (years) (569)							
Mean ± SD	42.9 ± 16.3						
Median, interquartile	42, 29-55						
Range (min-max)	18-83						
≥ 65, n (%)	62 (10.9)	14 (22.6)	48 (77.4)	**2.17 (1.13-4.17)**	**0.02**	**1.97 (1.01-3.87)**	**0.048**
18-65, n (%)	507 (89.1)	60 (11.8)	447 (88.2)	Ref		Ref	
Birthplace (571)							
Africa, n (%)	413 (72.3)	48 (11.6)	365 (88.4)	0.71 (0.41-1.24)	0.233		
Asia, n (%)	23 (4.0)	5 (21.7)	18 (78.3)	1.50 (0.50-4.50)	0.462		
Europe, n (%)	135 (23.6)	21 (15.6)	114 (84.4)	Ref			
Mean duration of residence in France for migrants (SD), range (min, max) (years) (480)	9.6 ± 15.7, 0-66						
Range of duration of residence in France for migrants							
> 1.5 years	255 (53.1)	35 (13.7)	220 (86.3)	1.27 (0.73-2.20)	0.38		
≤ 1.5 years[3]	225 (46.9)	25 (11.1)	200 (88.9)	Ref			
Mean duration of homelessness (SD), range (min, max) (years) (557)	2.6 ± 5.5, 0-63						
Range of duration of homelessness							
> 9 months	260 (46.7)	30 (11.5)	230 (88.5)	0.8 (0.49-1.34)	0.424		
≤ 9 months[3]	297 (53.3)	41 (13.8)	256 (86.2)	Ref			
Tobacco use (569)							
Yes, n (%)	345 (60.6)	50 (14.5)	295 (85.5)	**1.41 (0.84-2.37)**	**0.192**	--	
No, n (%)	224 (39.4)	24 (10.7)	200 (89.3)	Ref			
Frequent alcohol consumption (568)							
Yes, n (%)	64 (11.3)	9 (14.1)	55 (85.9)	1.10 (0.52-2.34)			
No, n (%)	504 (88.7)	65 (12.9)	439 (87.1)	Ref			
Cannabis (marijuana) (569)							
Yes, n (%)	100 (17.6)	14 (14.0)	86 (86.0)	1.10 (0.59-2.07)	0.745		
No, n (%)	469 (82.4)	60 (12.8)	409 (87.2)	Ref			
Drug addiction (569)							
Yes, n (%)	26 (4.6)	5 (19.2)	21 (80.8)	1.65 (0.59-4.47)	0.34		
Injecting illicit substances	2 (0.4)	0 (0)	2 (100)	NA			
Snorting illicit substances	20 (3.5)	4 (20.0)	16 (80.0)	NA			
Using opioid agonist treatment	9 (1.6)	2 (22.2)	7 (77.8)	NA			
No, n (%)	543 (95.4)	69 (12.7)	474 (87.3)	Ref			

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▶

Tab. I. Characteristics and associations between multiple factors and pneumococcal nasopharyngeal carriage among 571 homeless individuals in a survey conducted between 2015 and 2018 (univariate and multivariate analysis).

Characteristics	Total	Positive	Negative	Univariate		Multivariate	
				OR (95%CI)	P-value	aOR (95%CI)	P-value
Total, n (%)	571 (100)	74 (13.0)	497 (87.0)				
Yes, n (%)	111 (19.6)	22 (19.8)	89 (80.2)	**1.92 (1.10-3.32)**	**0.02**	-	-
HIV infection	2 (0.4)	0 (0)	2 (100)				
Cancer	6 (1.1)	2 (33.3)	4 (66.7)				
Heart failure	3 (0.6)	1 (33.3)	2 (66.7)				
Chronic respiratory failure[4]	49 (8.7)	10 (20.4)	39 (79.6)				
Severe asthma	27 (4.8)	7 (25.9)	20 (74.1)				
Hepatitis	23 (4.1)	7 (30.4)	16 (69.6)				
Renal failure	2 (0.4)	0 (0)	2 (100)				
Diabetes mellitus	41 (7.2)	6 (14.6)	35 (85.4)				
No, n (%)	456 (80.4)	52 (11.4)	404 (88.6)	Ref			
Body mass index (542)							
Mean BMI (SD) (kg/m^2)	24.2 ± 4.0						
Range of BMI (kg/m^2)	14.7-38.8						
Underweight, n (%)	22 (4.1)	6 (27.3)	16 (72.7)	**2.80 (1.06-7.45)**	**0.038**		
Others	518 (95.9)	61 (11.8)	457 (88.2)	Ref			
Normal weight, n (%)	318 (58.9)	35 (11.0)	283 (89.0)				
Overweight, n (%)	150 (27.8)	20 (13.3)	130 (86.7)	1.24 (0.69-2.23)	0.47		
Obesity, n (%)	50 (9.3)	6 (12.0)	44 (88.0)	1.10 (0.43-2.77)	0.83		
Seasonal vaccination against influenza (562)							
Yes, n (%)	83 (14.8)	10 (12.0)	73 (88.0)	0.92 (0.45-1.87)	0.82		
No, n (%)	479 (85.2)	62 (12.9)	417 (87.1)	Ref			
Clinical symptomsand signs (568)							
At least one respiratory symptom and sig							
Yes, n (%)	206 (36.3)	41 (19.9)	165 (80.1)	**2.47 (1.51-4.06)**	**< 10^{-4}**	**2.55 (1.54-4.21)**	**< 10^{-4}**
Cough, n (%)	142 (24.8)	33 (23.2)	109 (76.8)				
Expectoration, n (%)	69 (12.1)	14 (20.3)	55 (79.7)				
Rhinorrhoea, n (%)	48 (8.4)	6 (12.5)	42 (87.5)				
Dyspnoea, n (%)	47 (8.2)	7 (14.9)	40 (85.1)				
Sore throat, n (%)	44 (7.7)	7 (15.9)	37 (84.1)				
Sibilants, n (%)	23 (4.0)	9 (39.1)	14 (60.9)				
Ronchi, n (%)	20 (3.5)	4 (20.0)	16 (80)				
Crackles, n (%)	1 (0.2)	0 (0)	100 (0)				
No, n (%)	362 (63.7)	33 (9.1)	329 (90.9)	Ref		Ref	
Fever (≥ 37.8%)							
Yes, n (%)	13 (2.8)	1 (7.7)	12 (92.3)	0.61 (0.07-4.85)	0.65		
No, n (%)	455 (97.2)	54 (11.9)	401 (88.1)	Ref			

Ref: reference; NA: not applicable; OR: odds-ratio; aOR: adjusted odds-ratio.
[1] The variable was not included in the analysis, given that no intervention could be performed based on this criterion; [2] Number of individuals for whom data was available; [3] Median of the variable was used for analysis; [4] including chronic bronchitis, chronic obstructive pulmonary disease, emphysema; bold lines indicate the variables recruited in initial multivariate mode.

Tab. II. Characteristics of homeless participants and non-homeless participants in a survey conducted in 2018, Marseille, France.

Characteristics	Homeless group	Non-homeless group	P-value
Total	**98**	**54**	
Gender: male, n (%) (98, 54) (1)	98 (100)	54 (100)	1.0
Age (years): mean ± SD, range (98, 54)	39.3 ± 17.6	34.4 ± 17.6	0.48
18-34, n (%)	51 (50.0)	33 (61.1)	0.12
35-49, n (%)	16 (16.3)	13 (24.1)	
50-65, n (%)	23 (23.5)	7 (13.0)	
> 65, n (%)	8 (8.2)	1 (1.8)	

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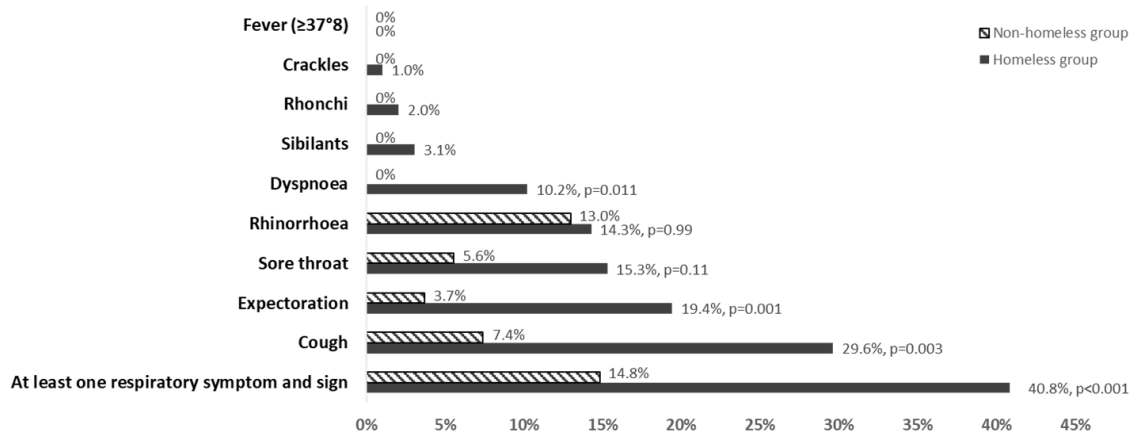
Tab. II. Characteristics of homeless participants and non-homeless participants in a survey conducted in 2018, Marseille, France.

Characteristics	Homeless group	Non-homeless group	P-value
Total	**98**	**54**	
Origin, n (%) (98, 54)			0.06
Europe	22 (22.4)	19 (35.2)	
North Africa	45 (45.9)	18 (33.3)	
Sub-Saharan Africa	28 (28.6)	10 (18.5)	
Eastern Mediterranean	1 (1.0)	2 (3.7)	
Asia	2 (2.0)	4 (7.4)	
America	0 (0)	1 (1.9)	
Mean duration of homelessness (years) (SD) (96, NA)	2.68 (0-7.2)	NA	NA
Mean duration of residence in France (years) (SD) for migrants (min-max) (85, 35)	8.2 ± 16.1 (1 week-63 years)	3.8 ± 3.9 (5 months-17 years)	0.053
Addiction, n (%) (97, NA)			
Tobacco use	58 (59.2)	13 (24.1)	$< 10^{-4}$
Alcohol consumption	13 (13.3)	6 (11.1)	0.89
Cannabis (marijuana)	25 (25.8)	0 (0)	$< 10^{-4}$
Drug addiction	12 (12.2)	0 (0)	0.018
Injecting illicit substances	8 (8.2)	0 (0)	
Snorting illicit substances	7 (7.1)	0 (0)	
Using opioid agonist treatment	0 (0)	0 (0)	
Chronic diseases[2], n (%) (97, NA)	22 (22.4)	0 (0)	$< 10^{-4}$
HIV infection	1 (1.0)	0 (0)	
Cancer	1 (1.0)	0 (0)	
Heart failure	1 (1.0)	0 (0)	
Chronic respiratory failure[2]	7 (7.1)	0 (0)	
Severe asthma	4 (4.1)	0 (0)	
Hepatitis	6 (6.1)	0 (0)	
Renal failure	1 (1.0)	0 (0)	
Diabetes mellitus	5 (5.1)	0 (0)	
Body mass index (95, NA)		NA	
Mean BMI (SD) (kg/m2)	23.1 ± 4.0		
Range of BMI (kg/m2)	14.7-38.8		
Normal weight	5 (5.3)		
Underweight	70 (73.7)		
Overweight	12 (12.6)		
Obesity	8 (8.2)		
Personal hygiene habits		NA	
Taking a shower (96, NA)			
Less than once a week	4 (4.2)		
1-2 times a week	22 (22.9)		
3-4 times a week	21 (21.9)		
Every day	49 (51.0)		
Changing underwear (95, NA)			
Less than once a week	5 (5.2)		
1-2 times a week	30 (31.6)		
3-4 times a week	23 (24.2)		
Every day	37 (39.0)		
Tooth brushing (92, NA)			
Less than once a day	29 (31.5)		
Equal or more than once a day	63 (68.5)		
Vaccination against pneumococcus, n (%) (98, 54)	3 (3.1)	4 (7.4)	0.24
Pneumococcal nasopharyngeal carriage, n (%) (98, 54)	**15 (15.3)**	**2 (3.7)**	**0.033**

N: number; NA: not applicable; SD: standard deviation; HIV: human immunodeficiency virus; BMI: body mass index.
[1]Number of individuals for whom data was available (homeless group, non-homeless group); [2]indication for pneumococcal vaccination according to French guidelines: Ministère des Solidarités et de la Santé. Calendrier des vaccinations et recommandations vaccinales 2019 - available at: https://solidarites-sante.gouv.fr/IMG/pdf/calendrier_vaccinal_mars_2019.pdf (accessed 08 September 2020); [3]including chronic bronchitis, chronic obstructive pulmonary disease, and emphysema; [4] including cough, expectoration, rhinorrhoea, dyspnoea, sore throat, sibilants, rhonchi, crackles.

Fig. 1. Prevalence of clinical signs and symptoms in 2018 (homeless group versus non-homeless group).



Pneumococcal nasopharyngeal carriage

All participants underwent both nasal and pharyngeal sampling. During the 2015-2018 period, 74 homeless individuals (13.0%) tested positive for pneumococcal carriage. The prevalence of pneumococcal carriage varied significantly according to the study years ($p < 0.001$), with the highest prevalence (23.6%, 29 of 123) found in 2015. We found that pneumococcal carriage in 2018 was significantly higher among people living in shelters (15 of 98, 15.3%) than among the non-homeless group of controls (two of 54, 3.7%), with $p = 0.033$.

Table I shows pneumococcal carriage rates among homeless people according to demographic characteristics, housing facility, chronic medical condition, and clinical findings. In univariate analyses, living in shelter A, being aged ≥ 65 years, having chronic diseases, being underweight and suffering from at least one respiratory sign or symptom at enrolment were significantly associated with pneumococcal carriage. In multivariate analyses, pneumococcal carriage was associated with living in shelter A [16.0% *vs* shelter B (9.4%), OR = 1.80, 95% CI: 1.06-3.05], being aged ≥ 65 years [22.6% *vs* being aged < 65 years (11.8%), OR = 1.97, 95% CI: 1.01-3.87], and presenting with at least one respiratory sign or symptom at enrolment [27.3% *vs* no respiratory symptoms (9.1%), OR = 2.55, 95% CI: 1.54-4.21].

