

ORIGINAL ARTICLE

Evaluation study of treatment outcome in Tuberculosis patients receiving DOTS under RNTCP

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Abstract

Background: Tuberculosis is a global emergency and its control in community wholly depends on outcome of treatment taken by patient. India has 2nd position in total number of cases in World. **Objective:** To evaluate the factors which affect treatment outcome? **Material & Methods:** The study was a follow up study, for treatment outcome of tuberculosis patients receiving DOTS under RNTCP. Data were collected into SPSS version 16 and analyzed using appropriate statistical tests. **Results:** 241 patients were included in the study. Overall treatment success rate was 87.1%, default rate was 4.6%, failure rate was 2.1% and death rate was 6.2 %. Treatment success rate was 91.2% in category I and 70.2% in category II. Failure rate was 0.5% and 8.5%, default rate was 3.6% and 8.5%, death rate was 4.6% and 12 % for category I and category II respectively. In univariate analysis, variable education, occupation, socio-economic status, overcrowding, habit of tobacco consumption, presence of pre-existing illness and category of tuberculosis significantly affect the treatment outcome but on multiple logistic regression analysis education, occupation, habit of tobacco consumption and category of TB had significant effect on treatment outcome. **Conclusion:** Treatment success was 87.1% in present study conclude that DOTs is an effective form of tuberculosis treatment. Education, occupation, socio economic status and overcrowding have significant effect on treatment outcome.

Keywords

Treatment Outcome; Cure; Treatment Completed; Failure; Defaulter

Introduction

In 1990 the World Health Organization report on the Global Burden of Disease ranked tuberculosis as the seventh most morbidity-causing disease in the world, and expected it to continue in the same position up to 2020.(1) WHO declared Tuberculosis a global emergency in 1993.(2) Owing to widespread poverty, inequity and conflict, suboptimal health

services in many countries and the impact of HIV/AIDS pandemic, there are more cases of tuberculosis today than at any previous time in human history.(3)

A National Tuberculosis Programme (NTP) was implemented in 1962 which did not make a measurable impact on the disease situation of TB in the country. Henceforth, India had adopted WHO recommended directly observed treatment short

course (DOTS) strategy under Revised national tuberculosis control programme (RNTCP) for better control of TB in 1992. The revised strategy was introduced in country as pilot project since 1993 in a phase manner and by 2006 entire country was covered under this national programme and phase II of RNTCP has been launched in country from 1st October 2006.(4) Different studies shows, improved communication between DOTS providers, TB patients and community contribute for better case detection, case holding and therapeutic outcome.(5,6)

Once the case of tuberculosis has completed treatment, he is then given any of the six outcomes under RNTCP as cured or treatment completed or died or failure or defaulted or transferred out. A case of tuberculosis can have only one outcome and this is then mentioned in his treatment card.

Aims & Objectives

To study the various treatment outcomes of tuberculosis patients receiving DOTS under RNTCP in urban area of Ujjain, Madhya Pradesh.

Material & Methods

The study is a follow up study about treatment outcome of tuberculosis patients receiving DOTS under RNTCP. Study was conducted at selected DOTS centres located in Ujjain city (M.P.). Two designated microscopy centres (DMCs) selected out of six DMCs in Ujjain city by simple random sampling with the help of computer generated random numbers. These are Ujjain Charitable Trust Hospital (UCTH) and Civil Hospital Madhav Nagar (CHMN).

Study Population: The study population comprised of diagnosed cases of tuberculosis who received treatment under RNTCP at the selected DOTS centres (UCTH & CHMN) of Ujjain during the study period.

Period of Study- The study was conducted from June 2011 to September 2012. Data collection was carried out from June 2011 to Aug. 2012.

Sample Size and Sampling Procedure: Out of 253 TB patients, who were registered in the DOTS centres at the time of study, during 01 June 2011 to 31 Jan. 2012, 241 were included in the study as sample. Rest 12 tuberculosis patients opted to stay out of this study, were excluded. All the subjects were followed up till their treatment was completed (6 months for Cat I and 8 Months for Cat II).

Inclusion criteria:

1. Adult tuberculosis cases (pulmonary and extra-pulmonary) registered at the selected DOTS centres
2. Patients of all categories of tuberculosis
3. Patients who were willing to participate in the study and provided written consent

Exclusion criteria:

1. Patients who were not willing to participate in the study and did not provided written consent
2. Transfer out Patients

Ethical Consideration: The study was started after obtaining ethical approval from the Institutional Ethic Committee, R. D. Gardi Medical College, Ujjain, MP and from the Officer In-charge of District Tuberculosis Centre, Ujjain, MP. All the study subjects were explained in detail about the purpose and methodology of the study, potential risk and benefit. Procedure of maintaining confidentiality and right to not to participate in this study, was provided to them. Thereafter a written consent was obtained in consent form.

