

## Original Research Article

# Association of socio-demographic profile with types of tuberculosis among patients attending a rural DOTS centre in central Kerala, South India

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## ABSTRACT

**Background:** Re-evaluation of the epidemiological profile of tuberculosis (TB) patients can help to eliminate the number of cases. This study was aimed to analyse the association of socio-demographic profile with type of TB among patients attending a rural DOTS centre in central Kerala.

**Methods:** A cross sectional study was conducted among TB patients at a rural DOTS clinic in central Kerala during January 2020-June 2021. Various socio-demographic parameters such as age, gender and socio-economic status and comorbidities of patients with pulmonary and extrapulmonary TB were retrieved from the DOTS register. The data was analyzed.

**Results:** A total of 241 patients (134 males and 107 females) were enrolled. In general, age group 41-60 years showed maximum incidence ( $p=0.0283$ ). Lower middle (32.7%) and middle class (36.5%) strata constituted the majority of burden ( $p=0.9091$ ). The distribution of cases was not associated to occupation ( $p=0.06$ ). Extrapulmonary form (55%) was found to be predominant with very poor awareness ( $p=0.06$ ). A significant delay of at least 1-3 months in recognizing the symptoms and thus the clinical diagnosis particularly in extrapulmonary cases was found. Diabetes mellitus was the most frequent comorbidity in TB patients.

**Conclusions:** The prevalence was most common in age group 41-60 years without any association to occupation. Since the diabetes mellitus is the most frequent comorbidity in TB patients, early screening will make an effective management. Society oriented awareness programme about the extrapulmonary TB is inevitable.

**Keywords:** Directly observed treatment short course, Diabetes mellitus, Tuberculosis, Epidemiology

## INTRODUCTION

Tuberculosis (TB) which is caused by Mycobacterium tuberculosis is one of the top-ten causes of death worldwide and the leading cause of death from a single source of infection.<sup>1,2</sup> It can affect anyone anywhere. Thirty high TB burden countries account for almost 90% of those who fall sick with TB each year. Globally, an estimated 10 million (8.9–11.0 million) people fell ill with TB in 2019, a number that has been declining very

slowly in recent years.<sup>3</sup> Most people who develop the disease are adults. There are more cases among men than women. Men (aged  $\geq 15$  years) accounted for 56% of the people who developed TB in 2019; women accounted for 32% and children (aged  $< 15$  years) for 12%. Among all those affected, 8.2% were people living with HIV.<sup>3</sup> World Health Organization's End TB Strategy (2016-35) aims to end the global tuberculosis epidemic by 2035.<sup>4</sup> The strategy includes targets to reduce absolute mortality by 95% and incidence by 90% and also to make sure that

the TB affected families did no longer have to bear catastrophic tuberculosis-related costs by 2030.<sup>4,5</sup>

Globally, TB incidence is falling at about 2% per year. The cumulative reduction was 9% between 2015 and 2019. This was less than halfway to the end TB strategy milestone of 20% reduction between 2015 and 2020.<sup>3</sup> In India, notifications of people newly diagnosed with TB between 2013 and 2019 was rose from 1.2 million to 2.2 million (+74%).

With an increase in life expectancy and the resultant elderly population, there has been an increase in the number of TB cases in geriatric age group as well. Evidence from state wide TB prevalence surveys, study of anti-tuberculosis drug sales in the private sector and new analysis of mortality data show that TB epidemic is more significant than previously estimated.<sup>6</sup> Many measures of general hygiene, public awareness and drug distribution such as Directly Observed Treatment Short-Course (DOTS) under the Revised National

Tuberculosis Control Program have been implemented by the government, as a measure to curb the increasing incidences of TB in our country. Kerala, a state of Southern India, with the highest literacy rate, (93.91%, according to the 2018 census) is well known for their public health strategy which has contributed to the state being ranked first, for two times in a row in terms of overall health performance according to health index launched by NITI Ayaog in 2019.<sup>7</sup>

The state of Kerala has successfully engaged with the private healthcare sector for the last 17 years to improve reporting of cases and treatment of patients. The computerized Nikshay portal for online notification of TB patients has improved our understanding of TB prevalence.

An understanding of the changing demographic profile, types and clinical presentation of the disease is crucial for the early screening, diagnosis and management.

Furthermore, a population-based study about the presentation and types of TB will allow the resources to focus for an affordable and effective treatment. This study was aimed to analyse the association of socio-demographic profile with type of TB among patients attending a rural DOTS centre in central Kerala.

