RESEARCH ARTICLE

DETERMINANTS OF DELAYS IN DIAGNOSIS AND TREATMENT OF PULMONARY TUBERCULOSIS IN A NEW URBAN TOWNSHIP IN INDIA: A CROSS-SECTIONAL STUDY

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ABSTRACT

Background: The period of infectiousness of a new sputum smear-positive pulmonary tuberculosis case is important in determining the risk of exposure faced by the community. Early detection and effective treatment of TB case reduces the period of transmission and the risk of exposure of the community. It is for this reason that the delay in TB diagnosis and treatment should be minimal to control disease transmission and patient suffering.

Aims & Objective: To measure delays in diagnosis and treatment of pulmonary tuberculosis, and to identify and assess the risk factors associated with these delays.

Material and Methods: A cross-sectional study was conducted of all new smear-positive pulmonary TB patients diagnosed between January 2012 and June 2013 at RNTCP clinic. The time from the onset of symptoms to first health care consultation (patient delay) and the time from first health care consultation to the date of TB diagnosis (health system delay) were analysed. Bivariate and logistics regression were applied to analyse the risk factors of delays.

Results: A total of 122 patients with a mean age of 29.9 years were included in the study. Mean total delay between the onset of symptoms and treatment initiation was 53.42 days (median 50, range 14-128), with a mean patient delay of 29.24 days (median 25, range 5-94) and mean health system delay of 21.7 days (median 17, range 3–93). The mean treatment delay was 2.48 days (median 2, range 1-6). Factors independently associated with total delay were cough symptom (OR 3.36, P = 0.038), completed secondary school (OR 0.41, P = 0.018), good knowledge of TB symptoms (OR 0.39, P = 0.011), first visit to a public health facility (OR 0.45, P = 0.044), sputum testing at first health care consultation (OR 0.46, P = 0.048) and stigma attached to TB disease (OR 2.89, P = 0.021). Those associated with patient delay were male sex (OR 0.42, P = 0.020), large family size (OR 2.30, P = 0.027), completed secondary school (OR 0.43, P = 0.025) and good knowledge of TB symptoms (OR 0.45, P = 0.029); while those associated with health system delay were first visit to a public health facility (OR 0.31, P = 0.006), sputum testing at first health care consultation (OR 0.22, P = 0.001), number of health care consultations (OR 4.41, P < 0.001) and pre-diagnosis health care cost (OR 3.35, P = 0.001).

Conclusion: Health system delay was an important problem in the area studied, with patient delay being of most concern.

Key-Words: Pulmonary Tuberculosis; Patient Delay; Health System Delay; Treatment Delay; Risk Factors

Introduction

India has the highest burden of tuberculosis (TB) in the world, accounting for approximately one fifth of the global incidence. An estimated 2.3 million cases occur annually, of which 0.8 million are sputum-smear positive.[1] A case of untreated smear positive TB can infect up to 15 people annually and over 20 during the natural course of untreated disease.[2,3] The period of infectiousness of a TB case is of crucial importance in determining the risk of exposure faced by the community. The delay in TB diagnosis and treatment should be as short as possible, not only to control disease transmission, but also to reduce patient suffering. This can be achieved by shortening the time interval between the onset of first symptom and first health facility visit (patient delay) and the time interval between first health facility visit and TB diagnosis (health system delay).

According to the latest Revised National Tuberculosis Control Programme (RNTCP) annual status report 'TB India 2012', the RNTCP has achieved treatment success rate of 88%.[4] Although the new smear-positive case detection rate had reached above 70% it is extremely important to assess whether these cases were detected and treated in a timely manner. Delay in the diagnosis and treatment of TB cases spreads the infection in the community, increases severity of the disease and is associated with higher risk of mortality.[5] In a passive case-finding programme, early case detection and prompt effective treatment is dependent upon patients perceiving the need to seek care immediately at the onset of pulmonary symptoms, then visiting a health facility and being properly diagnosed and treated.[6]

Since the implementation of RNTCP in 2001, there were no assessments in Navi Mumbai of delays in TB diagnosis and

treatment, which can be used as a guide in planning TB control. Navi Mumbai is a planned township in Mumbai on the west coast of the Indian state of Maharashtra. It was developed in 1972 as a new urban township and is the largest planned city in the world. As per provisional reports of Census India, population of Navi Mumbai in 2011 was 1,119,477 of which male and female were 611,501 and 507,976 respectively.[7] The huge population growth due to immigration from all over India, poverty, overcrowding, poor living condition and excess demand for health care services may have led to an increase in TB diagnosis and treatment delays. Hence the present study aims to assess the delays in TB diagnosis and treatment and associated risk factors among smear-positive pulmonary TB patients treated in Navi Mumbai.