Discussion

This is the first epidemiological study aiming to directly assess the carriage of pneumococcal DNA in nasal/pharyngeal samples from sheltered homeless population. We found a high (13.0%) prevalence of pneumococcal nasopharyngeal carriage among sheltered homeless people in Marseille, France, and the prevalence was higher than in non-homeless people. Using the same molecular method, the prevalence of *S. pneumoniae* carriage was 3.6% among Hajj pilgrims in summer 2014-2018 before their departure from Marseille (unpublished data), and 2.5% among medical students sampled before travelling abroad in summer 2018 [11]. A retrospective survey conducted among homeless people hospitalised in infectious disease units in our hospital between 2017 and 2018 revealed that *S. pneumoniae* was responsible for two (among 98, 2.0%) cases of community-acquired pneumonia or acute exacerbation of chronic obstructive pulmonary disease [12].

In this study, a low rate (3.1%) of homeless people reported had been vaccinated against IPD prior to recruitment. However, according to French guidelines, 23.5% of these individuals should have been vaccinated because they had chronic conditions, whilst according to American guidelines, which include being ≥ 65 years as a risk factor, 26.5% should have been vaccinated [13, 14]. In other studies, vaccination coverage among homeless populations ranged from 9.0 to 37.0% [3, 5, 8, 10].

In our study, being aged ≥ 65 years and having respiratory symptoms at enrolment were potential risk factors for pneumococcal carriage among homeless people. This bacterium was possibly responsible for the respiratory symptoms observed. Indeed, such an association was also observed in medical students from Marseille taking part in an elective abroad [15].

In addition, pneumococcal carriage was associated with the type of housing (shelter A). A significantly higher transmission of SARS-CoV-2 and infestation with body lice in people living in shelter A has also been found in previous studies conducted during the same period [16, 17]. This may be a result of the higher number of individuals per room in this shelter, as compared with shelter B, which may have facilitated the transmission of infectious agents. A sub-population of homeless people with a high level of precariousness was housed in a special sector of shelter A, which may partially explain our results. Unfortunately, being housed in the special unit was not recorded on a regular basis in our surveys.

Our study has several limitations. The population was not randomly and homogenously recruited. Only

homeless people present in the shelters were enrolled on a voluntary basis leading to a 40% participation rate. Furthermore, we cannot exclude the possibility that those with respiratory symptoms might have been more likely to enrol in the survey. Moreover, our study took place in winter, so we could not have an overview of seasonal variations of pneumococcal carriage among homeless people, whereas these impact the airway microbial community in adults and children [18, 19]. Future studies will be conducted at least twice a year (in winter and in summer).

Conclusions

Pneumococcal nasopharyngeal carriage, which is a precursor for pneumococcal disease in at-risk individuals, is frequently found among French homeless people. Studies conducted in other countries have also reported outbreaks of pneumococcal infections in this population. Although a quarter of homeless people present risk factors for IPD, vaccination against IPD is clearly suboptimal [3, 5]. We therefore suggest that pneumococcal vaccination should be systematically considered for residents of homeless shelters in France, as is being done in Canada since 2008 [5].

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Conflict of interest statement

The authors declare no conflict of interest.

Authors' contributions

TDAL, and PG contributed to the experimental design, data analysis, statistics, interpretation and writing. LP contributed to the writing. TDAL, VTH, TLD administered questionnaires, examined patients, collected samples and provided technical assistance. PG coordinated the work.

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Non com Diseases

The effect of early tranexamic acid on bleeding, blood product consumption, mortality and length of hospital stay in trauma cases with hemorrhagic shock: a randomized clinical trial

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Keywords

Tranexamic acid • Placebo • Trauma patients • Acute bleeding

Summary

Introduction. *Because no medication has been approved for coagulation support in trauma, the current study was aimed to evaluate the effectiveness of intravenous injection of Tranexamic acid (TXA) in patients with acute traumatic bleeding.*
Methods. *In the current randomized controlled clinical trial, 68 patients with acute bleeding and hemorrhagic shock presentation due to blunt trauma of the abdomen, pelvis, and thorax, randomly assigned into two groups of TXA and placebo.*
Results. *There was no statistically significant difference between the two groups in terms of Systolic blood pressure, pulse rate, Base excess, serum hemoglobin changes, bleeding volume, the incidence of thrombotic events, and the number of deaths ($p > 0.05$). But Systolic blood pressure, pulse rate, base excess, and serum hemoglobin, changed significantly within each group over time($p < 0.05$). The median time for the length of hospital stay among the TXA group was lower than the Placebo group (6 days vs 10 days, $p = 0.004$). Also, there was a significant difference between the two groups about the median of pack cell, Platelet consumption, and bleeding Volume ($p < 0.05$).*
Conclusion. *The use of TXA is associated with lower use of blood production and reduced length of hospital stay, however, thrombotic events incidence and mortality rates between the TXA and placebo groups were not different.*

Introduction

Acute bleeding is one of the leading causes of death globally, and the estimate of death related to blood loss is about 1.9 million cases annually, that most of them are due to injuries. Uncontrolled bleeding is the cause of approximately one-third of trauma-related deaths [1]. In the United States, about 60,000 deaths per year are caused by acute bleeding [2]. About 90% of injury-related deaths occurred in low and middle-income countries annually. In Iran, as a middle-income country, injury-related deaths and bleeding due to trauma are among the leading causes of mortality and burden of diseases [3, 4].
Due to decreased oxygen delivery, severe blood loss leads to widespread tissue ischemia [5], followed by a cascading inflammatory response that causes further tissue damage and cell deaths [6]. Concomitant abnormalities in blood coagulation can cause rapid bleeding, and Cerebral and myocardial hypo perfusion with bleeding can be fatal within minutes [7]. Current approaches to controlling acute bleeding are varied depending on the availability of treatment options and local expertise in critical care and trauma. In general, bleeding management aims is to achieve rapid homeostasis, restore tissue flow, treat blood clotting, and reduce inflammatory responses [1].
Recent studies have shown great interest in the role of fibrinolysis in hemorrhagic shock and the effect of TXA in reducing fibrinolysis. TXA, discovered in 1962, has remained a treatment option in the management of surgical and gynecological hemorrhages for five decades [8, 9]. Recent researches focusing on the role of fibrinolysis in bleeding has paid close attention to the part of TXA in various clinical contexts [10, 11]. Although cessation of fibrinolysis appears to be the primary mechanism that TXA can reduce mortality, there is evidence for additional anti-inflammatory agents [12]. Numerous studies have described the use of TXA in patients after traumatic injury, administered as 1 g intravenously, with subsequent 1 gr injection for continuous or recurrent bleeding [13]. Due to the importance of controlling bleeding in patients with trauma, the current study was aimed to evaluate the effectiveness of early intravenous injection of TXA in patients with acute bleeding and hemorrhagic shock presentation due to severe trauma.

Methods

Study design and participants

The present study was a randomized and parallel clinical trial (Superiority Trial) performed on 68 traumatic

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patients referred to Hazrate- Rasoul Akram Hospital in Tehran in 2020.

Under studied patients and sample size

In the current study, The main inclusion criteria were patients with acute bleeding and hemorrhagic shock presentation due to blunt trauma of the abdomen, pelvis, and thorax with severe trauma(an injury severity score greater than 15) [8] were selected. The used sample size was 68 patients (34 cases in the TXA group versus 34 subjects in the placebo group) (Fig. 1). The sample size was determined according to following formula:

$$n= \frac{(Z_{(1-\alpha/2)}+Z_{(1-\beta)})^2(p_1(1-p_1)+p_2(1-p_2))}{d^2}$$

Where P_1 (death rate in Intervention group) was considered 17% and P_2 (death rate in control group) was considered 52%. $Z_{(1-\alpha/2)}$ and $Z_{(1-\beta)}$ was considered 1.96 and 0.84 respectively. In the current formula d (effect size) was 35%. The calculated sample size was 29 cases for each group and by considering the 15% attrition this amount increased to 34 cases per group.

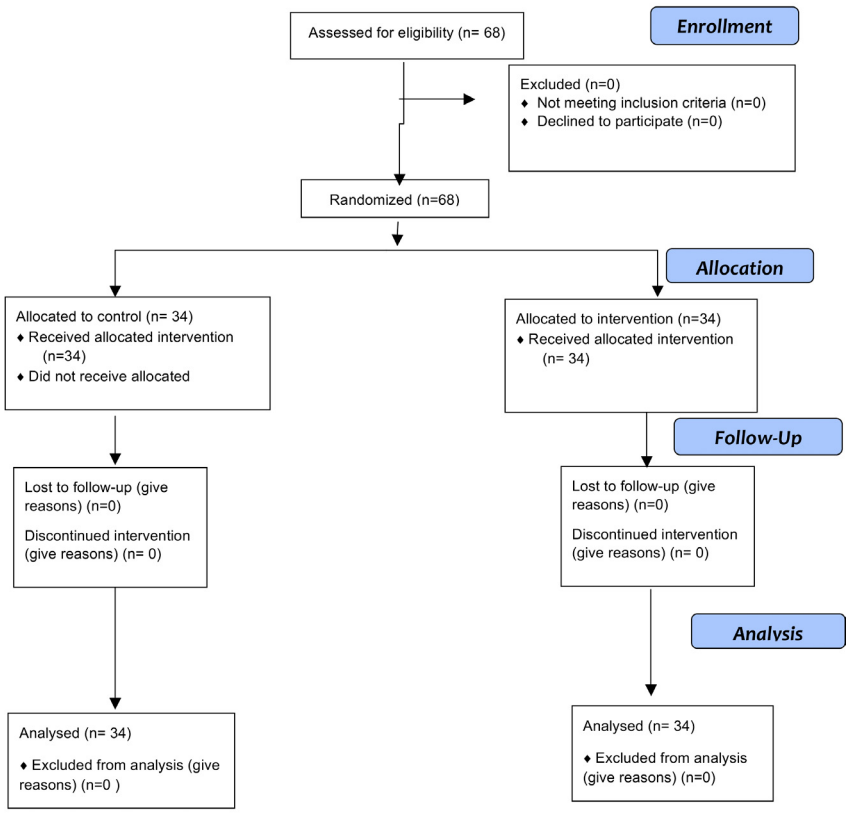
Inclusion and exclusion criteria

Inclusion criteria were acute bleeding, due to blunt trauma of the abdomen, pelvis, and thorax with hemorrhagic shock presentation (unstable vital signs: systolic blood pressure less than 90 mm and pulse rate more than 110), Injry Severity Score of more than 15 and age more than 18 years old which were arrived to hospital in within 3 hour from the trauma. Individuals with renal insufficiency (serum creatinine greater than 1.5 mg/dL), pregnancy, hematuria, history of coagulation disorder, and anticoagulant use were excluded.

Randomization and masking

The patients were divided into intervention and control groups based on block randomization. For the block randomization, the blocks with size 4 were used for the block randomization. For this purpose, the desired treatment was named with A and the control treatment was named with B. Then all the cases in which these treatments could be put together were placed inside the blocks. The generated blocks were numbered and randomly selected. This selection of blocks continued until the sample size was completed. This process was applied and completed before the patient's recruitment. The intervention group was given 1 gr TXA of intravascular infusion in 100 ccs of normal saline and then 1 gr every 12 hours for up to 24 hours. TXA was used in 3 doses. The initial dose (1 gram) was injected within 10 minutes and the following two doses at 12-hour intervals. Patients in the control group were given a placebo (normal saline). The clinicians evaluated all patients during hospitalization about the number

Fig. 1. The consort 2010 flow diagram for the current study.



of blood products transfusion, serum hemoglobin, and vital signs. Patients were followed for one month for possible thrombotic events, including Deep Vein Thrombosis (DVT), Pulmonary Thromboemboly (PTE), Cerebrovascular accident (CVA), and myocardial infarction (MI). Also, the final status of the patient's (recovery or death status) and length of hospital stay were recorded in the designed checklist. The double blinding method was used to masking patients and physicians. In addition to the randomization number, the drug pack label was identical for TXA acid and placebo. In addition, the selected blocks were placed in opaque envelopes with no known contents. That is until the patients were assigned, the envelopes were closed and no one knew the order of interventions inside (randomization concealment).

This research conducted according to the World Medical Association Declaration of Helsinki. The recruitment of participants was initiated from the February to December 2020 and this process finished end of the 2020 year. But the follow up patients lasted until the beginning of 2021.

Outcome

The effect of TXA on Mortality, Hospital Length of Stay, and Use of Blood Production was the understudy's outcomes.

Data analysis

Descriptive statistics such as mean ± standard deviation and median (interquartile range) were used to express quantitative findings, and frequency (percentage) was used to present qualitative findings. Data analyzed using the Independent sample t-test or Mann Whitney u test, chi-square, or Fisher exact test and repeated measure one-way ANOVA. The equation of variance (sphericity assumption) was assessed using Mauchly's test of sphericity. Due to the lack of this assumption, the difference between the means at the different times was evaluated using the Greenhouse-Geisser correction. The statistical significance level was considered as α:0.05. All data analyzed using the SPSS software Version 22.0. Armonk, NY: IBM Corp. IBM Corp. Released 2015.

Results

Descriptive statistics

The mean of age among the TXA and Placebo group was 37.76 ± 8.85 and 34.82 ± 7.37 years, respectively, and there was no statistically significant difference between the two groups about the age distribution (p = 0.14). The 26 (76.5%) of total cases among the TXA group were males, and this percent among the placebo group was 30 (88.2%) (p = 0.20). There was no statistically significant difference between the two groups about the variables such as Etiology of bleeding, Spleen rupture, Hemothorax, Retroperitoneal hematoma, Rupture of the intestinal mesentery, and Hepatic injury (Tab. I).

Tab. I. Comparison of demographic characteristics and etiology of bleeding in TXA and placebo group.

Variables	TXA	Placebo	P-value
Age	37.76 ± 8.85	34.82 ± 7.37	0.14
Males	26 (76.5%)	30 (88.2%)	0.20
Etiology of bleeding			
Spleen rupture	17 (50.0%)	13 (38.2%)	0.32
Hemothorax	3 (8.8%)	5 (14.7%)	0.33
Retroperitoneal hematoma	14 (41.2%)	18 (52.9%)	0.33
Rupture of the intestinal mesentery	4 (11.8%)	2 (5.9%)	0.33
Hepatic injury	11 (32.4%)	5 (14.7%)	0.08

Baseline characteristics

The mean of baseline hemoglobin (g/dL) among TXA and placebo groups was 13.59 ± 1.20 and 13.34 ± 2.25, respectively (0.66). The mean of systolic blood pressure (mm/Hg) among TXA and placebo groups was 93.52 ± 16.21 and 97.64 ± 22.43 respectively (0.96). Also, there was no significant difference between the two groups in the mean of pulse rate, GCS and Base excess (mmol/L) (p > 0.05). More information was shown in Table II.

