

ORIGINAL ARTICLE

Quality and management care improvement of patients with chronic kidney disease: from data analysis to the definition of a targeted clinical pathway in an Italian Region

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Keywords

Clinical pathway • Kidney chronic disease • Patient centered care

Summary

Background. *Clinical Diagnostic Care Pathways (CDCP) are management tools widespread throughout the world to improve the quality of patient care through a well-organized care continuum and to enhance the patient’s “risk-adjusted” outcomes; indeed they could optimize the management of resources. They are particularly effective in the management of patients with chronic degenerative diseases, such as chronic kidney disease, with increasingly incidence and prevalence, with an estimated 11-13% of the population being affected. The aim of this study is to apply the Health Services Research methods to estimate the relationship between need, demand and supply in patients with stage 5 Chronic Kidney Disease (CKD) for; then to describe the definition of a CDCP dedicated to patients in Lazio Region, so to allow an appropriate patient management, to reduce the likely*

complications and the patients’ migration to facilities outside the region.

Methods. *The study was conducted in 2017 in collaboration between the National Institute of Health, the University of Messina and the S. Giovanni Addolorata Hospital.*

Results. *We analyzed the data for the CKD in Roma and in the San Giovanni Addolorata Hospital Trust and we found a drop out in the patients’ attendance towards other regions and/or hospitals. So we defined a CDCP to be adopted at the San Giovanni Addolorata hospital.*

Conclusions. *To define management and care tools to provide adequate, efficient and patient centered care is a nowadays “must”, to ensure the sustainability of the Italian NHS, which today is comparable to a “ship that is heading towards a perfect storm”.*

Introduction

Today, the right to health is universally recognized: each Country has in fact ratified at least one of the international human rights treaties sanctioning it [1]. Healthcare, however, is provided differently on different continents, ranging from private systems with the need for insurance coverage by citizens, as in the US, to public systems with costs borne by the National Health Service as in Italy, where public funds support healthcare provision [2]. All developed countries are putting more resources into health, but this increased investment is totally inadequate to meet the steady increase in community needs; which is primarily due to a change in the population that is “growing older” and as life expectancy increases so does the number of subjects with chronic degenerative diseases who require access to treatment [3]. This is linked to the greater availability of new and more expensive diagnostic technologies; since health is an asset to be safeguarded and all citizens, regardless of age, must be assured equal treatment opportunities. Thus, the demand for health care (and consequently the costs) is

ever-increasing creating a vicious circle [4]. The continuous effort to improve health therefore requires the performance of healthcare systems and policies be measured, with subsequent adaptation of the system based on the assessment. Given the limited availability of funds in Italy, their correct and timely management is vital. This necessitates a well-structured therapeutic diagnostic process and this is where Clinical Diagnostic Care Pathways (CDCP) come into play. CDCPs are widespread throughout the world and their objectives are to improve the quality of patient care through a well-organized care continuum, and to enhance the patient’s “risk-adjusted” outcomes; the third objective is to optimize the management of resources, not only economic but also structural and human [5, 6]. One of the most widespread chronic degenerative diseases is chronic kidney disease (CKD), and its incidence and prevalence is increasing worldwide: with an estimated 11-13% of the population being affected by CKD, particularly stage 3 [7]. Once the terminal stage of the disease has been reached, the patient must undergo renal replacement therapy by specialized dialysis. The main replacement methods of renal func-