Collection of data: Preliminary data (name & address) of patients receiving DOTS at UCTH & CHMN was collected from respective DOTS register. Rest of the data was collected by conducting home visits and taking personal interview of registered TB cases, to elicit information on their socio-demographic profile and other relevant information by using pretested questionnaire. Questionnaire included data on identification, sociodemographic profile (was filled at 1st visit) and data related to treatment compliance (was filled at subsequent visits). In case of a locked house, it was ensured that the house was visited later (at least two visits in seven days) to cover the missed case.

Treatment outcome: The treatment outcome of the tuberculosis patients was recorded from treatment cards of the patients at the DOTS Centres.

Compilation and Analysis of Data: Data entry was done simultaneously as data were collected into SPSS version 16 and coded appropriately. Data analysis was done from August 2012 to September 2012. Data was analyzed using appropriate statistical tests keeping in view the aim and objectives of the study. Following statistical methods were applied in present study: Percentage, Univariate (Chi-square test and odds ratio) Analysis, Multiple Logistic Regression Analysis (MLR).

Results

Out of 241 study participants, 194 belonged to treatment category I. Among these new cases pulmonary sputum positive, pulmonary sputum negative and extra pulmonary cases were 101 (52.1 %), 44 (22.7 %), 49 (25.2 %) respectively. 47 participants belonged to treatment category II. Among these retreated cases relapse, failure and defaulter were 33(70.2%), 03(06.4%), 11 (23.4%) respectively. Ratio of Category I and Category II in present study was 4.3:1. ([Table 1](#)).

Distribution of treatment outcome according to form of tuberculosis- Treatment outcome of sputum positive pulmonary cases showed that cure rate was 77.6%, treatment completion rate was 5.6%, failure rate was 3.5%, default rate was 5.6% and death rate was 7.7%. Treatment completed rate for sputum negative pulmonary cases was 93.2%, failure rate was 0%, default rate was 2.3% and death rate was 4.5%. For extra pulmonary cases treatment completed rate was 92.6%, failure rate was 0.0%, default rate was 3.7% and death rate was 2%. Treatment success was seen in 85.6% of pulmonary and 92.6% of extra pulmonary tuberculosis cases. This association was not found to be statistically significant ($p = 0.17$).

Treatment success was 86.2% in participant had positive history of contact with tuberculosis case and it was higher (87.4%) in those who did not have history of contact. Although this difference was not statistical significant ($p = 0.08$). Treatment success was seen in 82.9% and 88.9% of study participants those had family history of tuberculosis and those did not have family history of tuberculosis respectively. ([Table 2](#))

49 study participants had history of preexisting illness and out of these 49, treatment success was observed in 73.5% of participants however out of 192 participants, who did not had any preexisting illness, treatment success was observed in 90.6% of participants. Influence of preexisting illness over treatment outcome was statistically significant ($p = 0.001$). ([Table 2](#))

Association of treatment outcome with treatment category of study participants -Treatment success rate was 91.2% in category I and 70.2% in category II participants. Failure rate, default rate and death rate were high in Category II (8.5%, 8.5%, and 12.8%

respectively) in comparison to Category I (0.5%, 3.6%, and 4.6% respectively). This difference in treatment success was statistically significant ($p < 0.05$) in category I and category II participants. ([Table 2](#)).

Sputum conversion among Sputum positive pulmonary cases during treatment- Out of 143 initially sputum positive participants, 6.4% were positive at the end of intensive phase and at the end of treatment 4.3% were remain sputum positive. Sputum conversion rate was 93.6% at the end of intensive phase and it was 95.7% at the end of treatment.

