

Treatment Outcome and Follow-up of Tuberculosis Patients Put on Directly Observed Treatment Short-course Under Rural Health Training Center, Paithan, Aurangabad in India

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Abstract

Background: Revised National Tuberculosis Control Program (RNTCP) was found successful in achieving its objectives; still there is concern of relapse cases and defaulters. **Aim:** The aim of this study is to know the treatment outcome, to assess the reasons for relapse, default, death of patient and to assess the follow-up status of tuberculosis (TB) patients put on directly observed treatment short-course (DOTS). **Subjects and Methods:** This cross-sectional survey was conducted in 140 TB patients put on DOTS during year 2005-2007 under Rural Health Training Center, Paithan. The personal interview was carried out by an investigator with pre-tested questionnaire during month of July-August 2008. **Results:** Out of total 140, 125 TB cases could be traced: Category I 48% (60/125), Category II 16% (20/125) and Category III 36% (45/125). Cure rate among Category I was calculated to be 61.7% (37/60). Defaulters were observed to be 18.3% (11/60), 25% (5/20) and 20% (9/45) among Category I, Category II and Category III respectively. Death rate was higher (5%) among patients of Category II. During the follow-up visit, 82.4% (103/125) were found to be alive while 17.6% (22/125) dead. A total of 18 deaths were related with TB and its sequelae. Around 20% (5/25) defaulted because of feeling of well-being. During the follow-up visit, 5.8% (6/103) were again put on DOTS. **Conclusions:** Defaulters were high in present study. The majority of patients left the treatment due to feeling well. This can be tackled by effective counseling. Higher percentage of the patients showed improvement in their weight after completion of DOTS treatment. More emphasis was to be given toward existing TB patients to get successful results of RNTCP.

Keywords: Defaulters, Follow-up, Treatment outcome

Introduction

The burden of tuberculosis (TB) is the highest in Asia and Africa. India and China together account for almost 40% of the world's TB cases. TB remains a major public health problem in India causing immense morbidity, mortality and distress

to individuals, families and communities. About 40% of the population in India is estimated to be infected with TB bacillus. More than 900 people die of TB (two deaths every 3 min) in India. India accounts for one-fifth of global incidence of TB and tops the list of 22 high TB burden countries. Unless sustained and appropriate action is taken, approximately 20 lakh people in India are estimated to die of TB in next 5 years. TB kills more adults in India than any other infectious disease.^[1,2]

Despite the existence of a national tuberculosis program since 1962, there was little impact on the TB burden till 1992. This program could not achieve the objectives because of low priority, managerial weaknesses, over dependence on X-rays for diagnosis and inadequate funding. Incomplete treatment was the norm rather than exception due to low rates of

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Quick Response Code:



Website: www.amhsr.org

DOI:
10.4103/2141-9248.129047

treatment adherence and lack of supervision.^[1] The Revised National Tuberculosis Control Program (RNTCP), based on the internationally recommended directly observed treatment short-course (DOTS) strategy was launched in 1997 expanded across the country in a phased manner with support from the World Bank and other development partners. India started RNTCP with the objectives of not less than 85% cure rate of infectious TB cases under DOTS and at least 70% detection of new cases through quality sputum microscopy.^[2,3]

DOTS ensure the best possible results in treatment of TB. Here, an observer watches and assists the patient in swallowing the tablets, thereby ensuring that patient receives the right drugs, in the right doses, at the right intervals and for the right duration.^[2] The control of TB in India has shown remarkable progress with the entire country being covered under the RNTCP.^[2] Despite encouraging results and high cure rates achieved in RNTCP, queries are often raised by clinicians regarding effectiveness of RNTCP regimens, particularly the dosage recommended and the intermittent drug administration. These concerns could be convincingly addressed through an assessment of treatment outcome. The health status of TB patients' years after course of DOTS treatment is unknown. The knowledge of health status of these patients is necessary to know long-term effect of program strategy. The aim of the present study was to assess the treatment outcome of TB patients, various demographic factors associated with treatment outcome and to assess the follow-up status of TB patients put on DOTS.