tion are hemodialysis and peritoneal dialysis. In 2010, 284 individuals per million population were estimated to be receiving maintenance dialysis in the world. Although the use of peritoneal dialysis is increasing in some countries, including China, United States and Thailand, it has proportionally decreased in parts of Europe and in Japan [8, 9]. Well-functioning vascular access is a prerequisite for good dialysis treatment; vascular access failure (VAF) is the most common reason for hospitalization among hemodialysis (HD) patients. The economic burden of VAF is estimated to exceed 1 billion dollars per year and continues to rise. The possible acute complications related to vascular access (bleeding, stenosis and/or thrombosis, AVF malfunction, malfunction, dislocation, central venous catheter (CVC) infection) must be managed in a specialized environment and by highly specialized personnel [10-12]. Arterio-venous fistula (AVF) with native vessels is the preferred method of vascular access as it allows greater survival, reduced risk of infection and fewer complications. The Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines recommend packing vascular access when creatinine exceeds 4 mg/dL or when the Glomerular filtrate is less than 25 ml/min (Guideline 8 of KDOQI) and at least one month before (better 3-4 months) cannulation [13]. In the Italian region of Lazio at 31/12/2015 there were 90 outpatient facilities providing dialysis services ("dialysis centers"), 37 public and 53 private, with a non-homogeneous coverage across the region. This wide supply availability induces high patient mobility in Rome area, with patients migrating towards dialysis centers located in healthcare districts other than that of residence. This phenomenon is also found in the other municipalities of Lazio, albeit to a lesser extent. Over the period 2008-2013, the rate of first hospital admissions in Lazio region due to cardio-circulatory problems was 21.0%, and a mortality rate of 20.9%, both within two years from the start of dialysis. Even taking into account the uneven distribution of clinical and demographic features among patients treated according to the P.Re.Val.E procedure (risk adjustment), there remains inconsistency between dialysis centers and areas of residence [14]. The aim of the present study is to: 1) analyse according to a Health Services Research perspective the relationship between need, demand and supply for patients with stage 5 CKD in a given area in Rome [15]; b) to define a clinical diagnostic care pathway for patients in the Lazio region that allows, first, a more appropriate and timely patient management by all medical figures involved, to reduce the likely disease complications and, secondly, a reduction in patients' migration to facilities outside the region; c) to build up a monitoring system to evaluate the forthcoming impact of the implementation of the CDCP.

Materials and methods

The Health Services Research analysis was conducted in collaboration between the Istituto Superiore di Sanità (National Institute of Health), the University of Messina

and the Complex Operative Unit of Vascular Surgery at the S. Giovanni Addolorata Hospital, a Hospital Trust in Rome metropolitan area. The database used was the national database of Hospital Discharge Cards (SDO) available at the ISS Statistical Technical Service, provided by the Ministry of Health. Reasons for hospitalization are classified by means of the international system called the ICD-9 CM (International Classification of Diseases - Clinical Modification), which is also used in Italy (the latest version is 2007) [16].

The analysis was carried out in November-December 2017 and covered residents in the Lazio Region admitted to facilities in the Lazio Region and to the San Giovanni Addolorata Hospital, in particular. The years analyzed were 2015 and 2016 with prevalent cases counted separately for these two years. The analysis covered both inpatients and outpatients; in order to obtain the most accurate estimate of the prevalence of pathological conditions. The SDO database was considered in its entirety including daytime admissions, while naturally excluding long-term hospitalizations and rehabilitations. Each SDO reports a "Diagnosis/main procedure" and up to five "secondary diagnoses/procedures" (Law Decree 380/2000). The database was queried for all the diagnosis/procedure fields thereby enabling the number of cases to be estimated more accurately.

Results

THE APPLICATION OF THE HEALTH SERVICES RESEARCH APPROACH

The resident population in Lazio was 5,898,124 inhabitants at 31/1/17 (ISTAT data) and the total number of patients with stage 5 CKD (eg, Lazio cod. 5856) was 2,116 for the year 2016 (SDO data). Thus, the estimated prevalence of the disease stage in Lazio was 0.036% for the year 2016. The number of patients admitted under IRC cod 5856 were 2,695 and 2,926 for the years 2015 and 2016 respectively, with the number of admissions with severe complications of 1,757 and 1,826.

The population served by S. Giovanni Addolorata Hospital is 413,749 inhabitants, thus the predicted number of patients at the San Giovanni-Addolorata hospital with CKD Cod. 5856 (to be estimated according to the SDO database) is approximately 148.4. However, the number of patients treated was 90 and 102 for the years 2015 and 2016 respectively (estimated according to the SDO database). This means a likely migration of stage 5 CKD patients to other centers of as many as 46 patients for the year 2016. A more focused analysis of the data available showed migration to facilities outside the Lazio region of 6.3% of cases for the year 2015 and 6.4% of cases for the year 2016. The results obtained are summarized in Tables I and II.

