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Factors Affecting Mortality and Treatment Completion of Tuberculosis Patients in Isfahan Province from 2006 to 2011

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ABSTRACT

Background: Regarding cases of infectious diseases tuberculosis (TB) is the most important cause of death and according to the DALY criteria, this disease has the seventh position in global disease ranking. In this study, we aim to determine the risk factors, which have a significant effect on the treatment completion and mortality of TB patients.

Methods: This study is a retrospective cohort study. The sample is made up of registered TB patients in the Isfahan Province from 2006 to 2011. Information of the patients was collected from their files in health centers in the Isfahan Province. Variables such as age, sex, weight, nationality, residence, type of TB, imprisonment, human immunodeficiency virus, TB case were measured. Descriptive statistics (including frequency, percentage, mean and standard deviation) and statistical analysis (including Cox proportional hazard model) were used.

Results: The result showed that imprisonment (hazard ratio [HR] = 4.76, P = 0.019), age (HR = 4.44, P = 0.001) and the TB case (HR = 2.73, P = 0.037) of pulmonary TB had significant impacts on mortality of the patients, also in the case of treatment completion, the TB case (HR = 0.34, P < 0.001) proved to have a significant impact on completion of the treatment. Type of extra-pulmonary TB in extra-pulmonary TB patients also had an effect on treatment completion.

Conclusions: We can conclude that factors such as age, imprisonment, TB case and type of extra-pulmonary TB are effective on the treatment completion and mortality of the patients. It may be useful for policy makers to make more control of high-risk patients.

Keywords: Extra-pulmonary tuberculosis, mortality, pulmonary tuberculosis, treatment completion

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INTRODUCTION

Tuberculosis (TB) is an infectious disease caused by *Mycobacterium tuberculosis*. The disease shows itself in two cases of pulmonary and extra-pulmonary. About 58% of the time the disease shows itself in the case of pulmonary and almost 15% of the time it is displayed in the form of

extra-pulmonary case.[1] In recent years, demographic changes, inadequate medical care, failure to control the disease, incidence of human immunodeficiency virus (HIV) and imbalance of income and poverty in some countries, especially in Asian and African countries have caused the international community to focus on TB.[2] TB is the most important cause of death in the case of infectious diseases (even more than AIDS, malaria and measles). According to the DALY criteria, it has the seventh position in global disease ranking. It is predicted to continue to maintain its current position by the year 2020, that's why this disease is considered as a major source of illness in the future.[3] In terms of cause of death, TB has the second ranking after the HIV.[4,5] About 95% of TB occurs in developing countries.[6] Annually between 8 and 9 million people are infected with TB and 2 million people die from it, and more than half the patients are from Asia and developing countries. TB has almost had a stable position with no reduction in its place in disease rankings.[7-10] In 2012, 8.6 million were infected with this disease all over the world and 1.3 million died from it, out of these people 320,000 were patients also suffering from AIDS.[11] About 60% of the mentioned patients were living in Asian countries.[12] Age prevalence of TB varies in different communities, in poor countries, the highest prevalence is among adolescents and young people[13] but in developed countries and countries where TB is treated seriously, the highest rate is seen in the elderly.[14,15] HIV infection has been the major cause of the spread of TB in recent years.[16] The death rate from TB declined with the implementation of DOTS (short-term treatment with a direct method by which a health care personnel or one of the patient's family members controls his/her consumption of anti-TB drugs daily).[17] However, mortality in patients with drug resistance and treatment failure or virus infection remains high.[18] According to the World Health Organization (WHO) report, the optimal improvement of this disease in the society is when over 85% of these patients are cured after treatment.[19] The most effective factor regarding the improvement or curing of patients is their compliance with the correct use of drugs[20] whereas lack of compliance will lead to relapse, drug-resistance, increase in treatment costs and the disease being prolonged.[21] Now by considering the importance of TB which is mentioned in the introduction and the existence of variables acting as risk factors, we decide to determine which of these risk factors have significant effects on prevention, development, death and treatment outcomes of the disease.

