

A Study on Epidemiological Parameters of Tuberculosis among Treated Patients in an Urban Area of Pune, Maharashtra

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ABSTRACT

Background: Tuberculosis, an ancient infectious disease, affects all persons and all organs of human body. Various parameters of tuberculosis are studied worldwide to assess the epidemiological profile of TB in relation to patients under treatment, with varied results. This study was intended to assess the profile of tuberculosis parameters in relation to treated patients under RNTCP in an urban area, as it was not done here in the recent past.

Materials and methods: It's an observational and combined retrospective-prospective cohort study, carried on 429 tuberculosis patients. Data was collected by trained personnel in structured and pretested formats from a Tuberculosis Unit, under which patients were receiving treatment and through direct visits and interviews with patients. The statistical analysis was done by subjecting data to 'EPI INFO' and WIN PEPI software.

Results: Of all 429 patients, 66% were male, 62% pulmonary, 78% new and 56% belonged to 15-34 year age group and sputum conversion rates were 89% and 51% for new and retreatment cases respectively.

Conclusions: The proportion of tuberculosis is found to be significantly higher in males, adults, pulmonary type and in new category.

Key words: Tuberculosis, parameters, Pulmonary, Sputum positive, extra pulmonary, Sputum conversion, RNTCP etc

INTRODUCTION

Tuberculosis (TB) being an ancient infectious disease, is considered as a major social and public health problem in developing countries including India.^[1,2,3] During 2015, global incidence of TB was 10.4 million and in India 2.8 million with mortality of 1.4 million and 0.48 million respectively.^[4] Because of the NTCP's (National TB Control Program)^[5] unsuccessful outcomes,^[6, 7] government of India in collaboration with WHO and SIDA (Swedish International Development Agency) adopted newly devised DOTS strategy^[8] and launched RNTCP during 1993 (pilot phase), which evolved through the DOTS strategy (1997-2006), the Stop TB Strategy (2006-2015)^[1, 2, 3, 9, 10], the National Strategic Plan (2017-2025)^[11] and currently, The End TB

Strategy^[12] with vision of TB Free World and Goal of TB Elimination (End the global TB epidemic) by 2035. Various parameters of tuberculosis are studied worldwide to assess the epidemiological profile of TB in relation to patients under treatment. These studies reveal different-different findings regarding the TB situation in different areas. Such study is not conducted after initiation of Revised National Tuberculosis Control Program (RNTCP) in study area so far. Since 2007, RNTCP is successfully achieving its objectives nationwide, (85% cure and 70% detection), but the actual situation of TB in study area – in the form of epidemiological parameters like types of disease (pulmonary and extra pulmonary), types of patients (sputum positive and negative), treatment category wise proportions of patients (new and retreatment), and sputum

conversion rate etc, in relation to patients under RNTCP – was not known. To explore such situation, this study was undertaken. In order to further enhance the achievements of RNTCP, the government of India has shifted its treatment approach from intermittent DOT (Directly Observed Treatment) to daily DOT during 2017^[13].

METHODOLOGY

It's an observational and combined retrospective-prospective cohort study. An urban field practice area of a private medical college in Pimpri; Pune, Maharashtra (India) catering to a population of 1, 10,000 (mostly slum) covered by one Designated Microscopy Center (DMC) with 30 DOT providers under a Tuberculosis Unit (TU) located in a municipal corporation hospital served as the study area. The study period was fixed from 1st July 2010 to 30th June 2013, the cut-off point between retrospective and prospective data collection being 1st July 2011. A chronological list of all TB patients taking treatment in study area, during study period was obtained from TU through regular visits and data collected from TU, DMC and DOT centers' records as secondary data for all 429 patients and through interviews with contacted patients for certain socio-demographic factors as prospective primary data, in structured and pretested formats, by trained PG students and medical interns through regular visits. This way, total 429 patients formed the study cohort. The collected information was compiled, presented in tabular and text form and statistically analyzed by using EPI INFO and 'WIN PEPI' software to examine the association between various factors studied and the epidemiological situation of TB under RNTCP in study area. A written informed consent was obtained from contacted patients before interview and the institutional ethical committee approval was obtained before study. Operational Definitions for New case, Sputum positive, Sputum Negative, Extra pulmonary TB, Retreatment case, Sputum conversion etc were collected and used in this study as they are available in standard sources. ^[1, 2, 3, 9]