Materials and Methods

Study Area: In India there are different types of health care institutions where pulmonary TB is diagnosed using sputum smear examination. The institutions vary from tertiary level hospitals such as Medical colleges, District TB centers at district level, TB Units at sub district level and Peripheral Health Institutions. Designated Microscopy Centres (DMCs) are placed in the busier government health facilities and cover approximately 100,000 population.[8] All persons suspected of having pulmonary TB are referred to DMCs for sputum smear examination. In Navi Mumbai, there are three TB Units: Belapur, Vashi and Airoli. Each TB Unit consists of 4-5 DMCs depending on the population. We have randomly selected one DMC from one TB Unit.

Study Population: A cross-sectional community based study was carried out that included all new sputum smear-positive pulmonary TB patients diagnosed between January 2012 and June 2013. In Navi Mumbai, the public health system provides health services, through a network of hospitals and health posts. Like in other parts of the country, TB diagnosis and treatment are provided by the public health system and are free of charge.

Data Collection Techniques and Tools: The information obtained from patients included socio-demographic characteristics, knowledge about TB symptoms, active TB symptoms (cough, hemoptysis, chest pain, breathlessness, night sweat, fever and weight loss), date of onset of pulmonary symptoms, type of first health facility, date of visit to a first health facility, distance between subject's home and nearest health facility. The date of diagnosis and treatment was confirmed using laboratory register and treatment card respectively. The interviews were conducted at health facilities. Patients who could not be interviewed at health facilities were visited at home to obtain the required information. Community health visitors (CHVs) assisted in locating the patients' residential address in the community. Before starting the interview each respondent was explained in brief about the need and purpose of the study. The importance for their cooperation for the success of the study and possible benefits to the community through the finding of the study were emphasized. The study protocol and questionnaire was approved by Institutional Ethical Committee at Terna Medical College and Hospital. The informed consent was obtained from each interviewee before enrolment in the study and confidentiality of the information was maintained throughout the study.

Study Definitions: *(a) Patient Delay:* interval (in days) between the onset of pulmonary symptoms and first visit to a health facility. *(b) Health System Delay:* interval (in days) between first visit to a health facility and confirmation of TB diagnosis by a physician with the help of sputum smear results. *(c) Treatment Delay:* interval (in days) between confirmation of TB diagnosis by a physician with the help of sputum smear results and start of TB treatment. *(d) Total Delay:* interval (in days) between the onset of pulmonary symptoms and start of TB treatment.

Statistical Analysis: Data was entered and analysed using SPSS version 16.0 (SPSS Inc, Chicago, IL). Descriptive statistic procedures were used for the calculation of central tendency and dispersion measures. To dichotomize dependent variables, 50 days was used as the cut-off for total delay and 25 days as the cut-off for both patient delay and health system delay. To assess the effects of the socio-demographic variables and other risk factors on various types of delays, odds ratios (OR) and their 95% confidence intervals (CI) were calculated. P value < 0.05 was considered significant and all tests were 2-sided.

Results

Socio-Demographic and Clinical Characteristics: Among 134 new sputum smear-positive pulmonary TB patients initiated on treatment during the study period, 122 (91%) were interviewed. A total of 12 patients were excluded because of missing data regarding the date of onset of symptoms. Of 122 patients, 52.5% were males, 59% completed secondary school, 50.8% were employed and 61.5% were married. The socio-demographic and clinical characteristics of patients are shown in Table 1. The mean age was 29.9 years (median 26, range 15–65). The mean age of males and females were 32.2 years and 27.4 years

respectively, the difference being statistically significantly (P<0.05). As expected, we observed significant association between education level and knowledge of TB symptoms, young age and male sex. The median monthly household per capita income was INR2472 (range 667.00–12000.00), i.e., approximately US$38. The median time spent in travel to cover the distance of the subject's home from the nearest health facility was 10.0 min (range 5.0–30.0) regardless of the form of transport used.

Reported TB Symptoms: Majority of patients presented with a combination of symptoms. However, the most frequently reported symptoms were cough (86.9%), fever (74.6%), weight loss (30.3%), hemoptysis (27%) and chest pain (17.2%). Hemoptysis was reported more by men than women (P = 0.002).