METHODS

Study design and participants

This study is a retrospective cohort study. The study population is made up of all registered TB patients in Isfahan province during the years 2006–2011. Patients' Information was collected from the TB patient forms of groups engaged with the disease in the Isfahan Province. These forms have been provided by the WHO and are used for reporting purposes all over the world. According to the guideline of TB declared by WHO, the main symptom of pulmonary TB is persistent coughing, which continues for 2 weeks or more and is often associated with bloody sputum. Furthermore, if symptoms such as swollen lymph nodes, pain and swelling, deformity of bones, headache, fever, stiff neck, urinary dysfunction, and infertility are observed extra-pulmonary TB can be one the possible diagnosed diseases.[22] When a person is diagnosed with TB by a doctor, their information is instantly sent to a central database by an electronic online system called TB register software. DOTS is the treatment for TB. The inclusion criteria for this study were patients with pulmonary TB or extra-pulmonary TB or both in the Isfahan province from 2006 to 2011, and the exclusion criteria were changes in the disease diagnosis. After the primarily diagnosis, by more accurate testing and evaluation it might be diagnosed later that the patient may be suffering from a problem other than TB, like cancer. The sample was the total number of the recorded TB patients in the Isfahan Province from 2006 to 2011. At first, due to the strategic importance of this disease, arrangements were made in Isfahan University of Sciences, and a letter was sent to the health departments of the Isfahan Province and patient information remains confidential.

Variables assessment

After the agreement of health departments and other coordinations that were made, access to TB information was provided. Information such as age, sex, weight, nationality, residence, type of TB, imprisonment, HIV, TB case, treatment start date, date of outcome, treatment outcome choices (such as completion, recovery, failure, deaths from TB, absence, other causes of death, cause of death unknown, transfer) was collected from the patients recorded files, however only deaths from TB and completion were used in this study as the outcome variables. Validity of the questionnaire was already approved by the WHO.[23]

Statistical analysis

Then, the data were given to the SPSS version 18 (PASW statistics for windows Chicago: SPSS Inc) to be analyzed. The outcomes were treatment completion (i.e., patients who received anti-TB drugs, but had none of the classification criteria of the cured group or the failure group), and death. For analyzing data, descriptive statistics, including frequency, percentage, mean, standard deviation were used. Statistical analysis

including cox proportional hazard model, the *t*-test (for the analysis of quantitative variables between the two groups) and Chi-square test and Fisher exact (for the relationship between qualitative variables) were used. $P < 0.05$ was considered as significant.

RESULTS

The study was performed on all TB patients in Isfahan province from 2006 to 2011. The sample consisted of 2265 TB patients. After applying the exclusion criteria, 41 patients (1.8%) were excluded from the study due to the change in their diagnosis of the disease and finally, 2224 patients remained in the study. From these patients, 102 (4.5%) were infected with both types of TB, 716 (32%) only had extra-pulmonary TB and 1406 (63.5%) were only infected with pulmonary TB. Because of lack of sufficient information on the group, which were diagnosis to have both type of TB, this group was not included in the statistical analysis. Table 1 (frequency distribution (%) of outcomes of the population of TB from 2006 to 2011 in Isfahan province) shows the frequency.

The results showed that for patients with pulmonary TB, the variable of TB case ($P = 0.014$) had a significant relationship with the death of the patients and also in the same group, the variables weight ($P = 0.001$), TB case ($P = 0.002$) and age ($P = 0.016$) proved to have significant relationships with treatment completion [Table 2].

The results also showed that for patients with extra-pulmonary TB the variables weight ($P = 0.036$) and HIV ($P = 0.017$) as well as type of extra-pulmonary TB ($P = 0.04$) had significant relationships with the death of the patients. Also in this group, the variables sex ($P = 0.007$), nationality ($P = 0.041$) and type of extra-pulmonary TB ($P = 0.01$) had significant relationships with treatment completion [Table 3].

Table 1: Frequency distribution (%) of outcomes of the population of TB from 2006 to 2011 in Isfahan Province

Outcome	Frequency (%)		
	Pulmonary TB	Extra-pulmonary TB	Both of TB
Completion of treatment	361 (25.9)	608 (87.5)	52 (53.1)
Recovery	776 (55.7)	-	30 (30.6)
Failure	48 (3.4)	-	1 (1)
Deaths from TB	22 (1.6)	4 (0.6)	3 (3.1)
Absence	68 (4.9)	49 (7.1)	3 (3.1)
Other causes of death	66 (4.7)	21 (3)	8 (8.2)
Cause of death unknown	37 (2.7)	7 (1)	1 (1)
Transfer	15 (1.1)	6 (0.9)	0
Total	1406	716	102

TB=Tuberculosis

Since, variables such as diabetes, malignancy, and drug effects had a high rate of missingness, they were not included in the Cox model, variables with a higher significance level than 0.15 were also not included in the Cox model, but all other variables were included.