THE DEFINITION OF THE CDCP

The clinical pathway must be the tool to sensitize the problem of the "life line" of the uremic patient starting

Tab. I. Admissions and procedures in the Lazio Region and San Giovanni Addolorata hospital.

Lazio	Year 2015	Year 2016
Number of admissions for CKD (cod. 5856)	2,695	2,926
Number of admission for complications (V56.1, V56.2, 996.1, 996.62, 996.73)	1,757	1,826
Number of surgical procedures (39.27, 39.49, 39.50, 39.52, 39.29, 39.42, 39.43, 38.95, 86.07)	10,923	11,393
Numbers of surgical procedures outside region Cod. 39.27, 39.49, 39.50, 39.52, 39.29, 39.42, 39.43, 38.95, 86.07	703	780
Numbers of patients with CKD at end stage cod.5856	1,961	2,116
San Giovanni Addolorata		
Number of admissions cod. 5856	90	102
Number of admissions	82	84
Number of surgical procedures (39.27, 39.49, 39.50, 39.52, 39.29, 39.42, 39.43, 38.95, 86.07)	372	495
Number of admissions for complications (V56.1, V56.2, 996.1, 996.62, 996.73)	8	7

Tab. II. Codex of procedures and complications.

Procedures and complications	Cod.
Numberof admissions for CKD	5856
Number of admission for complications	
Placement and arrangement of extracorporeal dialysis catheter	V56.1
Positioning and arrangement of peritoneal dialysis catheter	V56.2
Mechanical complications of other devices, implants and vascular grafts.	996.1
Infection of vascular grafts	996.62
Other complications from prostheses, implants and renal dialysis grafts	996.73
Number of surgical procedures	
Arteriovenostomy for renal dialysis	39.27
Other revision of vascular interventions	39.49
Angioplasty or atherectomy of a non-coronary vessel	39.50
Other repair of aneurysms	39.52
Other vascular anastomoses or by-pass (peripheral)	39.29
Revision of arterio-venous anastomoses for renal dialysis	39.42
Removal of A-V anastomosis for renal dialysis	39.43
Venous catheterization for renal dialysis	38.95
Insertion of a totally implantable vascular access device	86.07

with the family physician who will single out which patients to send to the nephrologist to plan for the creation of a usable vascular access when the need arises for dialysis. It will be the nephrologist who will identify when the vascular surgeon will have to perform the surgery. The emergency doctor of the first aid who will manage the acute uremic patient through nephrological counseling, and will activate the path for urgent vascular or endovascular surgical treatment in order to avoid the insertion of a central venous catheter unless absolutely indispensable. It will be necessary to sensitize the hemodialysis centers of the territory on which the hospital company insists, in order to inform them of the possibility of using a 24-hour service for the management of complications of vascular access or for the creation of complex arteriovenous fistulas. It is therefore necessary to create an interdisciplinary team consisting of: emergency doctor, nephrologist, vascular surgeon and interventional radiologist. The aims of the clinical pathway are as follows:

- optimization of patency surveillance, the correct planning of vascular access packaging and avoiding the insertion of CVC for acute hemodialysis;

- reducing the number of uremic patients requiring urgent hemodialysis treatment, without vascular access (avoiding the insertion of central venous catheters that are linked to high morbidity in terms of infection and thrombosis of central veins thereby compromising the feasibility of future vascular accesses for hemodialysis);
- reducing the number of patients who acutely need revision of vascular access due to occlusion/thrombosis or malfunction (avoiding urgent repacking and insertion of CVC);
- intercepting patients with acute occlusion of the vascular access for surgical or endovascular correction in order to restore the functionality or eventual packaging of arteriovenous prosthetic fistula “early cannulation” in order to avoid insertion of CVC;
- avoiding extra-regional migration of hemodialysis patients who have difficulty accessing vascular surgeries in Lazio;
- clinical surveillance of vascular accesses for the early diagnosis of dysfunction in the dialysis room, with the aid of instrumental diagnostics (Color Doppler ultrasound, angiography);

- using the resources of 24-hour centers to deal with vascular access complications and to restore the patency and usability of the arteriovenous fistula as soon as possible. The “Quick access” CDCP complies with the National Kidney Foundation KDOQI guidelines and those of the Italian Society of Vascular and Endovascular Surgery [17, 18].