Awareness of TB Symptoms and Perceived Causes: Sixty one (50%) and 69 (56.6%) of patients had good knowledge of TB symptoms and possible ways of TB transmission, respectively. Fifty nine (48.4%) were aware that cough is a TB symptom. Other symptoms mentioned were: coughing blood (14.8%), fatigue (13.1%), chest pain (12.3%) and fever (5.7%). As noted, there was a low level of awareness of TB symptoms and its causes in this study population. More than half of all patients (68.29%) were aware that TB is curable.

Place of First Health Care Consultation: Of 122 patients, 68% attended a private clinic first and 32% a public health facility. The main reasons given for approaching private clinic first were faith in the provider (61.5%), physical proximity (31.1%) and lack of awareness of free and effective TB treatment services close to their house (7.4%). 76.6% of men visited a private clinic first compared to 58.6% of women whereas 23.4% of men visited a public health facility first compared to 41.4% of women (P < 0.05). Amongst patients presenting to a private clinic first, only 4.8% were investigated for TB using sputum microscopy, whereas in public health facility 95% of patients were advised for sputum microscopy (P < 0.001). The mean health system delay when a patient consulted a public health facility first was 13 days compared to 25.82 days for those consulting a private clinic (P < 0.05).

Patient Delay: The mean patient delay was 29.24 days (median 25, range 5–94). An association between patient delay of ≤25 days or >25 days and socio-demographic and other risk factors was observed (Table 2). There was a significant association between patient delay of <25 days and male sex (P = 0.020), completed secondary school (P = 0.025) and good knowledge of TB symptoms (P = 0.029). The patient delay of >25 days was associated with large family size (P = 0.027). There was no association of patient delay with per-capita income or occupation. We were not able to demonstrate an association between stigma and patient delay.

Health System Delay: The mean health system delay was 21.7 days (median 17, range 3–93). Table 3 shows the association between health system delay of ≤25 days or >25 days and socio-demographic and other risk factors. The health system delay of <25 days was significantly associated with first visit to a public health facility (P =

Table-1: Socio-demographic and clinical characteristics of patients

Characteristics		No (%)
Age (Years)	< 30	76 (62.3)
	≥ 30	46 (37.7)
Sex	Female	58 (47.5)
	Male	64 (52.5)
Marital Status	Single	47 (38.5)
	Married	75 (61.5)
Completed Secondary School	No	50 (41.0)
	Yes	72 (59.0)
Occupation	Non-working	60 (49.2)
	Working	62 (50.8)
No. of Household Members	≤ 5	76 (62.3)
	> 5	46 (37.7)
Per-Capita Income (INR)	≤ 2000	51 (41.8)
	> 2000	71 (58.2)
Type of First Health Facility	Private	83 (68.0)
	Government	39 (32.0)
Good Knowledge of TB Symptoms	No	61 (50.0)
	Yes	61 (50.0)
Number of Health Facility Visits	≤ 5	67 (54.9)
	> 5	55 (45.1)

Table-2: Relation between patient delay and socio-demographic and other risk factors

Characteristics		Patient Delay			
		≤ 25 Days N (%)	> 25 Days N (%)	OR (95% CI)	P-value
Age (Years)	< 30	45 (59.2)	31 (40.8)	1.00	
	≥ 30	21 (45.7)	25 (54.3)	1.73 (0.82-3.62)	0.145
Sex	Female	25 (43.1)	33 (56.9)	1.00	
	Male	41 (64.1)	23 (35.9)	0.42 (0.20-0.88)	**0.020**
Marital Status	Single	28 (59.6)	19 (40.4)	1.00	
	Married	38 (50.7)	37 (49.3)	1.43 (0.69-3.00)	0.337
Completed Secondary School	No	21 (42.9)	29 (58.1)	1.00	
	Yes	45 (62.5)	27 (37.5)	0.43 (0.21-0.91)	**0.025**
Occupation	Non-working	29 (48.3)	31 (51.7)	1.00	
	Working	37 (59.7)	25 (40.3)	0.63 (0.31-1.29)	0.209
No. of Household Members	≤ 5	47 (61.8)	29 (38.2)	1.00	
	> 5	19 (41.3)	27 (58.7)	2.30 (1.09-4.86)	**0.027**
Per-Capita Income (INR)	≤ 2000	26 (51.0)	25 (49.0)	1.00	
	> 2000	40 (56.3)	31 (43.7)	0.81 (0.39-1.66)	0.558
Distance Between Home & Health Facility	≤ 1 km	41 (57.7)	30 (42.3)	1.00	
	> 1 km	25 (49.0)	26 (51.0)	1.42 (0.69-2.93)	0.340
Good Knowledge of TB Symptoms	No	27 (44.3)	34 (55.7)	1.00	
	Yes	39 (63.9)	22 (36.1)	0.45 (0.22-0.93)	**0.029**

