

# Epidemiological profile of tuberculosis patients in Delhi, India: A retrospective data analysis from the directly observed treatment short-course (DOTS) center

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### ABSTRACT

**Background:** Tuberculosis (TB) has been a public health menace for decades. India harbors its highest burden globally. The present study was conducted to study the epidemiological profile of patients taking treatment from a directly observed treatment short-course (DOTS) center in Delhi, India. **Method:** Retrospective analysis of past 1-year treatment records of a total of 227 patients undergoing treatment in DOTS since June 2014–2015 was undertaken. Socio-demographic information, data related to disease status, and HIV testing were collected and analyzed. **Results:** The majority of cases were new (77.1%) and pulmonary TB (69.2%). The highest disease burden was found in the 20–60 year age group (72.2%) and males (58.6%). Genitourinary TB was present only among females. None of the patients was HIV positive. A significant association was found between the age group of 20–60 years and relapse and loss to follow-up cases (*P* < 0.05). **Conclusions:** A higher proportion of adult males aged 20–60 years constituted the majority of patients treated in the DOTS center. Focussed interventions can be designed for this age group in future public health policies to reduce disease burden in the total population. Further research is required to be undertaken in exploring reasons for higher prevalence among males and productive age group and role of age, gender in disease causation

Keywords: Directly observed treatment short-course, occupational profile, revised national tuberculosis control program, tuberculosis

# Introduction

Tuberculosis (TB) is a major public health problem worldwide. It was among the top 10 leading causes of death worldwide in 2017.<sup>[1]</sup> Due to the slow pace of progress in reducing the disease burden, TB continues to be a headache for public health experts around the world. While TB incidence has declined in most regions of the world, globally there was a gap of 36%

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Received: 19-05-2019 Revised: 20-05-2019 Accepted: 13-09-2019

Access this article online				
Quick Response Code:	Website: www.jfmpc.com			
	DOI: 10.4103/jfmpc.jfmpc_409_19			

between the estimated incident and notified cases in 2017, with India, Indonesia, and Nigeria, accounting for almost half of this gap.<sup>[1]</sup>

India has the highest burden of this disease worldwide.<sup>[2]</sup> The estimated TB incidence rate in the year 2017 for India is 204 per 1 lakh population with approximately 2.7 million people being newly diagnosed with TB.<sup>[1]</sup> Within TB, the phenomenon gaining precedence is multi-drug resistant (MDR) and in India, about 2.8% of new cases and 11.6% of previously treated cases are MDR.<sup>[3]</sup> India is the second-largest country with highest human immunodeficiency virus (HIV) associated TB incidence

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How to cite this article: Sharma P, Verma M, Bhilwar M, Shekhar H, Roy N, Verma A, *et al.* Epidemiological profile of tuberculosis patients in Delhi, India: A retrospective data analysis from the directly observed treatment short-course (DOTS) center. J Family Med Prim Care 2019;8:3388-92.

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contributing to 10% of the global burden of the same.<sup>[3]</sup> During 2000–2015, accumulating evidence infers that there were upward revisions in the estimates of the burden of TB disease. Evidence from household surveys, state-wide TB prevalence surveys, studies of anti-TB drug sales in the private sector, notification data, and new analysis of mortality data show that TB epidemic is more significant than previously estimated.

Although the total number of TB deaths in India continues to follow the declining global trend with 37% fall from 2000 to 2016, about 1.9 million TB cases were notified to national authorities and reported to the World Health Organization (WHO) in 2017.<sup>[1]</sup> As notification in India increased by 37%, it contributed to a global increase in several notified cases from 2013-2016. This reflects new and better data collected from surveillance and surveys.<sup>[4]</sup> Under the Revised National Tuberculosis Control Program (RNTCP), DOTS has proved to be an effective strategy. The decline in mortality and increased adherence to therapy in India can be attributed to the implication of DOTS majorly.

