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Clinico- Epidemiological Profile of Tuberculosis Patients Diagnosed in a Tertiary Care Hospital of Northern India: A Cross-Sectional Study

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Abstract: TB is an infectious disease caused by the bacillus *Mycobacterium tuberculosis*. Worldwide, TB is one of the top 10 causes of death and the leading cause from a single infectious agent (above HIV/AIDS). Millions of people continue to fall sick with TB each year. To reduce the TB burden and ultimately elimination, country as well as regional epidemiology regarding TB should be known. We conducted the present study at Indra Gandhi Medical College (IGMC) and Hospital Shimla, India. This study was a cross-sectional record-based study. We collected information using a self-designed, structured questionnaire containing information regarding various sociodemographic, clinical and laboratory variables. Information was collected from Tuberculosis (TB) notification register kept at DOTS centre. Statistical analysis was done using statistical software Epi Info v7.2.2. A two-sided p-value of less than 0.05 was taken as statistically significant. Among all the age group of 18-59 years contained 75% of TB cases. 84% of study participants resided in rural area. Only 18% of study participants were previously treated and 52% were of extrapulmonary in origin.52% of the participants had microbiological confirmed TB in our study and among them microscopy (56%) was most common. EPTB was found to be more common in rural areas as compare to urban area. There were a greater number of previously treated patients in PTB (22.7%) as compare to EPTB (13.5%) and this difference was found statistically significant (p value 0.016). Majority of PTB patients (89.6%) were microbiologically confirmed as compare to 17.3% of EPTB patients (p value 0.001). There was higher number of Extra Pulmonary TB cases than Pulmonary TB in Himachal Pradesh, which were more in rural areas. There should be more emphasis on EPTB under RNTCP especially in rural areas. Necessary steps should be taken to reduce the number of previously treated Pulmonary TB cases.

Keywords: Epidemiology, Pulmonary Tuberculosis, Extra pulmonary Tuberculosis, Himachal Pradesh, DOTS Centre.

INTRODUCTION

TB is an infectious disease caused by the bacillus *Mycobacterium tuberculosis*. It typically affects the lungs (pulmonary TB), but can also affect other sites (extrapulmonary TB). Tuberculosis (TB) is an old disease – studies of human skeletons show that it has affected humans for thousands of years [1]. Worldwide, TB is one of the top 10 causes of death and the leading cause from a single infectious agent (above HIV/AIDS) [2]. Millions of people continue to fall sick with TB each year. Globally In 2017, TB caused an estimated 1.3 million deaths (range, 1.2–1.4 million) among HIV-negative people and there were an additional 300,000 deaths from TB (range, 266 000–335 000) among HIV-positive people. Globally, there were an estimated 10.0 million new (Incident) TB cases (range, 9.0–11.1 million) in 2017[2].

As per the TB India report 2017 the estimated incidence of TB in India was approximately 28, 00, 000 (211/100,000) accounting for about a quarter of the world's TB cases[3]. Number of deaths in HIV negative people due to tuberculosis in the same year was 423,000 making death rates of 32 per 100,000. The two types of clinical manifestations of Tuberculosis (TB) are pulmonary TB (PTB) and extrapulmonary TB (EPTB), of which PTB is more common. EPTB refers to the TB involving organs other than the lungs (e.g., pleura, lymph nodes, abdomen, genitourinary tract, skin, joints and bones, or meninges)[4]. According to the recent report in 2017, TB notification rate was 138.33 patients per lac in India from both private and public health settings. Approximately 18 % of the patients were suffered from extrapulmonary

Tuberculosis. Approximately 61 % of the TB patients were microbiologically confirmed and the proportion of children among new TB patients was 6% [3].

