Determinants of Categories of TB Retreatment with Special Reference to Sources of Primary Anti-TB Treatment

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Abstract

Introduction Retreatment (previously treated) cases are the tuberculosis (TB) patients who have been treated previously with anti-TB drugs for at least a month and who have now been registered for category II anti-TB therapy. Retreatment cases arise due to inadequate and improper treatment of the new TB cases.

Objective The aim of the study is to assess the information regarding sources of previous TB drug exposure and treatment practices leading to retreatment cases (category II) and determinants leading to retreatment.

Material and Methods It was a community-based cross-sectional study of patients registered as retreatment TB cases under revised national TB control program (RNTCP) in the TB unit of Puducherry between October 2013 and September 2014. The study was held between October 2013 and October 2015. Initially the quantitative data were collected and followed by qualitative data. Data were collected by interviewing the patients using a predesigned questionnaire. Data were entered and analyzed by using Epi Info (Version 3.4.3) software package.

Results Out of the 193 study participants, relapse cases were the most common 50.8%, followed by treatment after default cases 23.8%, failure cases 11.9%, and retreatment others 13.5%. There is a significant association between the retreatment categories such as failure, TAD (treatment after default), retreatment others, and ever usage of tobacco ($p < 0.05$). There is also a significant association between the retreatment categories such as TAD, retreatment others, and ever usage of alcohol ($p < 0.05$). The sources of previous antitubercular therapy for 90.16% retreatment cases were from government health care facilities under RNTCP, whereas for 9.84% retreatment cases the sources of previous antitubercular treatment were private health care facilities. There is a significant association between public health care facility where patients were previously treated for TB and relapse ($p = 0.001$) and private health care facility where patients were previously treated for TB and TAD ($p = 0.008$).

Conclusion As 90% of the patients have utilized the government health services for treatment, it shows the effective functioning of RNTCP-STF (state task force-revised national TB control program) mechanism in Puducherry.

Keywords

- previously treated
- retreatment
- sources of previous treatment
- tuberculosis

Introduction

Tuberculosis (TB) remains as one of the major public health problems; it was one of the top ten causes of death worldwide in 2015. The STOP TB strategy was developed by World Health Organization (WHO) with the goal of reducing the global burden of TB by 2015 in line with the millennium development goals. One of the principal components of STOP-TB strategy is addressing the multidrug-resistance TB cases (MDR-TB), which is a threat to global TB control.¹ In South East Asian Region, retreatment TB cases account for 16% of MDR-TB cases, which in turn account for 30% of world's MDR-TB cases in 2013.² Retreatment TB (previously treated) cases are the TB patients who have been treated previously with anti-TB drugs for at least a month and who have now been registered for category II anti-TB therapy. Retreatment cases arise due to inadequate and improper treatment of the new TB cases.^{3,4}

Newly diagnosed TB patients seek care from a wide range of private health care providers apart from public sector. These private health care providers may serve a large population of TB suspects and TB patients, but they may not always follow recommended treatment practices or reporting mechanisms.⁵ Failure to engage all these health care providers causes inappropriate and incomplete treatment, increases drug resistance, and places a huge unnecessary financial burden on patients. WHO has released its post-2015 Global TB strategy called "End TB strategy" which aims to eliminate TB by 2035. It is important to know the sources of previous TB drug exposure for patients registered as retreatment tuberculosis which is also one of the agenda for operational research under revised national TB control program (RNTCP).⁶ Hence our objective was to assess the information regarding sources of previous TB drug exposure and treatment practices leading to retreatment cases (category II) and to find the determinants leading to retreatment.

Materials and Methods

Study Area and Setting

The study was performed in the urban and rural localities of Puducherry district which comes under the State Tuberculosis Unit (TU) of Puducherry Union Territory. The study area is spread over a radius of 25 km. The Chest clinic as well as State TU is situated in the heart of the city and functions as a core of the Revised National Tuberculosis Control Program covering the urban and the rural population of Puducherry district. The present study was undertaken by the Department of Community Medicine, Sri Manakula Vinayagar Medical College and Hospital, Puducherry, which is an active member in STF-RNTCP (state task force-revised national TB control program) mechanism.

Study Design

An exploratory sequential design where quantitative methods (community-based cross sectional survey) followed by qualitative methods (Free listing) was used.

Sample Size and Sampling

Quantitative Method

All the patients registered as retreatment TB cases under RNTCP in the TU of Puducherry between October 2013 and September 2014 were invited to participate in the study. Out of the 209 retreatment cases registered for treatment during this period, ten cases expired and six cases were excluded from the study because of the reasons such as refusal to give consent, shifted to new place or defaulted again. Finally 193 retreatment cases were recruited for the study.