## METHODS

### *Study design and sampling*

A cross sectional study was conducted among TB patients who were diagnosed /undergoing treatment during January 2020-June 2021 at DOTS clinic, Amala Institute of Medical Sciences, Amala Nagar, Thrissur. Patients (all age groups) with newly diagnosed TB and

patients who were undergoing treatment with all details available in the DOTS register were included.

Patients who were not willing to participate or incomplete data available were excluded in the study. The study was approved by the District TB Officer, Thrissur, Kerala and obtained approval from the Institutional Research and ethical committee.

### *Sample size calculation*

The sample size was calculated based on the previous study by Sharma et al.<sup>8</sup> in which a highest disease burden was found in the 20-60 years age group (72.2%). Therefore, using the prevalence, p=72%, q=28% and d, relative precision as 10% of p. The minimum sample size at 5% significance level ( $Z\alpha=1.96$ ) was calculated as 150 using the equation,

$$N = \frac{Z^2 \alpha p q}{d^2}$$

### *Study procedure*

Patients were enrolled based on the sputum positive tests in pulmonary cases while in sputum negative patients CBNAAT positivity was the major criteria for initiating therapy. In extrapulmonary TB cases, positive evidence was obtained from mycobacterial stain and culture, histopathology and nucleic acid amplification test. Various epidemiological parameters such as age, gender, socioeconomic status of patients with pulmonary and extrapulmonary TB were retrieved. The various economic categories were analyzed based on the ration card norms of Kerala Government.

As per the income eligibility criteria, yellow ration card owners with an annual income of less than Rs 15,000 are categorized as lower class. Pink ration card holders with an annual income of between Rs 15,000-25,000 are categorized as lower middle class. Blue ration card holders with annual income exceeding Rs 25,000 are categorized as upper middle class. White ration card holders with an annual income above Rs1,00,000 are categorized as upper class.

Data collected was entered into excel sheets and analysis was done.

### *Statistical analysis*

Data was analysed using SPSS software version 23. Data was presented as percentage and Chi-square test was done to find the significant difference.  $P<0.05$  was considered significant.

## RESULTS

A total of 241 TB patients were enrolled in the study. Among the total patients, 134 were males and 107 were

females (Figure 1). The common comorbidity was found to be diabetes mellitus (Figure 2).

Total number of patients and distribution of type of TB were depicted in table 1. Out of the total 241 tuberculosis patients enrolled, 134 were extrapulmonary and 107 were with pulmonary TB. Pulmonary TB was predominant in males while extrapulmonary TB was found in females. The difference in number of patients was found to be statistically significant ( $p=0.000016$ ).

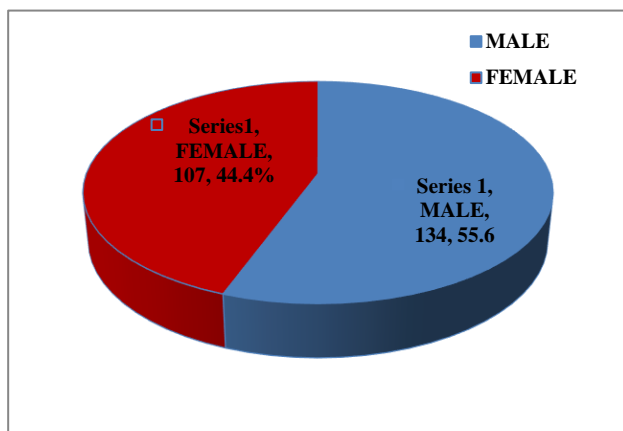
The overall ratio between males and females was found to be 1.25:1. The overall age group showed the maximum incidence of TB was 41-60 years.

However, the pulmonary TB was highest among the age group of 61-80 years and extrapulmonary TB was highest in 41-60 years age group (Table 2).