From the onset of the disease to its outcome were fitted in the cox model. The model for mortality outcome in pulmonary TB patients showed that imprisonment, age and TB case have significant effects on mortality in such a way that death is higher in nonnew cases (hazard ratio [HR] = 2.73; 95% confidence interval [CI]: 1.06–7.02; $P = 0.037$) and mortality in people aged under 65 is lower than in people aged over 65 (HR = 4.44; 95% CI: 1.89–10.55; $P = 0.001$). Inmates proved to have a 4.76 (95% CI: 1.29–20.00; $P = 0.019$(times higher death rate compared patients who were not imprisoned.

The results show that the type of extra-pulmonary TB is also effective in treatment completion, in a way that miliary, vertebral, bone, meninges and other TB have significantly lower treatment completion rates compared to lymph TB, and gynecologic and pleural TB have higher treatment completion rates compared to the Lymph, but they are not significant. More details can be seen in Table 4.

DISCUSSION

The results of our study showed that in the pulmonary and extra-pulmonary TB groups, sex had no effect on the outcomes of mortality and treatment completion. Srinath *et al*. showed that successful outcomes were higher in female patients of extra-pulmonary TB.[24] Chan-Yeung *et al*. showed that women complete their treatments more than men.[25] While, other studies showed that males were more at risk of reaching the death outcome.[26,27]

The results of this study indicated that the variable weight had no significant effect on the death and the completion outcome of the treatment. Some studies indicated that low body weight is a risk factor for death[28] and is also a risk factor for recurrence of the disease.[29] In contrast body weight at initiation of anti-TB treatment (<35 kg) was an independent predictor for death.[30]

Our study showed that the nationality variable did significant effect the outcomes. Chin *et al*. also achieved similar results.[31] In contrast Mitruka *et al*. showed that being born in a foreign country is an effective risk factor of failure of completion.[32]

Our result showed age to have a significant effect on mortality in pulmonary TB patients. The results also showed that mortality in people aged over 65 is more than in people aged <65. Cruz-Hervert *et al*. showed age above 65 to be a risk factor for treatment failure and

Table 2: Frequency distribution (%) of the variables based on outcomes of death and completion of treatment in pulmonary TB in 2006-2011 years in Isfahan province

Variables	Pulmonary TB					
	Death		*P*	Completion of treatment		*P*
	No	Yes		No	Yes	
Sex						
Male	724 (52.8)	13 (60)	0.560	548 (53.1)	189 (52.6)	0.902
Female	646 (47.2)	9 (40)		484 (46.9)	170 (47.4)	
Nationality						
Iran	764 (55.7)	15 (68)	0.240	575 (55.7)	204 (56.8)	0.712
Foreigners	607 (43.3)	7 (32)		458 (44.3)	155 (43.2)	
Residence						
City	91 (95.8)	3 (100)	1	912 (88.9)	325 (91)	0.273
Rural	4 (4.20)	0 (0)		114 (11.1)	32 (9)	
Prison						
Yes	75 (5.5)	3 (13.6)	0.123	58 (5.6)	20 (5.6)	0.973
No	1296 (94.5)	19 (86.4)		975 (94.4)	339 (94.4)	
Diabetes mellitus						
No	335 (92)	1 (50)	0.155	248 (90.5)	87 (95.6)	0.124
Yes	29 (8)	1 (50)		26 (9.5)	4 (4.4)	
Side effects						
No	359 (98.6)	2 (100)	0.100	271 (98.9)	89 (97.8)	0.600
Yes	5 (1.4)	0 (0)		3 (1.1)	2 (2.2)	
Age						
0-15	26 (1.9)	0 (0)	0.089	22 (2.1)	4 (1.1)	0.016
15-25	287 (21)	4 (18.2)		23 (22.3)	61 (17)	
25-35	216 (15.8)	0 (0)		161 (15.6)	55 (15.4)	
35-45	138 (10.1)	1 (4.5)		100 (9.7)	39 (10.9)	
45-55	159 (11.6)	2 (9.1)		105 (10.2)	56 (15.6)	
55-65	177 (12.9)	3 (13.6)		124 (12)	55 (15.4)	
More than 65	365 (26.7)	12 (54.5)		289 (28)	88 (24.6)	
Weight						
Mean (SD)	54.08 (12.41)	50.17 (13.2)	0.154	53.37 (12.06)	55.97 (13.22)	0.001
Median (range)	53 (95)	50 (47)		52 (80)	55.(95)	
HIV						
Yes	13 (0.9)	0 (0)	1	8 (0.8)	5 (1.4)	0.229
No	1358 (99.1)	22 (100)		1025 (99.2)	354 (98.6)	
TB case						
New	1203 (87.7)	15 (68.2)	0.014	886 (85.8)	331 (92.2)	0.002
Not new	68 (12.3)	7 (31.8)		147 (14.2)	28 (7.8)	

