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Quality of diagnostic and treatment practices of pulmonary tuberculosis management amongst health practitioners in Haryana, north India

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ABSTRACT

Introduction: Early diagnosis and supervised treatment remains the mainstay for tuberculosis (TB) control in India.

Methods: A facility-based cross-sectional study was conducted to assess diagnostic and treatment practices of tuberculosis management as per the Revised National Tuberculosis Control Programme at a secondary level health facility in north India. This hospital mostly caters to rural and peri-urban populations in the Ballabgarh block of Faridabad district, Haryana. A sample size of 244 was calculated. Consecutive chest symptomatic patients were recruited in the study. Information about socio-demographic characteristics and treatment was obtained from a routine history-taking process in the outpatient clinic. Results were expressed as mean, standard deviation (SD) and odds ratio (OR) with 95% confidence interval (CI).

Results: A total of 250 pulmonary TB suspects were recruited, out of which 55.4% were males and mean age of study participants was 35.4 years (SD 14.6). Almost half (47.1%) of the participants had sought treatment from government hospitals, followed by 46.7% from private hospitals. Those who had visited a private facility were significantly more likely not to receive sputum acid-fast bacillus (AFB) diagnostic testing (OR=7.26, 95% CI 4.04–13.08), likely to be taking a second-line anti-TB drug as an antibiotic trial (OR=3.65, 95% CI 1.17–11.30), be empirically taking anti-TB drugs (OR=5.28, 95% CI 1.50–118.64) and getting a serological test done (OR=9.58, 95% CI 1.20–76.0) than those who went to a government health facility. Those who made at least three visits to a private facility were significantly more likely to have taken a second-line anti-TB drug as an antibiotic trial (OR=3.56, 95%

CI 1.36– 9.28) and be empirically taking anti-TB drugs (OR=5.75, 95% CI 2.18–15.20) than those that made fewer than three visits.

Conclusions: This study documented inappropriate diagnostic and treatment practices in TB management and highlights the need to generate awareness about it among health practitioners in north India.

Key words: diagnostic practices, India, quality health practitioners, TB management practice, tuberculosis.

Introduction

Tuberculosis (TB) remains a major public health problem in India. WHO estimated that for the year 2011 India contributed nearly 20% of the total cases[1]. Early diagnosis and supervised treatment remain the mainstay for TB control. The same has been recommended in the Revised National Tuberculosis Control Programme (RNTCP) in India[2]. The RNTCP has set a target of case detection of new smear-positive pulmonary TB and treatment as 70% and 85% respectively[3]. India has been able to achieve the target for these key indicators at national level[3]. However, studies across India and other developing countries have documented that treatment practices for TB management are not as per prescribed guidelines, particularly in private care settings[4-8]. Systematic review of 37 studies showed that prescribing inappropriate regimens was common[9]. In rural India, the public healthcare system consist of three tiers: subcenters, primary health centers and community health centers. Service utilization of public health facilities is poor due to lack of infrastructure and inadequate human resources. This is the reason for the 'mushrooming' of unqualified private practitioners in rural areas[10]. According to the 3rd National Family Health Survey, private practitioners, both qualified and unqualified, are major healthcare providers, catering to nearly three-quarters of households[11]. In a recent survey across 40 districts of India, 44% of the re-treatment cases had their previous treatment at a facility outside the purview of a TB control program[12]. Also, patients who made more visits to a health facility were more likely to have unnecessary investigations and treatment. Thus, it is hypothesized here that patients having treatment at private facilities are prescribed inappropriate treatment regimens. Also, those patients who make frequent visits for their symptoms suggestive of pulmonary TB are likely to be exposed to unwarranted diagnostic and treatment practices.

