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Research Article

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A study on clinical profile of indoor patients receiving anti-tuberculosis treatment at KPC Medical College and Hospital, Kolkata, India

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ABSTRACT

Background: India is the biggest contributor of TB cases globally. About 2.5 million prevalent cases and 0.22 million deaths from the disease were reported in India in 2015. The objective of this study was to assess the sociodemographic and clinical profile of the indoor patients receiving treatment from the DOTS centre of KPC Medical College and Hospital, Kolkata, India.

Methods: An observational, descriptive, record based study was conducted on TB patients admitted in indoor wards under various departments of KPC Medical College and Hospital. Data were analyzed using IBM SPSS (version 20). **Results:** Of 80 study subjects, 73.8% were male and 25% belonged to 20-30 years age group. Records reflected 41.3% subjects had pulmonary TB, 51.2% had extrapulmonary TB and the rest had both pulmonary and extrapulmonary TB. New cases comprised 91.3% subjects and previously treated cases were 8.7% subjects. HIV status was negative in 67.5% subjects and records were unavailable in 32.5% subjects. Diabetes was present in 27.5% subjects, negative in 67.5% and information was unavailable in 5% cases. Among the patients with known Diabetes status, the result of association between TB-Diabetes and gender of the subjects was found to be statistically significant.

Conclusions: Information regarding occupation, investigations other than sputum test, HIV and Diabetes status were not mentioned in some treatment cards; hence emphasis should be given on proper record maintenance. Awareness generation and proper counseling on TB-HIV co-infection among all the patients should be focused on so that all the patient's turn up for HIV testing.

Keywords: Tuberculosis, Anti-tuberculosis treatment, Clinical profile

INTRODUCTION

Tuberculosis (TB), caused by Mycobacterium tuberculosis, is one of the major public health problems globally.

Pulmonary tuberculosis (PTB) accounts for about 85% cases, while Extra-pulmonary tuberculosis (EPTB) can involve bones and joints, intestines, meninges, lymph nodes, genitourinary tract, skin and other parts of the

body. This disease is not only a chronic disease, but can also be fatal unless managed in time. India, even though is the second most populous country in the world, is the biggest burden of TB globally.

WHO Global TB Report 2015 shows annually there are 9.6 million incidence cases globally in 2015, of which India alone contributed 2.2 million incidence cases. About 2.5 million prevalent cases and 0.22 million deaths from the disease were reported in India in 2015. 1

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After the introduction of National Tuberculosis Control Programme (NTP), followed by Revised National Tuberculosis Control Programme (RNTCP) with Directly Observed Treatment Short-Course chemotherapy (DOTS) strategy in 1997, there has been a steady decline in prevalence and death from TB in India. As compared to 1990, by 2013 there was a reduction of 50% mortality and 55% prevalence.²

Annual Status Report 2016 shows, in 2015, total 58,408 patients were diagnosed with smear positive PTB, 87,468 patients were registered for treatment, 85% new smear positive cases were cured, 1,78,166 retreatment cases were registered and 68% of retreatment relapse smear positive cases were cured in the state of West Bengal.¹

Tuberculosis affects people across all age groups, but more commonly young adult males. Apart from socioeconomic factors, one of the most important contributing factors leading to causation of TB is suppressed immunity. Infections (e.g. HIV), chronic diseases (e.g. diabetes), immunosuppressive therapy (cancer chemotherapy, steroid therapy) etc. can lead to reduced immunity that puts a person at higher risk to develop the disease.

Tuberculosis is one of the most common opportunistic infections in HIV/AIDS. In 2013, total of 1,063,644 HIV patients were screened for TB and 44,027 HIV positive patients were reported to have TB in India. In 2015, total number of new cases of TB along with HIV was 30,988 (13% death) in India and 826 (15% death) in West Bengal, while total number of retreatment cases along with HIV was 13,269 (14% death) in India and 406 (13% death) in West Bengal. People with HIV-TB co-infection need prompt initiation of Anti-Tubercular treatment, since not only it can cure TB in the patient, but it can also add years to the lives of the PLHIVs. In the patient of 1,063,644 HIV patients and 1,064,644 HI

RNTCP has been recognized as the largest and fastest growing TB control programme in the world. Focusing on quality sputum examination for early diagnosis of TB cases followed by judicious use of Anti-Tubercular Drugs (ATDs), under DOTS, have not only increased the proportion of TB cases being detected and cured, but also decelerated the emergence of Multidrug Resistance TB (MDR-TB) and Extensive Drug Resistance TB (XDR-TB).