Comparing the outcome of interest

Systolic blood pressure

The mean ± SD of Systolic blood pressure at the time of admission, 12,24 and 48 hours after the entry in the TXA group was 93.53 ± 16.21, 108.24 ± 15.27, 112.94 ± 7.40, and 115 ± 10.80 respectively. This increasing trend in the TXA group over time was statistically significant (p < 0.001). Also, the mean of Systolic blood pressure at the time of admission, 12, 24, and 48 hours after the entry in the placebo group was 97.65 ± 22.44, 102.35 ± 13.72, 113.53 ± 11.25, and 111.76 ± 5.76. This increasing trend in the TXA group over time was statistically significant (p < 0.001). The difference in mean of the systolic blood pressure between the two groups over time was not statistically significant (p = 0.12). Also, in overall, the difference of SBP between the TXA and Placebo group was not statistically significant (p = 0.59) (Tab. III, Fig. 2).

Tab. II. Baseline clinical and laboratory characteristics in TXA and placebo group.

Variables	TXA	Placebo	P-value
Baseline hemoglobin (g/dL)	13.59 ± 1.20	13.34 ± 2.25	0.66
systolic blood pressure (mm/Hg)	93.52 ± 16.21	97.64 ± 22.43	0.96
pulse rate (per minute)	124.71 ± 17.44	125.88 ± 28.93	0.35
GCS	14.41 ± 0.85	14.52 ± 0.99	0.35
Base excess (mmol/L)	-2.85 ± 3.00	-3.94 ± 4.47	0.57

Hemoglobin

The mean ± SD of Hemoglobin at time of admission and 12, 24 and 48 hours after entry in the TXA group was 13.49 ± 1.20, 10.82 ± 1.28, 9.87 ± 1.07, and 9.38 ± 1.04 respectively. This decreasing trend in the TXA group over time was statistically significant ($p < 0.001$). Also, the mean of Hemoglobin in time of admission and 12, 24, and 48 hours after entry in the placebo group was 13.34 ± 2.25, 10.86±1.42, 9.27 ± 1.62, and 8.59 ± 1.52. This decreasing trend in the TXA group over time was statistically significant ($p < 0.001$). The difference in mean of the Hemoglobin between the two groups over time was not statistically significant ($p = 0.15$). Also, in overall, the difference of Hemoglobin between the TXA and Placebo group was not statistically significant ($p = 0.16$) (Tab. III, Fig. 2).

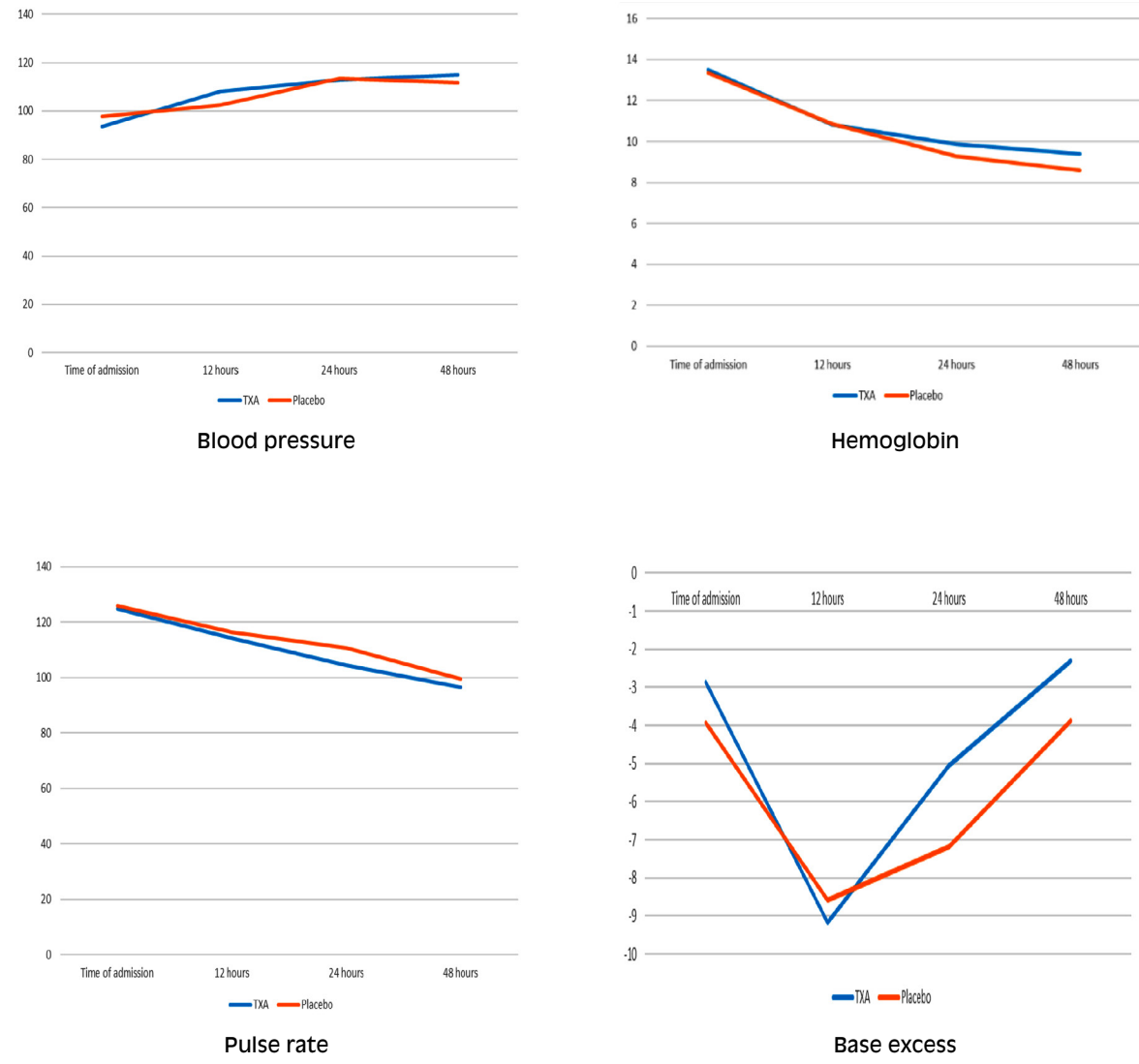
Pulse rate

The mean of Pulse rate in time of admission and 12, 24, and 48 hours after entry in the TXA group were 124.71 ± 17.45, 114.12 ± 16.17, 104.47 ± 11.43, and 96.47 ± 9.01. This decreasing trend in the TXA group over time was statistically significant ($p < 0.001$). Also, the mean of Pulse rate in time of admission and 12, 24, and 48 hours after entry in the placebo group was 125.88 ± 28.93, 116.47 ± 10.41, 110.59 ± 10.70, and 99.38 ± 12.99. This decreasing trend in the TXA group over time was statistically significant ($p < 0.001$). The difference in mean of the Hemoglobin between the two groups over time was not statistically significant ($p = 0.56$). Also, in overall, the difference in Pulse rate between the TXA and Placebo group was not statistically significant ($p = 0.29$) (Tab. III, Fig. 2).

Base excess

The mean of Base excess in a time of admission and 12,24 and 48 hours after admission in the TXA group was -2.85 ± 3.01, -9.18 ± 3.32, -5.06 ± 3.78, and -2.29 ± 4.48. This decreasing trend in the TXA group over time was statistically significant ($p < 0.001$). Also,

Fig. 2. The trend of different clinical and laboratory factors between two groups duration the follow-up period.



the mean of Base excess in a time of admission and 12,24 and 48 hours after admission in the placebo group was -3.94 ± 4.48, -8.59 ± 4.61, -7.18 ± 4.12, and -2.29 ± 4.48. This decreasing trend in the TXA group over time was statistically significant ($p < 0.001$). The difference in mean of the Base excess between the two groups over

Tab. III. Comparison of different clinical and laboratory factors between two groups duration the follow-up period.

Group	Group	Mean	Std. deviation	Between-group	Time* group	Time
Blood pressure						
Admission Systolic BP	TXA	93.53	16.21	0.59	0.12	< 0.001
	Placebo	97.65	22.44			
	Total	95.59	19.54			
Systolic BP (12 hours)	TXA	108.24	15.27			
	Placebo	102.35	13.72			
	Total	105.29	14.71			
Systolic BP (24 hours)	TXA	112.94	7.40			
	Placebo	113.53	11.25			
	Total	113.24	9.45			
Systolic BP (48 hours)	TXA	115.00	10.80			
	Placebo	111.76	5.76			
	Total	113.38	8.74			
Hemoglobin						
Admission HB	TXA	13.49	1.20	0.16	0.15	< 0.001
	Placebo	13.34	2.25			
	Total	13.42	1.79			
HB (12 hours)	TXA	10.82	1.28			
	Placebo	10.86	1.42			
	Total	10.84	1.34			
HB (24 hours)	TXA	9.87	1.07			
	Placebo	9.27	1.62			
	Total	9.57	1.40			
HB (48 hours)	TXA	9.38	1.04			
	Placebo	8.59	1.52			
	Total	8.98	1.35			
Pulse rate						
Admission Pulse rate	TXA	124.71	17.45	0.29	0.56	< 0.001
	Placebo	125.88	28.93			
	Total	125.29	23.72			
Pulse rate (12 hours)	TXA	114.12	16.17			
	Placebo	116.47	10.41			
	Total	115.29	13.55			
Pulse rate (24 hours)	TXA	104.47	11.43			
	Placebo	110.59	10.70			
	Total	107.53	11.41			
Pulse rate (48 hours)	TXA	96.47	9.01			
	Placebo	99.38	12.99			
	Total	97.93	11.19			
Base excess						
Admission Base excess	TXA	-2.85	3.01	0.15	0.06	< 0.001
	Placebo	-3.94	4.48			
	Total	-3.40	3.83			
BE (12 hours)	TXA	-9.18	3.32			
	Placebo	-8.59	4.61			
	Total	-8.88	3.99			
BE (24 hours)	TXA	-5.06	3.78			
	Placebo	-7.18	4.12			
	Total	-6.12	4.06			
BE (48 hours)	TXA	-2.29	4.48			
	Placebo	-3.88	3.58			
	Total	-3.09	4.10			

Tab. IV. Comparison use of blood products and length of hospital stay in TXA and placebo group.

Variable	TXA, Median (IQR)	Placebo, Median (IQR)	P-value
Bleeding volume (cc)	1,000 (2,000-800)	1,500 (2,000-950)	0.03
Length of stay (day)	6 (12-6)	10 (26-8)	0.004
Pack cell (250 ml/unit)	3 (4-1)	3(5-3)	0.02
Fresh Frsh plasma (225 ml/unit)	2 (6-2)	10 (26-8)	0.08
Platelet (70 ml/unit)	0 (0-0)	0 (6.25-0)	0.008

time was not statistically significant (p = 0.06). Also, in overall, the difference in Pulse rate between the TXA and Placebo group was not statistically significant (p = 0.15) (Tab. III, Fig. 2).

Use of blood products and mortality

The number of deaths in TXA and placebo groups was 2(5.9%) and 4 (11.8 %), respectively (p = 0.33). The median (IQR) of bleeding volume for TXA group was significantly lower than the control group [1,000 (1,200) *vs* 1,500 (1,050), p = 0.03]. The median time for the length of hospital stay among the TXA group was lower than the Placebo group (6 days *vs* ten days, p = 0.004). Also, there was a significant difference between the two groups about the use of blood product consumption such as Platelet. More information was shown in Table IV.

Thrombotic events

The incidence of thrombotic events among TXA cases was 0, and this amount in the placebo group was 4 (11.8%). There was no statistically significant difference between the two groups (p = 0.06)

Discussion

In our study, the mortality rate in the intervention group (TXA) was lower than in the control group, but this difference was not statistically significant. For the first time, clinical evidence of the effect of early TXA administration on trauma-induced mortality was demonstrated in a CRASH-2 randomized clinical trial [14, 15]. A subsequent observational study (MATTERs) [16] showed that TXA administration in patients injured on the battlefield was associated with lower mortality (6.5% decrease in patients mortality), this finding was similar to the CRASH2 trial (2.2% mortality decrease among TXA admitted cases) [11, 15]. Also, another study showed that the TXA administration was associated with an 8% reduction in 28-day mortality [17]. In contrast, in the Goethe study, TXA administered before hospitalization did not significantly reduce 30-day mortality [18]. Other observational studies have shown a similar risk of death in patients receiving TXA and control groups [12, 19]. In another study, TXA was associated with an increased risk of mortality in individuals requiring emergency blood transfusion and surgery [20]. Such controversy can be due to different criteria for patient inclusion criteria. The CRASH-2 trial included patients with suspected persistent bleeding in which 50% of patients had a blood transfusion, because inclusion factors in CRASH2 were all kinds of blunt or penetrating trauma with different amount of bleeding. In comparison, nearly 96% of the subjects in our study had any blood transfusion, which was higher than the CRASH-2 trial values [14, 15]. Another study showed that excessive mortality by TXA, also 97% of cases received blood transfusions [20]. The different sample size is another factor that can lead to different results. Studies with larger sample sizes have more reliable results.

According to our results the use of blood production in TXA group was fewer than placebo group. Despite the reported association between TXA administration and reduced need for blood transfusion in patients who undergo mainly elective surgery [21], it has been suggested that reduced tranexamic acid mortality may be along with the increasing demand for blood transfusion in injured patients [12, 16, 19, 22]. In particular, some researchers have identified a phenomenon called "fibrinolysis extinction," in which fibrinolysis observed on thromboelastographic is severely impaired in more than half of severely injured patients [23]. This could theoretically explain the contradictory effects of antifibrinolytic drugs in studies and indicate that TXA should be considered selectively [24, 25]. However, there is no evidence supporting the statistical interaction between TXA administration and the degree of fibrinolysis in clinical outcomes.

