

Outcome of Directly Observed Treatment Short Course ATT in New Sputum Positive Pulmonary TB Patients under RNTCP

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Abstract

Background: India is the highest TB burden country accounting for more than one-fifth of the global burden of tuberculosis (TB). To tackle this problem, Revised National Tuberculosis Control Programme (RNTCP) based on the directly observed treatment short course (DOTS) strategy has been made available in the entire country. The present study was undertaken to assess the compliance, bacteriological sputum conversion rates, cure rates, symptomatic improvement during treatment and adverse effects due to DOTS in new sputum positive pulmonary tuberculosis patients.

Methods: This prospective study was conducted at DMC, DOTS Center and Department of Medicine, Silchar Medical College and Hospital, Silchar over a one year period on 50 new sputum smear positive patients (aged >12 years) on Category I DOTS treatment. Patients were followed 2nd, 4th and 6th months. On follow up repeat sputum sample was taken and patients were assessed for improvement and adverse effects.

Results: Majority of patients was symptomatically better at the end of second month; improvement has taken in the form of resolution of cough (70%), hemoptysis (77%), fever (92%), breathlessness (63%) and chest pain (71%). The sputum conversion rates were 84% at 2nd month and 78% at 4th month. The overall cure rate was 78%, default rate was 12%, failure rate was 8% and death rate was 2%. Gastrointestinal intolerance was the most common side effect (40%) of initial phase of DOTS.

Conclusion: DOTS is the best available strategy for curing TB patients even in the context of limited resources, resulting in high cure rates and better patient compliance.

Keywords: Tuberculosis, RNTCP, DOTS, ATT, Sputum smear, Hemoptysis, Breathlessness.

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1. Introduction

Tuberculosis remains a major public health problem worldwide, despite of advances in science and availability of highly effective drugs against it. So, one of the greatest challenges facing health care systems at the dawn of the 21st century is the fight against tuberculosis. In 1990 the World Health Organization (WHO) report on the Global Burden of Disease ranked TB as the seventh most morbidity-causing disease in the world and expected it to continue in the same position up to 2020. Worldwide statistics are staggering [1]. However, it has been estimated that about 8 million individuals develop new clinical disease and 3million people die of tuberculosis each year [2]. India alone accounts for approximately 1/5 of total

global tuberculosis incidence. Every year 1.8 million new cases occur in India of which 0.8 million are infectious [3].

Recognizing that tuberculosis epidemic is out of control in many parts of the world, the WHO declared tuberculosis to be a global health emergency in April 1993. It developed a five point strategy known as Directly Observed Treatment Short-course (DOTS) in order to combat the increasing incidence of the disease. DOTS are the main strategy for TB control globally, relies on self-presentation of adults from the community and sputum smear for diagnosis. Even in the presence of substantial drug resistance, it is highly effective at reducing tuberculosis transmission [4]. The Government of India also evolved a revised strategy and launched the Revised

National Tuberculosis Control Programme (RNTCP) based on DOTS strategy in 1997 [3].

Since its inception RNTCP in India has achieved its objectives of not less than 85% cure rate of new smear positive cases under DOTS and at least 70% detection of new cases through quality sputum microscopy [5,6]. Vital information regarding the efficacy of the DOTS regimen is lacking in many aspects. In India, especially in North East state of Assam adequate studies are yet to be conducted in medical colleges to know about performance of programmed. This is an attempt to reaffirm the efficacy, so that the burden of TB in North East and response to treatment can be evaluated.

2. Materials and Methods

This prospective study was conducted at DMC, DOTS Center and Department of Medicine, Silchar Medical College and Hospital, Silchar over a one year period on 50 new sputum smear positive patients having aged >12 years on Category I DOTS treatment (who never had treatment for tuberculosis or treated for less than 4 weeks). The exclusion criteria of the study were sputum smear positive relapse, failure, defaulter and sputum smear positive patients with EPT. A semi structured, pretested pro-forma was filled by interviewing patients and clinical examinations were done by the investigator himself. Once baseline data from patients was collected, then, subsequent follow up was done at 2nd, 4th and 6th months. On follow up repeat sputum sample was taken and patients were assessed for improvement and adverse effects. Total duration of follow up for each patient was 6 months.