Himachal Pradesh is a small state of Northern India situated in Western Himalayas with a total population of 6.9 million [5]. According to latest TB India report the incidence of TB in Himachal Pradesh is found to be 226 per 100,000 in 2017[4]. In the list of top 30 high burden district for tuberculosis in India there are seven districts from Himachal Pradesh only [6]. In 2014 the World Health Assembly adopted the World Health Organization (WHO)'s "Global strategy and targets for tuberculosis prevention, care and control after 2015″. This twenty-year strategy aims to end the global TB epidemic and is unsurprisingly called the End TB Strategy. Ending TB is defined as an incidence rate of less than 10 people per 100,000 populations per year. India is also a signatory to this strategy. The main targets in the End TB Strategy are to reduce TB deaths by 95%, to cut new cases of TB by 90% between 2015 and 2035 and to ensure that no family is burdened with catastrophic expenses due to TB [7]. In the year 2017 Government of India has launched the National Strategic Plan (NSP) 2017-2025 which builds on the success and learning's of the last NSP and encapsulates the bold and innovative steps required to eliminate TB in India by the year 2025. It is crafted in line with other health sector strategies and global efforts, such as the draft National Health Policy 2015, World Health Organization's (WHO) End TB Strategy and the Sustainable Development Goals (SDGs) of the United Nations (UN)[3]. To reduce the TB burden and ultimately elimination, country as well as regional epidemiology regarding TB should be known. With this background we conducted the present study at Indra Gandhi Medical College (IGMC) and Hospital Shimla, India.

MATERIALS AND METHODS

Aim and objectives

The aim of the study was to describe the Clinico- Epidemiological profile of pulmonary and extra pulmonary tuberculosis patients in DOTS centre of Indira Gandhi Medical College (IGMC) Shimla, Himachal Pradesh.

Study design

This study was a cross-sectional record-based study.

Study area and Population

The study included all the patients who were diagnosed with Tuberculosis during the study period at Directly Observed Treatment Short-course (DOTS) centre of a tertiary care hospital (IGMC Shimla) of Himachal Pradesh, India.

Study duration

Data for this study was collected for three months from1st July 2017 through 30th sept 2017.

Study tool and strategy

We collected information using a self-designed, structured questionnaire containing information regarding various sociodemographic, clinical and laboratory variables. Information was collected from Tuberculosis (TB) notification register kept at DOTS centre.

STATISTICAL ANALYSIS

The data was collected and entered in Microsoft Excel Spreadsheet. Statistical analysis was done using statistical software Epi Info v7.2.2. All the qualitative variables were expressed in the form of frequencies and percentages whereas the quantitative variables were expressed as means and standard deviation. We used chi square test for significance testing of proportions. A two-sided p-value of less than 0.05 was taken as statistically significant.

RESULTS

We enrolled a total number of 465 cases of TB. In which 52%participants were male (n=244). Among all the age group of 18-59 years contained 75% of TB cases. The geriatric age group contributed to only 16% of study participants.84% of study participants resided in rural area. Only 18% of study participants were previously treated and 52% were of extrapulmonary in origin.52% of the participants had microbiological confirmed TB in our study and among them microscopy (56%) was most common. (Table 1)

In our study we found that there was no statistically significant difference in age and gender distribution among the cases of pulmonary tuberculosis (PTB) and extrapulmonary (EPTB). EPTB was found to be more common in rural areas as compare to urban area. There were a greater number of previously treated patients in PTB (22.7%) as compare to EPTB (13.5%) and this difference was found statistically significant (p value 0.016). Majority of PTB patients (89.6%) were microbiologically confirmed as compare to 17.3% of EPTB patients (p value 0.001) (Table 2).

DISCUSSION

Study results indicated that PTB and EPTB appear as disease affecting economically productive age (18-59 Years) group more commonly. No particular age group was found to be free from the disease. Mean age (SD) of participants was 37.3 years (18.4). A similar finding of involvement of younger age in EPTB has been observed in study done by Gaur *et al.* [8]. A study from South Delhi, India also shows the similar finding; 38% of the patients were in the age 15-24 years followed by 25% in age 25-34 years [9].

The incidence of EPTB was remarkably high (52%) in the present study. Similar findings were

present in the study done by Asyel *et al*. where they found incidence of EPTB was 49%[10]. The percentage of EPTB cases estimated by the national control program in India for HIV negative adults is between 15% and 20%, the percentage of patients with EPTB in tertiary care centres in India varies between 30% and 53%[8].