**Table 1: Distribution of sex according to type of TB.**

Sex	Extrapulmonary TB		Pulmonary TB	
	N	%	N	%
Male	58	43.3	76	71.0
Female	76	56.7	31	29.0
Total	134	100.0	107	100.0

$P=0.000016$  (Chi square test)



**Figure 1: Distribution of cases according to gender.**

**Table 2: Distribution of age according to type of TB.**

Age (yrs)	Extrapulmonary TB		Pulmonary TB	
	N	%	N	%
≤20	8	6.0	3	2.8
21-40	34	25.4	15	14.0
41-60	52	38.8	37	34.6
61-80	37	27.6	48	44.9
>80	3	2.2	4	3.7
Total	134	100.0	107	100.0

$P=0.0283$  (Chi-square = 10.84)

**Table 3: Distribution of occupation according to type of TB.**

Occupation	Extrapulmonary TB		Pulmonary TB	
	N	%	N	%
Housewife	41	30.50	18	16.80
Service	24	18	20	18.70
Skilled labourer	24	18	25	23.50
Unskilled labourer	22	16.40	18	16.80
Student	7	5.20	1	0.90
Unemployed	7	5.20	3	2.80
Business	4	3.00	18	16.80
Retired	3	2.20	1	0.90
Teacher	2	1.50	3	2.80
Total	134	100%	107	100%

$P=0.1361$  (Chi-square= 6.9)

Based on the occupation, homemaker/housewives constituted 25.3 % of the total TB cases enrolled (Table 3).

**Table 4: Extra-pulmonary TB site.**

Extrapulmonary TB site	No. of cases	%
Lymph node	55	22.8
Pleural effusion	33	13.7
Spine	11	4.6
Bone	6	2.5
Omentum	5	2.1
Abdomen	3	1.2
Meninges	3	1.2
Pericardium	3	1.2
Brain	2	0.8
Peritoneum	2	0.8
Pleural fluid	2	0.8
Breast	1	0.4
Genitourinary	1	0.4
Meningitis	1	0.4
Neck abscess	1	0.4
Ocular TB	1	0.4
Pre and para-aortic lymph nodes	1	0.4
Pre sacral abscess	1	0.4
Psoas abscess	1	0.4
Submandibular gland	1	0.4
Total	134	100

**Table 5: Distribution of socio-economic status according to type of TB.**

Socioeconomic status	Extrapulmonary TB		Pulmonary TB	
	N	%	N	%
Lower class	1	0.7	0	0
Lower middle class	43	32.1	36	33.70
Middle class	48	36.00	40	37.40
Upper middle class	42	31.20	31	28.90
<b>Total</b>	<b>134</b>	<b>100</b>	<b>107</b>	<b>100</b>

P=0.9091 (Chi-square = 0.1906)

There was no statistical significance in the incidence between patients in various occupation was found. The pulmonary TB was found among the skilled labor workers.

Lymph node TB was the major extrapulmonary form of tuberculosis constituting 22.8% of the total extrapulmonary cases (Table 4).

In a state like Kerala with high literacy and health index, lower middle and middle class strata constituted majority of tubercular burden (Table 5).

The distribution of TB cases in Kerala was not related to the level of education and proportion of cases among various occupations was similar.

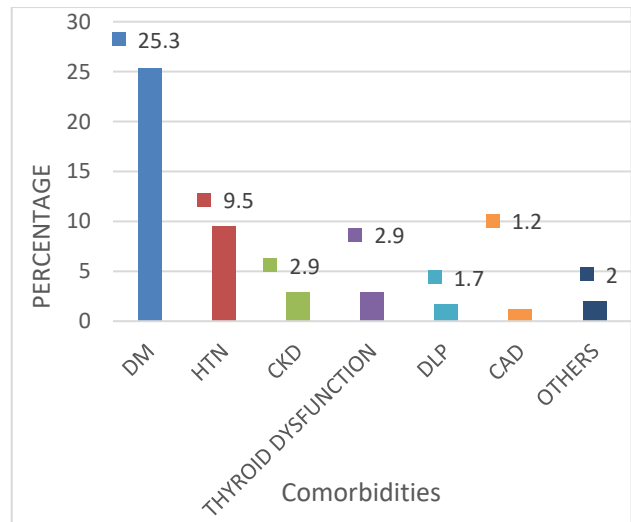
**Table 6: Distribution of cases according to knowledge about TB.**

Knowledge about TB	Extrapulmonary TB		Pulmonary TB	
	N	%	N	%
Yes	22	16.4	28	26.2
No	112	83.6	79	73.8
<b>Total</b>	<b>134</b>	<b>100.0</b>	<b>107</b>	<b>100.0</b>

P=0.06 (Chi-square = 3.440)

**Table 7: Period between appearance of symptoms and clinical diagnosis.**

Period between appearance of symptoms and clinical diagnosis	Extrapulmonary TB		Pulmonary TB	
	N	%	N	%
< 1 week	3	2.2	1	0.9
< 1 month	38	28.4	30	28.0
1-3 month	52	38.8	47	43.9
3-6 month	19	14.2	14	13.1
>6 months	17	12.7	11	10.3
Incidental	5	3.7	4	3.7
<b>Total</b>	<b>134</b>	<b>100.0</b>	<b>107</b>	<b>100.0</b>



**Figure 2: Distribution of cases according to comorbidities.**

Out of the total 134 cases of extrapulmonary cases, 112 (83.6 %) of cases didn't have any knowledge of tuberculosis and this shows that awareness about extrapulmonary forms of TB is very poor (p=0.06) and ignorance about it is lacking in community (Table 6). A significant delay of at least 1-3 months in recognition of symptoms and clinical diagnosis was found in both forms of TB (Table 7).