2.1 Data Analysis

The collected data was analyzed using Statistical Package for Social Sciences (SPSS) version 10. Chi-square test was used to find out the association and p value of <0.05 was taken as significant. Comparison is made between data at initial presentation and data after six months.

3. Observations and Results

Out of 50 patients studied, 34 (68%) were male and 16 (32%) were female. The majority (38%) of patients were in the age group of 25-34 years followed by 15-24 years (24%) as shown in table 1. Maximum cases (82%) were literate. Majority of cases (30%) were laborer followed by housewife (26%), Govt. servant (16%), farmer (14%) and student (14%). Out of 50 patients, 48% have sputum smear result 3+ followed by 2+ (30%) and 1+ (22%).

Table 1: Distribution of study group according to age

Age group (in years)	No. of cases	Percentage
15-24	12	24%
25-34	19	38%
35-44	08	16%
45-54	03	06%
55-64	04	08%
>65	04	08%

Table 2 shows the presenting complaints of the patients. Cough (96%) was the most common complaint. 80% of patients had cough more than 2 weeks duration and 16% had cough less than 2 weeks duration.

Table 2: Distribution of study group by presenting complaints

Presenting Complaints	No. of cases	Percentage
Cough	48	96%
Expectoration	47	94%
Hemoptysis	09	18%
Fever	38	76%
Evening rise of temp. (ERT)	28	56%
Breathlessness	11	22%
Chest pain	07	14%
Anorexia	38	76%

The overall cure rate was 78%, default rate was 12%, failure rate was 8% and death rate was 2%, (figure 1). Out of 6 defaulters commonest reason for default was alcohol intake (3 cases) and other was, not interested to continue (1), distance to travel (1) and jaundice (1). Table 3 show the outcome in relation with baseline characteristics.

Figure 1: Outcome after DOTS treatment

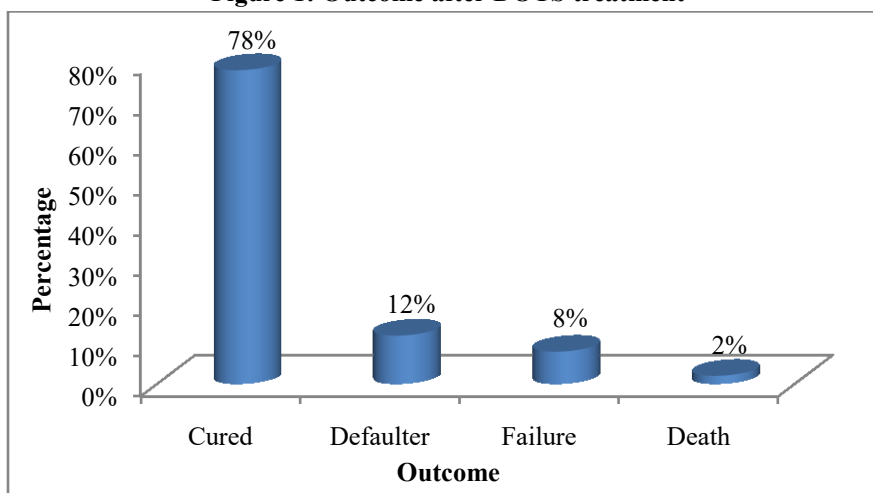


Table 3: Outcome in relation with baseline characteristics

Baseline Characteristics		Outcome			
		Cured	Default	Failure	Death
Age (In years)	15-24	09	02	01	00
	25-34	14	03	01	01
	35-44	07	01	00	00
	45-54	02	00	01	00
	55-64	04	00	00	00
	>65	03	00	01	00
Sex	Male	27	04	02	01
	Female	12	02	02	00
Literacy status	Literate	32	06	02	01
	Illiterate	07	00	02	00
Occupation	Laborer	11	03	01	00
	Housewife	10	01	02	00
	Govt. servant	07	00	00	01
	Farmer	05	01	01	00
	Students	06	01	00	00
Sputum status	3+	17	03	03	01
	2+	11	03	01	00
	1+	11	00	00	00
Body mass index	<18	26	05	02	01
	18-25	12	01	02	00
	>25	01	00	00	00
Smoking	Smoker	16	03	02	01
	Non- smoker	23	03	02	00
Alcohol Intake	Alcoholic	11	04	00	01
	Non-alcoholic	28	02	04	00

The sputum conversion rates were 84% at 2nd month and 78% at 4th month as shown in table 4. Cure rate was more among patients with 1+sputum (100%) followed by 2+ (73.33%) and least among 3+ (70.83%).