RNTCP and National AIDS Control Programme (NACP) have been working hand in hand for cross reference between Integrated Counseling and Testing centres (ICTC) and RNTCP diagnostic and treatment services to decrease the burden of HIV-TB co-infection.

Designated Microscopy Centres (DMC) and DOTS centres across the country have been functioning under expert supervision, along with continuous monitoring and evaluation, with a common goal to achieve a status of 'Tuberculosis free India'. In the year of 2015, at DMC of

KPCMCH, Kolkata a total 1007 TB suspects had undergone sputum examination for diagnosis, sputum positive TB was found in 72 patients, sputum negative TB in 21 patients and 79 patients were diagnosed to have extrapulmonary TB.

In last seven years (2009-2015), 5575 TB suspects had undergone sputum examination for diagnosis at DMC, KPCMCH. In this context, our study has embarked upon assessing the socio-demographic and clinical profile of the indoor admitted patients who were receiving ATD from the DOTS centre of KPC Medical College and Hospital (KPCMCH), Kolkata, India.

METHODS

An observational, descriptive, record based study was conducted on socio-demographic and clinical profile of TB patients admitted in indoor wards under various departments of KPC Medical College and Hospital. These patients were registered and were receiving antitubercular treatment from the DOTS centre of KPCMCH, under RNTCP. The RNTCP treatment cards of the patients admitted in different wards were used as study tool for secondary data analysis.

All the patients who had begun their treatment at DOTS centre, KPCMCH, between 1st May 2015 and 30th April 2016 (a period of one year), were considered as the study subjects. There were total of 80 study subjects who had begun treatment in the said duration. Parameters regarding socio-demographic profile include age, sex, district of stay and occupation.

Study variables about clinical profile include type of disease, investigations conducted, sputum examination result, type of patient, category of treatment etc. available information on comorbidities of TB, like HIV/AIDS, Diabetes were also noted. Case definitions, treatment outcome definitions and other protocols have been followed as per WHO guidelines, revised on 2013 (updated on December 2014). The data were analyzed using IBM SPSS (version 20).

RESULTS

The secondary data analysis of the treatment card of 80 patients receiving treatment from DOTS centre of KPCMCH showed that 59 (73.8%) study subjects were male and 21 (26.2%) subjects were female. Most of them (20 subjects, 25%) belonged to 20-30 years followed by 16 (20%) subjects in 50-60 years and only one subject (a child aged 2 years) belonged to 0-10 years age group.

In this study, 12 (15%) subjects were students, 11 (13.7%) subjects were retired, 16 (20%) subjects were housewives and 9 (11.2%) had business as their occupation. Information regarding occupation status of 5 (6.2%) was not mentioned in the treatment card (Table 1). Majority of the patients (46 subjects, 57.5%) were

from Kolkata, followed by 23 (28.8%) from 24 Parganas (South) and 5 (6.3%) from 24 Parganas (North), which are the nearby districts of Kolkata (Figure 1).

Table 1: Distribution of study subjects according to socio-demographic profile.

Socio-demographic profile	Frequency (n=80)	Percentage
Gender		
Male	59	73.8
Female	21	26.2
Age group (years)		
0-10	1	1.3
10-20	3	3.8
20-30	20	25.0
30-40	13	16.3
40-50	10	12.5
50-60	16	20.0
60-70	9	11.2
70-80	6	7.5
80-90	2	2.5
Occupation		
Service	5	6.2
Laborer	7	8.8
Driver	3	3.7
Farmer	2	2.5
Housewife	16	20.0
Business	9	11.2
Rickshaw puller	1	1.3
Student	12	15.0
Unemployed	4	5.0
Retired	11	13.7
Professional	3	3.7
Maid servant	1	1.3
Guard	1	1.3
Record not available	5	6.2

Table 2: Distribution of study subjects according to disease profile.

