

An Epidemiological Profile of Previously Treated Patients Registered in Tuberculosis Units in Urban Visakhapatnam

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Abstract

Background: Tuberculosis (TB) remains a major global public health problem. Retreatment patients have higher risk of drug resistance compared with new cases. The objective of the study is to describe the types of retreatment (previously treated) patients and assess the Socio demographic characteristics, co morbid and behavioural conditions of retreatment patients and to identify the factors associated with relapse under Revised National Tuberculosis Control Program (RNTCP) in the tuberculosis units located in Urban Visakhapatnam. The main aim of the study is to study epidemiological profile of previously treated patients to identify the factors which make tuberculosis patients prone for retreatment so that necessary action can be taken.

Methods: This is an Observational Analytical Cross-sectional study done in Tuberculosis units in GVMC. All the subjects(193) who were registered as Previously treated patients in TUs during the second and third quarter of the year 2016 i.e April to September 2016. A pretested semi structured schedule was administered. Categorical data was analysed by Chi square test. Quantitative variables were represented as means and standard deviation. Unpaired t test was used for testing statistical significance in quantitative data.

Results : Among 193 study subjects 168 (87%) were having pulmonary TB and remaining 25 (13%) were having extra pulmonary TB. Majority of the study participants, 141 (73%) were males whereas only 52 (27%) were females. Relapse patients were 125(64.9%) Defaulters were 12 (6.2%), Treatment failure was 9 (4.6%) and Others previously treated were 47 (24.3%). Chi square test was used for testing statistical significance of association between categorical variables.

Conclusion: Socio demographic factors, behavioural and co morbid factors have an effect on Relapse and modifying these risk factors may bring about favourable outcomes. There is further need for exploring the reasons for high rates of relapse.

Keywords: Previously treated patients, Relapse, Retreatment, Tuberculosis Units, Visakhapatnam.

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Introduction

India has the highest burden of TB in the world, an estimated 2 million cases annually. This accounts for approximately one fifth of the global incidence of TB. It is estimated that about 40% of the Indian population is infected with TB bacteria.¹

Retreatment tuberculosis patients are those who have been treated previously for one month or more with anti TB drugs and are once again diagnosed with the disease. These patients include relapses, defaults, treatment failure and other previously treated patients.²

Retreatment for TB has long been a neglected area in global TB control. India, however, disproportionately accounts for nearly half of retreatment TB cases notified globally.³

Besides disease burden, tuberculosis also causes huge socio economic burden. Tuberculosis is a disease of poor as it is widely found in developing countries like India.⁴

In 2020 5.8 million people were reported as having developed TB. This is a decrease from 7.1 million in 2019. TB affects all countries and age groups. Overall in 2020 fifty eight per cent of notifications were of reports of TB in adult males. Thirty five per cent were adult women. Seven per cent were children aged 0-14.⁵

Estimates of TB Burden in India (as per Global TB report 2021)⁶

Incidence - 188 cases per 100,000 population.

Deaths - 36 deaths per 100,000 population.

Incidence of Multi Drug Resistant TB: 9.9 cases per 100,000 population.

The data from the reports indicates a rise in the mortality from Tuberculosis in the Country.

At the start of 2020, in view of End TB targets the central government of India renamed the Revised National Tuberculosis Control Programme (RNTCP) to National Tuberculosis Elimination Program (NTEP).⁷

Government of India has been striving to prevent and control Tuberculosis through intensified efforts

under RNTCP with a vision of "TB free India" with reduction of the burden of the disease until it is no longer a major public health problem.

The main objective of the study is to describe the Socio demographic characteristics, co morbid and behavioural practices of retreatment patients and to identify the factors associated with relapse.