Table 4: Follow-up Sputum Status

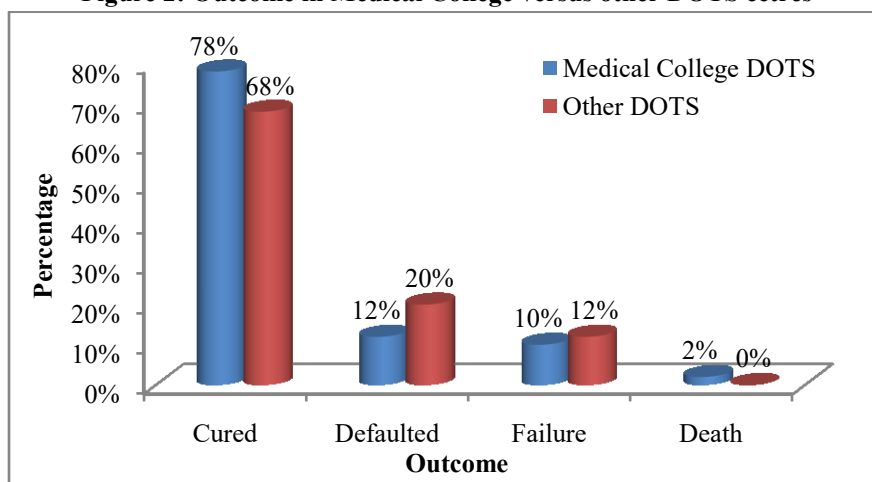
Duration of treatment	Status of Sputum			
	Positive		Negative	
	No. of cases	Percentage	No. of cases	Percentage
After 2 nd month	06	12%	42	84%
After 4 th month	04	08%	39	78%
After 6 th month	04	08%	39	78%

Majority of patients was symptomatically better at the end of second month; improvement has taken in the form of resolution of cough (70%), hemoptysis (77%), fever (92%), breathlessness (63%) and chest pain (71%), (Table 5). Gastrointestinal intolerance was the most common side effect (40%) of initial phase of DOTS.

Table 5: Follow-up of presenting complaints

Duration of treatment	Duration of treatment					
	After 2 nd month		After 4 th month		After 6 th month	
	Present	Absent	Present	Absent	Present	Absent
Cough	13	34	03	41	02	41
Hemoptysis	02	45	01	43	01	42
Fever	03	44	02	42	00	43
Breathlessness	04	43	02	42	00	43
Gatro-intestinal intolerance	20	27	13	31	05	38
Chest pain	02	45	01	43	00	43
Anorexia	06	41	03	41	00	43
Urine colour	46	01	40	04	14	29

In present study, we have also studied 50 new sputum positive pulmonary TB cases retrospectively from DOTS centre other than medical college and found that the cure rate in medical college DOTS centre was more (78%) than patients diagnosed at other DOTS centre (68%). Default rate was less in medical college DOTS centre (Figure 2).

Figure 2: Outcome in Medical College versus other DOTS centres

4. Discussion

The current study was a prospective study which included fifty cases of new sputum smear positive pulmonary tuberculosis to study the outcomes of treatment among the patients put on DOTS under RNTCP. The outcomes were categorized as: those cured, treatment failure, defaulters and death. Cured patients were those who were sputum smear positive before commencement of treatment and then subsequently confirmed to be sputum negative at 5th (or 6th) months and on at least one previous occasion. Treatment failure included patients who remained sputum smear positive at 5 months or later during treatment. Patients who failed to collect medication for more than 2 consecutive months during the course of treatment were classified as defaulters.