Association of treatment outcome with socio-demographic Profile of study participants- to know the effect of age on treatment outcome, the study subject were regrouped into two groups, those with age less than or equal to 45 years and those with age more than 45 years. No significant difference in treatment outcome was noticed in these two groups (87.0% and 87.5%). Of the total 153 male study participants, treatment was successful in 85.0% while treatment success was more in female (90.6%) participant. This difference in treatment outcome was not statistically significant ($p = 0.18$). ([Table 2](#)) Treatment success was observed 91.2% in literate group and 74.6% in illiterate group. This association of literacy with treatment outcome was statistically significant ($p = 0.001$). Treatment success was higher in the study participants who were employed (90.2%) in comparison to unemployed (79.1%) participants. This association of occupation with treatment outcome was statistically significant ($p = 0.02$). ([Table 2](#))

For the purpose of analysis study participants were regrouped into two groups as upper and lower socio-economic status and association with treatment outcome was determined. Class I, II and III were merged in upper class while class IV and V were merged in lower class. Treatment success was 94.4% in upper class and 84.1% in lower class. Thus, treatment outcome was influenced by socio-economic status (as per modified Kuppuswamy scale) (7) of study participants which was found to be statistically significant ($p = 0.03$). ([Table 2](#))

Treatment success was 87.9% in Hindu religion and 83.3% in other religions while it was 84.6% in married and 92.5% in singles. Association of religion ($p = 0.41$) and marital status ($p = 0.08$) with treatment outcome was not statistically significant. Treatment success

was present in 86.1% of study participants residing in nuclear family while it was 88.9% in those residing in joint family. Treatment was successful in 86.9% and 87.7% participants those living in kutcha house and pucca house respectively. Treatment success was present in 87.2% of study participants those preferred vegetarian diet and 87.0% in participants preferred non-vegetarian diet. No statistical significant association was found between treatment success and type of family ($p = 0.53$), type of housing ($p = 0.25$) and dietary habits ($p = 0.98$) of study participants. (Table 2)

Treatment success was observed in 91.0% of study participants having adequate space for living in household against 82.2% of study participants having overcrowding in their households ($p = 0.04$). (Table 2)

Table 2 Depict univariate and multivariate analysis of study variables on treatment outcome. In univariate analysis variable, such as education, occupation, socio-economic status, overcrowding, habit of tobacco consumption, presence of pre-existing illness and category of tuberculosis significantly affect the treatment outcome but on Multiple logistic regression analysis education, occupation, habit of tobacco consumption and category of TB had significant effect on treatment outcome and habit of tobacco consumption is most important cause among others (failure, defaulter, death).

Discussion

Present study shows that out of total 241 enrolled study participants, treatment success rate was 87.1%, default rate was 4.6 %, failure rate was 2.1% and death rate was 6.2. Treatment success rate was 85.6% among pulmonary cases and 92.6% among extra pulmonary cases. Among 143 sputum positive cases, cure rate was 77.6%, treatment completion rate was 5.6%, failure rate was 3.5%, default rate was 5.6% and death rate was 7.7%. Among 44 sputum negative pulmonary cases, treatment completion rate was 93.2%, failure rate was 0%, default rate was 2.3% and death rate was 4.5%. Among 54 extra pulmonary cases, treatment completion rate was 92.6%, failure rate was 0%, default rate was 3.7% and death rate was 2.0%. Treatment success rate was 91.2% in category I and 70.2% in category II. Failure rate was 0.5% and 8.5%, default rate was 3.6% and 8.5%, death rate was 4.6% and 12.8% for category I and category II respectively.

Failure rate and Default rate in present study was lower than RNTCP (8) norms that are <4% and <5%. Death rate was much higher than RNTCP norm of <2%. The treatment outcome for new smear positive cases for India in 2010 through RNTCP (8) was 85.1% cured, 2.6% treatment completed, 4.2% died, 1.9% failure, 5.5% defaulted and 0.7% transferred out while in retreatment cases treatment outcome was approx. 63.8% Cured, 70.8% treatment success, 7.8% died, 5.5% failure, 14.3% defaulted and 1.7% transferred out. Treatment outcome for extra pulmonary cases was 92.6% treatment completed, 2.5% died, 0.1% failure, 3.7% defaulted, 1.2% transferred out.