Some studies don't show significant association between the TXA administration and blood transfusion rate [12, 14, 20], but this association was showed in MATTERs study [16]. The results of the Tenxa study showed that early administration of TXA was not associated with a reduction in the use of blood products, and administration of TXA at an earlier time doesn't have any benefit to the patient [26]. Also, a multicenter observational study in Japan showed no significant difference between TXA and control groups in terms of the need for blood transfusion [17]. An observational study showed that TXA was associated with better survival in traumatized patients with unstable hemodynamic status [12].

According to our results, the hospital length of stay among TXA admitted cases was lower than the placebo group. It can be due to other factors such as less blood loss and so on.

Limitations

The current study had some limitations that include, due to time constraints as well as the outbreak of COVID-19 disease, which leads to a decrease in trauma patients

referred to the hospital and consequently decreases the sample size, so the insufficient sample size effects on study power and lead to insignificant results. Also because of few sample size, we cannot perform the subgroup analysis according to important variables.

Conclusions

Overall results of this study showed that TXA administration, was associated with better hemodynamic status, lower use of blood production, reduced bleeding and length of hospital stay but does not have a significant association with the incidence of thrombotic events, and mortality rate in trauma patients with severe acute bleeding.

Ethical approval

This study approved by ethical committee of Iran University of medical sciences with ID: IR.IUMS.FMD.REC.1399.603.

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Conflict of interest statement

The authors declare no conflict of interest.

Authors' contributions

AN and TT collected data and analysis, provided initial drafting. MV Comments and development of the manuscript, YA data analysis. All authors approved the final draft.

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Non com Diseases

The relationship between illness perception and medication adherence in patients with diabetes mellitus type II: illness perception and medication adherence

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Keywords

Illness perception • Medication Adherence • Type II diabetes

Summary

Introduction. *One of the most well-known chronic diseases in the world is diabetes. Disease perception is the patient's organized cognitive representation of his or her illness and can affect treatment adherence. The aim of this study was to investigate the relationship between illness perception and adherence to the medical regimen in patients with type II diabetes mellitus (T2DM).*
Methods. *This cross-sectional study was performed among 260 patients with type II diabetes referred to Gonabad Diabetes Clinic by systematic random sampling in 2019. Data collection tools were demographic questionnaire, Morisky medication Adherence Scale (MMAS-8), and Brief illness Perception Questionnaire (BIPQ). Data were analyzed by SPSS 20 software. And using descriptive statistics, Pearson correlation coefficient. $P < 0.05$ was considered significant.*
Results. *The results showed that the mean score of illness perception of type II diabetes was 46.39 ± 9.45 (range 0-70) and the mean score of medication Adherence was 2.93 ± 1.9 (range 0-8). The results of Pearson correlation test showed a significant relationship between illness perception and medication Adherence ($P < 0.001$, $r = 0.199$). Also, the regression model showed that the dimensions of disease comprehension and personal control from illness perception were significantly related to medication Adherence of type II diabetic patients ($P < 0.001$).*
Conclusion. *Based on the results of this study on the relationship between illness perception and medical adherence in diabetic patients, it is suggested that in order to understand the increase in adherence to therapy, the perception of the disease should be increased through education to patients. Patients' illness beliefs are candidates for a psycho-educational intervention that should be targeted at improved disease management practices and better adherence to recommended healthy behaviors.*

Introduction

Diabetes is of the most well-known chronic diseases across the world [1]. the number of people with diabetes mellitus was 30 million in the last decade, 1.7 million in the current decade, and is projected to reach 366 million in 2030 [2]. More than 18 million people (6.3%) of the US population have diabetes [3]. The prevalence of diagnosed and undiagnosed diabetes in Iranian men is 8.1% and 5.1%, respectively, and this prevalence in women is 10% and 4.7% [4]. Type II diabetes (T2DM) leads to decreased life expectancy (up to 8 years), increased cardiovascular, cerebral, peripheral vascular disease, vision problems, depression, nephropathy, and 60% of amputations [5]. The financial burden on society is increasing due to the health care cost and population aging with diabetes, so that half of diabetics over 65 years are hospitalized every year [6]. Diabetes is not curable, but it can be controlled [7]. Diabetes medication is very complex [8]. Studies have shown that patients adhere to a complex medication less than a simple one [9]. Patients' poor been medication adherence is one of the major clinical concerns that health system employees often face, which has considered by many researchers and international symposia as one of the complex and essential problems of the present age in the last two decades [10]. Non-adherence to medication in diabetic patients is correlated to frequent hospitalizations, non-receipt treatment benefits, high treatment costs, and many physician visits. The death rate in patients who do not adhere to their medication is twice as high as other patients [11]. Illness perception is one of the most critical factors. Illness perception refers to the patient's organized cognitive representation of his/her illness [12]. According to Leventhal's theory, patients regulate their behavior and emotional response to disease based on their perception of nature, causes, outcome, controllability, and illness duration. Bandura states that illness perception provides an essential framework for examining patients' beliefs and the impact of its components on health behaviors [13]. Illness perception includes 7 areas of identity (illness perception symptoms), course of the disease (chronic or acute), disease outcome, individual control, therapeutic control, coping with the disease, a period without disease, and emotional manifestations of the disease [14]. Various studies have supported the relationship between illness perception and medication adherence [15, 16]. Rajpura and Nayak (2014) showed

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that the illness perception and positive beliefs about treatment in the elderly with hypertension correlate with medication adherence [15]. Chen et al. (2011) showed that illness perception is correlated to medication adherence [17]. Illness perception has a predictive value in using the health behaviors of patients with chronic diseases. Perceptions of the disease can vary in different socio-cultural contexts. Moreover, no study has been found on patients with T2DM and its impact on medication adherence. The purpose of this research was to investigate the relationship between illness perception and medication adherence in patients with type II diabetes referred to the diabetes clinic of Allameh Bohlool Gonabadi Hospital (Gonabad University of Medical Sciences & Health Services) in 30/9/2019.

Methods

This research has employed a cross-sectional descriptive method. The research population included type II diabetes patients referred to the only specialized diabetes clinic of Allameh Bohlool Gonabadi Hospital in 2019. The sample size was obtained according to the study of Dost Mohammadi et al. [21] and based on the formula below, as many as 242 people with 95% confidence interval and 80% test power. Finally, 260 was set given about 10% of exclusion.

$$n = \frac{\left(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta}\right)^2}{(\omega)^2} + 3$$

Sampling was conducted through systematic random sampling. The inclusion criteria were diagnosis of T2DM by a specialist, no cognitive problems, ability to communicate in Persian, consent to participate in the study, being over 35 years old, and having at least one year of diagnosis of T2DM with active medical records. The exclusion criteria were dissatisfaction with completing the questionnaire and incomplete completion of the questionnaire.

Measures

The data collection tool in this research is a questionnaire with three sections.

Demographic

The first section is related to personal characteristics, including age, gender, marital status, residence status, level of education, employment status, number of hospitalizations, duration of diagnosis, family history of diabetes, smoking, economic status, and smoking, which was completed based on the patient's statements and medical record.

The Brief-Illness-Perception-Questionnaire (BIPQ)

In the second section, The Brief-Illness-Perception-Questionnaire (BIPQ) form was used to assess the illness perception. This questionnaire has 9 subscales that have been designed by Broadbent et al. based on the revised form of this questionnaire. The range of scores of the first 8 questions is from 1 to 10. Question 9 is open-answer and questions the three leading causes of the disease, respectively. Each subscale measures a component of illness perception. Five subscales measure cognitive response to disease, including the perception of outcomes, duration of illness, personal control, control through treatment, and symptom recognition. Two subscales measure worry about illness, emotions, and emotional response, and one subscale measures the illness perception ability. Cronbach's alpha for this questionnaire was as much as 0.8. The reliability coefficient of the 6-week retest for different questions was reported from 0.42 to 0.75 [22].

MMAS-8 Drug Adherence Questionnaire

In the third section, medication adherence was used using the 8-item MMAS-8 Drug Adherence Questionnaire developed by Morisky, Aang and Wood et al. (2008). This questionnaire has 8 items. The method of scoring and interpreting this questionnaire is formulated only in item 8 on a 4-point Likert scale. Other items are answered by yes = 1 and no = 0. Items 5 and 8 are graded, unlike other items. The scores of all items in the questionnaire are summed to calculate the questionnaire's overall score. Its overall score range is between zero and 8. A score greater than 2 is poor drug adherence, 1 and 2 is moderate adherence, and 0 is considered as high adherence. In the research of Koushiar et al. (2013), while measuring the face and content validity of this tool by expert professors, its reliability was reported by Cronbach's alpha method as much as 0.68 [23].

Ethical considerations

This research has been approved by the ethics committee of Gonabad University of Medical Sciences under the No. IR.GMU.REC.1398.104. the researcher obtained the necessary permits to conduct the research with the director of Allameh Bohlool Gonabadi Hospital's permission after being introduced to the research environment to comply with the ethical standards for conducting research. The researchers referred to the diabetes clinic of Allameh Bohlool Gonabadi Hospital to collect the data. The units were provided to patients to answer and ensure the confidentiality of information after stating the purpose of the study to the patient and obtaining consent and declaration of readiness. If the patient was illiterate, the questions were read to him/her by the researcher. Moreover, medical information was extracted from patients' records. First, the obtained data were initially examined.

Statistical analysis

The data were imported to SPSS20 software. Data were

described using descriptive statistics, and then data analysis was performed. Chi-square test was used to compare the grouped data, Pearson correlation coefficient was used to determine the relationship, and Independent t-test and ANOVA were used to compare quantitative data in groups related to contextual variables. The significance level in the tests was considered as much as 0.05.

Results

The present research was conducted on 260 patients with type II diabetes to determine the relationship between illness perception and medication adherence. The mean and standard deviation of patients' age was 59.05 ± 11.55, and 154 (59.23%) were women (Tab. I).

Tab. I. Frequency of demographic and severity of medication adherence of patients with type II diabetes (n = 260).

Characteristics	N (%) Mean ± SD
Gender	
Male	106 (40.77)
Female	154 (59.23)
Marital status	
Single	7 (2.69)
Married	226 (86.92)
Widow	8 (30.8)
Divorced	19 (7.31)
Education	
High school	198 (76.15)
Diploma	34 (13.08)
University	28 (10.77)
Economic status	
Good	14 (5.39)
Moderate	186 (71.53)
Weak	60 (23.08)
BMI	26.47 ± 4.27
HbA1C	8.43 ± 1.38
High adherence	0 (0)
Medium adherence	106 (40.8)
Low adherence	154 (59.2)

Based on the results of this study on the relationship between perception of the disease and adherence to the treatment regimen in diabetic patients, it is suggested that in order to understand the increase in adherence to therapy, the perception of the disease should be increased through education to patients. Illness perception in patients with type II diabetes was 45.9 ± 39.46 (range 0-70), and the duration of the disease was 7.97 ± 2.67.
The medication adherence score was 1.69 ± 2.93 (range 0-8). According to the severity of medication adherence of type II diabetic patients, 154 patients (59.2%) had poor drug adherence (Tab. I).
According to the study of the relationship between gender with different dimensions of illness perception and medication adherence of type II diabetic patients, the results show a significant relationship between total scores of illness perception and gender ($P < 0.001$) (Tab. II).
A significant relationship between illness perception and medication adherence in patients with type II diabetes ($r = 0.199$, $P = 0.001$) (Tab. III).

Discussion

The results indicated relatively low medication adherence, which is not consistent with Dost Mohammadi et al., Who reported high medication adherence in the elderly with hypertension [20]. It can be explained that patients with hypertension possibly were more aware of the disease and its risks.
The illness perception results in patients with Type II Diabetes participating in the research showed that more than half of the patients report their illness perception as moderate and above. These results are consistent with studies of Doust Mohammadi et al. [18] and Taheri-Kharameh et al. [19] In Iran, Angell et al. [20] and Christensen in USA [21] and Mosleh in Jourdan [22].
Research results on the relationship between illness perception and medication adherence can be, according to cognitive theories describing the factors explained the effect on the occurrence of a behavior. In cognitive theories and models, it is assumed that the characteristics and perceptual organization of individuals lead to

Tab. II. The relationship between education and different dimensions of illness perception and medication adherence of type II diabetic patients

Education Variable	High school	Diploma	University	ANOVA P-value
Perception of consequences	8.03 ± 2.58	6.52 ± 3.57	5.18 ± 3.70	< 0.001
Duration of the disease	7.83 ± 2.65	8.45 ± 2.39	8.30 ± 3.12	0.374
Personal control	3.00 ± 2.17	2.88 ± 2.58	2.18 ± 1.66	0.193
Control through treatment	2.98 ± 2.63	3.44 ± 2.73	2.49 ±2.48	0.369
Recognizing patients' symptoms	6.83 ± 2.40	5.61± 2.88	6.37± 3.11	0.034
Worry about the disease	7.92 ± 2.49	6.88 ± 2.99	7.00 ± 3.66	0.045
Illness perception ability	3.18 ± 2.59	2.54 ± 2.41	1.41± 1.00	0.001
Emotions and emotional reactions	8.06 ± 2.75	5.85 ± 3.90	5.85 ± 3.90	0.001
Total perception of illness	48.03 ± 8.26	42.27 ± 10.89	39.27 ±11.35	< 0.001
Total medication adherence	3.07 ± 1.77	2.97 ± 1.40	2.88 ± 1.42	0.834

Tab. III. Correlation matrix between some demographic variables with illness perception and medication adherence of type II diabetic patients

Variable	Illness perception		Medication adherence	
	Correlation coefficient (r)	Significance (P)	Correlation coefficient (r)	Significance (P)
Age	0.166	0.008*	0.137	0.029*
Duration of diabetes	0.151	0.042*	0/059	0.344
Number of hospitalizations	0.134	0.082	-0.047	0.541
FBS	-0.173	0.006*	-0.153	0.043*
HgA1C	-0.288	p< 0.001*	-0.191	0.005*
BMI	-0.050	0.465	-0.078	0.187
Perception of consequences	-	-	0.090	0.149
Duration of the disease	-	-	-0.023	0.079
Personal control	-	-	0.179	0.004*
Control through treatment	-	-	0.064	0.305
Recognizing patients' symptoms	-	-	0.158	0.308*
Worry about the disease	-	-	0.020	0.751
Illness perception ability	-	-	0.252	p < 0.001*
Emotions and emotional reactions	-	-	0.085	0.173
Total Illness perception	-	-	0.189	0.002*

shape there are some behavioral characteristics that have different consequences has it. Some of these features and perceptual organizations, such as sensory, Being emotional, perceiving low risk and not paying attention to the consequences of behavior, consequences Negative brings with it a weakness in problem solving, emotional processing Weakness, irritability as well as the development of certain behavioral characteristics Which disrupts adherence to personal care orders and at a particular level, adherence to the treatment regimen [23]. Various protective mechanisms have been proposed to explain the effects of illness perception on medication adherence. Most of these mechanisms are summarized in two areas, which are physical factors and psychological mediators. The factor that has received the most experimental support concerning physical factors is the lower activity of the hypothalamic-pituitary-adrenal axis in people who have a rational perception of illness and believe in appropriate treatment [24]. Regarding psychological mediators that mediate the illness perception with medication adherence, medication adherence can affect psychological factors. On the other hand, these factors affect medication adherence. Mohammad pour et al., in a study in Iran showed that lack of awareness about the illness is one of the factors correlated to medication non-adherence [25].