TB is a significant cause of loss of disability-adjusted life years (DALY) and out of the pocket expenditure.<sup>[5]</sup> With an estimated 35% of families facing catastrophic expenditure due to tuberculosis alone, the goal of achieving universal health coverage seems far from achievement. Despite the special budgetary allocation to the dedicated RNTCP, which has tripled in 2017–18 compared with previous years,<sup>[3]</sup> a significant proportion of cases were left to their fate when it is mandatory for each health facility and health care provider to notify each case of tuberculosis.

The estimates related to TB for India are still interim, pending a national TB prevalence survey which was scheduled for 2017-2018 in India,<sup>[6]</sup> but have been rescheduled for 2019-2020<sup>[1]</sup> and have a significant impact on global estimates. The interim projections were based on the extrapolation of data from Gujarat only.<sup>[6]</sup> The new data has undoubtedly raised concerns about the current perceptions regarding the disease and program. Based on descriptive epidemiology, the revelations suggested a broader interest in providing a thorough assessment of the patients who are diagnosed and treated for tuberculosis, taking into consideration the impact and the association with the other comorbidities prevalent in the modern world. There is paucity of literature on the epidemiological profile of TB patients in Delhi and factors associated with it. Some studies were done in the past but it is essential to reassess the same considering the temporal changes. Therefore, this study was conducted with the main aim of re-evaluating the epidemiological profile of the tuberculosis patients who were taking treatment from the DOTS center of a primary health center (PHC) in Delhi.

#### Methodology

## Study setting

Delhi, the capital of India, is home to approximately 1.68 crore people contributing to 1.39% of the total country's population.<sup>[7]</sup> Rapid growth and development offering ample job opportunities

to both skilled and unskilled workers have led to an increasing migrant population in the city.<sup>[8]</sup> Delhi has nine districts in total. The present study was conducted in the South Delhi district, which has a population of 27.3 lacs<sup>[7]</sup> with two government PHCs.<sup>[9]</sup> One of the PHC was selected as it was the field practice area of an affiliated institution of authors and the study was conducted in its DOTS center.

DOTS treatment card is maintained at each DOTS centre in which identifying and socio-demographic information, contact number, unique identity number of patient (NIKSHAY ID), disease information, smear results, weight of patient, treatment information, HIV testing results, advocacy, counseling and social mobilization whether done or not, information about DOTS centre and TB unit, DOTS provider, etc., is maintained. This is retained by the treatment supervisor of that DOTS center. Retrospective data analysis was done by reviewing data for all patients enrolled in the DOTS center for treatment in the past year, i.e. from June 2014 to 2015, irrespective of their diagnosis. All patients, in conjunction with pediatric patients, were included in the present study. Socio-demographic information, TB category whether it was the category I or II depending on previous treatment history, type of disease if it was new, relapse, retreatment after failure or loss to follow-up, sputum examination results, HIV status, etc., were recorded. Data related to the history of contact was incomplete, so was excluded from the final analysis.

#### Data analysis

Data collection was done by a single observer, minimizing information bias. Collected data were entered in the MS Excel spreadsheet, cleaned and coded appropriately. The analysis was carried out using Statistical package for social sciences (SPSS) for Windows version 17.0, Released 2008 (SPSS Inc., Chicago, IL). Chi-square/Fischer exact test was employed to find out the association between proportions and categorical variables. A P value of less than 0.05 was considered significant for bi-variate analysis.

#### Ethical issues

Necessary permissions were obtained from the concerned authorities before the initiation of data collection (Permission to conduct study was obtained from the Medical Officer in charge of the PHC. As it was a secondary data analysis, the ethical clearance was waived off by the department). The use of pseudonyms was used to protect the subject's identity. A log of all replacements, aggregations, or removals was made and stored separately from the anonymized data files to cross-check any discrepancies in the data.

#### Results

A total of 227 patients' data records were available, and all of them were analyzed. The age range of the patients was 4 to 76 years with a mean age of 32.65 years (SD, 15.7).