Qualitative Method

A sample of four category—two patients and two TB health visitors were purposely selected. All the participants were literate. These patients were asked to list out the (free list) the reasons for the previous treatment exposure. The TB health visitors (TBHVs) were asked to list out the common reasons told to them by the patients during their DOTS treatment. This method was used as it was convenient and less time consuming. The free listing was conducted in local language by the principal investigator who is trained in qualitative research methods. The process was stopped at saturation point when no new information received.

Data Collection

The quantitative study was conducted from October 2013 to September 2014, while qualitative study was continued up to 2015. A predesigned questionnaire was pilot tested among 20 retreatment cases to check the wording and the appropriateness of the questions in the questionnaire. The questionnaire used in this study included three parts. First part included details regarding socio-demographic characteristics of the respondent. Housing, environmental conditions, personal habits such as smoking and alcohol history were also enquired in this part. The second part of the questionnaire included details regarding knowledge, attitude, and practices of the respondents regarding TB. The third part of the questionnaire included details of previous TB treatment. After obtaining permission from the concerned primary health centers (PHC)/community health centers (CHCs) Medical Officers, interview sessions were arranged with the help of the concerned TB health visitor. After obtaining informed consent from the respondent, the questionnaire was administered and data were collected.

Data Analysis

Data were entered and analyzed using Epi Info (Version 3.4.3) software package. Descriptive statistics such as frequency, percentage, and mean were used to analyze the socio-demographic details, source of previous treatment, retreatment categories, current knowledge about TB, and co-morbidities. Chi-square test (χ^2) (Fischer exact test was used for cells with values less than 5) was used to assess the association between retreatment categories and socio-demographic details, sources of previous treatment, etc. The manual content analysis of qualitative data was done by the co-investigator.

Ethical Issues

Ethical principles such as respect for the persons, beneficence, and justice were adhered. Ethical clearance was obtained from the Research Committee and Institutional Ethics Committee of Sri Manakula Vinayagar Medical College and Hospital, Madagadipet, Puducherry.

Results

In our study, majority of the retreatment cases 82.9% were male and 17.1% were female. Majority of the study participants 52.8% were in the age group 36 to 55 years. The mean age of the male respondents 46.91 (± 12.47) was significantly higher than that of female 37.39 (± 17.75) ($p < 0.05$). Most of them 62.7% were residing in urban area. About 52.3% were belonging to below poverty line. About 90.2% of the study participants were literate and 9.8% were illiterate. Among the study participants approximately 22.8% were unemployed. Among the currently employed 43.5% were laborers by occupation.

► **Table 1** mentions the determinants for the retreatment cases, out of the 193 retreatment cases 65.3% reported ever usage of tobacco whereas, current usage of tobacco was reported by 23.3% of study participants. Among both ever users and current users, smoking form of tobacco was reported to be most commonly used by 80.2 and 86.7% study participants, respectively. Ever usage of alcohol was reported by 61.7% study participants, whereas 21.2% study participants reported current usage of alcohol. Lack of adequately ventilated house was reported by 48.7% and lack of

cross ventilation was reported by 60.6%. About 81.3% were diagnosed with having TB during their previous treatment from government health care facility, whereas 17.1% were diagnosed by private health care providers. About 1.6% study participants were not able to recall about the place of diagnosis. The source of previous antitubercular therapy for 90.16% retreatment cases was from government health care facilities under RNTCP, whereas for 9.84% retreatment cases, the source of previous antitubercular treatment was private health care facilities. Overall, the ever usage of tobacco, alcohol usage, and noncompliance to the treatment were more common among male which was statistically significant.

► **Table 2** shows the significant association between the retreatment categories such as failure, TAD, retreatment others, and ever usage of tobacco ($p < 0.05$). There is also a significant association between the retreatment categories such as TAD, retreatment others, and ever usage of alcohol ($p < 0.05$), and also between health care facility where previously treated for TB and relapse ($p = 0.001$). There is also association between cross-ventilation and other category of retreatment ($p = 0.01$).

As mentioned in ► **Table 3**, the categories emerged from the free listings of the TB patients are: (1) side effects of anti-TB drugs, (2) too many drugs/long duration of treatment, (3) Loss of job/inability to work, and (4) lack of adequate knowledge. The categories emerged from TBHV are (1) addiction, (2) supervision and monitoring related issues, (3) poor support from family, stigma, and (4) lack of adequate knowledge.