The two components of personal control and illness perception ability in the illness perception group had a significant relationship in medication adherence in patients with type II diabetes, which means that those who have a greater perception of their illness, their health status is subject to their personal control, feel more responsible for their health, and follow higher treatment. The results of this research are in line with the previous studies on illness perception level and their medication adherence [26-28]. Rajpura and Nayak, in a study in USA reported a positive relationship between illness perception and positive beliefs about treatment in the elderly with hypertension with high medication adherence [15]. Taheri Kharameh et al. conducted a study they concluded that the two components of personal control and illness perception ability were the most important predictors of medication adherence, consistent with this research [19]. Ross et al., in a study in UK concluded that illness perception and beliefs about hypertension predict patient adherence [26]. Kretchy et al., in a study in Ghana showed that patients with better perceived health status were more likely to adhere to medication [27]. Alluhayyan in study in Saudi Arabia found a significant positive correlation between illness perception subscales of personal control, treatment control, and understanding with all domains Medication Adherence [28].

Among different disease groups, such as asthma, chronic renal failure and diabetes, several studies have presented illness perception as an important framework for predicting patients' capacity to cope and for developing interventions to prompt self-management in chronic disease.[29-31] Appropriate health beliefs, such as perceived seriousness of illness, vulnerability to complications and efficacy of treatment can predict better compliance among diabetic and hypertension patients [32, 33]. Hand et al. found that asthmatic patients adhered well to recommended treatment when the treatment regimen made sense to them and when they felt they had the ability to succeed at the regimen. [34] In addition, a significant association was found between patients' illness perception and osteoarthritis patients' decisions to seek medical help and adherence to medical advice [35].

One of the limitations of this study is that the present research tests are self-assessment tests. The measured abilities and characteristics in this self-assessment are based on individuals' self-perception, which is closely related to their self-concept. If self-concept does not correspond to reality, such scales cannot well reflect the

individual's true characteristics and abilities and only express the individual's self-perception.

Conclusion

In conclusion, we found that low medication adherence is predictable when the illness perception is low. There is a significant relationship between illness perception and medication adherence in patients with type II diabetes. Strengthening illness perception to increase patient's medication adherence is a critical treatment strategy in educational interventions. Therefore, it is suggested that educational programs appropriate to the level of education of diabetic patients in order to increase health literacy and illness perception in diabetic patients should be considered.

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Conflicts of interest statement

The authors declare no conflict of interest.

Authors' contribution

SSB and ADN designed the study, SSB and HA were involved in collecting the data and patient's management, ADN performed the data analysis. SSB drafted the manuscript. All authors read and approved the final manuscript.

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History of Medicine and Ethics

The avid eaters of lives. New and old infectious diseases in Italy at the time of World War I: a historical overview of military medicine and public health

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Keywords

Infectious diseases • History of military medicine • History of public health • WWI • History of hygiene • Epidemiology

Summary

World War I hit Italy from different perspectives. The one here described under an historical point of view regards the health of military and civil population, with a special focus on infective diseases. The 20th Century was the fuse of degeneration and eugenetics theories; which grew in the melée of war and technological innovation. Indeed, war is interestingly depicted as an entity capable of emphasizing the differences between those who wore a uniform and those who did not. As a matter of fact, some infections spared the civilian population while others felt with greater vengeance on this subgroup. Moreover, the incidence of different feared diseases was brought back to the rates of the late 19th Century. Thanks to a statistician, Giorgio Mortara (1885-1967) the impact of infective diseases in Wolrd War I on Italian demography is well established. Moreover, different military and civilian sources contribute to enrich the picture of the consequences of war. In conclusion World War I could see considered as a litmus paper. The litmus paper of successes and failures of italian public health management to face new medical challenges exacerbated by the crisis.

Introduction: the litmus-paper war and the "degeneration discourse"

World War I was an extreme trial for the drafted generations [1]. In Italy, like in all other involved countries, the Great War (1914-1918) made structural health and hygiene problems visible and had years-lasting effects both on the health of the military and on the health of the general population. The neurologist and social medicine activist Ettore Levi (1880-1932) stated in 1921: "The war is a litmus paper: it has abruptly highlighted and multiplied the infinite misery dormant in individuals and in social masses. Because of the war, multitudes of tuberculosis sufferers, psychopaths, crippled and maimed men are now living at the expense of the State The State was thus suddenly obliged to realize the huge moral and economic importance of public health in time of peace" [2].

Italy, which was at war from May 24th 1915 until November 4th 1918, was mostly a traditional agricultural country. The war made structural problems of the Public Health organization evident, e.g. the strong inequality between urban environment and rural regions. Another specific war-related inequality was the one between the military and the civil population: while the former had access to better food resources, the latter suffered from a curtailed production and distribution of food. This provoked protests and played without doubt a role in the general health conditions of the Italian civilians. On the academic (and literary) level, at the time of the outbreak of World War I a *degeneration* discourse was ongoing and for some authors the war could work as a medicine against it (The futurist literary movement, initiated by Filippo T. Marinetti, used the metaphor of "war as hygiene") [3]. The idea of degeneration was influential in Europe starting in the Enlightenment – both Georges – Louis Buffon (1707-1788) and Jean Baptiste Lamarck (1744-1829) believed in the inheritability of acquired traits among the living beings in general. The *Traité des dégénerescences* (Paris 1857) by the french-austrian psychiatrist Bénédict Morel (1809-1873) was influential for its strong moral underground because he maintained, following Buffon and Lamarck, that habits (particularly negative ones) are inheritable.

According to Morel, behaviors like drinking, and conditions like syphilis, are inheritable and lead to familiar degeneration, which occurs at the psychological-moral and at the physical level. This idea of a biological *worsening* of humans began to circulate strongly during the complex phenomena subsumed under the name industrial revolution and urbanization.

Growing numbers of people moved to the cities from the beginning of the nineteenth century and showed increasing rates of infections due to overcrowding and poor sanitary resources.

Alcohol addiction and crime, which rose as urban phenomena, contributed to the spreading of the

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degeneration discourse about the risks and negative sides of industrialization and economic progress. Another trait of the degeneration discourse was the sinking birth rate in urban environments in countries like England and France. Morel's *Traité des dégénerescences* was paralleled by the discussion of the concept of eugenics by Francis Galton (1822-1911). In 1883 Galton defined eugenics as "the cultivation of race" [4], meaning that positive characteristic in a population must be cultivated, in analogy to the improving of livestock or plants. In Italy the degeneration and eugenics discourse began half a century later, primarily in two 1898 and 1889 publications by the anthropologist Giuseppe Sergi (1841-1936) [5] and by the forensic pathologist Angelo Zuccarelli (1854-1927) [6]. Both proposed the sterilization of habitual criminals, though, it was never practised in Italy. Eugenics as a discipline became an academic subject in 1912, when the first professorship for *Eugenica sociale* was created at the University of Genoa, and in 1913 a *Comitato Italiano per gli studi di eugenica* was founded [7]. During World War I the army surgeon and psychiatrist Placido Consiglio (1877-1959), another supporter of sterilization, pleaded for using the war as an instrument of selection in a particular way: "There is no other way in science: we have to clean the army from the not-normal by gathering them in special units and assigning them possibly to particularly dangerous tasks. Thus we can practice a fatal, beneficial selection" [8]. This radical, paradoxical approach did not gain a foothold, but, again, the idea of war as a sort of "litmus paper" for the biological characteristics of populations and nations spread, on the background of the degeneration-eugenics ideas.

In the war years there were new tendencies on the demographic level as well. On the eve of World War I (1914) Italy had 37,255 million inhabitants, 1919 they were 37,195 million. This decline does not look particularly dramatic, but let us take into consideration the birth and the death rate. The birth rate (the number of live births per thousand of population) was 30,51 in 1914, had dropped to 19,35 in 1917 and to 18,2 in 1918. The death rate of 1914 was 18,04 and 35,29 in 1918. That is to say, during the war the birth rate in Italy had nearly halved and the death rate had doubled. This is even more visible in absolute numbers: in 1914 there were 1,145,000 births and 677,000 deaths, in 1918 676,000 births and 1,324,000 deaths [9].

The data on the pre-war years: the pivotal role of Giorgio Mortara

Giorgio Mortara (Mantova 1885 - Rio de Janeiro 1967), the statistician and demographer who illustrated the demographic and public-health consequences of war in 1925 [10], had earned a degree in Law at the University of Neaples in 1905 and had worked in Berlin on "Probability Theory". He was professor in Messina, Rome and Milan until 1938, when he immigrated to Brazil due to the anti-Semitic laws of fascist Italy. He worked in Rio de Janeiro as a statistician and after World War II he taught again at the faculty of Statistics in Rome, but he remained Brazil-centered [11]. His analysis of the Great War was conceived from the perspective of a civil servant who had pleaded for the intervention of Italy in war and had fought in it. Demographic research was for Mortara at the service of the national interests [12].

But his view on war was devoid of triumphal considerations, in contrast to the view of the influential Italian futurists, who had enthusiastically taken part in it. He characterized war as follows: "War, this avid eater of lives, has always deeply modified the demography of the countries involved in its dismal game. Carnage of fighters, epidemics in the armies and from them in the civil population, drought and famine, devastation of territories, oppression and flight of populations, destruction of families, hindrance of marriage, all of these are concomitant phenomena of every war between peoples. Human history is entwined with the horrors of myriads of wars and they mark the stages of what we call, ironically, the path of progress" [10].

Mortara collected and elaborated data about deaths and disease from the Army and from civilian institutions [13] and on the death causes in the year immediately preceding the war. The question for Mortara was "To which modification of the intensity of single causes can we ascribe the diminution of the death causes? We ought to answer to this question if we want to adequately understand how the war has contributed to modify the preexisting trends toward the increase or decrease of the mortality rate from certain diseases" [10].

In the years before the war, between 1889 and 1913, the yearly death rate in the Reign of Italy had dropped from 27 to 19.43‰. This was due both to medical and hygienic advances such as water supply (which e.g. reduced the cases of cholera), wide vaccination practice (reduction of smallpox) and combinations of hygienic and therapeutic innovations (e.g. the measures against malaria and diphtheria). Particularly, in the three years 1887-1889 all the infectious diseases (typhoid fever, typhus, malaria, smallpox, measles, scarlet fever, pertussis, diphtheria, flu, cholera, erysipelas, dysentery, leper, mumps) were cause of 4,648 deaths of a million inhabitants a year, whereas in the three-year-period 1911-1913 the rate number was 1,300 [10]. For example, meningitis as a death cause decreased, while circulatory, gastric and kidney diseases remained constant as a death cause or even rose, due to the aging population. Respiratory diseases and diarrhea, in their turn, decreased due to "better hygiene and clothing", and puerperal fever, which caused 7 deaths of thousand births in 1889, sank to 3 in 1913 [10].

Tuberculosis occupied a special place among the infectious diseases, because its decrease, more than in the case of other infectious diseases, was due to the "improved economic situation and […] a less low living standard" [10] in the country. In the three-years-period 1887-1889 there were an average of 2,128 deaths of a million inhabitants a year from all form of tuberculosis (lung tuberculosis, tubercular meningitis and other

types). In the period 1911-1913 the rate sank to an average of 1,567 a year. Notwithstanding this progress, in Italy there was a lot to do to improve the hygienic conditions, particularly in the rural regions. In 1916, for example, the roman professor Gherardo Ferreri (1856-1929) stated "cemeteries, sewers, hospices and houses are prehistorical" [14].

Giorgio Mortara's data on the war years

According to Mortara, during the war 651,000 of the 5,600,000 drafted Italian soldiers died: 378,000 were killed in action or died subsequently from the wounds, 200,000 lost their lives from diseases (80,000 of them in captivity). Further 87,000 died after the war, between the 12th November 1918 and the 30th April 1920, from war-related conditions and most of all from the Spanish flu; the 30th April 1920 was conventionally the last death day that the Commission for War Reparation considered suitable for paying a war pension to the families of the fallen [10].
When we take into account that the military were men born in the years between 1874 and 1899, and the death rate for this age group in the years preceding the war (1911-1913) was 70,000/75,000 a year, it results an excess of 525,000/530,000 deaths [10].
The deaths among civilians, too, significantly exceeded the death rate of the previous years. In the years 1911-1913 the general death rate was 681,000 a year, while in the four years 1915-1918 the deaths among civilians were 3,277,963 in total. The absolute numbers were as in Table I.
Civilians and army, in conclusion, showed a similar death toll in the war years.
Leaving other death causes besides, from what infectious diseases did soldiers and civilians die in excess, in comparison with the previous years?
In general, infectious diseases were responsible as a group (see above) for an increasing number of deaths both in the army and among the civilians, as the absolute figures show.
In 1914 there were 32,744 (out of a population of 37,255 million) and 1919 there were 74,373 deaths due to infectious disease out of a population of 37,195 million. In 1918, the year of the Spanish flu, the death from infectious diseases in general had increased to 314,762 (only 40,721 deaths were due to other infectious diseases, i.e., more than 270,000 were Spanish flu-deaths). Only in 1921 the deaths from this group of diseases came back to the pre-war figures with 34,299 deaths [10]. Having stated that the Spanish flu was the main death cause,

Tab. I. Absolute numbers of deaths 1915-18[10]

Deaths	Year
732,421	1915
708,544	1916
688,463	1917
1,148,000	1918

These data represent a total excess of about 600.000 deaths in the four years [10].