Methods

Study design and study setting

This was a facility-based cross-sectional study conducted in October–November 2011 at a subdistrict hospital in the Ballabgarh block of Faridabad district in Haryana. The study facility was a 60-bed secondary-level healthcare facility in a peri-urban area about 34 km from India's capital, Delhi. The facility catered mostly to middle- and low-income populations. The study facility was also serving as a first referral hospital for nearby primary health centers. Many private practitioners had their clinic close to this facility. This facility had a TB unit, through which diagnostic tests for TB such as sputum acid-fast bacillus (AFB) and chest X-ray were being provided. Daily general outpatient (OPD) attendance was nearly 400–500, including 20–25 chest symptomatic patients.

Study population

In this study, all pulmonary TB suspects aged ≥12 years attending general OPD were included. A pulmonary TB suspect was defined as a person presenting in general OPD with a complaint of a cough of more than 2 weeks duration, or HIV positive and contact with TB patients with cough of any duration. The patients who had consulted any healthcare

facility, including the study facility, for the present complaints were included. All patients who were attending the health facility for the first time were excluded from the analysis.

Sample size and sampling

A conservative expected prevalence of 50% was taken to achieve a maximum sample size. The sample size of 244 was calculated by considering 7% as absolute error and a 20% non-response rate at 95% confidence level. Patients were recruited consecutively in general OPD as per eligibility criteria to achieve estimated sample size.

Study tool and data collection

In the OPD, the treating physician routinely enquires about details of complaints, treatment history and laboratory investigation to all patients, including pulmonary TB suspects. This information was recorded on the patient's OPD card. In this study, the investigator was a treating physician and systematically recorded this information from the pulmonary TB suspects on their OPD cards as well as on a record sheet for analysis. The information included in the analysis was non-prescription of sputum for AFB although cough present for more than 2 weeks, chest X-ray for pulmonary TB suspects without prescribing a sputum AFB, use of second-line anti-TB drugs as an antibiotic trial, prescription of anti-TB drugs without formally diagnosing TB, and serological testing for detection of anti-TB immunoglobulin (Ig)M and IgG antibodies. This information was obtained from the patients and validated by reviewing previous reports and prescriptions that patients brought to the OPD. Information regarding age and sex of the patient, place of residence, place of previous treatment, and number of visits made before recruitment in the study were also recorded.

Ethics approval

All information collected in the present study was a part of routine history taking in general OPD and no extra information was collected from the patients exclusively for research purposes. An informed verbal consent was obtained from all the eligible participants (≥18 years) who were interviewed. For participants aged 12–17 years, verbal consent was obtained from the accompanying adult. The information recorded was kept confidential with the investigators. Patients were not asked to spend any extra time for consultation in OPD. All recruited patients were provided treatment as per guidelines envisaged by RNTCP.

Data entry and analysis

The data was entered into Epi Info v3.5.4 (Centers for Disease Control and Prevention; http://wwwn.cdc.gov/epiinfo). The data back-stored in Microsoft Access were cleaned with all the string variables and the identifiers removed. The data was analyzed in the Statistical Package for the Social Sciences v13.0 (SPSS; http://www.spss.com). Mean and proportion were reported with standard deviation (SD) and confidence interval (CI) respectively. Socio-demographic variables (age, sex and place of residence) and health-seeking pattern (place of seeking treatment and number of visits made for this episode before coming to the interviewer) were compared with various diagnostic and treatment practices for association. Place of treatment was recorded as 'private', 'government' or 'both'. Place of treatment was made a dichotomous variable by clubbing the category 'both' with that of 'private'. The results were very similar when 'both' was included in 'government' or removed from analysis. Frequency of visits was recorded as told by the patient or as seen from the records. Frequency of visits was later made a dichotomous variable as either 'one to two visits' or 'three visits or more'. This was done because 'one or two visits' was the most common response, had a similar strength of association and differed from the category 'three visits or more'. Chi-squared test and Fischer's exact test, wherever applicable, was performed. $P<0.05$ was considered statistically significant. Odds ratio (OR) was calculated and is reported with 95% CI.