Table 1 Distribution of retreatment cases by determinants of retreatment category

Variable	Male <i>n</i> = 160	Female <i>n</i> = 33	Total <i>n</i> = 193	χ^2 , df, <i>p</i> -value
Tobacco ever usage				
Yes	121 (75.6)	5 (15.2)	126 (65.3)	43.92 (0.001)
No	39 (24.4)	28 (84.8)	67 (34.7)	
Alcohol ever usage				
Yes	118 (73.8)	1 (3)	119 (61.7)	57.58 (0.001)
No	42 (26.2)	32 (97)	74 (38.3)	
Place where first diagnosed				
Government health care facility	147(91.9)	26 (78.8)	174 (90.1)	3.42, 1, (0.06)
Private health facility	13 (8.1)	6 (18.2)	19 (9.9)	
Previous knowledge of TB				
Yes	140 (87.5)	26 (78.8)	166 (89.1)	0.215 (0.642)
No	20 (12.5)	7 (21.2)	27 (10.9)	
Supervision				
Yes	137 (85.6)	23 (69.6)	160 (86)	0.969 (0.324)
No	23 (14.4)	10 (30.3)	33 (14)	
Compliance				
Compliance	104 (65)	29 (87.8)	133 (69)	6.65 (0.001)
Noncompliance	56 (35)	4 (12.2)	60 (31)	

Note: Figures in parenthesis are percentages.

Table 2 Association of retreatment category with ventilation, Government health care facility, ever used tobacco and alcohol usage

Retreatment category	Ventilation adequate <i>n</i> = 98	Ventilation inadequate <i>n</i> = 95	<i>p</i> -Value (χ^2 test)
Relapse	52 (53.1)	46 (48.5)	0.51
Failure	11 (11.2)	12 (12.6)	0.76
TAD	19 (19.4)	27 (28.4)	0.14
Others	16 (16.3)	10 (10.5)	0.23
Retreatment category	Cross ventilation present <i>n</i> = 77	No cross ventilation <i>n</i> = 116	
Relapse	38 (49.3)	60 (51.7)	0.74
Failure	8 (10.4)	15 (13.0)	0.59
TAD	15 (19.5)	31 (26.7)	0.24
Others	16 (20.8)	10 (8.6)	0.01
Retreatment category	Government health care facility <i>n</i> = 174	Private health care facility <i>n</i> = 19	
Relapse	95 (54.6)	3 (15.8)	0.001
Failure	22 (12.7)	1 (5.3)	0.611
TAD	36 (20.7)	10 (52.6)	0.008
Others	21 (12)	5 (26.3)	0.182
Retreatment category	Ever used tobacco: yes (<i>n</i> = 126)	Ever used tobacco: no (<i>n</i> = 67)	
Relapse	60 (47.6)	38 (56.7)	0.229
Failure	20 (15.9)	3 (4.5)	0.020
TAD	38 (30.2)	8 (11.9)	0.004
Others	8 (6.3)	18 (26.9)	0.0001
Retreatment category	Ever used alcohol: yes (<i>n</i> = 119)	Ever used alcohol: no (<i>n</i> = 74)	
Relapse	59 (49.6)	39 (52.7)	0.67
Failure	17 (14.3)	6 (8.1)	0.19
TAD	36 (30.2)	10 (13.5)	0.007
Others	7 (5.9)	19 (25.7)	0.0001

Abbreviation: TAD, treatment after default.

Note: Figures in parenthesis are percentages.

Discussion

In the present study, majority of the retreatment cases were male 82.9%. Majority of the study participants 52.8% were in the age group 36 to 55 years. The study conducted by Sarpal et al⁷ in Chandigarh, shows similar findings as our present study with respect to gender and age. As per the census 2011 data, Pondicherry has an average literacy rate of 85.85%, higher than the national average of 74%.^{8,9} In our study 90.2% of the study participants were literate and 9.8% were illiterate. Among the study participants approximately 22.8% were unemployed.

Present study shows that, there is a significant association between the retreatment categories such as failure, TAD, retreatment others, and ever usage of tobacco ($p < 0.05$). There is also a significant association between the retreatment categories such as TAD, retreatment others and ever usage of alcohol ($p < 0.05$). Similarly the study conducted by Dooley et al in Morocco shows that substance use appeared to be a risk factor for default.¹⁰ The study conducted by Thomas et al in Thiruvallur district, Tamil Nadu shows that smoking is a risk factor for relapse and relapse rate could be effectively reduced by effective counseling

about quitting smoking.¹¹ Similarly the study conducted in West Bengal also reported similar findings.¹² This study was conducted in 20 districts of six states and have reported that even though smoking and alcohol were associated with default, but they were specific to few regions only.¹³