Table-3: Relation between health system delay and socio-demographic and other risk factors

Characteristics		Health System Delay			
		≤ 25 Days N (%)	> 25 Days N (%)	OR (95% CI)	P-value
Age (Years)	< 30	47 (61.8)	29 (38.2)	1.00	0.415
	≥ 30	25 (54.3)	21 (45.7)	1.36 (0.65-2.86)	
Sex	Female	37 (63.8)	21 (36.2)	1.00	0.307
	Male	35 (54.7)	29 (45.3)	1.46 (0.70-3.02)	
Marital Status	Single	29 (61.7)	18 (38.3)	1.00	0.337
	Married	43 (57.3)	32 (42.7)	1.20 (0.57-2.53)	
Completed Secondary School	No	30 (60.0)	20 (40.0)	1.00	0.854
	Yes	42 (58.3)	30 (41.7)	1.07 (0.51-2.23)	
Occupation	Non-working	29 (48.3)	31 (51.7)	1.00	0.209
	Working	37 (59.7)	25 (40.3)	0.63 (0.31-1.29)	
Hemoptysis	No	50 (56.2)	39 (43.8)	1.00	0.295
	Yes	22 (66.7)	11 (33.3)	0.64 (0.28-1.48)	
Per-Capita Income (INR)	≤ 2000	29 (56.9)	22 (43.1)	1.00	0.682
	> 2000	43 (60.6)	28 (39.4)	0.86 (0.41-1.78)	
Sputum Testing at First Health Facility Visit	No	39 (48.1)	42 (51.9)	1.00	**0.001**
	Yes	33 (80.5)	8 (19.5)	0.22 (0.09-0.55)	
Type of First Health Facility	Private	42 (50.6)	41 (49.4)	1.00	**0.006**
	Government	30 (76.9)	9 (23.1)	0.31 (0.13-0.73)	
Number of Health Facility Visits	≤ 5	50 (74.6)	17 (25.4)	1.00	**0.000**
	> 5	22 (40.0)	33 (60.0)	4.41 (2.04-9.53)	
Pre-Diagnosis Health Care Cost (INR)	≤ 1000	51 (70.8)	21 (29.2)	1.00	**0.001**
	> 1000	21 (42.0)	29 (58.0)	3.35 (1.57-7.15)	

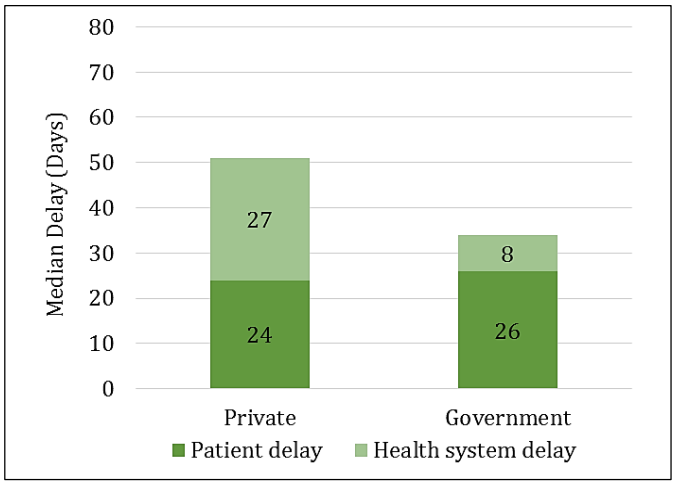

Figure-1: Place of first health care consultation versus median delay to treatment initiation among new smear-positive pulmonary TB patients

0.006) and sputum testing at first health facility visit (P = 0.001). In 41% of patients, the health system delay was >25 days and was associated with increased number of health visits (P < 0.001) and pre-diagnosis health care expenditure (P = 0.001). After presenting to a health facility, patients made an average of 5.6 visits to the health system before obtaining a final diagnosis. There was no significant association between health system delay and gender, education level, per-capita income and knowledge of TB symptoms. One third of all patients were diagnosed and treated at the first health facility visit. The mean smear examination delay was 1.94 days (median 2, range 1–4). Only 1.6% of patients had a smear examination delay of >3 days.

Treatment Delay: The mean treatment delay was 2.48 days (median 2, range 1–6). Only 1 patient took >5 days to initiate treatment, the reason being patient had to visit village for some emergency purpose.

