Study of treatment outcomes in tuberculosis patients on DOTS therapy at five centres in Goa

Dilip D. Motghare, Geetanjali M. Sardessai, Frederick S. Vaz*, Manoj S. Kulkarni

Department of Preventive and Social Medicine, Goa Medical College, Bambolim, Goa, India

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*Correspondence:
Dr. Frederick S. Vaz,
E-mail: frederickvaz@rediffmail.com

ABSTRACT

Background: The objective was to study the treatment outcomes in tuberculosis patients on DOTS therapy in five centres in Goa in terms of cure rates, treatment completion rates, unfavourable outcomes and factors responsible for unfavourable outcomes.

Methods: Study setting: It was a facility based study at five DOTS centres from the Panaji Tuberculosis Unit (TU). Study design: prospective follow up design was used for the study. Study subjects: All patients registered at the selected five DOTS centres for DOTS therapy under RNTCP in the period from 1st April 2011 to 31st December 2011 were selected as study subjects and followed prospectively for a period of nine months till 30th September 2012. Study instruments: data was collected from patients by personal interview and a pretested structured questionnaire. Data was also obtained from patient treatment cards and by interviewing the DOTS provider. Statistical analysis: Data was analysed using SPSS software. The statistical tests used were frequencies, descriptive, Chi square test, odds ratio and logistic regression analysis.

Results: Overall 42.9% of the patients were declared cured, 42.3% had treatment completed as the outcome, 4.9% were defaulters, 2.7% patients died, 2.2% were classified as treatment failure, 1.6% were transferred out and 0.5% of the patients were shifted to Non-DOTS treatment regimen while in 2.7% of the patients treatment outcome was not available. Presence of diabetes mellitus, hypertension and alcohol use were found to be significantly associated with unfavourable outcomes in Tuberculosis patients on DOTS.

Conclusions: Patients with alcohol addiction and concomitant hypertension were found to have higher levels of unfavourable outcomes; therefore such patients require continuous monitoring and support to ensure treatment success.

Keywords: Tuberculosis, DOTS, Outcomes, Treatment

INTRODUCTION

Tuberculosis is the world’s foremost cause of death from a single agent with nearly 90 million new cases and 30 million deaths annually.1

The economic impact of the disease by way of direct and indirect costs to patients in lost income is enormous. An increasing number of cases converting to multi drug resistant tuberculosis could escalate these costs dramatically.

In 2009, out of the estimated global annual incidence of 9.4 million tuberculosis cases, two million were supposed to have occurred in India, contributing to a fifth of the global burden of tuberculosis.2 Revised National Tuberculosis Control Programme (RNTCP) was evolved with the objective of laying emphasis on cure of infectious cases through administration of Directly Observed Therapy of Short course chemotherapy (DOTS). RNTCP in India is perhaps the most important public health intervention of the last decade of the 20th century.3
The Revised National Tuberculosis Control Programme (RNTCP) has been implemented in the state of Goa since 2004 and the population covered under the programme is around fifteen lakhs. This study was aimed at assessing to what extent the objectives of RNTCP programme have been met & is aimed at gauging strength and weaknesses of programme, in order to help to take appropriate measures for successful implementation of programme.

METHODS

The present study was carried to study the treatment outcomes in tuberculosis patients on DOTS therapy in five centres in Goa in terms of cure rate, treatment completion rates, unfavourable outcomes and factors responsible for unfavourable outcomes.

Study setting

It was a facility based study at five DOTS centres from the Panaji Tuberculosis Unit (TU).

Study design

Prospective follow up design was used for the study.

Study subjects

All patients registered at the selected five DOTS centres for DOTS therapy under RNTCP in the period from 1st April 2011 to 31st December 2011 were selected as study subjects and followed prospectively for a period of nine months till 30th September 2012. A total of 206 patients were registered at the five centres during the study period out of which 182 consented and were recruited in the study.