Material and Methods

An observational analytical Cross sectional study was conducted among Previously treated tuberculosis patient registered in Tuberculosis units in Visakhapatnam. Study period was November 2016 – April 2017. Inclusion Criteria included patients registered in Tuberculosis Units of Visakhapatnam and who were above the age of Eighteen and who have given consent to participate in the study. Those subjects who could not be traced or who were transferred out of the TUs were excluded. The sample size was calculated using formula $n = Z^2 P \times (1-P) / d^2$ where, $Z = 1.96$ (at 95% confidence interval [CI]), error of estimate $d = \pm 5$, assumed prevalence $P = 10\%$, the required estimated sample 144 study subjects. A total sample of 193 retreatment patients was drawn from tuberculosis units. All the patients aged above 18 years of age who were registered in each of the five tuberculosis Units and categorised as retreatment patients during the second and third quarters of 2016 were considered for the study. There are 5 Tuberculosis units under GVMC jurisdiction. The total patients registered in the selected Tuberculosis Units for second and third quarters of 2016 were 213. The selected TUs were visited and list of the patients was taken from the TU and the patients were contacted by telephone or through the TB Health Visitor. Among them, there were 15 deaths and 5 were not responsive. Finally 193 subjects were included in the study by Consecutive sampling technique.

Participants were included in the study only after obtaining their Informed consent. Institutional Ethics Committee approval was obtained for carrying out the study. Permission was also obtained from the District TB officer

A pretested semi structured schedule prepared in local language was administered and data was collected at either the home of the participant or at

the health facility as per the convenience of the study participant.

Operational definitions of variables in the study:

Socio-Economic Classification: The study participants were classified based on modified Kuppuswamy's socio-economic status scale, which is based on education and occupation of the head of the family and total family income revised for 2016.⁸

Smoker: A person who has smoked at least 100 cigarettes in their life time and who, at the time of survey, smoked either every day or in the last 30 days.⁹

Alcohol Consumption: Patients who said they habitually consumed alcohol every day or most days of the week during the study period were considered to be alcoholic for the purpose of this study.¹⁰

Diabetes: Participants were considered to have diabetes mellitus if previously they had been recognized by the doctor as having DM or any documents in favour of DM or they reported taking insulin or oral anti-diabetic drug.¹¹

Hypertension: the person was considered as hypertensive if the systolic blood pressure equal to or more than 140 mmHg or diastolic pressure equal to or more than 90 mmHg or on current use of antihypertensive drugs, or already diagnosed by a registered doctor as hypertensive.¹²

Relapse: Patients who have previously been treated for TB, were declared cured or treatment completed at the end of their most recent course of treatment, and are now diagnosed with a recurrent episode of TB (either a true relapse or a new episode of TB caused by re infection).

Treatment Failure: Patients are those who have previously been treated for TB and whose treatment failed at the end of their most recent course of treatment.

Default: Patients have previously been treated for TB and were declared lost to follow-up at the end of their most recent course of treatment.

Other Previously Treated Patients: are those who have previously been treated for TB but whose outcome after their most recent course of treatment is unknown or undocumented.

Data Entry and Statistical Analysis:

Data was entered into MS Excel worksheet 2007. Data analysis was performed using SPSS software (trial version 21). Categorical variables were represented as proportions/ percentages. Chi square test was used for testing statistical significance of association between categorical variables. Unpaired t test was used for testing statistical significance in quantitative data.

To find the predictors for relapse, the subjects were made into two groups which were Relapse and Non Relapse. In Non Relapse group three categories were combined i.e defaults, treatment failure and others previously treated. Univariate logistic regression was done for all the socio demographic characteristics to find the predictors for relapse

Results

The present study was conducted among 193 study subjects. Among them 168 (87%) were having pulmonary TB and remaining 25 (13%) were having extra pulmonary TB.

In the present study, majority of the study participants were Relapse patients 125(64.9%), Defaulters were 12 (6.2%), Treatment failure were 9 (4.6%) and Others previously treated were 47 (24.3%).

Table 1: Socio demographic details of study participants:

Socio demographic variable	Number	Percentage
Gender		
Male	141	73%
Female	52	27%
Socio economic status		
Lower	20	10.3%
Upper lower	129	66.9%
Lower middle	26	13.5%
Upper middle	18	9.3%
Social status		
BC	124	64.2%
OC	30	15.5%
SC	35	18.1%
ST	4	2.1%

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Religion		
Hindus	174	90.1%
Christians	14	7.3%
Muslims	5	2.6%
Marital status		
Married	160	82.9%
Unmarried	30	15.5%
Separated	3	1.6%
Education status		
Illiterate	99	51.3%
Up to class 10	69	35.7%
Above class 10	25	13%