Fig. 1. The cartoon by Giuseppe Scalarini (1873-1948) showing a napoleonesque flu agent appeared in the Milanese edition of the Socialist newspaper *L'Avanti* on 13th October 1918, p. 1 (Public Domain - https://www.google.de/url?sa=i&url=http%3A%2F%2Fwww.scalarini.it%2Fit%2Fopera-artistica%2Fdisegni%2Fpubblicazioni%2Favanti%2521%3Fpage%3D14&psig=AOvVaw1M4UQIltbFTXe7Q5Z_DFwc&ust=1635780963373000&source=images&cd=vfe&ved=0CAsQjRxqFwoTCODrwY399PMCFQAAAAAdAAAAABAb).

and well knowing that data on death causes other than wounds from the military were incomplete, Mortara analyzed the frequency of some diseases in order to find out different factors playing a role in the army and in the population. A relevant factor of the incomplete recording was the lack of doctors in the civilian population. The Italian military medicine cared for more than two million soldiers during the war years; in 1916 there were 8,000 military doctors at the front in the region of the rivers Isonzo and Piave and 6,000 in the zone behind, at the end of the war there were 18,000, included the 1,200 from the Red Cross. Generally, an *infirmary* consisted of an officer, one or two officer candidates and 30 nurses and stretcher-bearers and provided for immediate care (bandaging etc). These infirmaries were at the front. In the zone behind were the *ospedaletti da campo*, in which the wounds were disinfected and operated, and bigger *ospedali da campo* for men needing a long permanence because of infectious diseases and for the most seriously wounded [15] (Fig. 1).

Infectious diseases

Mortara reported that it was difficult to obtain complete data on the infectious morbidity in the army, but he could

collect a good amount of data on some principal infectious diseases. Regarding typhoid fever (the Salmonella-caused, fecal-oral transmitted condition with symptoms like fever and abdominal pain, in Italian *febbre tifoide* or *tifo addominale*, also called *paratifo)*, the registered cases in the army 1915 were 18,655 and in 1918 they had decreased to 5,992. The decrease correlated clearly with the vaccination, broadly practiced in the army since 1917 and in case of local outbreaks since 1915 [10].

Typhus (in Italian tifo *esantematico* or *tifo petecchiale*), which other than typhoid fever is caused by Rickettsia and spread by lice, came to Italy, according to Mortara, through Austrian-Hungarian troops and through war prisoners (who were detained overall in Italy) and spread mostly after the end of the war among ex-soldiers and civilians. In 1919, 5,736 cases were reported among Italian ex-soldiers and prisoners (5,416 among the prisoners and 320 among the soldiers). Mortara extimated the number of cases in the civilian population at 3,150, although the official reports said only on tenth. According to Mortara's calculations, the deaths from typhus in 1919 were one fifth of the total figure and he insisted that the number of the unknown cases must be high [10].

The 25 years infantry officer Antonio Ferrara, on a march in the region of Udine, wrote on September 27, 1915 in his diary about an outbreak of typhoid (which he named *tifo* and put wrongly in relation with lice): "We are surprised to see here and there yellow flags. Our medical officer, Fantozzi, says they indicate cholera or some other infectious disease. The worst thing is that we are all full of lice and it takes a huge amount of patience to get rid of them. There is a rumor that there have been cases of typhus. As a precaution, a vaccination is ordered for the whole regimental sector and, as officers, we have to set an example for the soldiers. To our comfort, we are given 48 hours rest in our tents" [16].

Ferrara's record shows that even officers were not always informed about the sanitary situation and that the practice of the typhoid-vaccination at this stage was experimental.

Another soldier noted his experience as typhus-sufferer (here typhus is meant). The disease began suddenly and was regarded as typical for the infantry: "As I was eating noodles, I felt a stroke in my back and fainted. As I recovered consciousness I heard a loud noise, I had 42 degrees fever. They took me to the military surgeon and he told me: 'It is our disease, typhus in the head! After fifty-two day in hospital I felt recovered'" [17].

The case of malaria shows the interdependence of health and environment: in the agricultural regions near the war zone most fields were abandoned and new swamps had formed. As a result, at the end of 1918 more than 85,000 malaria cases were reported in the army (they were 12,000 at the beginning of 1918) [10]. Smallpox showed a difference between the army, in which the vaccination was diligently practiced, and the civilians: in the army there were 79 cases in 1915 and 329 in 1918, in the civilian population in 1915 626 cases were registered, which increased to 4,519 in 1918 [10].

For scarlet fever, measles, and diphtheria, too, the data form the population were poorer than the data from the army. The Spanish flu was the main death cause from an infectious disease in the wartime worldwide. Up to 50 million died (3% of the world population), one third of the world population was probably infected [18]. In the army, following Mortara, in the period May 1918 - April 1919 the cases were 122,829 and the deaths 10,854 (one death out of 11/12 cases). In the whole country, some 500,000 people died and there were 5 to 6 million cases; one inhabitant out of seven was probably infected. The death toll was dramatic due to a combination of factors: not only there were no antibiotics, but most doctors were drafted and it was difficult to transport the ill to hospitals, due to a lack of vehicles and to the poor network of communications. Therefore, people in the rural regions had no or scarce access to medical care, to say nothing of hygienic housing. Moreover, in the first weeks of the pandemics (the news came in Spanish newspapers at the beginning of May 1918) it was forbidden to write about it in the belligerent countries, and that resulted in a waste of time. Finally, most people in the civilian population were weakened by the food rationing more than the soldier were. Being a civilian, particularly on the country, meant to be more at risk to die because of the war, even if not directly *in* war. The sublieutenant Renato Rossi died from Spanish flu on December, 4th 1918. The caplan Giovanni Dal Santo wrote to his father and gave a brief medical-religious description of the last moments of his life: "Sublieutenant Rossi was admitted to field hospital in the afternoon of November 30th due to Spanish flu and bronchopneumonia. On December 3rd he got worse. He piously became the last rites. The good Rossi was conscious of his approaching death. On Dec. 3rd he started to call for his mother and kept saying: - Mother, mother, I will come to see you soon, and he often repeated these words on the 3rd and the 4th. He did not undergo death struggle, as it often happens in such cases; he was suffocated by the blood coming out of his mouth. I stood by him until his last breath, he died putting himself in God's and the Virgin Mary's hands at 6 pm on December 4th 1918" [19].

In the civilian population the spanish flu was the bigger trauma of the wartime. Vincenzo Rabito, who was among the youngest generation drafted in Italy (1899) and whose diary was posthumously published in 2007, described the flu epidemics in his small Sicilian village: In Chiaramonte more of 20 people a day died from spanish flu. The police ordered the families to bring them soon to the graveyard, because the stench of the dead killed the living people ("… a Chiaramonte con la spagnola ne morevino più di 20 al ciorno […] Li muorte nelle famiglie, come morevino, subito le guardie stavino pronte, e li carabiniere ce li facevino portare subito al cimitero, perché con la puzza facevino morire a quelle vive") [20].

We do not know whether the archaic idea of disease transmission through stench was spread by the police to accelerate burials, or it was Rabito's own conviction. In any case, it expressed the ubiquity of the menace and the atmosphere of fear in which the population lived.

Cristina Robaldo told her experience of the Spanish flu to Nuto Revelli; Nuto Revelli (1919-2004) was a soldier and a partisan who wrote about the retreat of the Italian army in Russia in 1943 through the memories of fellow soldiers [21]. Later he devoted himself, although not having a formal historical education, to the oral history of the piedmontese region of Cuneo and published two books: "Il mondo dei vinti, in 1977, the work, emigration and war memories of 85 people from the valley around Cuneo, and *L'anello forte*, 1985, in which he interviewed only women". The author of seminal books on Piedmontese oral history wrote: "After the war of 1914 we all got the spanish flu, everyone, only my father did not get sick. We had no money to fetch drugs, we all had forty-one or forty-two degrees fever. We took only quinine and nobody came to look after us, because many people died" [22].

Quinine-therapy and lack of doctors were the two main traits of the Spanish flu epidemics. As Eugenia Tognotti noted, there was no consensus in the medicine about a therapeutic strategy. Quinine was employed as an antipyretic, typically in the treatment of malaria and as a symptomatic therapy for the spanish flu, and a vaccination was looked for, without success. Physicians were totally helpless, patients too [23]. The flu was correctly perceived as a major death cause in war, even when the people did not have statistical data, like a man and a woman from two Piedmontese villages stated in their oral memories: "I didn't fight in the war of 1915, I was too young. Three men from Pragudin died in that war, but more people died from the Spanish flu than at war. In 1918 my father died from the flu, too. When the doctor came, the people were already dead" [24].

"My family was poor, we had two acres of land and we were eleven siblings. But three died as they were infants, they died in 1919 from the Spanish flu. Everyone was in bed, my father, my mother, I was the one keeping working, I was the one who did not get the flu. One night three of my siblings died, and I had to bury them" [25] (Fig. 2).

Cholera was declining in Italy in the years before the war (see above), but in 1915 a new epidemic wave broke out. According to Mortara, this epidemics was imported Italy by the Austrian Army in 1915 and spread through the war regions in northern Italy. Among the military there were in 1915 15,744 registered cases with 4,229 deaths; among the civilians 731 cases and 324 deaths, i.e., about ¼ of the ill died [10]. Some units of the army were decimated by the cholera epidemics, particularly the infantry units. This is not surprising, taking into account the hygienic conditions in the trenches. In the trenches it was not only more probable to get the infection, but it was more difficult to promptly isolate the ills. Moreover, most units were continually dislocated from one war theatre to another, thus spreading the disease. A vaccination was administered from the winter 1915 onward in the army and clearly contributed to the decline of the cases: in 1916 only 283 cases and 93 deaths were registered in the army [10]. The terrible symptoms of cholera and the quick death that often followed are recurring subjects in diaries, letters and oral reports. Some literate soldiers described cholera outbreaks in impressive way, like the driver and soldier Gastone Bassi in his diary on July 29, 1915: "A terrible stench poisoned the air. The unfortunate sick lay in a sort of cellar, it was large, low, dark, nauseating. Few of them were dressed, some had just a shirt or bags were naked. There were some centuries of them […]. These poor men were emaciated and yellow, they had bluish bags and misty eyes. Some were dead and some were dying. We loaded them on the cars like infected rags and they complained: – Water, water, thirst! – And they twisted violently, stiffened with visceral pain. According to the instructions, we gave them some bits of lemon and some water with iodine drops. I strived to swallow lemon juice and furiously smoked cigarettes. We had to wander from hospital to hospital to find a place for those poor living human remains. At the end, we left them in the isolation hospital of Visco. One had died during the trip" [26].

Lemons and isolation were the therapy in another case of cholera outbreak, according to the diary of the soldier Giuseppe Battistel, who fought in the Austria-controlled port of Valona, Albania, in 1916 (the record was written on March 15th, 1916): "After a month the cholera began to rage and in the two companies we were almost all sick, because of the fear and because of the filthy water we were drinking. Then the command ordered us to work five hours a day. The seriously sick were isolated, one man in one tent, and they became lemons. Ten days later, thanks our medical officers, the danger was warded off but we had the first victims and they were buried near the camp. These were the first victims of the 56. Infantry" [27]. Measures against cholera, as noted above, were difficult to implement in the war situation. The soldier Emanuele Di Stefano wrote about causes and insufficient countermeasures: "Cholera spread fast

Fig. 2. As medicine was helpless against the Spanish flu, a beer or a cognac therapy were recommended in this ad (Public domain - http://www.castelbolognese.org/fatti-storici/xx-secolo/prima-guerra-mondiale/la-chiamarono-spagnola-ma-venne-dal-mare).

as a lightning and cut down for five months the teams of the Bergamo Brigade. What were the causes of the epidemics? Undoubtedly many factors played a role in its the beginning and diffusion: filthy water, absence of hygiene, the organic decay of the troops […]. The soldiers were dying at a worrying rate but they had nevertheless to keep working hard. Every morning an officer let special teams clean the camp accurately, but these measures were inadequate" [28].

Tuberculosis was the main endemic disease of united Italy. In the four-year period 1911-1915, according to official data, there were in total 274,117 deaths from tuberculosis (the trend was decreasing: in the preceding four-year period the deaths were 282,901). In the following four years (1916-1920) the total figure was 317,531 [29]. In the army, according to the paradigmatic study of Tommaso Detti, tuberculosis was responsible for one tenth of the deaths in general and for one fifth of the death from disease [30].

It is difficult to evaluate the number of the soldiers who contacted tuberculosis in war.

Mortara extimated, admitting the vagueness, that they were 50,000 to 100,000 [10].

During the war years the medical officer Antonio Fagiuoli stated that the war situation, particularly the trench situation, was a possible factor for the outbreak of latent forms of tuberculosis, i.e., soldiers who were already latent infected at the moment of the drafting developed the disease in the war zone through a "autoinfection" mechanism.

These, in their turn, communicated the disease to their fellows, particularly to those who were predisposed through fatigue or preceding illnesses. How could such infections be avoided? Fagiuoli stated that the military doctors were responsible of declaring ill men fit for service, because in war the bulk of the army was relevant and because they meant that soldiers tended to the simulation of diseases and to draft evasion. Moreover, Fagiuoli quoted cases of draftees who, knowing to be tuberculosis sufferers, denied their condition to be able to serve their country [31]. As a conclusion, Fagiuoli suggested including tuberculosis specialists (*tisiologi*) in the drafting commissions, in order to avoid future infection herds by excluding suspect cases from war service, even when they were willing to serve [31]. However, tuberculosis was perceived as a war consequence: "We won that war, but we lost it. Statistics say that the tuberculosis cases were more than the war casualties. I was wounded from mustard gas on the Montello and when I was back home I had only one day to celebrate, soon I got sick with pneumonia and suffered for two years" [32].