Cure rate was 91% and 73.3%, defaulter rate was 5.7% and 16.3%, treatment failure rate was 2.1% and 3.8%, death rate was 1.1% and 6.7% for category I and category II respectively in study by SL Chadha *et al*. (9) Study by T. Santha *et al* (10) Showed, Out of 676 registered patients, 19% patients defaulted, 3% failed treatment, and 6% died. Among 295 new smear-positive patients, 74% were cured, 17% defaulted, 5% died and 4% failed treatment. Study by A Mishra *et al* (11) included 312 study subject showed, over all cure rate was 61.3% while it was 85.04% for category I and 32.18% for category II. Study by Md. Shamim Akhtar *et al* (12) included 475 tuberculosis patients treated in DOTS group showed that cure rate was 81% (85.37% for category I and 74.1% for category II), default rate was 5.3% (1.6% in Cat. III, 6.1% in Cat. I and 11.2% for category II) and failure rate was 2.7% (2.2% for category I and 7.8% for category II). Study by Gurpreet Kaur *et al* (13) included 265 patients showed that for Category I and Category II patients, the success rate was 98.6% and 90.4%, default rate was 0% and 3.8%, failure rate was 1.2% and 5.8% respectively. Overall default rate was 1.1% and failure rate was 2.6%. Study by R. Prasad *et al* (14) included 237 tuberculosis patients showed that over all treatment success rate was 89.4%, default rate was 5.1%, failure rate was 2.1% and death rate was 3.4%. For category I and category II patients, treatment success rate was 89.4% and 86.6%, default rate was 5.3% and 4.5%, failure rate was 1.8% and 2.9% and death rate was 2.6% and 7.5% respectively. Study by Chennaveerappa P K *et al* (15) included 181 patients showed, total success rate was 83.4%, failure rate was 2.2%, defaulter rate was 8.2%, death rate was 6.1%. Study by Jyothi Conjeevaram *et al* (16) included 165 tuberculosis patients showed, 92.3% of new smear positives and

67.65% of sputum positive re-treatment cases were cured while in the smear negative category 91.8% cases completed treatment. The overall treatment success rate was 88.48% and defaulter rate was 3%. Mortality among new smear positive tuberculosis patients was 2.56%.

Sputum conversion rate during treatment: In 143 sputum positive participants of present study, sputum conversion rate was 93.6% at the end of intensive phase and 95.7% at the end of treatment. Similar finding was found in study of Gurpreet Kaur *et al* (13) in which sputum conversion rates at 2 months and 3 months among 146 new smear positive (NSP) cases were 88.4% and 93.8% respectively. The overall sputum conversion rate among smear positive re-treatment cases was 94.1% at 3 months of treatment. In study of S. L. Chadha *et al* (9), sputum conversion rate after 2 month of intensive phase was 92.6% in category I and 76.9% in category II. In study of Sukamal Bisoi *et al* (17) showed that sputum conversion rate for new sputum-positive TB cases at 2 month was 74.2% and among all 113 sputum smear-positive cases it was 76.1%. Sputum conversion rate among new sputum-positive cases was 82.6% at the end of Intensive Phase in study of Moharana P R *et al* (18) in both studies conversion rate was less than present study. Association of Treatment outcome with study variables in regression analysis: In present study regression analysis was conducted and final results shown that treatment success was significantly associated with patient literate (for illiterate AOR=0.15), employed (for unemployed AOR=0.18), non-tobacco users (for tobacco users AOR=0.07) and treatment category I (AOR=4.44). Study by Sophia Vijay *et al* (19) in 20 districts from six states showed that in the logistic regression analysis, factors independently associated with default were alcoholism (AOR=1.72), illiteracy (AOR=1.40), poor patient provider interaction (AOR=1.72), side effects to anti TB drugs (AOR=2.55) and dissatisfaction with services provided (AOR=1.73). Multivariate analysis in study of T. Santha *et al* (10) showed higher default rates were associated with irregular treatment (AOR=4.3), being male (AOR 3.4), history of previous treatment (AOR 2.8), alcoholism (AOR 2.2), and diagnosis by community survey (AOR 2.1). Study by Kelly E Dooley *et al* (20) showed that in multivariable logistic regression analysis, high risk of a composite endpoint of failure, default, or relapse were male (OR = 2.29), failed to have sputum smear conversion

to negative by 3 months of treatment (OR 7.14) and required hospitalization during treatment (AOR 2.09). Study by Hua Jianzhao *et al* (21) showed that Patient and treatment characteristics independently associated with non-cure were having no medical insurance, a low income, patient delay >30 days, a positive 2-month smear test result and refusal of direct observation of taking drugs.

Conclusion

Treatment success in form of cured and treatment completed was 87.1% in present study conclude that DOTs is an effective form of tuberculosis treatment and RNTCP have achieved its target in Ujjain city. Socio demographic characteristic of study participants such as education, occupation, socio economic status and overcrowding have significant effect on treatment outcome. Presence of pre-existing illness and addiction in form of tobacco or alcohol consumption adversely affect treatment outcome. Treatment success was significantly high in new cases of tuberculosis in comparison to retreated cases.

Recommendation

The message that needs to be conveyed to everyone is that DOTS is the best available strategy for curing TB patients and that all the elements of DOTS must be adopted in letter and in spirit.