RESULT

According to table 1, out of the total 429 patients, 266 (62%) were male and rest female, the male female ratio being 1.6. Also in all, about 239 (56%) belonged to age group 15-34 years. Both of these differences in age and sex distribution are statistically just significant as $P=0.045$. Pediatric group (up to age 14) included only about 8% patients. Table 2 reveals that, there were 268 (62%) pulmonary and remaining 161 (38%) extra pulmonary patients and amongst all, 335 (78%) were new cases (Cat-I)

and 94 (22%) retreatment (Cat-II) cases. Thus the proportions amongst new and pulmonary groups are significantly higher as $P=0.001$. Table 3 shows that, of all 268 pulmonary TB, 163 were sputum positive and 105 negative, and 193 were new (Cat-I) and 75 retreatment (Cat-II) patients. These differences are highly significant as $P=0.005$. Table 4 depicts that, combined in two categories (335 new and 94 retreatment), the proportions of sputum positive; negative and extra pulmonary were 163 (38%), 105 (24.5%) and 161 (37.5%) respectively and out of these, proportions of new patients were 128, 65 and 142 respectively. Thus the proportions of all three groups in new category are significantly higher as $P=0.001$.

Table-1: Distribution of all study subjects (TB patients) by age group and gender

Age group (years)	Gender		Total
	Male (%)	Female (%)	
Up to 14	19 (57.58)	14 (42.42)	33 (07.69)
15-34	136 (56.90)	103 (43.10)	239 (55.71)
35-54	78 (71.56)	31 (28.44)	109 (25.41)
55 and above	33 (68.75)	15 (31.25)	48 (11.19)
Total	266 (62.00)	163 (38.00)	429 (100)

Chi square (X^2) = 8.065, DF 3 and $P=0.045$.

Table-2: Distribution of all TB patients by treatment category and disease class/ type

Treatment category	TB Disease class/ Type		Total
	Pulmonary	Extra pulmonary	
New	193 (57.61)	142 (42.39)	335 (78.09)
Retreatment	75 (79.79)	19 (20.21)	94 (21.91)
Total	268 (62.47)	161 (37.53)	429 (100)

$X^2 = 14.465$ at DF 1 and $P=0.001$

Figure in parenthesis indicate percentage.

Table-3: Distribution of all Pulmonary TB patients by treatment category and patient type

Treatment Category	Pulmonary TB Types		Total
	Sputum positive	Sputum negative	
New	128 (66.32)	65 (33.68)	193
Retreatment	35 (46.67)	40 (53.33)	75
Total	163 (60.82)	105 (39.18)	268

$X^2 = 7.591$; $P=0.005$, Odds Ratio 2.25, CI 95% 1.31 - 3.87

Figure in parenthesis indicate percentage.

Table-4: Distribution of all patients by type of patient and treatment category

Type of patient	Category-I (New cases)	Category-II (Retreatment)	Total
Sputum positive	128 (78.53)	35 (21.47)	163
Sputum negative	65 (61.90)	40 (38.10)	105
Extra pulmonary	142 (88.20)	19 (11.80)	161
Total	335 (78.09)	94 (21.91)	429

$X^2 = 25.709$, DF 2 and $P=0.001$.

Figure in parenthesis indicate percentage.

Table-5: Distribution of all TB patients by age group, disease class and gender

Age group (years)	Disease class/ Type					
	Pulmonary TB (gender)			Extra pulmonary TB (gender)		
	Male (%)	Female (%)	Total (%)	Male (%)	Female (%)	Total (%)
Up to 14	12 (52.17)	11 (47.83)	23 (08.58)	07 (70.00)	03 (30.00)	10 (6.21)
15-34	89 (62.24)	54 (37.76)	143 (53.36)	47 (48.96)	49 (50.04)	96 (59.63)
35-54	55 (79.71)	14 (20.29)	69 (25.75)	23 (57.50)	17 (42.50)	40 (24.84)
55 and above	22 (66.67)	11 (33.33)	33 (12.31)	11 (73.33)	04 (26.67)	15 (9.32)
Total	178 (66.42)	90 (33.58)	268 (100)	88 (54.66)	73 (45.34)	161 (100)
Test results	$\chi^2 = 8.679$, DF 3 and $P=0.034$			$\chi^2 = 4.449$, DF 3 and $P=0.217$		

Table-6: Distribution of sputum positive patients by treatment category and Sputum conversion status

Treatment category	Sputum conversion status		Total (%)
	Turned negative at the end of intensive (2-4 months) phase (%)	Not turned negative at the end of intensive (2-4 months) phase (%)	
New sputum positive	114 (89.06)	14 (10.94)	128 (78.53)
Retreatment sputum positive	18 (51.43)	17 (48.57)	35 (21.47)
Total	132 (80.98)	31 (19.02)	163 (100)