Two war-specific, war-symbolic conditions

Apart from wounds, sepsis, and infectious diseases, some conditions were in a way epidemic in the trenches: trench foot and self-injury. The reign of Italy entered in war in May, 1915. In the first war winter the cold temperatures and the trench situation contributed to the emergence of the trench foot condition, caused by long standing in the water that gathered in the trenches. The feet became numb and capillaries were destroyed. Infections or gangrene could follow, and amputation was sometimes the only life saving measure. Prevention was possible, though: wool socks were a good solution to keep feet dry and warm and they were used instead of the puttees (in Italian *fasce mollettiere*) during the first year of war, but during the winter it was difficult to find wool on the market and they were therefore very expensive. An alternative solution was rubbing the feet with fat [33]. Officers became a small handbook with instructions to avoid trench feet in their troops [34]. This nine-page booklet invited the poorly equipped soldiers to "protect themselves from the cold" (p. 3), to envelope their feet with "sheets of paper (newspapers)" (p. 4) and keep their feet so clean and the trenches so dry as possible (p. 5). Most of this was mere wishful thinking and trench foot was common. It has been extimated that between 100.000 and 300.000 italian soldiers suffered from it. The range is wide because this condition was confounded and summed up with frostbite, although frostbite occurs only under zero degrees, while trench foot can occur even in water at warmer temperatures [35]. In fact, continuous rain could be a cause of trench foot "epidemics": "Last news: cholera cases begin. On one day there were six, quite serious cases. Moreover, soldiers who stay constantly in rainy trenches develop a new foot disease (skin oedema). They have strong pain and absolutely cannot walk. Every day many go to the hospital, some 40 or 50" [36] (Fig. 3).

Not always did the soldier follow officers' recommendation to grease their feet, as the above-mentioned Vincenzo Rabito noted: "Our feet froze and a group of orderlies had the task to grease the soldiers' feet to prevent them from freezing. The captain used to come and see if we had greased our feet and if we refused to do it, they punished us by not giving us our rations. Even if we did grease them, every day four or five soldiers ended up in the infirmary with frozen feet. Some naughty soldiers washed their feet with snow after having greased them or walked in the snow because they did not want to fight" [37].

Trench foot was sometimes, as we have seen, a self-inflicted condition that could lead to a welcome convalescence. Other forms of self-injury were practiced before the drafting and during the war; sometimes self-injury or disease were only "dreamed of", as we can read in some memories. A register of self-injuries does not exist, but they deserve a mention among the health-relevant factors and facts in World War I. Self-injury, nevertheless, should have been quite common: on July 26th 1915, only two months into the war, 46 soldiers were accused of self-injury (typically, they shot themselves in one hand or foot) and 27 of them were sentenced to 20 years prison. After the battle of Caporetto on October 27, 1917, self-injurers risked a death penalty [38]. Among the men Nuto Revelli interviewed quite many talked about self injury at home, a desperate decision they took when they received the draft notification in

Fig. 3. Misure Preventive contro le congelazioni. Istruzioni per gli ufficialil (Fonte: Intendenza Generale dell'Esercito. Public domain - https://www.idrometra.it/6444-large_default/intendenza-generale-esercito-misure-preventive-contro-le-congelazioniconge-lazioni.jpg).

the war years. The injuries were mostly planned to have only temporary consequence, but sometimes the plan did not work out, like in the cases of these three soldiers: "Some men spoiled their health not to go to war. They took tobacco tea or put strange things in their ears. Some of my comrades killed themselves at the front, when it became dangerous" [39].

"One of my brothers pulled his teeth by himself, some other from Margarita have their teeth pulled, their teeth were already foul. A man from Fossano poisoned himself with lead and died. Another one, a Southerner, got a petrol injection in his backbone, turned crooked and later ended up in jail" [40].

"Then I was drafted, but before the medical examination I drank twelve glasses grappa and ate half a cigar. I didn't feel like to be a soldier. As soon as doctor Abrate saw me, he asked: – What did you do? – and I said: – Nothing –. He understood, I was pale like a ghost, but he declared me fit. Many weren't fit, some because of asthma or some heart condition or because of the poor nutrition, ultimately because their hard life" [32].

In some cases, other soldiers or ranks suggested to recur to self-injury: "The major teaches me: – Put the cigars in a glass of water, be clever and get a tachycardia – Then I started to go on sick call: I ate a cigar and drank a glass of water. Thus I was granted six month convalescence leave" [17].

"I was told to pour gunpowder in the broth. I poured the powder of six bullets in it and drank. It was known that it would cause a high temperature and one could go to the hospital and avoid the charge, which was due for the next three days […] but the powder did not produce any effect" [41].

Others used the weapons to injure themselves: "We ran to the place of the shooting and find the sentry sitting on a carriage and moaning. His rifle was lying on the ground, the bayonet had be put aside. The rifle was still warm. The soldier was Felice Bisceglia and his knee was perforated. From the interrogation emerged that he had an extravagant character and had injured himself to avoid military service. They brought him to the hospital of Saletto" [42].

Diseases and wounds were sometimes hoped for as a lucky chance. In the following records jaundice and pneumonia are considered as means to avoid combat, at least for a while [43-45]. This attitude is found in among soldiers and officers as well. The infantry soldier Agostino Tonetto wrote on December 5th, 1916: "Dear wife, I have a piece of news that could be a half luck for me: today I will be admitted to hospital with jaundice, because a couple of day ago the jaundice broke out in me, but without fever. It would be better for me to have fever, at least some twenty days, so maybe I could have twenty days convalescence" [46].

We do not know the origin of this case of jaundice; *fever* was undoubtedly perceived as not serious nor invalidating. It had only to come at the right moment. Even serious illnesses could represent an opportunity, as described by Umberto Della Scala in a diary entry of November, 17th 1917: "Today I went on sick call and had 39 degrees fever. The doctor wrote the note for me and sent me to the hospital. Around nine o'clock I left from our camp and happily I found a wagon of machine gunners, otherwise I should have walked all the way. Anyway, I walked 6 or 7 km before that and I do not know how I managed it. I felt like drunk, and it was snowing. At last, at six we arrived at the hospital N. 119. Today the doctor came and said that my pneumonia is resolved and that he, too, would like to get it. I told him that he wouldn't have said that three or four days ago and he said sure, no, you were really sick. But he came to see me four or five times a day when I was really sick" [47].

The fear of death and, even more, to be wounded in battle made of serious diseases something desirable. This was the terrible paradox of the perception of health in such extreme conditions (Fig. 4).

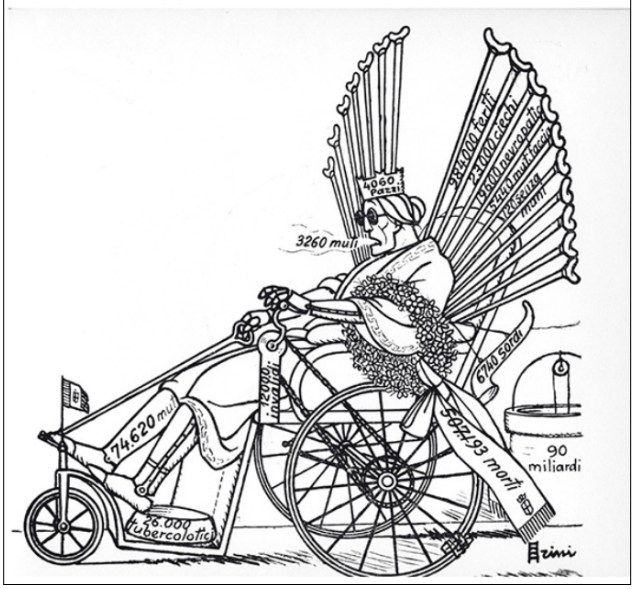
Conclusions

The war, displacing people and modifying the landscape, causing a lack of food supplies and of doctors, was something *new*: *new* conditions like trench foot or self-injury spread as if they were an infection; and the new infection came, the Spanish flu [48]. But World War I acted as a revelator and a multiplier of *old* conditions too, such as tuberculosis or malaria.

In fact, the Italians, between the end of the nineteenth century and the beginning of the twentieth century had many diseases, often accentuated by poverty and lack of hygiene but also by unhealthy behavior. During that period important health policies began to change this difficult situation and in the years immediately preceding the start of the war, good results were starting to be achieved, due to both health and social interventions.

These positive results were completely undermined by the war effort. During the war years and in the following years, the incidence of many diseases returned to values of the late nineteenth century. In the conclusion of his 1925 book Giorgio Mortara underlined, like Ettore Levi, that the consequences of World War I on the health

Fig. 4. The cartoon "Il carro della Vittoria" by Giuseppe Scalarini (1873-1948) was published in the Milanese edition of *L'Avanti* on August 1st, 1919, p. 1. It shows the consequences of the war: 4,060 insane, 3,260 dumb, 74,620 maimed, and 507,193 dead (Public domain).



conditions of the Italian population were to reach beyond the war years. The war had repelled Italy back.

"How many people die even today from tuberculosis or malaria contracted in war! And how many die from the consequences of other diseases contracted in war, or from war injuries? Even if we, today, could reach the malaria or tuberculosis mortality of 1913, we would admit that, without the war, the mortality would be lower" [49].

WWI was nevertheless not only a litmus paper but also a teacher and its teachings were at the origin of many prevention measures in the following years, most macroscopically, as it is known, during the fascism. Vaccinations (e.g. the above-mentioned typhoid and smallpox vaccination) proved themselves useful. The role of swamps in the diffusion of malaria was confirmed (and the fascist land reclamation became ideologically central during the regime). Tuberculosis, in its turn, proved itself a lasting danger and was, too, heavily targeted at in fascism. The fascist obsession with health, which is not subject of this paper, originated mostly in the pathogenic role of WWI.

In conclusion, we recall the words of Serafino Patellani, the first professor to hold a chair in social Eugenics in Italy in 1912 at the University of Genoa: "War is the only social phenomenon in which all people are clearly at a loss. The loser are not the ones who lose the war, but the ones who are most damaged at the eugenic level, even if they are the winners at the military level" [50].

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The authors declare no conflict of interest.

Authors' contributions

MM and APZ designed the study, conceived the study and drafted the manuscript; MM, OS, DO and EA revised the manuscript. MM, DO and APZ performed a search of the literature. All authors critically revised the manuscript. All authors have read and approved the latest version of the paper for publication.

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History of Medicine and Ethics

Strategic planning, components and evolution in zoonotic diseases frameworks: one health approach and public health ethics

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Keywords

Zoonotic diseases • Strategic planning • Health policy • Health system • Public health ethics

Summary

Zoonotic diseases are seen as a major public health concern. Routes of the rapid transmission of zoonotic diseases and the economic damage they cause to communities are all reasons why health institutions and systems need to pay more attention to these diseases. Strategic planning is one of the important tasks of policymakers in every organization and system. It is a very reliable and useful tool for leading all kinds of organizations, including health organizations. Countries with clear policy plans have succeeded in controlling and reducing zoonotic diseases. Such countries used appropriate strategic planning and pursued annual goals to control and prevent diseases. Three important steps (strategy development, strategy implementation and strategy evaluation) should be considered in developing a strategic planning for controlling and prevention of zoonotic diseases. Health systems need to develop strategic planning in order to upgrade their capabilities in combating zoonotic diseases. These programs must be flexible, in line with the one health approach, based on the current needs, and aligned with the new challenges faced with health systems. The strategic planning is directly related to national and international policies, organizational goals and missions, dynamism, degree of complexity, and organizational structure of each country's health system.

Introduction

Zoonotic diseases are seen as a major public health concern [1]. In this regard, it is estimated that about one billion new cases (zoonoses) occur worldwide each year. Of the emerging infectious diseases reported worldwide, 75% are caused by common human-animal diseases. Also, 60% of emerging destructive infectious organisms worldwide such as Ebola, Middle East Respiratory Syndrome, Avian Influenza (very high pathogenicity) are zoonotic, also known as bioterrorist agents [2]. Zoonotic diseases cause significant morbidity and mortality in humans and animals. In a long run, zoonotic diseases will affect public health resources, and ultimately disrupt international trade [3].

The exact burden of zoonotic diseases is not known yet, but in addition to their incidence and mortality, they impose a heavy burden on health systems worldwide [4]. Their significant economic effects include direct and indirect costs on care systems. The World Bank estimates that only six zoonotic pandemics caused more than $80 billion in economic losses during 1997-1999 [5]. Meanwhile, due to the dual impact of this type of diseases on humans and animals, it causes significant economic resources to be lost in poor societies which leads to a vicious cycle of poverty-health. In developing countries, the burden of the zoonotic diseases is most often on the poor [6].

Routes of the rapid transmission of zoonotic diseases and the economic damage they cause to communities are all reasons why health institutions and systems need to pay more attention to these diseases [7]. Experiences from the outbreak of zoonotic diseases show that effective diagnosis and response to emerging epidemics require a multi-level approach. In 2010, the World Health Organization (WHO), the Food and Agriculture Organization, and the World Organization for Animal Health recognized and initiated an international cooperation to address health threats of the diseases to humans, animals, and ecosystems. Thus, investment and innovation in the field of zoonotic diseases is urgently needed [8]. WHO hopes to control zoonotic diseases by providing a united health approach worldwide (interaction between environment, animals, and humans) with an effective and efficient management system [9]. Such an approach is based on the integration of human and animal health, encouraging joint local, national, and global multidisciplinary efforts to achieve optimal levels of health and cooperation among different disciplines in order to solve complex health problems [10].

One Health is an approach to designing and implementing programs, policies, legislations, and research in which multiple sectors plan, communicate, and work together in order to achieve better public health outcomes for the human beings, animals, and environment [10]. Due to the fact that world is being confronted with a recurrent epidemics and other public health issues, this approach improves our understanding of health and diseases as well as prediction, detection, prevention, and control of infections and other issues affecting health and well-being in the human-animal-ecosystem interface, which will lead to sustainable development goals, and ultimately to equity in the world. It is believed that any plan designed for zoonotic diseases should blle based on this approach [8-10].

Providing new solutions and tools for effective research and services to support the development of norms, regulations, and policies for the benefit of humanity, animals, and the environment is crucial for our present and future generations [11]. Also, this can increase the efficiency and cost-effectiveness of health policies, and play an important role in achieving the Sustainable Development Goals (SDGs) worldwide [12]. There is an urgent need to formulate national strategic plans to guide policy-makers, and increase the efficiency of services and control measures for these diseases. Achieving the goals of international commitments also benefits health systems [13]. On the other hand, health care costs are rising rapidly, and organizations involved in health care must continually adapt to survive in order to be able to develop a culture that supports constant change. Also, they should evaluate periodically the existing mission, vision, and values; this constant evaluation further provides the basis for the strategic planning process [14].

Why do health systems require strategic planning to prevent and control zoonotic diseases?