Subjects and Methods

Present cross-sectional survey was carried out at field practice area of Rural Health Training Center, Paithan under administration of Department of Community Medicine, Government Medical College in Aurangabad city of Maharashtra State of India. The list of total TB patients put on DOTS during year 2005-2007 was obtained from the TB treatment registers. Total 140 patients were started DOTS treatment during this 2 years period. Out of 140 patients, 125 patients could be traced. These patients were interviewed using pre-designed, semi-structured questionnaire at their residence by trained Health Visitors and investigator himself during July-August 2008 after taking informed consent. Under RNTCP, patients diagnosed on the basis of sputum smear results were treated by DOTS treatment regimen. The DOTS treatment consists of intensive phase during which anti-TB drugs are given in front of health worker followed by continuation phase during which first dose of anti-TB drugs is given under observation of health workers and remaining to be taken by the patient at home. The dosage strengths of drugs used under DOTS consists of H: Isoniazid (600 mg), R: Rifampicin (450 mg), Z: Pyrazinamide (1500 mg), E: Ethambutol (1200 mg) and S: Streptomycin (750 mg) and the treatment regimen consists of (2HREZ + 4 HR) Category I, (2 HREZS + 1 HREZ + 5 HRE) Category II and (2 HRZ + 4HR) Category III.^[2] A pilot study was conducted before starting the

actual survey. Accordingly, necessary modifications were done in the questionnaire structured for the study. Thus, the data on socio-demographic profile such as age, sex, education, occupation, alcoholism along with the type of TB, category of treatment regimen and outcome was obtained. The review of records like Out Patient Department registers, various registers maintained under RNTCP and treatment cards of patients was done to collect secondary data about TB patients. Several attempts were made to contact the defaulted patients through home visits. Those houses found locked during survey were revisited. The defaulted patients were persuaded to approach the DOTS center. All patients were examined to assess their general condition during visit. For patients reported "dead," cause of death was ascertained from close relatives by verbal autopsy through questionnaire-based interviews along with confirmation through scrutiny of available records including death certificates. The sputum samples were collected among those who were found chest symptomatic during visit. The samples were transported to designated microscopic center for sputum smear examination.

An ethical approval for the study was obtained from Institutional Ethical Committee. Data analysis was performed using Epi Info software version 7.0.9.34 (Centre for Disease Control [CDC] formulas and algorithm provided by open epi. com and EARS. Descriptive statistics were calculated for all variables. Proportions were compared by using the Chi-square tests of analysis.

Definitions

Cured

Initially sputum smear-positive patient who has completed treatment and had negative sputum smears, on at least two occasions, one of which was at the end of treatment.

Treatment completed

A sputum smear-positive patient who has completed treatment and had negative smears, at the end of Intensive Phase (IP), but none at the end of treatment.

Defaulted

A patient who has not taken anti-TB drugs for 2 months or more consecutively, after starting treatment.

Died

A patient who died during the course of treatment regardless of the cause of death.

Transferred out

A patient who has been transferred to another TB Unit or district and for whom the treatment result (outcome) is not known.^[4]

Results

Out of total 140 registered patients, we could trace only 125 patients. Out of total 125 patients 48% (60/125), 16% (20/125) and 36% (45/125) were registered for Category I, Category II and Category III treatment regimen respectively. Sputum conversion rate of the sputum positive cases at the end of Intensive Phase was 88% (54/60) among Category I while it was 100% (20/20 and 45/45) for both Category II and Category III respectively. The sputum results were found to be negative both at the end of continuation phase and at the end of treatment in all the categories [Table 1].

