



Smear grading at initial treatment association with treatment outcomes among new smear positive pulmonary tuberculosis patients: A retrospective study

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Keywords

DOTS • *Mycobacterium* sputum smear • Treatment failure • Tuberculosis • Smear grading

Summary

Introduction. Tuberculosis (TB) is one of the most challenging diseases in diagnosis, treatment and control. We aimed to assess the association of the initial grading of *Mycobacterium* Sputum Smear (MSS) on the outcomes of TB treatment.

Materials and methods. In a retrospective study, data of 418 positive pulmonary smear patients were retrieved from the TB registration system in Iran during 2014 to 2021. Patients' data included demographic, laboratory and clinical information and were recorded in our checklist. The grading of *Mycobacterium* Sputum Smear (MSS) at the initial treatment was assessed based on World Health Organization (WHO) guidelines. Chi-square test was used to assess the relationship between tuberculosis treatment outcomes and *Mycobacterium* grade at initial treatment in SPSS.

Results. The mean age of cases was 51.19 ± 22.29 years old and

varied between 14 and 95 years. Laboratory results showed that the rate of 1-9, 1+,2+ and 3+ *Mycobacterium* tuberculosis was 17.7%, 44.3%, 19.4% and 18.7%, respectively. The rate of cure, death and treatment failure in patients was 87.1%, 6.9%, and 1.2%, respectively. The highest mortality rate (11.5%) occurred in patients with 3+ and the lower rate of cure was 79.5% in this group. Moreover, by increasing the *Mycobacterium* grade the rate of transferred out and lost to follow up from treatment increased ($p = 0.024$).

Conclusion. High smear grading of sputum is inversely associated with lower curing and on-time treatment. Moreover, by increasing the *Mycobacterium* grade at initial treatment, treatment failure and lost to follow up increased. Therefore, improvement the health system and patient-diagnosis and screening programs is necessary to on-time diagnosis and facilitate the treatment process.

Introduction

Tuberculosis (TB) is the major cause of death from infectious diseases that caused by *Mycobacterium* tuberculosis. Two main type of TB are pulmonary and external pulmonary TB that affected only the lungs and other organs of the body, respectively [1]. On the threshold of the 21th century, the world health organization (WHO) has declared tuberculosis as a global emergency, since it is not well controlled in some parts of the world and due to comorbidity and occurrence of resistant *Mycobacterium* and Acquired Immunodeficiency Syndrome (AIDS) [2]. The WHO estimates that one-third of the world's population is infected with TB and one person is added to their number per second [3]. In 2016, 10.4 million people were affected to tuberculosis, and 25% of them died due to this disease [4]. The overall incidence of tuberculosis in Iran was 14.4 per 100,000 populations and the incidence of positive pulmonary smear disease that year was 7.07 per 100,000 populations [5, 6].

Tuberculosis is one of the most challenging diseases

in diagnosis, treatment and control. Despite the implementation of effective prevention and treatment programs, the expected success in reducing and controlling TB in Iran has not been achieved yet. Numerous factors are considered as related factors of failure of treatment, death and unsuccessful in TB control including drug resistance, delaying in diagnosis, immigration and the role of neighbor countries, poverty, ethnicity, gender, poor nutrition, smoking and drug use [7-9]. However, inappropriate patient management and using the wrong of medication dose and poor compliance of patients play significant role in the development of drug resistance [8, 10, 11]. The survival rate of untreated patients is 50% within the first 5 years of pulmonary tuberculosis, while 25% of TB patients will recover spontaneously due the desired immune system, and another 25% will remain chronic infectious tuberculosis [1]. Positive pulmonary smear patients with sneezing and coughing are the cause of microbial transmission in the community [12]. A positive sputum smear case can infect 10 to 15 people in a year [13]. Therefore, not only diagnosing TB cases is essential for successful control of the disease in the

community but also achieving appropriate treatment is important factor [14].

The WHO policy for TB control is a short-term treatment under direct supervision (DOTS) strategy that includes an effective structure for diagnosis (examination of sputum smears with a light microscope) and treatment (short-time drug therapy) [15]. The DOST strategy was launched by the WHO to control tuberculosis in 1995, and more than 180 countries are currently implementing the program [16]. Monitoring the outcome of TB treatment and understanding the reason for treatment failure important to assess the effectiveness of the TB control program [1, 16, 17]. Failure to treat patients create economic and health problems, including drug resistance and inability to perform daily activities in patients [12]. *Mycobacterium* Sputum Smear (MSS) at the beginning of treatment, known as an effective predictor of treatment [3, 14]. Studies have shown that there is a link between bacillus levels in MSS at the beginning of treatment and the outcome of treatment, so that the rate of recovery is higher in people with low levels of MSS [3, 7, 18]. Moreover, the rate of death and treatment failure among patients with more grade MSS is higher [19] and it is the cause a delay of negative smear conversion rate in patients [15, 20].