Study instruments

Data was collected from patients by personal interview and a pretested structured questionnaire. Data was also obtained from patient treatment cards and by interviewing the DOTS provider.

Statistical analysis

Data was analysed using SPSS software. The statistical tests used were frequencies, descriptive, Chi square test, odds ratio and logistic regression analysis.

Ethical clearance

Approval from the institutional ethics committee was obtained to conduct the study.

RESULTS

Out of the 182 study participants undergoing DOTS therapy in five DOTS centres 41.8% were in the age group of 20-39 years followed by 37.4% in the age group of 40-59 years. Around 10.9% were less than 20 years of age while 9.9% were more than 60 years old. Male patients comprised 60.4% of the study participants while female participants constituted the remaining 39.6%. As far as religion wise distribution is concerned 82.4% of the TB patients on DOTS were Hindu by religion, 8.8% were Christians and 7.7% were Muslims.

About 40.7% of the participants had 10-15 years of schooling, 34.1% had 5-10 years of schooling, 17.1% had more than 15 years of schooling, and 17% had less than five years of schooling while, 1.1% of participants were illiterate. As regards the socioeconomic status of the patients 47.3% belonged to lower middle class, 39% to upper lower, 7.1% to upper middle class, 3.9% to lower class and 1.6% to upper class according to BG Prasad classification.

As far as site of tuberculosis was concerned 66.5% of patients had pulmonary tuberculosis, 31.9% had extra-pulmonary TB while 1.6% had combination of pulmonary and extra-pulmonary TB. As far as type of Tuberculosis cases was concerned 75.8% were new cases, 13.2% were relapse cases, 5.5% were treatment after default, and 2.2% were failure cases.

The treatment outcomes in tuberculosis patients in the five DOTS centres are given in Table 1. Overall 42.9% of the patients were declared cured, 42.3% had treatment completed as the outcome, 4.9% were defaulters, 2.7% patients died, 1.6% were classified as treatment failure, 2.2% were transferred out and 0.5% of the patients were shifted to Non-DOTS treatment regimen while in 2.7% of the patients treatment outcome was not available.

<table>
<thead>
<tr>
<th>Treatment outcomes</th>
<th>Number</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cured</td>
<td>78</td>
<td>42.9</td>
</tr>
<tr>
<td>Treatment completed</td>
<td>77</td>
<td>42.3</td>
</tr>
<tr>
<td>Defaulted</td>
<td>9</td>
<td>4.9</td>
</tr>
<tr>
<td>Treatment failure</td>
<td>3</td>
<td>1.6</td>
</tr>
<tr>
<td>Deaths</td>
<td>5</td>
<td>2.7</td>
</tr>
<tr>
<td>Non DOTS</td>
<td>1</td>
<td>0.5</td>
</tr>
<tr>
<td>Transferred out</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Not available</td>
<td>5</td>
<td>2.7</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>182</strong></td>
<td><strong>100</strong></td>
</tr>
</tbody>
</table>

The treatment outcome was further classified as favourable and un-favourable outcomes, favourable outcomes encompassing cured and treatment completed outcomes and un-favourable included the other outcomes like treatment failure, default, death etc.

In around 85.2% of the patients treatment outcomes were found to be favourable (treatment success).
The various factors associated with favourable or unfavourable outcomes are described in Table 2. As far as HIV/AIDS was concerned, among TB patients with HIV/AIDS 80% had favourable outcomes compared to HIV negative patients wherein 85.5% had favourable outcomes (OR=1.5; 95% CI: 0.2-1.9).