The age and sex distribution of 50 patients showed that majority of the patients (38%) belonged to 2 and 3 decades (25-34 years) with male predominant (68%). As per WHO Report 2006 (country file India), Age and sex distribution provided for a subset of new smear-positive cases notified in 2004 showed that maximum cases reported varies from 1 decade to 4 decade and with male predominately affected. The present study also shows the same result. In a comparative study done by RNTCP [7] in 2005, patients in the age group 25-34 accounted for the maximum number showing sputum positivity for *tuberculous bacilli*. The study by Chan-yeung *et al* [8] also showed male (69.1%) preponderance. In Brahmapurkar, *et al* [9] study higher proportions of males were affected by pulmonary TB as compared with females. Likewise, similar results were seen in the study carried out at Paithan, Aurangabad, and Howrah district in India, [10,11]. The maximum patients were literate (82%) belonging to govt. servant, student and housewife. 44% were laborer and farmer, this was correlated with the survey carried out in Wardha District (Maharashtra) [12].

The national program states that all patients with cough more than 2 weeks should get their sputum tested for AFB. In present study 80% of the patients had cough more

than 2 weeks and remaining 16% had cough less than 2 weeks. Previously duration of cough required for test was 3 weeks. Other studies [13,14] have also found smear positivity before 3 weeks. In current study, 84% of patients were sputum negative for AFB in the 2nd month which was similar to the study done by Ruohonen *et al* [15] and Kumaresan *et al* [16]. The cure rate for patients with sputum 3+ was 70% versus 84% for patients with 1+ and 2+, this was comparable with the previous studies [17,18]. Failure rate for sputum 1+, 2+ and sputum 3+ were 3.8% and 12.5% respectively which was correlated with the study done by Singla *et al* [17]. The default rate was 12%, the commonest reasons for default rate were alcohol intake, and this finding was similar to the study done by Chandrashekar *et al* [19]. In current study, it was found that 40% of patients developed gastrointestinal intolerance at the end of the 2nd month, which then subsequently reduced to 25% at the end of the 6th month. It was also noticed that patients had specific complaints of gastrointestinal intolerance only on the day of medications. In comparison, the study by Tahir *et al* [20] showed 20% of patients developed gastro-intestinal intolerance.

5. Outcome

Sex: The incidence of default in males was (11.76%) in comparison to females (12.5%). Reports by Chandrashekar *et al* [19] also showed higher incidence of default in males (13.8%) in comparison to females (5%). Disparity may be due to limited sample size in our study.

Literacy: The cure rates in literates' patients were slight more (78.04%) than illiterates (77.77%). However the default rate was higher in the literate accounting for 14.63% in comparison to 0% in the illiterate. This may be attributed to the lower number of illiterate present in the study group. In the study conducted by Chandrashekar *et al* [19] the default rate in the illiterate is more (12.7%) when compared to the literate (7.9%).

Alcohol: It is evident that default rate was higher in alcoholics (25%) when compared to non-alcoholics

(5.88%). Chandrashekar *et al* [19] also reported a higher default rate in alcoholics (17.1%) than non-alcoholics (6%). **Smoking:** Default rate was higher in smokers (13.63%) as compared to non-smokers (10.71%) whereas Chandrashekar *et al* [19] reported illiteracy, alcohol intake and smoking as the causes for default.

Treatment outcome in medical college compared to outside DOTS centres: The present study showed a higher cure rate in medical college DOTS centres (78%) than other DOTS centres (68%) which is in agreement with Ambe *et al* [20] which have reported higher cure rate in medical colleges (88%) as compared to 85% in RNTCP facilities.

6. Conclusion

DOTS are the best available strategy for curing TB patients even in the context of limited resources, resulting in high cure rates and better patient compliance. It strengthens the patient both physically by rapid symptomatic improvement with minimal adverse effects and mentally by direct supervision and counseling. Diligent pursuance of DOTS strategy will help in better patient adherence and long term reduction of MDR and XDR-TB cases in future. All the elements of DOTS must be adopted both in letter and in spirit.

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