t-test, χ^2 and Fisher's exact test. TB=Tuberculosis, SD=Standard deviation, HIV=Human immunodeficiency virus

death.[23] In a study carried out in Brazil, it was shown that pulmonary TB patients under the age of 20 years had a better chance of recovery than patients older than 60 years.[33] Results of studies Sterling *et al*.[34] and Yen *et al*.[35] were also consistent with our study.

The results showed that nonnew cases have higher mortality rates in the pulmonary TB compared to new cases. The Brazilian study showed that new and relapsed patients had a greater chance of recovery than patients who had treatment again after failure.[33]

Inmate patients were shown to have more deaths compared to noninmates ($P = 0.019$). Many factors contribute to the high prevalence of TB in prison populations, their living conditions and other factors associated with incarceration. These factors include low education levels, the use of illicit drugs, previous treatment for TB,` history of incarceration, overcrowded cells with poor ventilation, lack of information and limited access to health services.[36]

Since in our study, only patients with TB who were at high risks of the disease such as inmates and drug addicts were tested

Table 3: Frequency distribution (%) of the variables based on outcomes of death and completion of treatment in extra-pulmonary TB in 2006-2011 years in Isfahan Province

Variables	Extra-pulmonary TB					
	Death		*P*	Completion of treatment		*P*
	No	Yes		No	Yes	
Sex						
Male	316 (45.80)	1 (25)	0.63	56 (57.70)	261 (43.70)	0.007
Female	374 (54.20)	3 (75)		40 (42.30)	337 (56.3)	
Nationality						
Iran	415 (66.7)	2 (60.1)	1	48 (50.1)	369 (61.70)	0.041
Foreigners	276 (39.9)	1 (33.1)		47 (49.9)	230 (38.3)	
Residence						
City	635 (92.40)	4 (100)	1	90 (94.80)	549 (92)	0.368
Rural	52 (7.60)	0 (0)		5 (5.20)	47 (8)	
Prison						
Yes	16 (2.30)	1 (25)	0.12	5 (5.2)	12 (2)	0.07
No	675 (97.70)	3 (75)		91 (94.8)	587 (98)	
Diabetes mellitus						
No	170 (95.40)	2 (100)	0.15	18 (90)	154 (96)	0.20
Yes	8 (4.60)	0 (0)		2 (10)	6 (4)	
Side effects						
No	176 (98.80)	2 (100)	0.1	20 (100)	158 (99)	1
Yes	2 (1.10)	0 (0)		0 (0)	2 (1)	
Age						
0-15	39 (5.7)	0 (0)	-	7 (7.3)	32 (5.4)	0.407
15-25	144 (20.9)	0 (0)		21 (21.9)	123 (20.6)	
25-35	148 (21.4)	0 (0)		14 (14.6)	134 (22.4)	
35-45	106 (15.4)	2 (50)		18 (18.8)	90 (15.1)	
45-55	108 (15.7)	0 (0)		12 (12.5)	96 (16.1)	
55-65	85 (12.3)	1 (25)		12 (12.5)	74 (12.4)	
More than 65	60 (8.7)	1 (25)		12 (12.5)	49 (8.2)	
Weight						
Mean (SD)	59.17 (16.71)	50.17 (13.2)	0.036	58.55 (18.64)	59.22 (16.37)	0.722
Median (range)	51.5 (7.89)	50 (47)		60 (130)	58 (144)	
HIV						
Yes	2 (0.3)	1 (25)	0.017	1 (1)	2 (0.3)	0.36
No	689 (99.7)	3 (75)		95 (99)	597 (99.7)	
TB case						
New	671 (97)	4 (100)	1	95 (99)	580 (97)	0.24
Not new	20 (3)	0 (0)		1 (1)	19 (3)	
Form of extra-pulmonary TB						
Lymph	196 (28.4)	0 (0)	0.04	18 (18.8)	178 (29.7)	0.01
Miliary	25 (3.6)	1 (25)		3 (3.1)	23 (3.8)	
Vertebral	65 (9.4)	0 (0)		10 (10.4)	55 (9.2)	
Pleural	114 (16.5)	1 (25)		19 (19.8)	96 (16)	
Bone	33 (4.8)	1 (25)		2 (2.1)	32 (5.3)	
Kidney	66 (9.6)	0 (0)		17 (17.7)	49 (8.2)	
Gynecologic	53 (7.7)	0 (0)		4 (4.2)	49 (8.2)	
Meningitis	33 (3.8)	1 (25)		7 (7.3)	20 (3.3)	
Other	33 (16.4)	0 (0)		16 (16.7)	97 (16.2)	