The Cure rate among Category I was calculated to be 61.7% (37/60) while it was 35% (7/20) in Category II. No one in Category III was cured. Treatment completion rate was 16.7% (10/60), 30% (6/20) and 75% (34/45) among Category I, Category II, Category III patients respectively. Defaulters were 18.3% (11/60), 25% (5/20) and 20% (9/45) among Category I, Category II and Category III respectively. Death rate was higher, i.e. 5% (1/20) among patients of Category II. No case of failure

to treatment was observed in present study [Table 2]. The observed difference was statistically significant ($P < 0.01$).

As shown in [Table 3] cure rate was higher among patients with age group of 25-44 years, whereas patients above the age 54 years showed low cure rate 23.5% (4/17). The percentage of treatment completion among the patients below 34 years and above 54 years was observed to be 45.4% (15/33) and 47% (8/20) respectively. As age advanced, percentage of defaulters was found to be increased. The Specific Mortality was high 10% (2/20) in the age group of 45-54 years as compared to other age groups. Table 4 summarized that treatment completion rate was high 57.4% (27/47) in females, but cure rate was higher 39.7% (31/78) among male patients. The percentage of defaulter was high among males 23.0% (18/78) as compared with females. The death rate was 5.1% (4/78) among males and no death was found in females. The observed difference was statistically significant ($P = 0.02$).

Table 5 illustrated that the proportion of defaulters was low 14.3% (2/14) in patients having education more than high

Table 1: Sputum results of patients of tuberculosis according to DOTS treatment categories

Sputum results	Number (%)	Pre-treatment		End of intensive phase		End of continuation phase		End of treatment	
		+ve	-ve	+ve	-ve	+ve	-ve	+ve	-ve
Cat I	60 (48)	50	10	6	54	Nil	60	Nil	60
Cat II	20 (16)	12	8	0	20	Nil	20	Nil	20
Cat III	45 (36)	0	45	0	45	Nil	45	Nil	45
Total	125	62	63	6	125	Nil	125	Nil	125

DOTS: Directly observed treatment short-course

Table 2: Distribution of patients of tuberculosis according to their treatment outcome

Treatment outcome	Cured	Treatment completed	Defaulted	Died	Transferred out	Total
Cat I	37 (61.7)	10 (16.7)	11 (18.3)	1 (1.7)	1 (1.7)	60 (100)
Cat II	7 (35.0)	6 (30.0)	5 (25.0)	1 (5.0)	1 (5.0)	20 (100)
Cat III	Nil	34 (75.6)	9 (20.0)	2 (4.4)	Nil	45 (100)
Total	44 (35.2)	50 (40.0)	25 (20.0)	4 (3.2)	2 (1.6)	125 (100)

$P < 0.01$

Table 3: Age wise distribution of treatment outcome among patients of tuberculosis

Age (years)	Cured	Treatment completed	Defaulted	Died	Transferred out	Total
15-24	7 (31.8)	10 (45.5)	5 (22.7)	Nil	Nil	22 (100)
25-34	11 (33.3)	15 (45.5)	6 (18.2)	1 (3.0)	Nil	33 (100)
35-44	16 (48.5)	9 (27.3)	5 (15.2)	1 (3.0)	2 (6.1)	33 (100)
45-54	6 (30.0)	8 (40.0)	4 (20.0)	2 (10.0)	Nil	20 (100)
Above 54	4 (23.5)	8 (47.1)	5 (29.4)	Nil	Nil	17 (100)
Total	44 (35.2)	50 (40.0)	25 (20.0)	4 (3.2)	2 (1.6)	125 (100)

Figure in parenthesis denotes percentage. $P = 0.48$

Table 4: Sex wise distribution of treatment outcome of patients of tuberculosis

Sex	Cured	Treatment completed	Defaulted	Died	Transferred out	Total
Male	31 (39.7)	23 (29.5)	18 (23.1)	4 (5.1)	2 (2.6)	78 (100)
Female	13 (27.7)	27 (57.4)	7 (14.9)	Nil	Nil	47 (100)
Total	44 (35.2)	50 (40.0)	25 (20.0)	4 (3.2)	2 (1.6)	125 (100)

Figure in parenthesis denotes percentage. $P = 0.021$

school as compared with the illiterates and those having education below high school (17.5% [7/40] and 22.5% [16/71] respectively). The cure rate was high 42.9% (6/14) in those having education above high school as compared with illiterates and those having education below high school (30% [12/40] and 36.6% [26/71] respectively).

