Original Research Article

Tobacco smoking trends and treatment outcomes in Tuberculosis patients of district Shimla, Himachal Pradesh, India: a cohort study

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ABSTRACT

Background: India carries the highest burden of tuberculosis worldwide. To achieve the goals of the ‘END TB’ strategy, it is imperative to understand the factors which can influence the treatment outcomes. The objectives were to study the socio-demographic characteristics of the subjects and to study the factors influencing treatment outcomes in the TB patients.

Methods: A prospective cohort 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. Home visits with patient interviews were conducted to collect information on determinants. 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 tobacco smoking [RR: 6 (1.27–28.37); p=0.02], 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] and alcohol use [RR: 6.13 (1.57–23.93); p=0.01] had higher risks of developing unfavourable treatment outcomes. The commonest cause of indoor air pollution was smoke surfacing out of fire-wood used for cooking and tobacco.

Conclusions: The treatment success rates conform to the END TB strategy targets of 90%. Tobacco smoking, second hand smoke, indoor air pollution and alcohol intake were associated with adverse outcomes. Health education regarding the ill effects of tobacco and alcohol with regards to the disease preventability and curability needs to be further intensified. Larger studies to determine the effect of indoor air pollution as a risk factor and its impact on treatment outcomes by contemporary scientific methods by collaborating with other agencies involved in environmental studies is highly recommended.

Keywords: Tuberculosis, Treatment outcomes, Tobacco, Indoor air pollution

INTRODUCTION

Worldwide in 2015, there were an estimated 10.4 million incident TB cases.¹ 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.¹ Complete cure is the most desirable outcome for an individual suffering from a disease whereas continued or recurrent morbidity, disability and mortality are the unfavourable 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 needs
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. TB is nearly always curable if the patients are treated with effective and uninterrupted anti-tuberculosis therapy. The paramount goal of TB-control programs is to ensure that TB patients adhere to and complete their prescribed course of therapy.

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.

In 2015, 13,932 new cases of tuberculosis were registered in the state out of which 1267 were registered in district Shimla.

To achieve the goals of END TB strategy and a TB free India it is imperative to understand the determinants of these adverse treatment outcomes. Moreover, understanding the local epidemiology will help in formulating appropriate control strategies at local 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.

METHODS

A Community based prospective cohort study was carried out from October 1, 2015 to September 30, 2016. All the newly registered pulmonary 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 and followed up at two occasions till the treatment outcome of the last enrolled patient was available. 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. Keeping in view the average registration of Category I treatment in the previous year, two tuberculosis units were enrolled for study out of the eight TUs by simple random sampling.

Primary data on various attributes was collected during the first personal contact with the patients from the included tuberculosis units. Secondary data was collected from the records of the TUs during scheduled follow-up till the treatment outcomes appeared. A predesigned, pretested, semi structured schedule was used.

After obtaining necessary approval from the Institutional Protocol Committee, The District Tuberculosis Officer and concerned authorities, individual patients were visited at their households to study the environmental factors and collect necessary data. 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±Standard deviation (SD). Chi-square/Fisher’s Exact test was used for qualitative variables. Risk ratios (RR) with 95% confidence intervals (CIs) were calculated as the measures of association. Variables found to be statistically significant in bivariate analysis were included in a multivariate model; adjusted risk ratios were calculated to assess the independent effects of each variable while the level of significance was set at 5%.

RESULTS

The present study has observed an almost equal male: female ratio i.e. 1:06:1 while the maximum proportions of cases were from the 20-39 age group (48.7%). The treatment success rate was 93.2%; 95% CI (88.6-97.8%). 0.9% were declared as failure. The default rate was 2.6%; 95% CI (0.3-5.5%) and the death rate was 2.6%; 95% CI (0.3-5.5%). The cure rate among NSP patients was recorded to be 87% (78-96%) and treatment completion rate was 100% among the NSP and EPTB cases. The maximum treatment success was achieved in the 20-39 years age group (96.5%) which had a 3.5% default rate while the maximum death rate was observed in the ≥60-year age group. Maximum success rates were observed in the student group (100%) while maximum default (7.7%) and death rates (7.7%) were observed in the illiterate group. Higher treatment success rates were observed in those living in nuclear families (96.6%) and in those who were unmarried (97.8%). The present study has observed excellent adherence rates. 2.6% missed 33.3% of their due doses and the most common reason was achieving a symptom free status or feeling better. The present study has found the prevalence of tobacco smoking among the TB patients to be 33.3% (95% CI=24.76% to 41.84%). While 39 (66%) of the males were current smokers and three were quitters (5%), only one out of the 58 females was a smoker (1.7%).