Table-1: Sociodemographic profile of tuberculosis cases (n=465)

Sr.No.	Variables	Frequency (n =465)	Percentage (%)	95% Confidence Interval
1	Age distribution(years)			
	<18	40	9	6.38 - 11.50
	18-59	348	75	70.70 - 78.57
	≥60	77	16	13.46 - 20.21
2	Gender			
	Male	244	52	47.93 - 56.9
	Female	221	48	13.26 - 19.98
3	Locality			
	Rural	389	84	80.02 - 86.74
	Urban	76	16	13.26 - 19.98
4	Type of patient			
	New	383	82	78.64 - 85.56
	Previously treated	82	18	14.44 - 21.36
5	Site			
	Pulmonary	222	48	43.24 - 52.28
	Extra-pulmonary	243	52	47.7 - 56.76
6	Case definition			
	MC	241	52	47.29 - 56.34
	CD	224	48	43.66 - 52.71
7	Microbiologically confirmed			
	Microscopy			
	CBNAAT	136	56	49.70 - 62.55
	Culture	95	39	33.06 - 45.72
	LPA	5	2	0.67 - 4.76
	Others	4	3	0.92 - 5.32
8	Result of microbiology			
	Scanty positive	18	15	9.14 - 22.67
	1+	27	23	15.38 - 31.02
	2+	25	21	13.96 - 29.20
	3+	50	41	32.74 - 51.02

Table-2: Comparison of Sociodemographic and Clinical variables among Pulmonary and Extra Pulmonary Tuberculosis Patients

Sr.no	Variables	PTB n = 222(%)	EPTB n =243(%)	P -value
1	Age distribution			0.516
	<18	20(9)	20(8.2)	
	18-59	161(72)	187(77)	
	≥60	41(18.5)	36(16.2)	
2	Gender			0.643
	Male	114(51.37)	130(53.4)	
	Female	108(48.6)	113(46.5)	
3	Locality			0.028
	Rural	177(79.72)	212(87.24)	
	Urban	45(20.2)	31(12.7)	
4	Type of patient			0.016
	New	173(77.9)	210(86.41)	
	Previously treated	49(22.7)	33(13.5)	
5	Case definition			0.001
	Microbiologically confirmed	199(89.6)	42(17.28)	
	Clinically diagnosed	23(10.36)	201(82.71)	

In our study it was observed that cases of PTB and EPTB were more in patients who were residing in rural area(84%).the prevalence of TB in India was first studied comprehensively in 150 villages ,six cities and

30 towns by Chakarborty *et al*. in 1950 and it was found that disease is more prevalent in rural population[11]. another study was done by Sharma et al in Faridabad district of Haryana where they observed that the 58.3% of cases were from urban area comparative to our study where only 16 % of population was from urban background this is because in Himachal Pradesh most of people are residing in rural area[12]. Our findings of microbiologically confirmed cases were comparable with TB report India where microbiologically confirmed cases were 55% [3].

New cases constitute the highest proportion of tuberculosis patients as a whole and both in rural and urban areas. Similar results were seen in study done at Lucknow by Sahoo *et al.* They found that 71% cases in rural TUs and 74.5% cases in urban TUs belong to new cases [13]. At large male patients were suffering from both PTB and EPTB forms more as compared to females although this difference was not found to be statistically significant. in contrary in a study by Asyel *et al*. women were more predominantly involved in EPTB group (52%) and men in PTB group (59%).6 Numbers of the patients falling in the category of previously treated were found to be more in PTB than in the EPTB and this difference was found to be statistically significant. More of patients of PTB were diagnosed by microbiological confirmation than EPTB.

CONCLUSION & RECOMMENDATION

There was higher number of Extra Pulmonary TB cases than Pulmonary TB in Himachal Pradesh, which was more in rural areas. There should be more emphasis on EPTB under RNTCP especially in rural areas. IEC activity regarding EPTB should also be included in the programme. Necessary steps should be taken to reduce the number of previously treated Pulmonary TB cases.

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