



## Alcohol Use in Tuberculosis Patients their Treatment Outcomes: A Cross Sectional Study

Authors

Harshvardhan Singh, Anita Thakur, Salig Ram Mazta, Tripti Chauhan  
IGMC, Shimla

### ABSTRACT

**Background:** India has the most number of TB cases among the six countries that account for 60 per cent of total cases worldwide. To progress towards the global goals of elimination, it is vital to understand the factors which can influence the outcome of treatment. The objectives of the present study were to learn about the socio-demographic characteristics of the subjects and to study the factors influencing treatment outcomes in the TB patients.

**Methods:** A Cross-sectional study design was employed and all patients (n=117) who were registered for Category I DOTS during the last quarter of 2015 were included after obtaining written informed consent. Patients were visited at their homes for interviews to note socio-demographic and environmental characteristics and secondary data analysis was done to note the outcomes. Univariate and binary logistic regression models were employed.

**Results:** The overall treatment success rate was 93.2% (Cure rate= 87%, treatment completion rate= 100%). Default, death, failure and lost to follow up rates were 2.6%, 2.6%, 0.8% and 0.8% respectively. Those with a history of alcohol use [OR: 6.13 (1.57-23.93); p=0.01], tobacco smoking [OR: 6 (1.27-28.37) and indoor air pollution [OR: 7.89 (1.10-62.13); p=0.02] and p=0.02] had higher odds of developing unfavourable treatment outcomes.

**Conclusion:** The study observed alcohol use, tobacco smoking and indoor air pollution to be associated with adverse outcomes. Health education regarding the ill effects of these with regards to the disease preventability and curability needs to be further intensified to bring a change the firmly embedded social behaviour so that the goals set for global TB control are met.

**Keywords:** Tuberculosis, Treatment outcomes, alcohol.

### INTRODUCTION

Worldwide in 2015, there were an estimated 10.4 million incident TB cases. India is now the country with the highest burden of TB disease in the world and the rate of its progress in TB control will have a major influence on whether the global milestones are achieved.<sup>1</sup>

Complete cure is the most desirable outcome for an individual suffering from a disease whereas continued or recurrent morbidity, disability and mortality are the un-favourable outcomes which limit the effectiveness of treatment or a health programme. Various factors are known to influence the treatment outcomes of a disease in

varying socio-demographic conditions and these need to be studied extensively for planning improvements in various components of the health care delivery system.

Historically, TB has been used as a prime example of a “social disease”, the control of which requires social, economic and environmental interventions.<sup>2</sup> Harmful use of alcohol increases the risk of TB threefold, and is also a strong risk factor for poor TB treatment adherence.<sup>3</sup>

Shimla is the third most populous district of Himachal Pradesh (out of 12), after Kangra and Mandi with a population of 0.8 million out of the total state's population of about 7 million. As per the 2011 census, the aggregate male and female literacy rates were 95.75% and 93.35% respectively.<sup>4</sup> In 2015 13,932 new cases of Tuberculosis were registered in the state out of which 1267 were registered in district Shimla.<sup>5</sup>

Understanding the local epidemiology will help in formulating appropriate control strategies at the basic level. Hence, the present study was undertaken with the objectives of studying the socio-demographic profile of patients, the magnitude and determinants of treatment outcomes of TB among the patients registered under RNTCP.

## MATERIALS & METHODS

A Cross-sectional study design was employed and the Tuberculosis patients initiated on Category I DOTS in the fourth quarter of 2015 who gave informed consent/assent at the included Tuberculosis units were enrolled for the study. The cases already diagnosed with Immuno-deficiency disorders or on corticosteroids were excluded.

Assuming a two-sided significance level of 95% and a power of 80%; assuming the percentage of un-exposed with favourable outcomes to be 90% and of exposed with favourable outcomes to be 80% and non-response rate of 10%, the sample size was calculated to be 117.

Primary data on various attributes was collected during house visits in the included Tuberculosis units for which a predesigned, pretested, semi-structured schedule was used. Secondary data was

collected from the TB registers at DTO office during scheduled follow-up till the treatment outcomes appeared.

After obtaining necessary approval from the Institutional Protocol Committee, The District Tuberculosis Officer and concerned authorities, the characteristics of individual patients were observed while no reinforcement was given. The patients were managed as per the programme protocol. The factors related to treatment outcomes as per the WHO were studied in each patient in detail as per the predetermined outcome and explanatory variables.

The data was double entered into Epidata and analysed using Epi Info 7 software. Qualitative data was expressed in percentages with 95% confidence intervals. Quantitative data was expressed in Mean  $\pm$  Standard deviation (SD). Chi-square / Fisher's Exact test was used for qualitative variables. Odds' Ratios (OR) with 95% Confidence intervals (CIs) were calculated as the measures of association.