$\chi^2 = 22.890$, DF 1 and $P=0.001$, Odds Ratio= 7.69, CI 95% 3.24 – 18.2

In both the groups (268 pulmonary and 161 extra pulmonary), maximum cases belonged to 15-34 year age group, 143 (53%) in pulmonary and 96 (60%) in extra pulmonary (Table 5). In both pulmonary and extra pulmonary groups, proportion of male is quite high, 178 (66%) and 88 (55%) respectively. The proportion of male aged 15-34 years in pulmonary group is significantly higher as $P=0.034$. Table 6 reveals that, sputum conversion rates at the end of intensive phase were 89% and 51% in new and retreatment cases respectively, the difference being highly significant ($P=0.001$).

DISCUSSION

Age and gender: According to table 1, the observed differences in age and sex distribution are statistically significant as the 'P' is 0.045. In a study by Mohammad Tahir et al, [14] the proportion of male patients was 151 (56.8%) and remaining 115 (43.2%) female and these were comparable with present study. In Ernakulum study [15] on 285 patients, 68% were male and rest females and this proportion in males is a little higher than that of present study. The male female ratio of 1.6 in present study is quite comparable with that of TB India 2017 Annual Status Report (ASR) [16] where it was 1.7 during 2016. These differences in age and sex distribution of patients could be because of regional and cultural differences amongst people and communities. The higher proportion amongst male and younger age group could be due higher chances of their exposure to TB patients. Only 48 (11.19%) patients in this study, were above 55 years of age whereas Raviglione et al, [17] in their study in Europe revealed that, there were 70% patients above the age of 65, which could be because of higher proportion of elderly population in developed countries with co-morbidities like diabetes

mellitus, cardio-vascular disease, malignancy etc as risk factors for TB, associated with old age.

Treatment categories and disease class: Table 2 depicts that these differences between pulmonary and extra pulmonary groups and new and retreatment categories were found to be statistically highly significant as $P=0.001$. TB India 2017 ASR [16] shows that extra pulmonary TB has increased from 17 to 21% over last ten years which is quite lesser than that of present study (38%).

Treatment Categories and pulmonary TB: Table 3 reveals that, the differences between sputum positive and sputum negative groups as well as new and retreatment category are very highly significant as $P=0.001$ and Odds Ratio 2.25, CI 95% 1.31 - 3.87. The proportion of sputum positive patients in present study is about 61% and TB India 2017 ASR [16] reveals proportion of such cases to be 55% during 2016, both are comparable.

Types of patient and treatment categories: There were 78% patients in new category and 22% in retreatment category (table 4). The difference in two categories, in relation to different three types of patients' groups (sputum positive, negative and extra pulmonary) is statistically very highly significant as 'P'= 0.001. TB India 2017 ASR [16] shows that, amongst all patients, 20% were previously treated (Cat-II) during 2016, that is quite comparable with that of present study which is 22%.

Age groups, disease class and gender: According to table 5, the differences in gender and age group distribution of 268 pulmonary patients are statistically significant as $P=0.034$. However, these differences in extra pulmonary group (161 patients) are statistically not significant as $P=0.217$. In a study by Saleem M et al [18] on 167 pulmonary TB patients, the proportion of patients belonging to age

group 15-34, was about 68% and that of male was about 72%, both of which are higher than present study. Amongst all patients in present study, 7.69% belonged to pediatric group (8.58% in pulmonary and 6.21% in extra pulmonary group). TB India 2017 ASR shows that, amongst all patients, 6% were pediatric cases during 2016, which is comparable with present study. These differences could be because of cultural and regional behavioral patterns amongst people and communities.

Sputum conversion rates: Sputum conversion rates are calculated at the end of intensive phase of treatment for patients who were initially sputum positive. As observed from table 6, the difference in two sputum conversion rates of new and retreatment patients is statistically very highly significant as $P=0.001$. In a China study, ^[19] sputum conversion rate was found to be 84% in new cases and in Delhi study, ^[20] these rates were 92.6% and 76.9% in new and retreatment cases respectively, of which rate in new cases is comparable with present study but that in retreatment category, it is quite higher than present study. These differences could be due to patients' treatment adherence behavior and program management

CONCLUSIONS

The proportion of tuberculosis is found to be significantly higher in males, adults (15-34 year age group), pulmonary type and new category. Also the sputum conversion rate is significantly higher in new category as compared to retreatment.

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