Disease profile	Frequency	Percentage		
Disease classification (n=80)				
Pulmonary	33	41.3		
Extrapulmonary	41	51.2		
Pulmonary +	6	7.5		
Extrapulmonary				
Type of extrapulmonary TB (n=49)*				
Pleural effusion	36	73.5		
Hydropneumothorax	2	4.2		
Caries spine	1	2.0		
Cold abscess	1	2.0		
Pyopneumothorax	1	2.0		
Abdominal TB	8	16.3		

^{*} Out of 41 subjects with extra-pulmonary TB, few had more than one manifestations.

Table 2 depicts 33 (41.3%) cases had pulmonary TB, 41 (51.2%) cases had extra-pulmonary TB and 6 (7.5%) had both pulmonary and extra-pulmonary TB. Among 41 extra-pulmonary cases, varying features were pleural effusion (36 cases, 73.5%), abdominal TB (8 cases, 16.3%), hydropneumothorax, caries spine, cold abscess and pyopneumothorax.

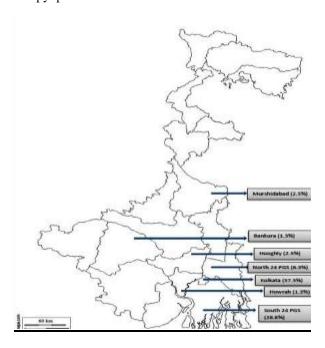


Figure 1: Study subjects from different districts of West Bengal admitted in different departments and receiving treatment under DOTS at KPCMCH, Kolkata, India.

Table 3 reflects about the sputum smear results of the study subjects. The results were negative in 8 (10%) patients, scanty in 3 (3.7%), '+' in 1 (1.2%), '++' in 6 (7.5%) and '+++' in 14 (17.5%) patients. Sputum smear examination was not conducted in 48 cases, among which 41 had extra-pulmonary TB, and in 7 (8.8%) patients treatment was initiated on the basis of Chest X-ray (CXR).

Table 3: Distribution of study subjects according to sputum smear result.

Sputum smear result	Frequency (n=80)	Percentage
Negative	8	10.0
Scanty	3	3.7
+	1	1.2
++	6	7.5
+++	14	17.5
Not done	7	8.8
Not applicable*	41	51.3

^{*}Sputum test was not done for extrapulmonary cases

Table 4 shows different investigations, apart from sputum smear examination, conducted on 80 study subjects. CXR was conducted on 31 (38.8%) subjects, Adenosine Deaminase (ADA) on 17 (21.3%), both CXR and ADA on 23 (28.8%). Other investigations done were FNAC, MRI, CT scan and USG (Thorax). Information regarding investigations was not mention in treatment cards of 5 (6.3%) patients. Among 80 study subjects, 73 (91.3%) were 'New cases' and 7 (8.7%) were 'previously treated' cases. Out of these 7 previously treated cases, 3 (3.7%) were 'treatment after default', 1 (1.3%) was 'relapse' case and 3 (3.7%) were 'others' cases (Table 5).

Table 4: Distribution of study subjects according to investigations done, other than sputum examination.

Investigations	Frequency (n=80)	Percentage
CXR	31	38.8
ADA	17	21.3
CXR +ADA	23	28.8
FNAC + MRI	1	1.2
CT +FNAC + MRI	1	1.2
CXR + FNAC	1	1.2
USG(Thorax)	1	1.2
Not mentioned	5	6.3

Table 5: Distribution of study subjects according to types of patients.