Despite the implementation of the national TB control and care program in the country, the TB disease remained as a public health problem [12, 17]. Therefore, knowing the factors affecting death rate and treatment failure from TB and preventive factors of smear conversion could helpful for health policy and providing medical education. This study aimed to determine the association of the grading of positive MSS at the beginning of treatment on the outcome of TB treatment in confirmed cases.

Method

This is a descriptive-analytical, a retrospective study on all 418 positive pulmonary smear patients during 2014 to 2021. All the patients were being treated free of charge based on Iranian national TB control and care protocol, and their treatment results were available and analyzed in SPSS software. The informed consent was taken from all patients and the study protocol approved in ethical committee of Qom University of Medical Sciences by IR.MUQ. Rec.1399.105 code.

The inclusion criterion was that patients had to be new cases suffering from positive pulmonary smear. The exclusion criteria were wrong diagnosis, a history of disease relapse and failed treatment. Patients' data included demographic, laboratory and clinical information retrieved from the TB registration system (TB Register) and other registration offices and were recorded in our checklist.

Based on standard definitions, a patient is assured to have contracted positive pulmonary smear in three situations. First, if he/she have undergone at least two sputum positive smear tests regarding fast-acid bacilli. Two, if

he/she have undergone only one test but their chest's radiographic changes show pulmonary tuberculosis and Three, if he/she have undergone only one test but they have one sputum positive culture. Moreover, the bacillus level in the initial treatment is assessed based on the number of *Mycobacterium tuberculosis* in the microscopic field according to WHO guidelines [21]. Accordingly, if there are 1-9 bacilli in every 100 microscopic field, the exact number of observed bacillus is reported. If 10-99 bacilli are observed in every 100 microscopic fields, the grading is determined as +1, and if the ratio is 1-10 the grading is quantified as +2. Finally, if there are more than 10 bacilli in every microscopic field, the grading is specified as sputum smear 3+ [21, 22]. According to WHO's definitions, treatment outcome was classified to six different standard definitions including cured, treatment completed, treatment failed, died, lost to follow up and transferred out [21].

A patient is regarded as cured if the result of their positive pulmonary smear test is negative at the end of the treatment process or if the result of their previous sputum test, carried out for treatment piloting, is negative. On the other hand, failed treatment happens when the patient suffering from positive pulmonary smear has been still positive for five months or more since the initial treatment, they have been positive again after being tested negative in the same period or the patient suffering from negative pulmonary smear dies. Lost to follow up means that the patient has stopped their own treatment for two months or more. Transferred out means that the patient has been transferred to another treatment unit after their initial treatment with no information about the final result of their treatment [22].

STATISTICAL ANALYSIS

After data collection by reviewing the medical records of patients in TB register system, all data were entered in SPSS (V.22) software. The Chi-square test was used to assess the relationship between tuberculosis treatment outcomes and *Mycobacterium* grade at initial treatment. The significance level was assigned as 0.05 for the statistical tests.

Results

This study conducted on 418 tuberculosis cases with the mean age of cases was 51.19 ± 22.29 years old and varied between 14 and 95 years. According to Table I, from all patients 46.7% (195 cases) were male and 53.3% (223 cases) were female. Our laboratory results showed that the rate of 1-9, 1+, 2+ and 3+ *Mycobacterium tuberculosis* in our patients was 17.7%, 44.3%, 19.4% and 18.7%, respectively. Therefore, 62% (259 cases) were affected to low grade of bacillus (1+ and lower bacillus) and 38% (159 cases) were affected to high grade of bacillus. The rate of cure, death and treatment failure in our patients was 87.1%, 6.9%, and 1.2%, respectively. Moreover, 4.8% (20 cases) were lost to followed or transferred out. Our results showed that gender, nationality, job and

Tab. I. Demographic characteristics of patients with tuberculosis.