### Table 2: Factors associated with treatment outcomes in tuberculosis patients on DOTS.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Unfavourable outcome No. (%)</th>
<th>Favourable outcome No. (%)</th>
<th>OR (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV/AIDS</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Present</td>
<td>2 (20.0)</td>
<td>8 (80.0)</td>
<td>1.5 (0.2-1.9)</td>
<td>0.45</td>
</tr>
<tr>
<td>Absent</td>
<td>25 (14.5)</td>
<td>147 (85.5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Present</td>
<td>8 (30.8)</td>
<td>18 (69.2)</td>
<td>3.2 (1.2-8.5)</td>
<td>0.02</td>
</tr>
<tr>
<td>Absent</td>
<td>19 (12.2)</td>
<td>137 (87.8)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Present</td>
<td>14 (33.3)</td>
<td>28 (66.7)</td>
<td>4.9 (2.06-11.58)</td>
<td>0.000</td>
</tr>
<tr>
<td>Absent</td>
<td>13 (9.3)</td>
<td>127 (90.7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alcohol abuse</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Present</td>
<td>9 (26.5)</td>
<td>25 (73.5)</td>
<td>2.6 (1.03-6.53)</td>
<td>0.037</td>
</tr>
<tr>
<td>Absent</td>
<td>18 (12.2)</td>
<td>130 (87.8)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

A significant association was observed between diabetes mellitus and unfavourable outcome. Among those with diabetes mellitus only 69.2% had a favourable outcome compared to 87.8% among non-diabetics. This difference was found to be statistically significant (OR=3.2; 95% CI: 1.2-8.5). As far hypertension was concerned patients with hypertension had lower favourable outcomes (66.7%) compared to normotensive patients (90.7%). This difference was statistically significant (OR=4.9; 95%CI: 2.06-11.58).

There was a significant association between alcohol abuse and treatment outcome (P = 0.03). TB patients with alcohol addiction were 2.6 times more likely to have unfavourable outcome compared to non-alcoholics. No significant association between tobacco use and treatment outcome was found.

Forward logistic regression was performed to identify factors which are the best predictors of un-favourable treatment outcomes. Hypertension and alcohol abuse were found to be the most significant predictors of unfavourable treatment outcome.

### DISCUSSION

A total of 182 tuberculosis patients on anti-tuberculosis treatment at five DOTS centres were studied.

Overall 42.9% of the patients were declared cured, 42.3% had treatment completed giving a success rate of 85.2%. Defaulter and treatment failure rate were 4.9% and 1.6% respectively.

In a similar study conducted in a chest clinic run by Municipal Corporation of Delhi the success rate was 91% in category I and 73.3% in category II patients respectively, defaulter rate was 7.7% and treatment failure rate was 1.6%. In a study at a teaching hospital in South India treatment success rate was 83.4% which included the outcome of smear negative pulmonary tuberculosis and extra pulmonary tuberculosis.

As far as HIV/AIDS was concerned, among TB patients with HIV/AIDS 80% had favourable outcomes compared 85.5% among HIV negative patients. In a study carried out in South India by Chennaveerapam PK et al one of the reasons for low success rate in DOTS treatment was co-infection with HIV.

A significant association was observed between diabetes mellitus and unfavourable outcome. Among those with diabetes mellitus only 69.2% had a favourable outcome compared to 87.8% among non-diabetics. The relationship between diabetes mellitus and tuberculosis has been explored by the research committee of the tuberculosis association of India. As far hypertension was concerned patients with hypertension had lower favourable outcomes (66.7%) compared to normotensive patients (90.7%). This however is not in concordance with other literature.

TB patients with alcohol addiction were 2.6 times more likely to have unfavourable outcome compared to non-alcoholics. Moharana PR et al. have reported that alcoholism as an important factor for non-compliance to DOTS regimen. Forward logistic regression identified
Hypertension and alcohol abuse as the best predictors of unfavourable treatment outcomes.

CONCLUSION

The study evaluated treatment outcomes in tuberculosis patients on DOTS at five centres in Goa. Over 85% treatment success was found, treatment failure and default rates were within acceptable limits. Patients with alcohol addiction and concomitant hypertension were found to have higher levels of unfavourable outcomes; therefore such patients require continuous monitoring and support to ensure treatment success.

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

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