Measures, targeting the modifiable socio – demographic variables should be taken to reduce the default rate and to improve the success rate. Increase collaboration of Government health services with other social welfare measures to improve the economic condition of patients. Efforts should be taken to create more job opportunities, so as to improve the overall socio-economic status of the individual and the community. As in western countries, tuberculosis infection had declined with improvement in living standard.

Limitation of the study

Study was conducted in urban area among adult patients excluding paediatric patients.

Relevance of the study

It is evaluation study and it is showing good outcome of RNTCP programme.

Authors Contribution

MJ: data collection and data entry. MS: data analysis and paper designing. SC: whole study done under guidance of him. VK: data analysis and paper editing

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Tables

TABLE 1 DISTRIBUTION OF STUDY PARTICIPANTS ACCORDING TO FORM OF TUBERCULOSIS

Form of TB	Treatment category		Total Number (%)
	Cat. I Number (%)	Cat. II Number (%)	
Pulmonary	145 (74.7)	42 (89.4)	187 (77.6)
Sputum positive	101 (52.1)	42 (89.4)	143 (59.3)
Sputum negative	44 (22.7)	0 (00)	44 (18.3)
Extra-pulmonary	49 (25.2)	05 (10.6)	54 (22.4)
Total	194 (100)	47(100)	241 (100)

TABLE 2 RESULTS OF UNIVARIATE AND MULTIVARIATE ANALYSIS OF SUCCESSFUL TREATMENT OUTCOME WITH RESPECT TO STUDY VARIABLES

Factors Study Variables	Treatment success (%)	Univariate analysis OR (95%CI)	P - value	Multivariate analysis OR (95% CI)	p- value
Age					
<45	161 (87.0)	0.95 (0.38-2.35)	0.92	-----	-----
>45	49(87.5)				
Sex					
Male	130 (85.0)	0.56 (0.24-1.32)	0.18	-----	-----
Female	80 (90.9)				
Education					
Illiterate	44 (74.6)	0.28(0.13-0.61)	0.001*	0.14 (0.03-0.64)	0.01*
Literate	166 (91.2)				
Occupation					
Unemployed	53 (79.1)	0.41(0.18-0.88)	0.02*	0.16 (0.04-0.58)	0.006*
Employed	157 (90.2)				
Income					
Low Income	173 (86.1)	0.50(0.14-1.73)	0.26	-----	-----
High income	37 (92.5)				
Socio-economic Status					
Upper class	67 (94.4)	3.16(1.06-9.40)	0.03*	2.93 (0.33-25.92)	0.33
Lower class	143 (84.1)				
Religion					
Hindu	175 (87.9)	1.45(0.58-3.64)	0.41	-----	-----
Others	35 (83.3)				
Marital status					
Married	136 (84.6)	0.44(0.17-1.12)	0.08	-----	-----
Single	74 (92.5)				
Type of family					
Nuclear	130 (86.1)	0.77(0.34-1.72)	0.53	-----	-----
Joint	80 (88.9)				
Type of house					
Kutcha	139 (86.9)	0.93(0.41-2.08)	0.25	-----	-----
Pucca	71 (87.7)				
Dietary habit					
Vegetarian	163 (87.2)	1.01(0.41-2.49)	0.98	-----	-----
Non-vegetarian	47 (87.0)				
Overcrowding					
Present	88 (82.2)	0.45(0.21-.98)	0.04*	0.44 (0.14-1.40)	0.17
Absent	122 (91.0)				
Tobacco consumption					
Yes	82 (75.9)	0.12(0.04-0.33)	<0.0001*	0.09 (0.02-0.45)	0.003*
No	128 (96.2)				
Alcohol consumption					
Yes	42 (80.8)	0.52(0.23-1.19)	0.12	-----	-----
No	168 (88.9)				
History of contact with active TB case					
Yes	50 (86.2)	0.89 (0.37-2.13)	0.80	-----	-----
No	160 (87.4)				
Pre-existing illness					
Yes	36 (73.5)	0.28 (0.12-0.63)	0.001*	0.43 (0.11-1.64)	0.22
No	174 (90.6)				
Form of tuberculosis					
Pulmonary	160 (85.6)	0.47(0.15-1.42)	0.17	-----	-----
Extra-pulmonary	50 (92.6)				
Treatment category					
Category I	177 (91.2)	4.41(1.98-9.82)	<0.0001*	3.55 (1.19-10.55)	0.02*
Category II	33 (70.2)				

*Result was statistically significant