The aforementioned CDCP has therefore been adopted as a model in the San Giovanni Addolorata hospital and the reduction of outpatient migration and emergency hospital access have been included in the CDCP monitoring plan and are currently being monitored.

Discussion and conclusions

By applying the Health Services Research approach, we found that patients admitted with a IRC coding were 2,695 and 2,926 for the years 2015 and 2016, respectively, with the number of admissions with severe complications of 1,757 and 1,826. Thus, a unsatisfactory management of the uremic patient by both general physicians and specialists would be underlined.

In addition, 6.3% of cases of patients with stage 5 KCD in 2015 and 6.4% of cases in 2016 accessed to facilities outside the Lazio region.

In addition, our analysis highlights shortcomings in patient management, despite the professional and structural resources available so to induce a high extra-regional migration for surgical procedures, that is reasonably not due to boundary migration. This is particularly heavy for patients with CKD and for their carers and is unacceptable for a region where specialized facilities and highly qualified personnel are available.

It is evident from clinical practice that the problems related to the packaging and maintenance of a vascular access usable for satisfactory hemodialysis are often neglected, despite their importance in terms of social and health impact. Since this surgical technique is specific to terminal uremic patients, while referrals for surgery are made only by the nephrologist, it is difficult for the vascular surgeon, to respond promptly to a demand for treatment. Complex vascular surgery units often have no specific competence and demand from the nephrologist the packaging of native arteriovenous fistulas, but at the same time, they are called upon to solve urgent complications for which complex surgical or endovascular procedures are required. The result is an erratic and imprecise management in a “no man’s land” that endangers the “life line” of the uremic patient, that is the Arteriovenous Fistula. It is therefore necessary, in our opinion, to delineate a care path that identifies a multidisciplinary team that will deal with all these patients, to plan the packaging of the vascular access and maintain its patency through clinical surveillance. This will lead to the reduction of complications related to any malfunction and reduce the need to insert CVC that compromise the quality of efferent blood vessels.

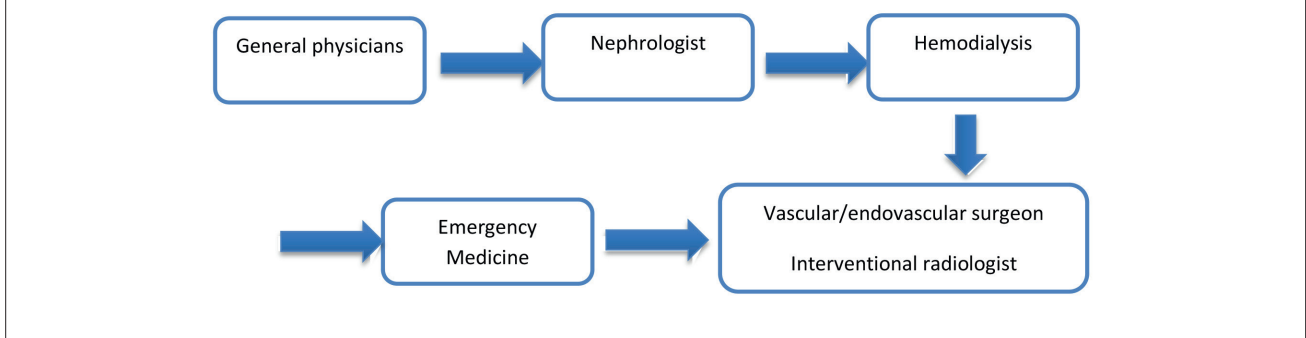
It is also necessary for diagnostic and therapeutic procedures to be implemented in environments where the pa-

