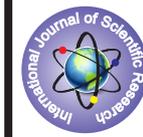


## A STUDY OF ASSOCIATION OF GENDER WITH DELAY IN DIAGNOSIS & TREATMENT INITIATION IN PULMONARY TUBERCULOSIS.



### Medicine

**KEYWORDS:** Pulmonary tuberculosis, gender differences, delay in diagnosis

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### ABSTRACT

The objectives of the study were to find the magnitude of delay in diagnosis and treatment initiation in Pulmonary Tuberculosis (TB) patients registered under RNTCP (Revised National Tuberculosis Control Programme) and to assess gender differences in these delay. For this we did an interview and record based institutional cross sectional observational study in Maharashtra for 6 months duration which included 393 new cases of pulmonary TB patients registered under RNTCP for treatment. We found out that contribution to total delay made by patients delay (48%) and diagnostic delay (45%) is almost equal. The delay was twice in males as compared to females at both patient level and diagnosis level.

### INTRODUCTION

Tuberculosis (TB) remains a public health problem in resource limited countries despite the fact that causative organism was discovered more than 135 years ago.<sup>1</sup> In 2014, there were an estimated 9.6 million new TB cases: 5.4 million among men, 3.2 million among women and 1.0 million among children. In India, it affects the adults in the most productive age group (15-54 years) with prevalence 20.9%.<sup>2</sup> While two-third of cases are male, TB takes disproportionately larger toll among young females, with more than 50% of female cases occurring before the age of 34 years and nearly one-third of female fertility in India is caused by TB.<sup>2</sup>

WHO has developed a post 2015 global TB strategy (the End TB strategy) that was approved by all Member States at May 2014, World Health Assembly (WHA). The overall goal of strategy is to end the Global TB epidemic, with corresponding 2035 targets of a 95% reduction in TB deaths & 90% reduction in TB incidence (compared with 2015).<sup>1</sup> With a timely diagnosis and correct treatment, almost all people with TB can be cured.<sup>3</sup> Early diagnosis and prompt effective therapy form the key elements of the tuberculosis control programme.<sup>3</sup> Delay in diagnosis of pulmonary tuberculosis results in increased infectivity in the community.<sup>3</sup> Such delay may occur at the level of the patient (patient delay) or at the level of the health system (system delay).<sup>3</sup> There were some studies highlighting the role played by gender in causing delays in diagnosis and treatment of TB.<sup>4,5</sup> It is important to identify and address these factors as per local settings in order to devise strategies for the national tuberculosis control programme (NTP).<sup>3</sup>

### METHODOLOGY

We did a institution based study in a TB unit in metropolitan city. There are 6 TB units in this city. Out of that we randomly selected 1 TB unit.

We conducted a cross-sectional observation study. Sample size was calculated using formula for sample size:  $n = Z^2_{(1-\alpha)} (1-P) / \Sigma^2 P$

Considering prevalence of delays in previous studies as 30%<sup>6</sup>, absolute precision 5% on either side, confidence level of 95% and non response rate as 10%, sample size required was calculated as 370.

As per last quarter report of the TB unit, total number of new pulmonary TB cases registered for treatment under RNTCP were 373. So we decided the study duration to be of 6 months. We included  $\geq 18$  years old of age new pulmonary TB cases diagnosed as per RNTCP definition<sup>7</sup> for pulmonary TB. To avoid recall bias, we included only those who had been registered for TB treatment under RNTCP since last 15 days of interviewing the patient. We excluded all Category II patients which includes lost to follow up, failure or relapse patients as well as all extra-pulmonary cases.

A structured questionnaire used in the WHO multi-country<sup>3</sup> study to estimate the diagnostic and treatment delay in TB was used to

interview the patients. The questionnaire was pre-tested by a pilot study on 50 patients. Ethics approval was taken from Institutional Review Board & also prior permission from RNTCP officials was obtained.

Study period was from from 1<sup>st</sup> June 2014 to 31<sup>st</sup> December 2014. Total 393 patients were included in our study. Patients were interviewed regarding their socio demographic characteristics and date of onset of TB related symptoms like cough, fever, weight loss, chest pain, haemoptysis. Patient's case paper was used to know the date patient had approached health facility. TB treatment card was used to know about the date diagnosis made & treatment initiated, as well as to know the sputum status. Medical records available with subjects included information on visits and treatment received in and out of the TB unit. Informed consent was obtained before interviewing every patient.

### Definitions for various delays

**Patient delay (PD):** time interval between onset of symptom and first health seeking behaviour.<sup>4</sup>

Patient delay was considered to be present if time between onset of TB related symptom and first health seeking behavior was more than 14 days, however, if it was  $\leq 14$  days patients delay was labeled as absent.