Variables		Frequency (%)
Gender	Male	195 (46.7)
	Female	223 (53.3)
Nationality	Iranian	217 (51.9)
	Afghan	187 (44.7)
	Other	14 (3.3)
Job	Worker	71 (17.0)
	Without job	43 (10.3)
	Non-governmental	19 (4.5)
	Housekeeper	181 (43.3)
	Other	104 (24.9)
Education	Illiterate	228 (54.5)
	Elementary	67 (16.0)
	High school	36 (8.6)
	Advanced	54 (12.9)
	College	33 (7.9)
Residency are	Urban	359 (85.9)
	Rural	59 (14.1)
Year	2016	76 (18.2)
	2017	70 (16.7)
	2018	96 (23.0)
	2019	90 (21.5)
	2020	86 (20.6)
Basil count	1-9	74 (17.7)
	+	185 (44.3)
	++	81 (19.4)
	+++	78 (18.7)
Final Outcome	Cured	364 (87.1)
	Death	29 (6.9)
	Treatment failure	5 (1.2)
	Lost to follow up/ transferred out	20 (4.8)

education were significant variables that related to higher death, treatment failure and lost to followed or transferred out from treatment of tuberculosis (Tab. II). Based on our results, the mortality rate in male was 10.3% that was significantly higher from female patients ($p = 0.004$). The treatment failure was higher in patients from other countries (except Iranian and Afghan) who lived in Iran such as Pakistan and Iraq people. The mortality rate was 11.5% in Iranian patients, 2.1% in Afghan and 0% in Pakistan and Arab countries ($P < 0.001$).

Chi square test showed that housekeeper have the highest rate of cured and the highest rate of treatment failure showed in patients with non-governmental ($p = 0.048$). The treatment failure rate increased among patients by decreasing the education and mortality rate was 8.8% in illiterate patients and 0% in patients with advanced education. However, the failure rate in college educated patients was highest as 9.1% ($p = 0.007$). Based on our results residency place was not significant variable on the outcome of tuberculosis ($p = 0.387$).

Table III showed that the highest mortality rate (11.5%) occurred in patients with 3+ and the lower rate of cure was 79.5% in this group. Moreover, by increasing the *Mycobacterium* grade the rate of transferred out and lost to follow up from treatment increased ($p = 0.024$). According to the Figure 1, treated rate was higher in patients with 1+ and lower *Mycobacterium* grade.

Discussion

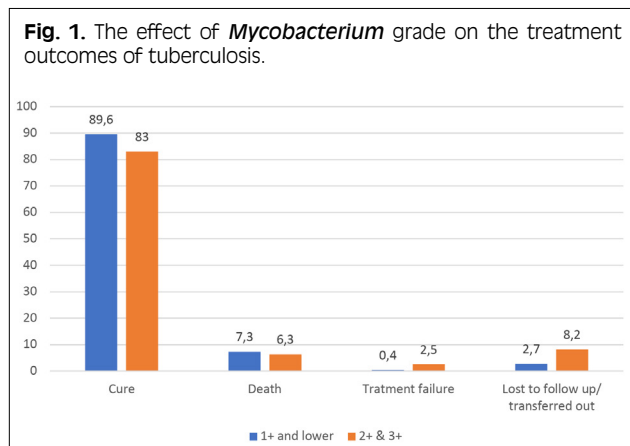
Literature shows that there is a significant relationship between the high bacillus grading of smear in the initial treatment and negative smear and when the number of bacilli increases in the smear in the initial treatment, the

Tab. II. The association of demographic characteristics on the outcome of tuberculosis.

Variables		Cure n (%)	Death n (%)	Treatment failure n (%)	Lost to follow-up/ transferred out n (%)	P value
Gender	Male	162 (83.1)	20 (10.3)	0	13 (6.7)	0.004
	Female	202 (90.6)	9 (4)	5 (2.2)	7 (3.1)	
Nationality	Iranian	185 (85.3)	25 (11.5)	1 (0.5)	6 (2.8)	< 0.001
	Afghan	169 (90.4)	4 (2.1)	2 (1.1)	12 (6.4)	
	Other	10 (71.4)	0	2 (14.3)	2 (14.3)	
Job	Worker	63 (88.7)	2 (2.8)	0	6 (8.5)	0.048
	Without job	34 (79.1)	4 (9.3)	1 (2.3)	4 (9.3)	
	Non-governmental	14 (73.7)	3 (15.8)	1 (5.3)	1 (5.3)	
	Housekeeper	167 (92.3)	8 (4.4)	1 (0.6)	5 (2.8)	
	Other	86 (82.7)	29 (6.9)	5 (1.2)	20 (4.8)	
Education	Illiterate	197 (86.4)	20 (8.8)	2 (0.9)	9 (3.9)	0.007
	Elementary	58 (86.6)	5 (7.5)	0	4 (6)	
	High school	33 (91.7)	1 (2.8)	0	2 (5.6)	
	Advanced	50 (92.6)	0	0	4 (7.4)	
	College	26 (78.8)	3 (9.1)	3 (9.1)	1 (3)	
Residence	Urban	310 (86.4)	28 (7.8)	4 (1.1)	17 (4.7)	0.387
	Rural	54 (91.5)	1 (1.7)	1 (1.7)	3 (5.1)	

Tab. III. The association of *Mycobacterium* grade at initial treatment on the outcome of tuberculosis.