Total Delay: The mean total delay was 53.42 days (median 50, range 14–128). It was 46.23 days for patients attending a public health facility first compared to 56.88 days for patients attending a private clinic first, the difference being statistically significant (P < 0.05). Nearly half of all patients had a total delay of >50 days. An association between total delay >50 days and stigma was observed (P = 0.021).

Discussion

This study showed an overall mean time from the onset of first pulmonary symptom to first health facility visit (patient delay) and first health facility visit to TB diagnosis (health system delay) for new smear-positive pulmonary TB patients of 29.24 days and 21.7 days respectively. Studies conducted in other countries reported patient delays in TB diagnosis to be between 7 and 60 days, while health system delays range between 6 and 63 days.[9-13]

In this study, the median total delay was 50 days. This value is similar to that found in Angola (45 days)[14], Hong Kong (49 days)[15], Pakistan (56 days)[16] and Uganda (56 days)[17], lower than that found in Iran (96 days)[18] and Brazil (110 days)[6] higher than that detected in Vietnam (28 days)[19]. The major contributor to total delay observed was patient delay (66.67%) which was lower than what was found in Brazil (74.3%).[6] Studies in Tanzania and Nepal also show dominance of patient delay in the total delay.[2,20] Unlike a study conducted in Vietnam[19], no association of total delay with sex was observed.

The median patient delay was 25 days, similar to those reported in Sudan (27.2 days)[21], Norway (28 days)[3], and Bangladesh (28 days)[22] well below that found in Brazil (76 days)[6] and higher than in Indonesia (7 days).[23] In this study, a shorter patient delay occurred in males, those who completed secondary school and in those who had good knowledge of TB symptoms. A longer patient delay occurred in those who stayed with large family. This factor

was reported only by Brazil.[24] In this study, the patient delay was the most important reason for total delay, a finding similar from a study in Mexico.[25]

Our findings showed that a private clinic was the first point of contact for 68% of patients and a public health facility for 32% of patients, compared to respectively 43% and 47% in study from the southern part of India.[26] This decrease in patients presenting to a public health facility first in our study could be due to lack of awareness among the community about the availability of free and effective TB treatment services under the RNTCP.

The median health system delay was 17 days, similar to those reported in Mwanza (15 days)[27], Nepal (18 days)[20] and Mexico (18.5 days)[25] lower than that observed in Tanzania (28 days)[2], Norway (33 days)[3], Bangladesh (56 days)[22] and Iran (75 Days)[18]. This suggests that the health system delay was not the main problem in the area studied. There was a significant health system delay when patient first approached private clinic in comparison to public health facility (P = 0.006), a finding similar from a study in the southern part of India.[26] The first consultation to a private clinic could be a risk factor for health system delay as only 4.8% of patients visiting a private clinic first were advised for sputum microscopic and radiographic investigations. Malaysia had a similar finding.[28] This can be explained by the fact that most private clinics are not equipped with TB diagnostic facilities.

With a median delay of 2 days, treatment delay clearly was not a main problem in the area studied. Once a TB patient is detected, the CHV from public health facility visits patient's home for the confirmation of address, both temporary and permanent. Immediately after registration, patient was started on DOTS. The treatment delay observed in this study ranged from 1 to 6 days, which was shorter than from other studies.[29,30]

The symptoms most frequently reported by patients were cough, fever, weight loss, hemoptysis and chest pain. As reported in a study conducted in Brazil[6], patients mentioned cough as the main TB symptom in this study. This is vital when making decisions about the content of TB awareness campaigns.

Only 61 patients associated their symptoms with TB, which indicates general lack of information on TB in the community. This could be the reason for the association between knowledge of TB symptoms and patient delay. Although more than half of all patients knew how the disease was transmitted, it is of concern that 43.4% of patients were not aware of modes of transmission, as they should have been clearly educated on different aspects of TB at the start of treatment.

Limitations

In this study, we observed two limitations. Firstly, there was high chance of recall bias as the interval between first presenting symptom and first health care consultation was self-reported. To overcome this limitation, local religious festivals and agricultural events were used to facilitate patients' recall to collect information. Besides, we reviewed the medical records available with the patients. Secondly, the findings of this study cannot be generalized to all smear-positive pulmonary TB patients in Navi-Mumbai because only those patients who were treated in public health facilities were interviewed, thus excluding patients from private health facilities.

Conclusion

Health system delay was an important problem in the area studied, with patient delay being of most concern. Community-based programs on awareness of TB need to be increased to reduce the patient delay. Greater awareness among private doctors regarding early referral of symptomatic patents for sputum microscopy and practice of standardized TB treatment is essential to reduce the health system delay.

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