The highest proportion of patients were housewives (28.2%, 64). Others in occupation include gardener, carpenter, caterer, sweeper, mason, shopkeeper, painter, etc. Sputum examination results were not available for 28.6% (65) patients, out of which 59 were having extrapulmonary TB (EPTB), and 6 were having pulmonary TB (PTB). Out of 55 patients having sputum smear negative for *Mycobacterium tuberculosis*, 11 were EPTB patients and rest were PTB patients [Table 1].

The most common site for EPTB was lymph nodes (47.2%) [Table 2]. As part of DOTS therapy, HIV testing was done for all patients and none of them were found to be positive. Advocacy, counseling, and social mobilization were done for all of the patients.

A significantly higher percentage of category II patients were males as compared to females (P < 0.05). PTB, pleural effusion, lymph node TB, and military TB were more common among males as compared to females while abdominal and genito-urinary TB were common among females. These sex-related differences were found to be significant (P < 0.05) [Table 3].

A higher percentage of patients in the age group of 20–60 years were category II as compared with other age groups with a significant finding (P < 0.05). Also, a significantly higher percentage of 20–60 years age group was among loss to follow-up as compared with other age groups (P < 0.05) [Table 4].

The loss to follow up was significantly higher among unemployed patients compared with other occupations (P < 0.05). Lymph node TB was higher among students while abdominal and genito-urinary TB was higher among homemakers, and these differences were statistically significant (P < 0.05) [Table 5].

### Discussion

TB, even after decades of availability of treatment, remains a challenge for public health personnel worldwide. Continuous research and evidence-based decision making can be essential to tackle this prevalent disease. The suspicion of tuberculosis relies on clinical symptoms but some of the determinants can possibly help in raising suspicion among high-risk groups even in the absence of quintessential symptoms. Therefore, the present study was done to aid in the identification of its determinants for early identification and management of patients.

In the present study, we found out a higher proportion of male patients. The highest caseload was in the age group of 20–60 years. This is in consistence with the existing knowledge about host factors associated with TB. In a previous study by Bagchi *et al.* in Mumbai, similar results were found.<sup>[10]</sup> This association of age and gender has to be explored further to find out such a biased distribution of the disease. The possibility of lower notification rates of TB among women couldn't be brushed aside. Also, as Mumbai and Delhi both being metropolitan cities with large migrant population, the

Variable	Frequency	Percentage		
Age (in years)				
0-9	3	1.3		
10-19	46	20.3		
20-60	164	72.2		
>60	14	6.2		
Sex				
Male	133	58.6		
Female	94	41.4		
Occupation				
Housewife	64	28.2		
Unemployed	46	20.3		
Labourer	39	17.2		
Student	33	14.5		
Security guard	7	3.1		
Driver	7	3.1		
Others	31	13.6		
Category				
I	175	77.1		
II	52	22.9		
Classification				
Pulmonary	157	69.2		
Extra-pulmonary	70	30.8		
Sputum Results				
+1	33	14.5		
+2	41	18.1		
+3	33	14.5		
Negative	55	24.2		
Not available	65	28.6		

Table 2: Distribution of patients according to the site ofExtra Pulmonary TB (n=70)

Sites of extrapulmonary TB	Frequency	Percentage				
Lymph nodes	33	47.2				
Pleural effusion	17	24.3				
Abdomen	16	22.9				
Genitor-urinary system	2	2.8				
Meningitis	2	2.8				

repercussions of migration on development of TB need further exploration.