Types of patients	Frequency (n=80)	Percentage
New	73	91.3
Treatment after default	3	3.7
Relapse	1	1.3
Transfer in	0	0
Treatment failure	0	0
Others	3	3.7

In the present study, out of 73 'New' cases who were receiving Cat-I, 71 (88.8%) were on Intensive Phase (IP) and 2 (2.5%) were on Continuation Phase (CP). All the 7 'Previously treated' cases were on IP of Cat-II (Table 6).

Table 6: Distribution of study subjects according to type of treatment under DOTS.

Type of treatment	Frequency (n=80)	Percentage
Category I		
IP	71	88.8
CP	2	2.5
Category II		
IP	7	8.7
СР	0	0

All the study subjects were referred to ICTC for HIV testing. Among 80 subjects, 54 (67.5%) had negative HIV result while record of HIV testing was not available for 26 (32.5%) subjects.

The reason of unavailability of HIV reports in these 26 subjects being noncompliance (patients didn't turn up for the test) in 21 subjects and pending reports in 5 subjects (Table 7). The status of Diabetes was assessed in the study subjects and the results were positive in 22 (27.5%), negative in 54 (67.5%). Diabetes status was not mentioned for 4 (5%) patients because of pending results (Table 8).

Table 7: Distribution of study subjects according to HIV serology report.

HIV report	Frequency (n=80)	Percentage
Negative	54	67.5
Not available*	26	32.5

*Reports were pending for 5 study subjects and the rest 21 subjects did not turn up for HIV testing.

Among the patients with known Diabetes status (76 subjects), the result of association between TB-Diabetes and sex of the subjects was found to be statistically significant (Chi square value 5.323, P = 0.02) (Table 9).

Table 8: Distribution of study subjects according to presence of diabetes.

Diabetes status	Frequency (n=80)	Percentage
Present	22	27.5
Absent	54	67.5
Record not available*	4	5.0

^{*}Reports were pending for 4 study subjects.

Among 80 subjects receiving treatment at DOTS centre, KPCMCH, 2 patients (2.5%) had household contacts less than 6 years. But none of them were receiving chemoprophylaxis against TB.

Table 9: Association between gender and diabetes status of the study subjects (N=76).

		Diabetes		p-value
		Present	Absent	
	Male	20	35 (46.1%)	$\chi^2 = 5.323$
Gender		(26.3%)		df=1
	Female	2 (2.6%)	19 (25.0%)	P = 0.02
Total		22 (28.9%)	54 (71.1%)	

DISCUSSION

TB was declared a global emergency in the year 1993; recently the Director General of WHO declared AIDS to be a global emergency as well. There exists a synergistic relationship between TB and HIV.⁴

In the present study; most of the subjects (73.8%) were male. Similar observations were found in studies conducted by Jethani S et al. where 74.8% were male, Sumana M et al. (70.5% male), Sunderam S et al. (71.1%

male) and Christian D et al. (68% male).⁵⁻⁸ This finding is in accordance with the statement that TB is more prevalent among male than female.⁹ In this study, maximum subjects were reported in the age group of 20-30 years (25%) followed by 50-60 years (20%). Studies reported by Sumana M et al and Jethani S et al revealed most of the subjects were from the age group of 25-44 years (47.5%) and 40-49 years (18.7%) respectively.^{5,6} Most of the subjects in the present study were housewives (20%), followed by student (15%), retired (13.7%), laborer (8.8%), service (6.2%), unemployed (5%) etc. The study conducted by Christian D et al. mentions occupations like laborer (46%), home based work (16%), service (14%), unemployed (14%) etc. among the study subjects.⁸

The study conducted at DOTS clinic of KPCMCH revealed that 41.3% subjects had pulmonary TB, 51.2% had extrapulmonary TB and the rest had combination of pulmonary and extrapulmonary diseases. Similar observations were reported by Prakash BC et al. where extrapulmonary cases (59.8%) exceeded pulmonary cases (40.2%). 10

Dey D et al. in their study mentioned pulmonary cases being 89.3% and extrapulmonary as 10.7%. ¹¹ Overall, in our study, the total number of different types of EPTB cases included pleural effusion (73.5%), followed by abdominal TB (16.3%), hydropneumothorax (4.2%), and the rest being caries spine, cold abscess and pyopneumothorax each being 2%.