TB=Tuberculosis, SD=Standard deviation, HIV=Human immunodeficiency virus

Table 4: Cox regression model for the completion of treatment and mortality outcome in TB patients in 2006-2011 years in Isfahan province

Extra-pulmonary tuberculosis			Pulmonary tuberculosis				
Variables	Completion of treatment		Completion of treatment			Death	
	P	Risk ratio (CI 95%)		*P*	Risk ratio (CI 95%)	*P*	Risk ratio (CI 95%)
Sex							
Ref=male		Ref					
Female	0.498	1.062 (0.89 1.26)					
Weight				0.053	1.00 (.99 1.01)		
Nationality							
Ref=Iran		Ref					
Not Iran	0.918	0.99 (.81 1.22)					
Prison							
Ref=yes		Ref				Ref=no	Ref
No	0.630	0.86 (.42 1.21)				yes	0.019 4.76 (1.29 20.00)
Tuberculosis case			Ref=New		Ref	Ref=New	ref
			Not new*	<0.001	0.34 (0.23 0.51)	Not new	0.037 2.73 (1.06 7.02)
Age		Ref	Ref (0-15)		Ref	Ref=(lower 65)	Ref
Ref (0-15)	0.303	0.82 (0.56 1.19)	(15-25)	0.728	1.19 (0.40 3.20)	(upper 65)	0.001 4.44 (1.89 10.55)
(15-45)	0.050	0.67 (0.45 1.00)	(25-35)	0.686	1.23 (0.45 3.39)		
(45-65)	0.122	0.69 (0.44 1.10)	(35-45)	0.514	1.46 (0.57 3.48)		
(Upper 65)			(45-55)	0.372	1.50 (0.44 4.83)		
			(55-65)	0.547	1.38 (0.40 4.81)		
			(Upper 65)	0.729	2.19 (0.48 4.56)		
Form of extra-pulmonary		Ref					
(Ref=lymph) Miliary	0.002	0.47 (0.27 0.72)					
Vertebral	0.000	0.31 (0.23 0.41)					
Pleural	0.119	1.22 (0.99 1.79)					
Gynecologic	0.195	1.29 (0.89 1.66)					
Bone	0.000	0.35 (0.24 0.41)					
Renal	0.069	0.74 (0.54 1.07)					
Meninges	0.000	0.33 (0.25 0.55)					
Other**	0.000	0.62 (0.47 0.89)					

for HIV, we had under numeration of AIDS, and therefore we excluded this variable from the model. However, many studies have shown an association between TB and AIDS.[34,37-40]

Also because of the missing data on diabetes, this factor was not included in the model. The relationship between diabetes and outcomes of TB patients were shown in several articles.[41-43]

Because our study was retrospective, we could not examine factors such as smoking, drugs, humidity, and job status.

CONCLUSIONS

We can conclude that factors such as age, imprisonment, TB case and type of extra-pulmonary TB are effective on the treatment completion and mortality of the patients. It may be useful for policy makers to make more control of high risk patients.

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