Although the percentage of treatment failure patients was low among category II patients, relapses and loss to follow-up patients posed a significant challenge. They are at higher risk of development of drug-resistant forms of the disease. Most of the category II patients were males and this association was found to be significant (P < 0.05). More males were categorized as lost to follow-up previously as compared to females. This could be attributed to the fact that most migrants are males. Therefore, the chances of male patients migrating to other places without treatment completion are more likely than females. Also, as the migrant population has to live in poorly ventilated and overcrowded areas, the chances of relapse also increase. The majority of the patients classified as lost to follow-up were in the productive

Table 3: Gen	der-wise distri	bution of TB	patients
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Variables	Ger	Р	
	Male	Female	
Category (n=227)			
Ι	96 (54.9)	79 (45.1)	0.038*
II	37 (71.2)	15 (28.8)	
Type of patients in category II ( $n=52$ )			
Relapse	17 (68.0)	8 (32.0)	0.424
Retreatment after failure	2 (50.0)	2 (50.0)	
Loss to follow-up	18 (78.3)	5 (21.7)	
Classification $(n=227)$			
Pulmonary	96 (61.1)	61 (38.9)	0.000*
Lymph nodes	17 (51.5)	16 (48.5)	
Pleural effusion	16 (94.1)	1 (5.9)	
Abdomen	3 (18.8)	13 (81.2)	
Genitor-urinary system	0 (0.0)	2 (100.0)	
Meningitis	1 (50.0)	1 (50.0)	
Available Sputum Results (n=162)			
+1	18 (54.5)	15 (45.5)	0.784
+2	27 (65.9)	14 (34.1)	
+3	20 (60.6)	13 (39.4)	
Negative	32 (58.2)	23 (41.2)	
*Significant association			

\*Significant associatio

	age-groups						
Variable	Age groups (in years)						
	0-9	10-19	20-60	>60			
Category (n=227)							
Ι	3 (1.7)	44 (25.1)	120 (68.6)	8 (4.6)	0.001*		
II	0 (0.0)	2 (3.8)	44 (84.6)	6 (11.6)			
Type of patients in category II ( $n=52$ )							
Relapse	0 (0.0)	1 (4.0)	19 (76.0)	5 (20.0)	0.009*		
Retreatment after	0 (0.0)	1 (25.0)	2 (50.0)	1 (25.0)			
failure							
Loss to follow-up	0 (0.0)	0 (0.0)	23 (100.0)	0 (0.0)			
Classification ( $n=227$ )							
Pulmonary	0 (0.0)	24 (15.3)	120 (76.4)	13 (8.3)	0.000*		
Lymph nodes	2 (6.1)	16 (48.5)	15 (45.4)	0 (0.0)			
Pleural effusion	0 (0.0)	3 (17.6)	13 (76.5)	1 (5.9)			
Abdomen	0 (0.0)	3 (18.8)	13 (81.2)	0 (0.0)			
Genitor-urinary system	0 (0.0)	0 (0.0)	2 (100.0)	0 (0.0)			
Meningitis	1 (50.0)	0 (0.0)	1 (50.0)	0 (0.0)			
Available Sputum							
Results (n=162)							
+1	0 (0.0)	3 (9.1)	27 (81.8)	3 (9.1)	0.700		
+2	0 (0.0)	8 (19.5)	29 (70.7)	4 (9.8)			
+3	0 (0.0)	6 (18.2)	24 (72.7)	3 (9.1)			
Negative	0 (0.0)	9 (16.4)	44 (80.0)	2 (3.6)			

\*Significant association

age group thus further supporting the above-mentioned reason. This finding was similar to the findings of a community-based survey in south India, indicating higher default rates among males than females.<sup>[11]</sup> A significantly higher percentage of category II patients and relapse cases was in the age range of 20–60 years as compared with other age groups (P < 0.05). PTB was present among the higher percentage of patients as compared to EPTB.

In India also, cases of PTB contribute to a more considerable extent to the burden of disease in comparison with EPTB. The bacillary load, as indicated by sputum smear results, was higher among males as compared to females and was higher in the age range of 20–60 years as compared with other age groups. This age-group is most likely to come in contact with other non-infected people, thereby augmenting the risk of the spread of infection. The finding is similar to another study which showed the rates of bacillary TB higher among males.<sup>[12]</sup> The annual risk of infection is already 1–2% in India. According to an estimate, one TB patient infects 15 healthy individuals throughout the disease. This highlights the need for strict airborne infection control measures in healthcare settings and other public places.