tient’s response can be constant within 24 hours. A systematic review and meta-analysis demonstrated a trend toward the benefit of the rate of thrombosis and access to patients with usual clinical monitoring [19]. Compliance with international guidelines, approved by the Italian scientific societies of nephrology and vascular and endovascular surgery, guarantees the correctness of procedures and result in improved outcomes [17, 18, 20]. Despite the presence of numerous hemodialysis centers and the same number of Vascular surgery units in the Lazio region, the data provided by the SDO cards, show an alarmingly high a number of urgent hospitalizations for chronic renal insufficiency that suggest incorrect planning and classification of uremic patients from that area. There is also a frequent need for urgent dialytic treatment and therefore the insertion of CVCs and vascular access packaging in post-acute conditions and this involves the reduction of the superficial venous heritage of the upper limbs for repeated venipuncture. All this translates into increased morbidity related to vascular access and a reduction of long-term patency, as also demonstrated by the existing literature [21]. These shortcomings in patient management, despite the professional and structural resources present, mean that there is also a discouraging and disconcerting fact: a need for a prompt, timely and appropriate treatment, is not encountered by the supply system and its causes a high extra-regional migration for surgical procedures, that is reasonably not due to boundary migration. This is particularly heavy for patients with CKD and for their carers and is unacceptable for a region where specialized facilities and highly qualified personnel are developed and recognized by the scientific community!

Therefore, an appropriate management of the uremic patient is necessary both by general practitioners and by nephrologists with the creation of an adequate care path. The early management of the patient with CKD and the sharing with the nephrologist of these patients constitute the pivot on which the different levels of care are articulated; with at least three possible different levels of care: region, outpatient and hospital management. Each of the three levels is not an end in itself, but may overlap with others depending on the patient’s clinical status, any complications and accelerations [13]. In order for care to be efficient, the creation of a clinical diagnostic care path based on the coordinated synergy of different professional figures is necessary to guarantee and enhance its effectiveness with the formulation of clear recommendations for shared management, to be reviewed periodically with any updates to be implemented, as new evidence arises [22, 23]. To enhance integration and continuity of care, the creation of shared data platform between the GP and the nephrologist is welcome as crucial to allow a useful exchange of information between the professionals involved and the monitoring of the process through shared indicators, in line with current Ministry of Health guidelines [24].

The optimization of patient management and the organization of adequate health care is therefore essential to ensure the sustainability of the Italian NHS, which today

Fig. 1. Clinical diagnostic care pathway.



is comparable to a “ship that is heading towards a perfect storm” [25, 26].

Some limitations of our study must be acknowledged. One limitation of the present study is the partial retrospective collection of cases.

Another one is due to the use of administrative data (eg, the SDO database) for epidemiological purposes, to describe the relationship between needs, demand and supply of care for patients with KCD. The national database of the SDO doesn’t receive informations on the incidence, residences adress and it isn’t possible to reason on the mobility of patients inside the area of Rome.

In addition, by calculating “incidence”, we didn’t analyse the likely increase over the years or other factors with an expected impact on access to care.

Such limitations in data source and integration also limited us in the analysis of an adequate relationship between demand and supply, that is of primary importance in a National Health Service like the Italian, where the free of choice of patients towards of providers of care in the health sectors care is an underpinning principle. We are confident that such a risk would be avoided by applying a ZIP code analysis or by studying patterns of patients fluxes due to other determinants by applying marketing strategies [27], internal “leaks” within the city of Rome, surveys on the customer preferences towards the delivery facilities. On the other hand, we consider of crucial importance to propose a quantitative approach to evaluate the capability to satisfy healthcare needs and to perform an advocacy role towards a better management of patients with CKD, who are at higher risk of inequalities and lower access to care in a period of economic constraints and of management weakness, as a consequence of the “perfect storm” [26].

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Conflict of interest statement

None declared.

Authors' contributions

CG and PT conceived and designed the study; VM acquired the data; CG, PT and RS analysed and interpreted the data; CG, PT and RM drafting the article; RS and AGdB revising it critically for important intellectual content; all authors give final approval of the version to be submitted and any revised version.

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