**DISCUSSION**

In this study, the prevalence of pulmonary TB was higher among male population i.e. 134 males out of 241 subjects while extrapulmonary TB was highest among females. Even after decades of availability of treatment, eliminating TB is remaining challenge. Continuous research and evidence-based decision making can be essential to eliminate this prevalent disease. Therefore, the present study was done to aid in the identification of its determinants for early diagnosis and management of patients with TB. These findings were comparable to a retrospective study done by Rao who found that out of 446 patients, 308 (69%) were males and 138 (31%) females.<sup>9</sup>

In this study, the prevalent age group was 41-60 years. These findings were comparable to the study done by Sharma et al who found that the highest disease burden of tuberculosis was in the 20–60 years age group and in males.<sup>8</sup> They found a significant association was between the age group and relapse and loss to follow-up cases. However, the extrapulmonary type was found in 61-80 years of age. This may probably due to declined immune status in the advanced age.

The most common occupational group associated with TB in this study was homemaker. These findings were in concordance with the study conducted by Singh et al who found a prevalence of TB among family members who

were regularly (daily) exposed to smoke from coking fuel and cigarette (passive smokers) inside the house.<sup>10</sup> There are multiple risk factors that are strongly associated with TB: smoke inside house, type of cooking fuel, separate kitchen, floor, roofing and wall material. Results strongly suggest that a contaminated household environment increases the risk of TB in India.

Delay in the diagnosis of extrapulmonary TB in this study suggests that the knowledge about extrapulmonary form is lacking even in Kerala which has higher literacy rate and health index. This is probably because most of public TB awareness programme focus on pulmonary forms of TB. The distribution of TB cases in Kerala was not found significant association with occupations. In a state like Kerala, lower middle and middle-class strata constituted most of the TB burden. This disparity was observed in national level as higher incidence of TB found in poor or lower socioeconomic status.

This may probably due to effective implementation of TB elimination programme focusing on all strata of population and increased health awareness among the public. Being a private hospital attached DOTS centre, very less number poor patients were observed in this study.

Diabetes mellitus is the most frequent comorbidity in TB patients. In a cross-sectional study conducted by Agarwal et al diabetes mellitus was the most common comorbidity which was noted in 15.4% of the study population which was in concurrent with this study where 25.3% patients had diabetes mellitus.<sup>11</sup> Diabetes Mellitus approximately triples the risk of active tuberculosis although the biological mechanism is still unclear.<sup>12</sup> It has been suggested that diabetes mellitus depresses the immune system by affecting the macrophage and lymphocyte functions which can facilitate the progression to symptomatic disease.<sup>13</sup> The opposite might be true that TB induces glucose intolerance which prevents good glycemic control in diabetes subjects. Screening people with diabetes early and to identify any association with TB will make us wiser in TB elimination strategy. Therefore, this highlights the need for stronger collaborative effort with diabetes screening programme and NTEP.

Even though the RNTCP with incorporation of DOTS strategy started in 1997, the burden of TB continues to deserve priority attention. India is one of the top 20 high tuberculosis burden countries with increasing risk for multidrug resistance, co-infection with HIV and diabetes mellitus.<sup>14</sup> Most of TB public awareness programme focus on pulmonary forms of TB. In this study, the extrapulmonary form of TB is more prevalent and also knowledge about extrapulmonary forms is very poor. This necessitates the need for a society-oriented awareness programme.

Small sample size (from a single DOT centre) collected during the 1.6 years and non-availability of risk factors associated with the types of TB were the major limitation of this study.

## CONCLUSION

TB was found prevalent in age group of 41-60 years. No association of socioeconomic status with incidence of TB was found. Diabetes mellitus was the most frequent comorbidity among TB patients. A better social awareness about extrapulmonary forms of TB will decrease the delay in diagnosis. Furthermore, early screening for TB among people with diabetes mellitus will make an effective management of TB.

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