All the patients of genitor-urinary TB were females of reproductive age-group. Genito-urinary TB could lead to infertility, pelvic inflammatory disease, etc. It is amongst the major contributors to primary as well as secondary infertility among women population of developing countries, including India. The possible reasons for this sex-selective distribution of genito-urinary tuberculosis should be sought to employ preventive measures. This could be a cost-effective method with the dual benefit of decreasing disease burden as well as infertility.

There are some obvious limitations to the study. The present study was record-based therefore only a limited number of factors were analyzed. As the research was conducted in one of the DOTS centers of Delhi, results only give us an overview of the latest trends and should be generalized to other parts of the country with caution note.

There is certain public health implication of the study that is important for family physicians and medical officers posted at PHC. They are the actual providers of the care and hence their knowledge should be regularly refreshed from time to time. It is our responsibility to update them with the latest disease trends and management protocols. They should be better trained to have higher suspicion of tuberculosis and actively look for latent TB infection among the known high-risk groups. The active cases on treatment should be further followed up for better compliance with treatment and reducing defaulters.

#### **Conclusion and recommendations**

A higher proportion of male and adult age-group of 20– 60 years constituted the majority of the patients undergoing treatment from the DOTS center. Most of the relapse cases were also adult males aged 20–60 years. Active case detection among this group can prove to be a more lucrative exercise. Also, adult male migrants can be a fruitful subgroup of a population for such surveillance activities. Identification of latent TB infection among this age group can prevent complications, thereby reducing the cost and duration of treatment and increasing positive outcomes. Moreover, counseling services, in line with integrated counseling and

Variable	Occupation					Р
	Student	Labourer	Housewife	Unemployed	Others	
Category (n=227)						
Ι	32 (18.3)	33 (18.9)	51 (29.1)	29 (16.6)	30 (17.1)	0.001*
II	1 (1.9)	6 (11.5)	13 (25.0)	17 (32.7)	15 (28.9)	
Type of patients in category II ( $n=52$ )						
Relapse	0 (0.0)	1 (4.0)	8 (32.0)	9 (36.0)	7 (28.0)	0.046*
Retreatment after failure	1 (25.0)	2 (50.0)	1 (25.0)	0 (0.0)	0 (0.0)	
Loss to follow-up	0 (0.0)	3 (13.0)	4 (17.4)	8 (34.8)	8 (34.8)	
Extrapulmonary TB classification $(n=70)$						
Lymph nodes	14 (42.4)	2 (6.1)	6 (18.2)	3 (9.1)	8 (24.2)	0.001*
Pleural effusion	1 (5.9)	6 (35.3)	1 (5.9)	4 (23.5)	5 (29.4)	
Abdomen	4 (25.0)	1 (6.2)	9 (56.4)	1 (6.2)	1 (6.2)	
Genitor-urinary system	0 (0.0)	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	
Meningitis	1 (50.0)	0 (0.0)	1 (50.0)	0 (0.0)	0 (0.0)	

testing services for HIV, should be established for better compliance. Provisions for assured drug delivery in cases of migration should be undertaken. Universal DOTS treatment card, which can be used in any part of country with proper linkage among DOTS centers, should decrease loss to follow up. NIKSHAY id can be used for this.

#### Acknowledgements

We are thankful to the medical officer Incharge of the UPHC and DOTS center Dr. Samarth Sarkar for motivating us to do this study and providing us the necessary permissions. We are also thankful to Mr. Sushil Mishra (Medical Social Worker) for helping us in data collection.

#### Financial support and sponsorship

Nil.

#### **Conflict of interest**

There is no conflict of interest.

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