Table 1 shows that among 193 study participants, 141 (73%) were males where as only 52 (27%) were females. The age of the study population ranged from 19 to 76 years. The mean age of study population 43.92 ±13.9 years. Mean age of males was 46.33 ± 12.4

years. Mean age of Females was 37.4 ± 15.6 years. On unpaired t test, difference between mean age of males and females was found to be statistically significant. (t value 4.09, p value- 0.000). Among study participants, 90 (46.7%) were in the age group of 41 - 60 years. More than half of the male study participants were in the age group of 41 - 60 whereas more than half of the female study participants were in the age group of 21- 40years

Majority of the study participants i.e 129 (66.9%) belonged to upper lower class and no study participants were in upper class. Regarding social status of the study population, 124 (64.2%) belonged to BC class. Based on religion among the study population, 174 (90.1%) were Hindus. Regarding marital status of the study participants, 160(82.9%) was married. In the present study 99 (51.3%) subjects were illiterates.

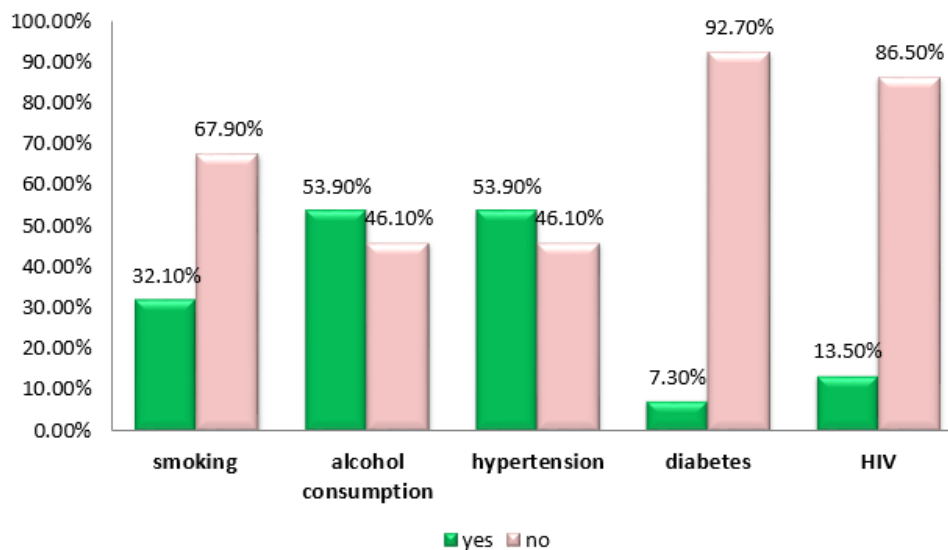


Figure 1: Distribution of Study subjects based on behavioural practices and co morbid conditions.

Smoking was present in 62 (32.1%) of the study subjects and among males 60 (42.5%) were smoking and among females 2 (3.8%) were smoking. On statistical analysis smoking was found to be significantly associated with male retreatment subjects. (Chi square value 26.1, p value 0.000). As the cell size in female smoking is less than 5.

The study shows that 104 (53.9%) of the study subjects were consuming alcohol and among males 101 (71.6%) of them and 3 (5.7%) of females were consuming alcohol. Association of alcohol

consumption with males was found to be highly statistically significant (chi square value 66.3, p value 0.000).

The study shows that 14 (7.3%) of the study subjects were hypertensive. The prevalence of Diabetes Mellitus in the study participants was found to be 13.5%. Among the total study participants, 8 (4.1%) of them were having HIV

Among total study participants, 80(56.8%) of males were underweight, 60(42.5%) were normal and

1(0.7%) were obese. Among females 22(42.3%) were underweight, 25(48.1%) were normal and 5 (9.6%) were obese.