Strategic planning is one of the important tasks of policymakers in every organization and system. It is a very reliable and useful tool for leading all kinds of organizations, including health organizations [15]. Unstable healthcare markets, dynamic and complex structures and cultures, rapidly changing medical technologies, knowledgeable and demanding customers, skilled and professional competitors, and resource constraints have created the condition in which strategic plan is a valuable and useful tool in achieving a competitive advantage [16]. The strategic planning process is planned, orderly, logical, and comprehensive, allowing health care organizations to focus on relevant and sustainable developments for the future [17]. Therefore, strategic planning is essential to provide quality, safe, and cost-effective services for health managers [18]. Strategic planning improves the management's awareness of external opportunities, threats, strengths, and weaknesses. Also, it strengthens internalization, improves managers' understanding of competitors' situations and strategies [19]. Meanwhile, strategic planning improves communication between managers and employees, increases employee productivity, improves competition, and even strengthens the health market. In addition, strategic planning strengthens and mobilizes the health managers' resources towards a definite and desirable system [20]. It also is the art of formulating specific strategies, implementing them, and evaluating the implementation consequences according to the goals or desires of a system. Therefore, strategic planning is essential to provide quality, safe, and cost-effective services for health managers. Successful implementation of strategic planning leads to a better organizational performance and economic success [21]. Organizations that use strategic plans will be more productive and profitable [16, 18]. However, the health industry lags behind other industries in formulating and implementing strategic plans [17]. Since 1980, health managers have developed and implemented a strategic plan to provide value-added services and meet the diverse needs of the population. Studies have confirmed the positive effect of strategic planning on the performance of health organizations [22].

Countries with clear policy plans have succeeded in controlling and reducing zoonotic diseases. Such countries used appropriate strategic planning and pursued annual goals to control and prevent diseases [23]. Strategic planning is the art of formulating specific strategies, implementing them, and evaluating the consequences of implementing them, according to the goals or desires of a system. It needs the serious support of health managers to achieve the desired results and improve the current situation. Proper planning, mobilization, and implementation of adequate measures to control diseases such as Ebola, SARS, H1N1 influenza, and even Covid-19 are useful not only in reducing the prevalence of the disease, but also in reducing their destructive effects on public health [24].

Steps of strategic planning

Typically, three important steps should be considered in developing a strategic planning for controlling and prevention of zoonotic diseases (Fig. 1).

Strategy development

Strategy in its broadest sense is the tool through which individuals or organizations achieve their goals. These strategies must be first developed for zoonotic diseases. At this stage, a health system must initially assess its current status in relation to zoonotic diseases by conducting an internal and external review. The purpose of this step is to help identify the strengths and weaknesses of the health system as well as the opportunities and threats that these diseases might pose. With the unpredictability of the human living environment, and the unknown effects that these diseases have on the health of the general population, this step must be taken carefully and unbiased [25, 26].

Figure 1. Steps of strategic planning.

Strategy implementation

Once the required and appropriate strategies related to zoonotic diseases have been developed for a health system; in the next step, they should be implemented. In the implementation phase of the strategy, the formulated strategies should be observed in practice by using appropriate communication, cross-sectoral cooperation, and all capacities related to the stages of zoonotic diseases, including prevention, control, and treatment. Strategy implementation involves managing some tangible variables such as staff motivation and commitment, organizational values and culture, and the behavior and power of managers and policy-makers. Proper and effective implementation of strategies requires the allocation of financial resources, adequate manpower, and equipment [26, 27].

Strategy evaluation

In health systems, no activity will be successful unless assessment and control programs are implemented consistently. Using the results of assessment and control programs, health managers will thus be aware of how to achieve the goals, and find ways to measure and fix the problems. On the other hand, without effective control and evaluation programs, health systems neither will be able to accomplish their missions, nor will be able to use their resources properly. Due to the nature of zoonotic diseases, many of the predictions and programs designed to deal with these diseases are not fully realized; therefore, the only option to fix the problems is evaluation and control [26-28].

Important components of the strategic planning in order to prevent and control zoonotic diseases

Determining the mission

Mission is the philosophy of existence or the role that a health system has taken on to the people of its community, by fulfilling it and providing the desired services, to meet the needs of the community. In the mission of any health system in relation to zoonotic diseases, the reason for zoonotic diseases and the activities of the health system should be considered. Also, in expressing the mission, the philosophy of existence of a health system must be stated in general terms. meanwhile, the existence of a mission allows for cross-sectoral cooperation in order to activate and involve a set of other organizations related to these diseases [29].

Vision

Health systems have a vision plan for their programs and activities. This vision, the ideal future, is a description of the probable future conditions; in other words, a picture of the future state of the system. This favorable future is usually the product of the thinking and creativity of the managers and policy-makers of the system, and is depicted based on various dimensions such as available system technology, knowledge, financial status, and manpower. Vision gives an insight into future, and describes what plans and policies the health system has. In many cases, the existence of a vision is also an inspirational statement to hope and motivate different stakeholders working with the organization. Due to the problems that zoonotic diseases have caused for health systems in recent years, researchers and health specialists recommend that having a vision should be based on the facts and potential of health systems. In this regard, the benefits of a principled vision which is based on the conditions of a health system are as follows: Clarifying the direction and purpose of a system, unifying policy-makers in order to achieve their success, determining a time frame in dealing with zoonotic diseases, planning for dealing with very critical pandemics such as COVID-19, prioritization of resource allocation, and utilization of facilities and opportunities [29].

Analyzing the current condition of the health system

An important component of strategic planning is the analysis of the current condition of the health system in relation to zoonotic diseases. In relation to these diseases, various social, cultural, political, economic, national, and international dimensions must be considered and analyzed. By analyzing these dimensions and various involved stakeholders, policymakers and planners help make changes in the system to fit into a proper strategic planning. Thus, it is claimed that not conducting a proper analysis of the current condition of the health system in relation to zoonotic diseases is a big strategic mistake [29]. In the COVID-19 crisis, many health systems boasted of having a strong and principled system for responding to health-related crises, but the experience of COVID-19 showed that perhaps a correct analysis of the condition of such health systems in the past in order to deal with a serious crisis have not occurred. In this regard, the weaknesses of strategic planning of the health systems was clear, as several countries were not able to respond properly to the crisis caused by zoonotic

diseases. Analyzing all components of the health system requires collaboration within or outside the system; thus, all stakeholders should be actively involved in analyzing the condition associated with zoonotic diseases. Also, a sound knowledge about the epidemiological status of the diseases, and its possible effects on the society is a key factor toward the analysis of the current condition. In addition, having a reliable data in strategic planning is a great help in formulating realistic plans and policies. Meanwhile, the awareness of the health system's response to crises caused by zoonotic diseases is another issue that should be considered in the analysis of the current situation; in this regard, policymakers should prepare programs, guidelines, and activities related to these diseases. Also, we believe that these activities should be organized in three areas of prevention, diagnosis, and treatment. Meanwhile, in the strategic planning, we need to have programs to treat unknown zoonotic diseases [30].

Investigating the weaknesses, strengths, opportunities, and threats of zoonotic diseases

A meticupous analysis of weaknesses, strengths, opportunities, and threats has a significant effect on development of the health system's strategic planning. In this regard, SWOT is a significant tool for learning about these four dimensions. SWOT examines the opportunities and threats of the environment outside the health system in contrast to its internal strengths and weaknesses [31] (Fig. 2).

SWOT, the most popular tool in strategic analysis, stands for strengths, weaknesses, opportunities, and threats. Proper use of SWOT leads to realistic policies and programs in dealing with zoonotic. By recognizing the weaknesses and strengths, we can effectively use the resources of the health system. With the emergence of new zoonotic diseases such as COVID-19, the optimal use of potential opportunities is no doubt vital. With respect to threats, more positive measures and strategies can be adopted by using the capabilities of health systems [32].

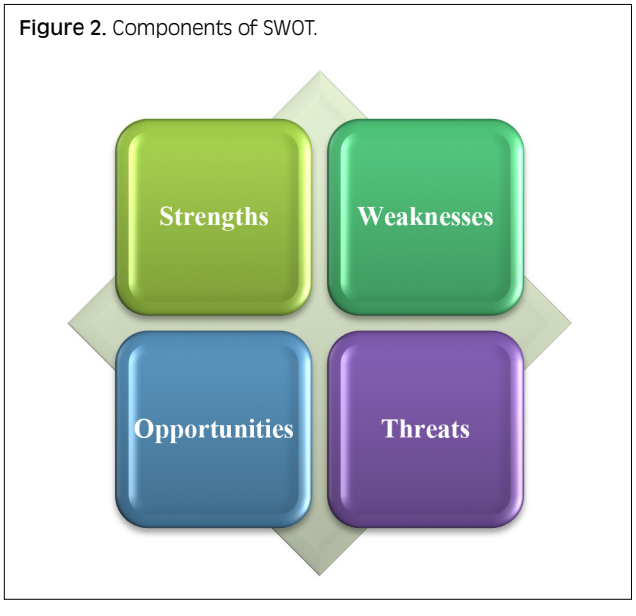

Figure 2. Components of SWOT.

Setting short-term and long-term goals

A deep understanding of the difference between long-term and short-term goals can also help us achieve the goals of a health system. Also, an accurate understanding of the current situation and the ability to have a vision for the future is not possible without understanding the difference between long-term and short-term goals. Long-term goals are inherently strategic. In organizations, long-term goals usually determine the overall direction of a health system in the future. With respect to short-term goals, they are more accessible and faster to achieve. With this in mind, health systems need to determine what their goals are in dealing with existing and new zoonotic diseases [33]. In setting short- and long-term goals, attention should be paid to the features summarized in the SMART format, which can help health systems to evaluate the goals they are considering [34]. These features include the following:

Specific

In health systems, goals should not be vague and general; they should focus on a specific issue such as zoonotic diseases. This focus should be such that all components of the health system know what they will achieve in the end [27].

Measurable

Judging the extent to which goals are achieved depends on their measurability. This provides a standard capability so that the progress of health systems in relation to zoonotic diseases can be measured. In this way, policymakers and managers of a health system can understand how close they are to achieve the goals [16].

Achievable

With respect to zoonoses in health systems, officials should conduct a proper evaluation of financial resources, manpower, and equipment in order to determine whether the goals are achievable or not. Achievability means checking to see if the goals of a health system are feasible and operationalizable [27].

Relevant

It should be noted that the goals set by health systems in relation to zoonoses are related to the programs for the diseases. In the meantime, proper planning should be conducted to use all the resources of health systems. Also, health managers are to be involved in inter-sectoral cooperation in order to identify unrelated activities in the field of combating zoonotic diseases so that they would be able to change the mechanisms to control these diseases [22].

Timely

Resources and facilities are not infinite; also, goals

have a limited time frame. The probability of achieving any goal depends on considering these limitations. On the other hand, identifying the limitations by using the available tools help fix program deviations. The experience of diseases such as SARS, Avian Influenza, and COVID-19 showed that in several countries there was no proper knowledge about their resources and facilities; therefore, the disease process caused many problems for them. Health systems need to be aware of their capabilities, and all the components affecting the control of zoonotic diseases so that the appropriate response can be implemented [29].

Determining the required staff, equipment, and financial resources

Having stable financial resources, efficient equipment, and sufficient human resources to meet the challenges of the health system should be considered in strategic planning. Providing sustainable and financially needed health resources helps strengthen the health system, health security, and universal health coverage [35]. If sustainable financial resources are not provided to health systems, they will face great difficulties in achieving their goals. In connection with zoonotic diseases, the nature of some of them, such as COVID-19, was not clear; therefore, there were not enough financial resources in order to implement various programs to deal with it [27]. Limited financial resources have posed various challenges to several health systems in terms of service delivery, efficiency, effectiveness, and justice. How to finance the health sector, prioritization, and equal allocation of financial resources are important issues in the health sector that should be seriously considered by policymakers when preparing strategic plans. The emergence of new diseases of zoonosis and lack of sufficient knowledge about their nature increase the amount of activities in the health sector. Therefore, in addition to providing their public services, health professionals must undertake new activities in order to control these diseases. Lack of manpower is a serious problem in many health systems; when preparing strategic plans, policymakers should pay attention to the number of available manpower [18]. In developing countries, there are not enough trained health professionals to provide medical care and prevent diseases such as COVID-19 at an early stage; therefore, in strategic planning, appropriate policies should be considered regarding the training of human resources. Providing equipment, medication, and vaccines has a key role in improving the countries' capacity in fighting against zoonotic diseases, an issue that has been well illustrated during the COVID-19 pandemic. In several countries, health systems faced a shortage of essential medical equipment, including special clothing, masks, and disinfectant solutions during the pandemic; it seems that such countries have not paid enough attention to critical situations such as COVID-19 [36].

Implementation of strategic planning

To improve the performance of health systems in dealing with zoonotic diseases, policymakers and health managers should pay attention to the implementation of programs and policies as well as its challenges [29] and it is important to consider the ethical aspects of public health. It is true that there is a high tendency toward developing the strategic planning among health managers; however, the implementation stage of such plans has always faced several problems [37]. The implementation of strategic planning is a complex phenomenon, and there are several elements associated with it. Strategic plans must be put in place to combat zoonotic diseases, and their implementation requires the design of a set of methods [27-38]. In order to implement strategic plans for zoonotic diseases, we need the cooperation of all relevant organizations and actors. In an international crisis like COVID-19, several countries had great difficulty implementing their programs. It seems that at the time of preparing their strategic planning, they did not have a crisis model on their agenda [18].

Conclusions

Health systems need to develop strategic planning in order to upgrade their capabilities in combating zoonotic diseases. These programs must be flexible, in line with the one health approach, based on the current needs, and aligned with the new challenges faced with health systems. The strategic planning is directly related to national and international policies, organizational goals and missions, dynamism, degree of complexity, and organizational structure of each country's health system. Therefore, we believe that in developing a strong strategic planning for zoonotic diseases, the above-mentioned components should be identified and considered.

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Ethics approval

The study received ethical approval from the Iran University of Medical Sciences (IR. IUMS.REC. 1399.11.93).

Conflict of interest statement

The authors declare no conflict of interest.

Authors' contributions

MKG, HAG and MB designed and conceived the study; MKG, HAG, MB drafted the manuscript; MKG,MB,

MM and AS revised the manuscript, performed a search of the literature. All authors critically revised the manuscript. All authors have read and approved the latest version of the paper for publication.

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