The findings of the present study show that, the source of previous antitubercular therapy for 90.16% retreatment cases was from government health care facilities under RNTCP. Among those who obtained previous antitubercular therapy from government health care facility, most of them (78.7%) obtained antitubercular therapy from PHCs, CHCs, and health subcenters. The union territory of Puducherry has five tertiary care level hospitals, two CHCs, 12 urban, and 15 rural PHCs, 14 urban and 35 rural subcenters. Majority of the people in Puducherry utilize the government health services; this was supported by the findings of study conducted by Prasad et al.¹⁴ Another study conducted in Puducherry has also reported similar finding.¹⁵ The reason could be due to successful involvement of Medical Colleges through State Task Force Mechanism. But the study conducted in 2011 by Sachdeva et al has reported that more than half of the retreatment cases had treatment from non-RNTCP sources.¹⁶

Table 3 Free listing among four retreatment patients and two TBHV

Patients	TBHV
Side effects of anti-TB drugs	Addiction
Severe vomiting	Chronic alcoholism: not able to quit alcohol
Abdominal pain	Unsuccessful quit attempts
Burning sensation in stomach	Tobacco usage, smoking
Developed jaundice	Supervision and monitoring-related issues
Generalized weakness	Could not retrieve the patients' address
Easy fatigability	Wrong address given
Drowsiness	Patient has migrated to new place
Too many drugs/Long duration of treatment	Patients house remains always locked
Has to take many tablets per day	Poor support from family
Very long duration of treatment which interferes with normal life functions.	Other family problems like living alone, broken family, widow or widower, elderly dependent person.
Loss of job/Inability to work	Lack of support from the family
Cannot resume to job after taking the drug	Stigma
Cannot do heavy work because of side effects	Social stigma still prevails
Feel very weak to carry out the job	Lack of adequate knowledge
Feeling weak after taking tablets, so could not work	Illiteracy, discontinues treatment as health improves
Lack of adequate knowledge	Carelessness about their health
Felt that health has improved after taking treatment for few weeks so discontinued treatment.	Uncooperative patients threatening TBHV for visiting their home.
Felt healthy after intensive phase.	Depression
Attained sputum smear negative after intensive phase	Feeling mentally weak because of the disease and side effects of treatment
Adopted other modes of treatment—Homeopathy, Siddha, Ayurveda	Economic problems
Lack of faith in allopathy medicines	No active income, nonearning member in the family

Abbreviation: TBHV, tuberculosis health visitors.

In our study, 80.3% reported that they were supervised for adherence of treatment during their previous antitubercular treatment by government health facility staff. About 19.7% reported that they were not supervised for adherence during their previous treatment. This 19.7% constitutes those who have obtained their previous anti-TB treatment from private health care facility and those who obtained treatment from government health facility before 15 to 20 years. As per the "Treatment of Tuberculosis Guidelines" by WHO, supervised treatment helps the patients to take their TB medications regularly and to complete the TB treatment.³ It is also meant to ensure that the providers give proper care and are able to detect treatment interruption. Adherence to TB treatment is crucial to achieving cure while avoiding the emergence of drug resistance and also protects the community from the spread of TB.

In the present study, 66.3% reported that they have taken the drugs regularly and have completed the course of treatment during the previous treatment. About 33.7% reported that they have not taken the drugs regularly, failed to complete full course of treatment. The

reasons for irregular treatment during the previous treatment reported by the study participants were (multiple responses) lack of knowledge and carelessness 50.7%, long duration of treatment 33.8%, too many drugs 33.8%, side effects of the drugs 24.6%, disturbance in day to day activities 24.6%, does not improve with the drugs 0.5%, shifted to new place 12.3%, declared cured after intensive phase 3.0%, alcohol dependence 10.7%, felt health improved 9.2%, and family issues 6.1%. The reasons reported in our study for nonadherence of treatment are also reported in the other studies.^{13,15,17,18} To confirm further the qualitative exploration of the reasons for retreatment category yielded similar responses.

Present study shows that, there is a significant association between previous health care facility for TB and relapse ($p = 0.001$). Relapse was significantly more among those who got previously treated in government health care facility under RNTCP. TAD cases were found to be significantly higher among those who were previously treated in private health facilities. Similarly, the study conducted by Sachdeva et al also shows that "relapse" and "failure" cases are more likely to have been previously treated under RNTCP sources.¹⁶

Conclusion

As 90% of the patients have utilized the government health services for treatment, it shows the effective functioning of RNTCP-STF mechanism in Puducherry. Further, qualitative studies can enlighten the reasons for the nonadherence of treatment and reasons in previously treated cases.

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Conflict of Interest

None declared.

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