Table 2: Distribution of study participants based on socio demographic Characteristics, behavioural and co morbid risk factors among Relapse and Non Relapse:

Characteristics	Relapse (n=125)n(%)	Non relapse (n=68)n(%)	Crude odds ratio	95% CI	P value
Gender					
Male	95(67.3%)	46(32.7%)	1.5	0.7 – 2.9	0.2
Female	30(57.6%)	22(42.4%)			
Age					
< 45	58(58%)	42(42%)	1.8	1.02 – 3.4	0.04
≥45	67(72%)	26(28%)			
Socio economic status					
Upper lower & lower	99(66.4%)	50(33.6%)	0.7	0.3-1.4	0.37
Upper middle & lower middle	26(59.1%)	18(40.9%)			
Marital status					
Married	104(65%)	56(35%)	0.9	0.4 – 2.05	0.88
Unmarried & Separated	21(63.6%)	12(36.4%)			
Education					
Literates	70(70.7%)	29(29.3%)	0.58	0.3 – 1.06	0.07
Illiterates	55(58.5%)	39(41.5%)			
Smoking					
Yes	46(74.2%)	16(25.8%)	1.8	0.9 – 3.6	0.059
No	79(60.3%)	52(39.7%)			
Alcohol					
Yes	74(71.1%)	30(28.9%)	1.83	1.01 – 3.3	0.045
No	51(57.3%)	38(42.7%)			
Hypertension					
Yes	11(78.5%)	3(21.5%)	2.09	0.5 – 7.7	0.26
No	114(63.7%)	65(36.3%)			
Diabetes					
Yes	18(69.2%)	8(30.8%)	1.2	0.5 – 3.07	0.6
No	107(64%)	60(36%)			

The age group ≥ 45 years was found to be associated with relapse and which was statistically significant. Being male was also found to be associated with Relapse but was not found to be statistically significant. On Univariate analysis alcohol consumption was found to be significantly

associated with relapse (OR – 1.83, 95% CI 1.01 – 3.3, p value – 0.045). Smoking, Hypertension and Diabetes were also found to be associated with relapse but was not statistically significant.

Discussion

Retreatment cases represent a serious threat to TB control in many settings and could significantly undermine the overall success of the DOTS strategy. It is a matter of concern as cases who fail treatment also infect others, which may be resistant to the first line drugs. In this study, the most common indication for retreatment among the study subjects were relapse (64.9%) followed by others (24.3%), defaults (6.2%) and treatment failure (4.6%). Sreelatha et al¹³ also reported similar findings where relapses were 51.76%, treatment after default were 9.65%, failure cases were 5.57% and others were 33.02%. In contrast to our study Giri Prasad et al¹⁴ study reported that default cases were more i.e 42.3%. The possible reasons for retreatment patients may be due to ignorance and inadequate knowledge about tuberculosis and importance of appropriate tuberculosis treatment.

In the present study of the total 193 population 141 (73%) were males and 52 (27%) were females. Study conducted by Santha T et al¹⁵ in Tiruvallur district showed that 75% of the study population were males 25% were females.

The mean age of males and females in the present study were 46.33 ± 12.4 and 37.4 ± 15.6 years, (on unpaired t test difference of means was statistically significant) which was similar to Sarpalet al¹⁶ study which was done among retreatment patients where there was a significant difference in the mean age of males and females.

Similar to this study, Katiyar K S et al¹⁷ study done among failure category II patients found that most of the cases were from lower socio economic strata and to them earning was more important than spending time at DOTS centre for treatment. The more prevalence in low socio economic class might be due to ignorance, poverty and closed proximity of positive cases in vicinity as well as within the family.

In the present study, 104 (53.9%) of the study subjects were consuming Alcohol and most of them were males and this association was found to be statistically significant. Susan et al¹⁸ reported that a significant relation between alcohol consumption and pulmonary tuberculosis in their study.

Retreatment cases pose a serious challenge to the

TB elimination program. Counselling must be given by the health personnel regarding the duration and benefits of treatment initiation before start of anti TB treatment. Health education must be provided to the retreatment tuberculosis patients to increase their awareness about aetiology of tuberculosis, its modes of transmission and importance of appropriate treatment so as to reduce unsuccessful treatment outcomes.

Conclusion

An analytical cross-sectional study was conducted to assess epidemiological profile of previously treated patients and to look for socio demographic characteristics, behavioural and co morbid factor associated with Relapse. Relapse cases are the most common cause for Retreatment which may be indicative that the present treatment regimens of RNTCP need to be relooked. The study indicates that socio demographic factors, behavioural and co morbid factors have an effect on Relapse and modifying these risk factors may bring about favourable outcomes.

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Conflict of interest: None declared

Ethical approval: The study was approved by the institutional ethics committee.

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