Different types of extrapulmonary involvement, as found in study conducted by Prakasha SR et al. were pleura (28%), lymph node (24.8%), CNS (12.5%), bones and joints (12.3%), abdomen (9.7%), and others (12.7%) which included genitourinary, skin, pericardium and breast lump. ¹² Similar observations were found by Mavila R et al. where extrapulmonary manifestation were lymph node (29.4%), gastrointestinal (24%), pleura (23.5%), skeletal (7.5%) and others. ¹³

The sputum smear results of the study subjects at DOTS clinic, KPCMCH, reflected that the results were negative in 10% patients, scanty in 3.7%, '+' in 1.2%, '++' in 7.5% and '+++' in 17.5% patients. A study conducted at Midnapur district, West Bengal, by Dey D et al. showed that sputum grade at diagnosis were scanty (6.9%), negative (19.3%), '+' (44.4%), '++' (12.1%) and '+++' (17.4%). ¹¹ Pre-treatment sputum results of treatment failure cases, in a study conducted by Mukhopadhyay S et al. were scanty (17.8%), '+' (37.6%)', '++' (23.8%) and '+++' (20.8%). ¹⁴

In present study 91.3% subjects were receiving Category I and rest 8.7% were on Category II treatment. Similar observations were reported by Dey D et al (89.3% Cat I; 10.7% Cat II) and Raghuraman S et al (74.2% Cat I; 25.8% Cat II). The study conducted by Dey D et al.

reported that out of 363 study subjects with TB, the HIV status was positive in 3.9%. 11

Another study conducted by Shrivastava SR et al. showed 10.2% of subjects with positive HIV status. ¹⁶ Observations in our study reflected that HIV status was negative in 67.5% patients. For the rest 26 (32.5%) patients, the HIV status was not known. All the patients who were diagnosed to have Tuberculosis were referred to ICTC for HIV testing as per RNTCP guidelines. The reasons of unavailability of the HIV report in these 26 patients were pending reports in 5 patients and noncompliance in 21 patients. These noncompliant patients did not turn up for HIV testing at ICTC, KPCMCH.

Blood sugar level was assessed in all subjects attending the DOTS centre, KPCMCH. Diabetes status was positive in 27.5% subjects. Among the patients with known Diabetes status (76 subjects), the result of association between TB-Diabetes and sex of the subjects was found to be statistically significant (Chi square value 5.323, P = 0.02). Similar observations were reported in the study conducted by Dey D et al. with 12.4% subjects with Diabetes and association between TB-Diabetes and sex being statistically significant (Chi square value 5.69, P = 0.02). Studies conducted by Prakash BC et al and Raghuraman S et al revealed presence of Diabetes in 9.2% and 29.03% subjects with TB respectively. P = 0.020.

In the present study, 2 subjects (2.5%) had household contacts less than 6 years, but none of them were receiving chemoprophylaxis against TB. The role of Isoniazid (INH) chemoprophylaxis, especially in developing countries like India, is doubtful because of its high cost, less effectiveness and risk of developing drug induced hepatitis, and thus not a worthwhile exercise for TB control.⁹

CONCLUSION

The present study, conducted at the DOTS centre of KPCMCH, was based on secondary data analysis of RNTCP treatment cards of indoor admitted patients and had its limitations. Data regarding occupation status and diagnostic procedure in extrapulmonary TB were missing for few cases. Thus, emphasis should be given on proper record maintenance. In 7 cases, ATD was initiated prior to sputum examination on the basis of clinical features and X-ray findings. Hence pre-treatment sputum examination results were not mentioned in treatment cards of these patients.

All the 80 study subjects were referred to ICTC for HIV testing, but 21 patients did not turn up for the test. Thus, awareness generation and proper counseling on TB-HIV co-infection among all the patients should be focused on to ensure 100% cross-referral between ICTC and RNTCP for diagnostic and treatment services.

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