Results

A total of 250 pulmonary TB suspects were recruited, from which eight patients opted out of the study without giving any

specific reasons. Information for 242 patients was included in analysis. Of the 242 patients, 55.4% were male; 45.9% were in aged 26–45 years and 52.5% were residing in urban areas. Mean age of study participants was 35.4 years (SD 14.6 years). Nearly a quarter (22.3%) of the patients had made at least three visits before being recruited into the study. Almost half (47.1%) of the participants had sought treatment from government (public) hospitals, and 46.7% from private hospitals. Few patients (6.2%) had consulted both private and government facilities for their complaint before visiting the study facility (Table 1).

Diagnostic and treatment practices

Of 242 pulmonary TB suspects, 61.6% were not prescribed a sputum AFB test, even after they had presented with complaints suggestive of pulmonary TB. A total of 54.7% pulmonary TB suspects had had a chest X-ray before consultation in the study facility. Out of those who had not been prescribed a sputum AFB test, 38.9% were prescribed a chest X-ray. More than half (59.5%) of the pulmonary TB suspects took antibiotics during treatment. Second-line anti-TB drugs such as fluoroquinolones were taken by 7.9% of the patients. Anti-TB treatment was started in 7.9% of the patients without following guidelines of diagnosis by sputum microscopy as envisaged in the RNTCP. Out of these, none of the patient had had either a positive sputum AFB result or a chest X-ray suggestive of TB. Out of all pulmonary TB suspect patients, 11 (4.5%) underwent a serological test for detecting TB antibodies as prescribed by a health practitioner (Table 2).

Association of diagnostic and treatment practices with selected variables

No statistically significant association was found between selected sociodemographic variables (age, sex, place of residence) and the treatment and diagnostic practices. Those who had visited a private facility were significantly more likely not to be prescribed sputum AFB (OR=7.26, 95% CI 4.04–13.08), be taking second-line anti-TB drugs as an antibiotic trial (OR=3.65, 95% CI 1.17–11.30), empirically taking anti-TB drugs (OR=5.28, 95% CI 1.50–118.64) or getting a serological test done (OR=9.58, 95% CI 1.20–76.0) than those who went to a government health facility (Table 3). Those who made at least three visits were significantly more likely to have taken a second-line anti-TB drug (fluoroquinolones) as an antibiotic trial (OR=3.56, 95% CI 1.36–9.28) or be empirically taking anti-TB drugs (rifampicin, isoniazide, pyrizinamide, ethambutol) (OR=5.75, 95% CI 2.18–15.20) than those that made only one or two visits (Table 3). Those who visited a private health facility were significantly less likely to have a chest X-ray done than those who visited a government health facility. However, association between health-seeking pattern and chest X-ray prior to sputum AFB test was found to be statistically non-significant (Tables 3 and 4).

Discussion

This study documented the diagnosis and treatment practices for pulmonary TB suspects by both government and private practitioners in Ballabgarh, Haryana. To the best of the authors' knowledge, this was a first attempt to document inappropriate practices of health practitioners for management of pulmonary TB suspects in north India. This study highlighted various issues that may hinder the effort to effectively manage pulmonary TB cases in India.

The Revised National Tuberculosis Control Programme has clear-cut guidelines for TB diagnosis and treatment. As per the RNTCP, every patient with a cough for 2 weeks or more needs to be investigated for TB, and sputum examination for AFB remains the mainstay of diagnosis. Chest X-ray has a high level of inter-observer disagreement, hence it has only a supportive role in confirmation of sputum smear negative pulmonary TB[13]. The present study reported that more than one-third of chest-symptomatic patients underwent chest X-ray before sputum examination. The irrational prescription of chest X-rays might lead to inappropriate and excessive utilization of resources, delay in initiation of appropriate treatment and increased treatment cost for the patient.