Those exposed to indoor air pollution (47%) had higher risk of developing adverse outcomes [RR: 7.89 (1.10-62.13); p=0.02] as were those who were exposed to
second hand smoke as compared to those who were not [RR: 8.75 (1.11-68.88); p=0.02]. Higher adverse outcomes were observed in those with a history of tobacco smoking [84.6%; RR: 6 (1.27-28.37) p=0.02] and in those with a history of alcohol use [80%; RR: 6.13 (1.57-23.93); p=0.01].

**Figure 1: Categorisation as per World Health Organisation.**

**Figure 2: Categorisation as per site of extrapulmonary tuberculosis.**

**Table 1: Associations between adverse treatment outcomes and socio-demographic and clinical characteristics among new drug-susceptible TB patients.**

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Adverse outcome* N (%)</th>
<th>Favourable outcome† N (%)</th>
<th>Risk ratio (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total patients (n=117)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>6 (10.2)</td>
<td>53 (89.8)</td>
<td>2.9 (0.62 - 14.02)</td>
<td>0.17</td>
</tr>
<tr>
<td>Female</td>
<td>2 (3.5)</td>
<td>56 (96.5)</td>
<td></td>
<td></td>
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<tr>
<td><strong>Age groups</strong></td>
<td></td>
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<tr>
<td>≥40</td>
<td>5 (10.9)</td>
<td>41 (89.1)</td>
<td>2.57 (0.64 - 10.25)</td>
<td>0.19</td>
</tr>
<tr>
<td>&lt;40</td>
<td>3 (4.2)</td>
<td>68 (95.8)</td>
<td></td>
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<tr>
<td><strong>Type of TB</strong></td>
<td></td>
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<tr>
<td>Bacteriologically confirmed TB</td>
<td>6 (11.2)</td>
<td>48 (88.8)</td>
<td>6.89 (0.86 - 55.43)</td>
<td>0.05</td>
</tr>
<tr>
<td>Clinically diagnosed TB</td>
<td>2 (3.2)</td>
<td>61 (96.8)</td>
<td></td>
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<tr>
<td><strong>Smoking tobacco status</strong></td>
<td></td>
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</tr>
<tr>
<td>Smokers</td>
<td>6 (15.4)</td>
<td>33 (84.6)</td>
<td>6.0 (1.27 - 28.36)</td>
<td>0.02*</td>
</tr>
<tr>
<td>Non-smokers</td>
<td>2 (2.6)</td>
<td>76 (97.4)</td>
<td></td>
<td></td>
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<tr>
<td><strong>Second hand smoke exposure</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Present</td>
<td>7 (13.5)</td>
<td>45 (86.5)</td>
<td>8.75 (1.11 - 68.87)</td>
<td>0.01*</td>
</tr>
<tr>
<td>Absent</td>
<td>1 (1.5)</td>
<td>64 (98.5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Indoor air pollution</strong></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Present</td>
<td>7 (12.8)</td>
<td>48 (87.2)</td>
<td>7.89 (1.10 - 62.13)</td>
<td>0.02*</td>
</tr>
<tr>
<td>Absent</td>
<td>1 (1.6)</td>
<td>61 (98.4)</td>
<td></td>
<td></td>
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<tr>
<td><strong>Alcohol use</strong></td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>Present</td>
<td>5 (20)</td>
<td>20 (80)</td>
<td>6.13 (1.57 - 23.93)</td>
<td>0.01*</td>
</tr>
<tr>
<td>Absent</td>
<td>3 (3.3)</td>
<td>89 (96.7)</td>
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</table>

**DISCUSSION**

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. A review article summarizing studies from the 1920s through the 1950s showed that nurses, physicians, and others working with tuberculosis patients had high rates...
of positive skin tests or skin test conversions compared to the rates expected in the broader community. In the present study, 1.7% were nursing students who were residing in a hostel and had contracted pleural effusion.