## RESULTS

Out of the total study subjects i.e. 117, 74.4% and 25.6% were registered at TU-1 and TU-2 respectively. The type of TB was Pulmonary in the majority of cases (58.1%). The present study has observed an almost equal male: female ratio i.e 1.06:1. The mean age of the patients was  $36.4 \pm 16.8$  years. The mean age in males was  $36.8 \pm 14.7$  years and in females it was  $36.1 \pm 18.7$  years. The maximum numbers of the patients were qualified up to senior secondary level 11.1% were illiterate. 10.2% of the patients were unemployed. Out of the females, 60.3% were housewives. Majority of the patients (49.6%) belonged to nuclear families. Overcrowding was not observed in the majority of the patients while a considerable number were exposed to inadequate ventilation (46.1%).

21.3% of the patients were alcohol users of which none was a female. 72% of the alcohol users reported quitting after the diagnosis was known to them while 28% reported continuation of the

habit. 33.3% of the patients were classified as current smokers out of which only one was a female. A per WHO classification, the maximum number of patients were new sputum smear positive (46.1%), followed by Extra-pulmonary (41.9%) and new sputum smear negative (12%). Pleural effusion was the commonest type of Extra-pulmonary TB, out of which right sided effusion was the commonest (47.8%).

Of the total, favourable treatment outcomes (Cured+ treatment completed) were achieved in 93.2% of the patients and 6.8% had adverse outcomes. 2.6% died, 2.6% defaulted, 0.9% were declared as failure and 0.9% were lost to follow up.

Higher default and death rates were observed in the middle socio-economic class patients who were 43.6%. Low treatment success rates were observed in the patients exposed to inadequate ventilation (90.7%). Alcohol users had a higher risk of developing adverse outcomes [RR: 6.13 (1.57-23.93); p=0.01] over non-users. Lower favourable outcomes were observed in those with a history of tobacco smoking who had higher risk of adverse outcomes [RR: 6 (1.27-28.37); p=0.02] as compared to non-smokers, those exposed to second hand smoke [RR: 8.75 (1.11-68.88); p=0.02] & indoor air pollution [RR: 7.89 (1.10-62.13); p=0.02] had higher risk as compared to those who were not exposed. All these results were statistically significant.