Table 1: Sociodemographic characteristics and treatment-seeking practices among study participants

Variable	Number	Percentage
Sex		
Male	134	55.4
Female	108	44.6
Age group (years)		
≤25	76	31.4
26–45	111	45.9
≥46	55	22.7
Place of residence		
Urban	127	52.5
Rural	115	47.5
Place of treatment		
Government	114	47.1
Private	113	46.7
Both	15	6.2
Number of visits to health facility		
1 or 2	188	77.7
≥3	54	22.3

Table 2: Tuberculosis management practices among study participants (*n*=242)

Variable	Number	Percentage
Sputum microscopy not done	149	61.6
Chest X-ray done	139	57.4
Second line anti-TB drugs prescribed as antibiotic trial	19	7.9
Anti-tuberculosis drugs given empirically before diagnosis	19	7.9
Serological tests done	11	4.5
Chest X-ray done without sputum microscopy (*n*=149)	58	38.9

The present study reported irrational antibiotic prescription, such as prescribing fluoroquinolones for chest-symptomatic patients. As per the RNTCP, antibiotic trials should be given to all pulmonary TB suspects while awaiting results of sputum investigation. Drugs used in an antibiotic trial before laboratory confirmation should be those acting on tubercular bacilli, such as fluoroquinolones. The present study also reported use of serological testing for diagnosis of TB. Although these tests are inaccurate in diagnosing TB, widespread use of serological testing was reported from data of 22 high-burden countries including India[14]. Guidelines prohibiting serological testing for diagnosis of TB has been recently incorporated under the RNCTP. Despite this, nearly 1.5 million serological tests are estimated to have been done in India with a cost implication of US$15 million[14]. This will contribute to out-of-pocket expenditure for patients. This will also have tremendous cost implications on the health system. Moreover, sputum microscopy and sputum culture have found to be more cost effective than serological testing in the Indian context[15].

Table 3: Association between place of treatment and tuberculosis management practices

Treatment and diagnostic practice	Place of treatment		*p* value	Odds ratio (95% CI)
	Private *n* (%)	Government *n* (%)		
Sputum microscopy?				
No	105 (82.0)	44 (38.6)	<0.001***	7.26 (4.04–13.08)
Yes	23 (18.0)	70 (61.4)		Referent
Chest X-ray?				
Yes	57 (45.5)	82 (71.9)	<0.001***	0.31 (0.18–0.54)
No	71 (55.5)	32 (28.1)		Referent
Second-line anti-TB drugs as antibiotic trial?				
Yes	15 (11.7)	4 (3.5)	0.029*	3.65 (1.17–11.3)
No	113 (88.3)	110 (96.5)		Referent
Anti-TB drugs as empirical treatment?				
Yes	16 (12.5)	3 (2.6)	0.004**	5.28 (1.50–118.64)
No	112 (87.5)	111 (97.4)		Referent
Serological test done?				
Yes	10 (7.8)	1 (0.9)	0.01*	9.58 (1.20–76.0)
No	118 (92.2)	113 (99.1)		Referent
Chest X-ray done without sputum microscopy (*n*=149)?				
Yes	37 (35.2)	21 (47.7)	0.154	0.59 (0.29–1.21)
No	68 (64.8)	23 (52.3)		Referent

*p<0.05, **p<0.01, ***p<0.001
CI, confidence interval. TB, tuberculosis

Table 4: Association between number of visits made to health facility and tuberculosis management practices