Bacillus count	Cure n (%)	Death n (%)	Treatment failure n (%)	Lost to follow-up/ transferred out n (%)	P value
1-9	66 (89.2)	6 (8.1)	0	2 (2.7)	0.024
+	166 (89.7)	13 (7)	1 (0.5)	5 (2.7)	
++	70 (86.4)	1 (1.2)	3 (3.7)	7 (8.6)	
+++	62 (79.5)	9 (11.5)	1 (1.3)	6 (7.7)	



smear becomes negative later [15, 23, 24]. Similarly, patients who have a huge number of bacillus in their smear remain infectious for a longer time and can easily transfer their disease to others [10, 15, 24]. In this study, a significant relationship was observed between the number of bacillus in the initial treatment and the cured rate. About 18.7% of the patients had high sputum smear grade (3+) whose rate of treatment was 79.5%. The rate of curing among these patients was lower than the rate of curing among all the patients (87.1%) and the cure expectation time among smear-positive patients (85%). Tiwari et al. [15] study showed similar results and they observed that there was a significant association between an initial positive smear and the treatment results so that those patients with a higher bacillus grading in their smears in the initial treatment had a weaker chance to be cured. Moreover, Buti et al. [25] found that high smear grading can negatively affect the process of smear conversion (changing from positive to negative). Qiao Liu et al. [26] reported the patients with high smear grade were less likely to respond to treatment.

Based on the results of this study, 6.9% of the patients died with a larger proportion (11.5%) belonging to those with high MSS grading (3+). Atif et al. [27] reported that high smear grading is a crucial factor in increasing the mortality of smear-positive patients. In addition, the higher rate of mortality among high smear grading patients was also reported by Hoa et al. [28]. We found that the rate of failed treatment in high smear grading patients (2+/3+) was higher than the rate in low smear grading patients. Similarly, Rajpal et al. [29] demonstrated that high smear grading patients experienced the highest rate of failed treatment. A study in Burkina Faso

also showed that there was a significant relationship between the number of bacilli and failed treatment [8]. A significant association was observed between gender and treatment result in this study, which is in agreement with the findings of Izudi et al. [30] study wherein they observed that treatment success rate was lower among male compared to female patients. In another study in Ethiopia, it was found that men experienced lower rates of treatment success, meaning that they experienced more mortality, failed treatment and treatment absence [24]. Another finding of this study was that a significant relationship was observed between patients' nationality and their treatment result as Afghani patients (90.4%) were cured more successfully than Iranians (85.3%) and patients from Pakistan and Arab countries (71.4%). Although there was no significant difference between Iranian and Afghan patients regarding to curing TB, higher centralization on Afghan immigrants people due to high percent of them in Iran could be justify the better curing of tuberculosis. Tok et al. [31] revealed a significant correlation between nationality and treatment result. Additionally, Shahrezaei et al. [32] observed that the nationality had significant effect on outcome.

Our result showed, there was no significant relationship between patients' residence and their rate of treatment success. Similarly, Sengul et al. [33] found that no association between patients' Living area and treatment success. Gebrezgabiher et al. [34] also demonstrated that patients' residence was associated with failed treatment in a way that rural patients revealed a higher risk of failed treatment. A significant relationship was observed between education and treatment results in the current study. Patel et al. [35] observed that education can be regarded as one of the significant factors impacting treatment success as educated patients were 2.4 times more likely to be cured of pulmonary tuberculosis [35]. Moreover, a significant correlation was found between patients' job and the rate of treatment success in this study as the results showed that businesspeople had lower chances of success for their treatments.

One of the main limitations of the current study was that causal relationships could not be exactly established among the variables in this cross-sectional study. Besides, no questionnaires or interviews were conducted in this study; thus, it was not possible to tap into the role of other factors influencing treatment results. On the other hand, the main advantage of this study was that it included all smear-positive patients. Additionally, this study investigated detailed information regarding patients' demographic and clinical status to provide

a thorough analysis of the relationship between such factors and treatment success.

Conclusion

The findings of the study showed that death, treatment failure, lost to follow up and transferred out is more common in patients who have higher MSS. High smear grading of sputum is inversely associated with lower curing and on-time treatment. Moreover, by increasing the *Mycobacterium* grade at initial treatment, treatment failure and lost to follow up increased. Therefore, improvement the health system and patient-diagnosis and screening programs is necessary to on-time diagnosis, facilitate the treatment process and prevent the transference of the disease in suspicious cases. Moreover, the successful treatment in TB patients should be assured, and the TB patients with their families should receive necessary consultations and educations.

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Conflict of interest

None.

Contribution of authors

All authors have same contributions to the conception or design of the work, or interpretation of data for the work; and Final approval of the article.

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