Cut off of 14 days was considered because as per RNTCP criteria for TB suspect, symptoms of cough, fever of less than 14 days should alert the person for seeking health care suspecting TB.<sup>8</sup>

**Diagnostic delay (DD):** time interval between first health seeking behaviour and labelling of the patient as a tuberculosis patient (tuberculosis diagnosis).<sup>4</sup>

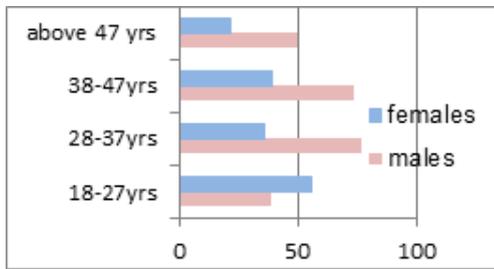
If time between first health seeking behavior and TB diagnosis made was  $\leq 14$  days-DD was said to be absent, whereas, if the time taken was  $> 14$  days DD was said to be present. Cut-off for diagnostic delay (DD) was taken as 14 days because as per treatment algorithm for TB suspect as per RNTCP guidelines<sup>8</sup> and opinion from clinicians, a period of 14 days of non response to empirical antibiotic therapy should alert the health care provider for TB possibility.

**Treatment delay (TD):** time interval between tuberculosis diagnosis and initiation of anti-tuberculosis drugs under RNTCP.<sup>4</sup> If time between TB diagnosis made and TB treatment initiated under RNTCP is  $\leq 7$  days- no treatment delay, if  $> 7$  days-treatment delay present cut off considered was 7 days because as per RNTCP guidelines, the patient should be put on TB drugs within 7 days of TB diagnosis made.<sup>9</sup> Epi info 7 and SPSS (Statistical Package for Social Science) version 23 were used for data analysis purpose. Delay was thus classified as dichotomous variable with outcome as either delay present or absent. For the dichotomous outcome, we compared the presence/absence of delay and the presence/absence of a suspected

risk factor of gender using Chi-square test and with its corresponding 95% confidence interval (CI). 2-sided test was applied.

**RESULTS**

A total of 393 TB patients were included in the study. The mean age of participants was 37 years ± 12.4 years.



X axis-number of participants, Y axis-age groups

**Figure 1-Distribution of Age with respect to Gender**

In all age groups, males outnumbered females, but in the age group between 18 to 27 years which consists of reproductive age group, number of females were quite high than males (58.94% vs 41% respectively). On cross tabulation, age distribution of participants with respect to gender was found to be significant. (p=0.001)

Total 211 (88.33%) men were literate whereas literates in females were 119 (77.12%). Also 221 (92.08%) of men were employed. In women, 53 (34.64%) were employed. Thus, number of literates and employed were more in men than in women and this association was found to be significant on cross tabulation. (p<0.001, p=0.007)

**Table 1-Magnitude of delays**

Delays (No. of patients)	Days (mean±SD)	Days (median)	Days(range)
PD (158)	26.4 ± 38.9	14	1-360
DD (226)	24.5 ± 26	19	1-150
TD (78)	4.1 ± 7.8	2	1-90

PD-patient delay, DD-diagnostic delay, TD-treatment delay, SD-standard deviation

In our study, the contribution to total delay made by patients delay (48%) and diagnostic delay (45%) is almost equal.

As per table no.2, gender was significantly associated with patients delay and diagnostic delay. Males seek treatment late as compared to females.

**Table 2.Association of types of delays with gender**

	Male (total=240)		Female (total=153)		Odds ratio (95% CI)	P value
	Delay present N(%)	Delay Absent N(%)	Delay present N(%)	Delay Absent N(%)		
PD	110 (45.83)	130 (54.17)	48 (31.37)	105 (68.63)	OR-1.85 (1.20-2.83)	0.004
DD	153 (63.75)	87 (36.25)	73 (47.71)	80 (52.29)	OR 1.92 (1.27-2.91)	0.001
TD	48 (20)	192 (80)	30 (19.6)	123 (80.4)	OR-1.02 (0.61-0.70)	0.9

**DISCUSSION**

Majority (61.07%) of the patients were males. Similarly, study done by Thakur et al<sup>10</sup> had 66.6% male participants..

In our study, male gender played an important role in both patient and diagnostic delays. Similarly, in a study conducted by Rajeswari et al in South India<sup>5</sup>, and in contrast to other studies done by Lawn et al in Ghanaia, Yamasaki and Ozasa in Nepal.<sup>11</sup> Men were more likely to

experience delay than women. Also, it was seen that male were more likely to be employed than women. This may be because almost half of the male participants in the study were daily wage earners who may find it difficult to take leave to attend government diagnostic facilities during working hours.

Patients delay in our study (14 days) is closer to lower bound of the range (10–119 days) reported in studies done by Tamhane, Ambe, Vermund in Mumbai<sup>12</sup>

Patient delay was less in our study population as compared to others in the literature. This may be due to better availability and accessibility of health care facilities in our settings.

Among 393 subjects in our study, 226 (57.50 %) experienced diagnostic delay.

Similar study done in Bangalore showed a median DD delay of 18 days.<sup>13</sup>

Median treatment delay was 2 days.

This average of 4 days of treatment delay is similar to study done by Pradhan in Mumbai.<sup>14</sup>

**CONCLUSIONS**

It is important to identify and address factors that contribute to patient or system delay in order to devise strategies for minimizing these delays in the national TB control programme.

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