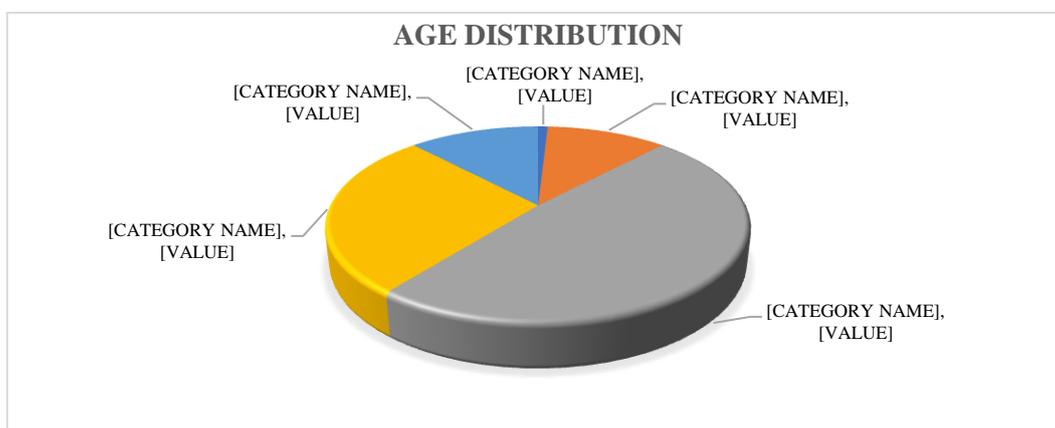


Figure I: Distribution of study subjects (n=117) by age

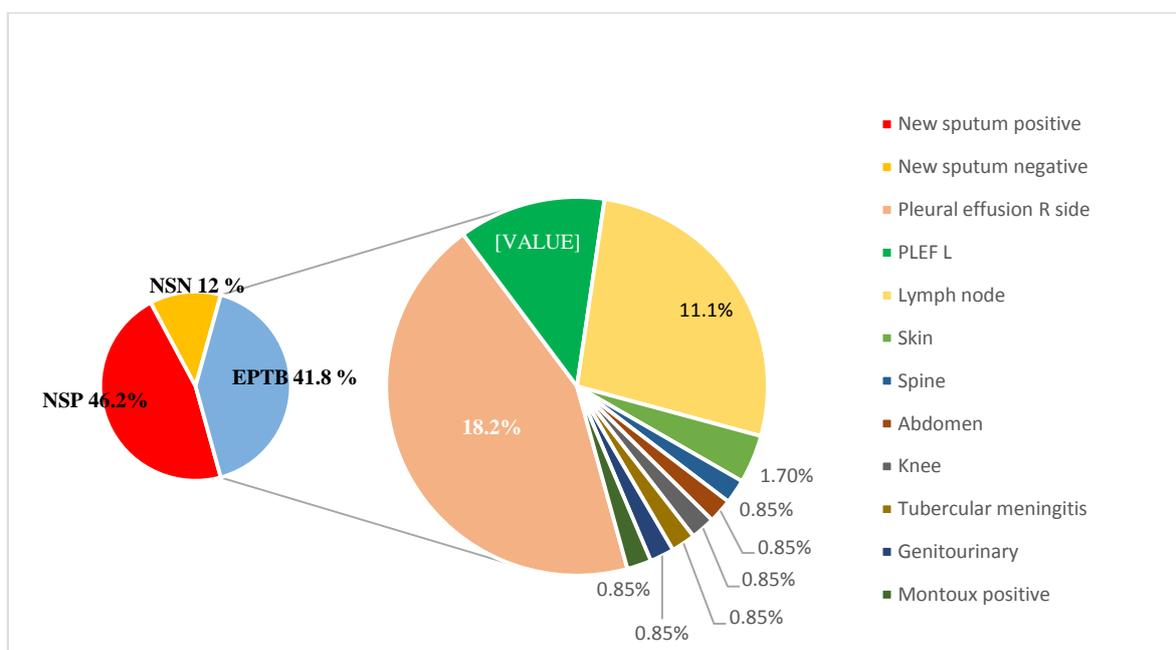


Figure II: Site distribution of Extra-pulmonary TB

**Table 1:** Associations between ADVERSE TREATMENT OUTCOMES and socio-demographic & clinical characteristics among new Drug- susceptible TB patients

Characteristics	Adverse outcome N (%)	Favourable outcome N (%)	Odds Ratio (95% CI)	p value
Total patients (n=117)				
Sex				
Male	6 (10.2)	53 (89.8)	2.9 (0.62 - 14.02)	0.17
Female	2 (3.5)	56 (96.5)	1	
Age groups				
≥ 40	5 (10.9)	41 (89.1)	2.57 (0.64 - 10.25)	0.19
< 40	3 (4.2)	68 (95.8)	1	
Type of TB				
Bacteriologically confirmed TB	6 (11.2)	48 (88.8)	6.89 (0.86 - 55.43)	0.05
Clinically diagnosed TB	2 (3.2)	61 (96.8)	1	
Alcohol use				
Present	5 (20)	20 (80)	6.13 (1.57 - 23.93)	0.01*
Absent	3 (3.3)	89 (96.7)	1	
Smoking tobacco status				
Smokers	6 (15.4)	33 (84.6)	6.0 (1.27 - 28.36)	0.02*
Non-smokers	2 (2.6)	76 (97.4)	1	
Indoor air pollution				
Present	7 (12.8)	48 (87.2)	7.89 (1.10- 62.13)	0.02*
Absent	1 (1.6)	61 (98.4)	1	

## DISCUSSION

The present study was carried out to understand the local epidemiology of TB i.e. the magnitude and determinants of adverse treatment outcomes in two TUs among the registered cases of TB on Category I of DOTS during the last quarter of 2015.

Among the 117 patients studied, an almost equal male: female ratio i.e 1.06:1 was observed. Male to female ratio of TB cases reported to the WHO is around 1.5-2.1 in all regions of the world (WHO 2000). TB prevalence is significantly higher among men than women in low- and middle-income countries.<sup>6</sup>

A WHO technical meeting at Cape Town in July 2008 concluded that there was sufficient evidence for a causal impact of alcohol on TB incidence and on worsening the disease.<sup>7</sup> A systematic review to assess the association between alcohol use, alcohol use disorders and Tuberculosis (TB) found that heavy alcohol use strongly influences both the incidence and the outcome of the disease and was found to be linked to altered pharmacokinetics of medicines used in treatment of TB, higher rate of re-infection, higher rate of

treatment defaults and development of drug-resistant forms of TB.<sup>8</sup> Regarding the course of the disease, there is sufficient evidence indicating that heavy alcohol consumption disrupts medication intake regimens and negatively affects help-seeking and treatment processes, leading to worse treatment outcomes compared to abstinence.<sup>9</sup>

A longitudinal study done in India found that the hazard for unsuccessful outcome was significantly higher among patients who consumed alcohol during treatment (adjusted hazard ratio, 4.3; 95% CI, 1.1-17.6) than those who did not. The hazard for unsuccessful outcome was significantly higher among patients who consumed alcohol during treatment (adjusted hazard ratio, 4.3; 95% CI, 1.1-17.6) than those who did not.<sup>10</sup>

Tuberculosis and tobacco smoking are both global public health threats. Innumerable studies have established significant associations between tobacco smoking, prevalence of TB and adverse outcomes<sup>11,12,13</sup> and have concluded that smoking roughly doubles the risk of tuberculous infection, active TB disease and death.<sup>14</sup>

In this study too, higher adverse outcomes were observed in those with a history of alcohol use and

tobacco smoking which usually go hand in hand. The results can be attributed to the social acceptance of alcohol and lack of insight regarding the hazards of drinking. The trends of smoking observed despite a nation-wide campaign and legislations also indicate towards a hard to change social behaviour.

## CONCLUSION

The present study shows significant associations of adverse treatment outcomes with alcohol and tobacco smoking reiterating the age old 'social disease' status of Tuberculosis. Health education regarding the ill effects of alcohol and tobacco smoking with regards to the disease preventability and curability needs to be further intensified to ultimately bring about a change in the firmly embedded social behaviour. Mass education regarding the importance of proper ventilation and avoidance of indoor air pollution also needs further strengthening to achieve the Sustainable development goals set for TB control.

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