![Figure 3: Treatment outcomes among new drug susceptible tuberculosis patients on category I DOTS at TUs Mashobra and Chirgaon registered during October-December, 2015 (n=117).](image)

Various international and Indian studies have found positive associations between overcrowding and poor ventilation with higher prevalence of TB. In the present study, a considerable number of patients were exposed to inadequate ventilation [54 (46.1%)] while overcrowding was not observed in the majority of the patients [6 (5.1%)].

Indoor air pollution arising as a result of firewood smoke emissions from household “chullahs” has been recognised as an independent risk factor for TB in various studies. The present study has found second hand tobacco smoke exposure to be present in 44.8% of the patients and exposure to indoor air pollution in 47% of the households which was mostly due to indoor tobacco smoking and use of firewood and kerosene for cooking and heating. No significant associations were established with the types of TB (p=0.85).

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.

Various studies in India and abroad have found significant associations between tobacco smoking and prevalence of TB and have concluded that smoking roughly doubles the risk of tuberculosis infection, active TB disease and death. The present study has found the prevalence of tobacco smoking among the TB patients to be 33.3% (95% CI=24.76% to 41.84%). While 39 (66%) of the males were current smokers and three were quitters (5%), only one out of the 58 females was a smoker (1.7%). No significant associations were noted between smoking status and the type of TB. (76.9%) of the current smokers reported to smoke more than a pack of cigarettes or bidis per day and confessed to have quit the habit after getting the symptoms or being aware of the diagnosis. 23.1% of the smokers continued to smoke even after being aware of the diagnosis though the number of cigarettes/bidis smoked were lesser in number than earlier. The trends of smoking observed despite a nationwide campaign and legislations indicate towards a hard to change social behaviour.

Prevalence of alcohol use disorders among TB patients have ranged from 10% to 50% as per various international and a recent Indian study. The present study has observed a prevalence of alcohol use among TB patients to be 20.5% (95% CI=13.18% to 27.82%) and all of them were males. However, no significant associated was noted between alcohol use and the type of TB.

Highest treatment success rates were achieved in the new sputum negative patients (100%) followed by extra-pulmonary (95.8%) and new sputum positive patients (87%).

The results are concordant with the global priority indicators and targets for monitoring the implementation of the end TB strategy (2015-2025) which have set the target of achieving 90% treatment success rate.

The present study has observed excellent adherence rates, 2.6% missed 33.3% of their due doses and the most common reason was achieving a symptom free status or feeling better. A study conducted outside India established that 29.8% of TB patients failed to comply with TB drug taking regimen once they started feeling better. Excellent adherence rates ultimately leading to successful treatment outcomes can be attributed to the self-motivation of patients complemented by regular follow-up by the programme staff.

Household air pollution use is an important risk factor for TB, especially among adult women who are primary cooks in India using biomass fuel for cooking and are also exposed to tobacco smoke. This study has also found the proportion of housewives to be high (60.3%) indicating a higher susceptibility of acquiring the infection. A very recent Indian study has found indoor air pollution to be independently associated with adverse TB treatment outcomes [AOR: 3.66 (1.46–9.18); p=0.006].

In our study, those exposed to indoor air pollution (47%) had higher risk of developing adverse outcomes and those exposed to second hand smoke had higher risk of developing adverse outcomes as compared to those who were not. The results indicate that the knowledge about the ill effects of second hand smoke and indoor air pollution is still a grey area in TB control and need to be further explored.

In this study, higher adverse outcomes were observed in those with a history of tobacco smoking. 76.9% of the current smokers reported to smoke more than a pack of cigarettes or bidis per day and confessed to have quit the habit after getting the symptoms or being aware of the
diagnosis. 23.1% of the smokers continued to smoke even after being aware of the diagnosis though the number of cigarettes/bidis smoked were lesser in number than earlier. The trends of smoking observed despite a nationwide campaign and legislations indicate towards a hard to change social behaviour.

Our study observed higher adverse outcomes in alcohol users. The results can be attributed to the social acceptance of alcohol and lack of insight regarding the hazards of drinking.

No significant difference was observed in the patients experiencing different adverse effects. Side effects had no direct bearing on treatment outcomes, indicating that minor side effects were taken care of and adherence was maintained. Self-motivation of the patients complemented by the effective education and communication may be the most likely reasons for achieving 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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