Treatment and diagnostic practice	Number of visits		*p* value	Odds ratio (95% CI)
	≥3 *n* (%)	1 or 2 *n* (%)		
Sputum microscopy?				
No	34 (63.0)	115 (61.2)	0.811	1.07 (0.58–2.02)
Yes	20 (37.0)	73 (38.8)		Referent
Chest X-ray?				
Yes	30 (55.6)	109 (58.0)	0.751	0.90 (0.49–1.67)
No	24 (44.4)	79 (42.0)		Referent
Second-line anti-TB drugs as antibiotic trial?				
Yes	9 (16.7)	10 (5.3)	0.006**	3.56 (1.36–9.28)
No	45 (83.3)	178 (94.7)		Referent
Anti-TB drugs as empirical treatment?				
Yes	11 (20.4)	8 (4.3)	<0.001***	5.75 (2.18–15.20)
No	43 (79.6)	180 (95.7)		Referent
Serological test done?				
Yes	3 (5.6)	8 (4.3)	0.713	1.32 (0.34–5.17)
No	51 (94.4)	180 (95.7)		Referent
Chest X-ray done without sputum microscopy (*n*=149)?				
Yes	12 (35.3)	46 (40.0)	0.621	1.22 (0.55–2.71)
No	22 (64.7)	69 (60.0)		Referent

*p<0.05, **p<0.01, ***p<0.001
CI, confidence interval. TB, tuberculosis

Various studies in India have documented delays in diagnosis and treatment, at both patient and health system levels[16-18]. Delay in treatment leads to increased likelihood of transmission and it hampers control of TB. All irrational practices reported in this study, particularly failure to prescribe sputum AFB at the stipulated time, leads to a delay in diagnosis and treatment. Prescription of unnecessary investigations increases the delay in diagnosis and treatment and the spread of disease to others. However, the study design did not allow the authors to document the delay with respect to various diagnostic and treatment practices. Irrational prescription of antibiotics as a part of an antibiotic trial and use of anti-TB drug empirically increases the chance of antibiotic resistance. This has an adverse effect on curbing transmission and diminishes favorable treatment outcomes, leading to a high failure, relapse and default rate[19].

This study documented that patients who made three or more visits to and sought care from a private practitioner were at more risk of irrational diagnostic and treatment practices. Although RNTCP has a widespread network of Directly Observed Treatment Short Course treatment centers and a designated microscopy center, nearly half (46%) of the TB patients were estimated to be taking treatment from outside RNTCP facilities and most of these were private facilities[20]. As reported in the present study, private practitioners were more likely to irrationally prescribe antibiotic use and advise unwarranted serological investigations. Similar findings were documented by Srivastava DK et al. in their study amongst health practitioners in India[21]. It has been estimated recently that for nearly two-thirds of TB patients the first contact was an informal practitioner and more than half reached RNTCP services after having at least three visits elsewhere[22]. Although not well studied, the situation may not be very different in government health facilities. Better awareness regarding TB and its management as per RNTCP guidelines is expected among medical staff working at government facility and was observed as compared to private practitioners in this study.

Conclusions

The authors conclude that irrational prescription of diagnostic and treatment practices are common in this part of India. It is responsible for the delay in treatment, cost of treatment, propensity for unfavorable treatment outcome, and antibiotic resistance. Thus it increases the burden on both the patient and the health system. Patients visiting a private facility and making more visits are at higher risk of these practices.

Although this study has provided evidence about irrational treatment practices of TB management in India, it has a few limitations. First, the study was done in only one secondary care health facility, which may be different from other health facilities across India. Information about previous investigations was obtained from the patients and validated by reviewing previous investigation reports and prescription. Completeness of the information was limited by factors such as availability of prescription records, recall bias of the patients and understanding of patients about medicines and investigation procedures. Second, patients attending this health facility may not be representative of all chest-symptomatic individuals in the population. There is a need for a large-scale nationally representative study to get reliable information about this problem. Notwithstanding these limitations, the study is relevant for programmatic consideration at the national level. The authors recommend more emphasis on sputum AFB examination. Despite being an easy and cheap diagnostic test, it seems to be highly under-utilized. Also, greater emphasis should be given to the practitioners, both public and private, by conducting a refresher sensitization program. Public–private partnership is an essential cornerstone under TB control in India. Active involvement of private practitioners in service delivery under public–private partnerships through regular training and sensitization may reduce the prescription of unnecessary diagnostic tests and use of irrational treatment practices.

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