Out of the patients of pulmonary TB 41.1% (44/107), 38.3% (41/107) and 15.9% (17/107) were cured, treatment completed and defaulted respectively while 2.9% (2/107) were died [Table 6]. No one found to be cured from those suffered from extra pulmonary TB and death rate was also higher 5.6% (4/18) in extra pulmonary than pulmonary TB. The observed difference was statistically significant ($P < 0.01$).

During follow-up visits of the TB patients, it was observed that out of 125 patients, 103 were alive while 22 were dead. 18 deaths were related with TB and its sequelae [Table 7].

Out of total 125 TB patients, 4 were dead on record and during follow-up 23 patients could not be traced due to death and migration. Out of remaining patients visited, 86.7% (85/98) patients showed increase in their weight and 3% (3/98) patients found with decreased weight [Table 8].

Out of total 125 patients, 93% opinioned that laboratory diagnosis, treatment as well as the services provided by DOTS provider was good. 5 (4%) defaulted because of feeling of well-being. 2 (1.6%) left treatment because of side effects of oral drugs. Five patients had shown lack of trust on treatment provided by government health center. A total of 18 patients (14.4) were symptomatic at the time of visit and out of those 6 (4.8%) patients again put on DOTS.

Discussion

The present study was carried out to assess the factors associated with treatment outcome, reasons for default and to find out the follow-up status of TB patients treated under RNTCP. The study showed that pulmonary TB accounted for 85.6% (107/125) of

cases while the extrapulmonary TB accounted for 14.4% (18/125) of cases. This data coincides with the national figure, which stated that 85-90% of cases are pulmonary TB and 10-15% of cases were extrapulmonary TB.^[5] In the present study, higher proportion of males were affected by TB as compared with females. Similar results were seen in study at south India.^[6] The sputum conversion rate after 2 months intensive phase treatment in DOTS was 88% (54/60) for Category I patients and 100% (20/20) for Category II patients. The cure rate after completion of DOTS treatment (intensive and continuous phase) was 100% for Category I (60/60) and Category II (20/20) patients respectively. The sputum conversion and cure rates were better. Thus, DOTS is an effective strategy in treating the patients with TB. Verma *et al.* study^[6] at Lucknow revealed a treatment success (cured treatment completed) in Category I, Category II and Category III patients of 89.8%, 84% and 94.3%, respectively. The overall treatment success was 89.9%. A study from Delhi^[7] reported treatment success rate in Category I and Category II patients as 91.0% and 73.0%, respectively. The present study revealed treatment success rate as 78.3% (47/60), 65% (13/20) and 75.6% (34/45) among Category I, II and III respectively. Thus, low treatment success rate may be due to high default rate in present study. Death rate was 3.2% in the present study. Death rate was higher in male patients. This may be due to high default rate in male (23%) as compared to female (14.9%). In this study, it was observed that cure rate was very low and mortality was high among elderly patients. TB in this age group is most often associated with reactivation of endogenous infection. Due to poor nutritional status, atypical clinical and radiological features and other comorbid states and misperception of symptoms, diagnosis of TB is difficult and delayed in elderly patients. The disease may have more advanced disease at the time of diagnosis leading to highest mortality.^[8]

Patients having education above high school were associated with high cure rate. The proportion of defaulters was less among the patients having education above high school. Thus, literacy increases the awareness regarding adherence to treatment. Incomplete treatment leads to reappearance of symptoms and continued transmission of disease. Under DOTS the health system shoulders the responsibility of patient care

Table 5: Literacy status wise distribution of treatment outcome of patients of tuberculosis

Literacy status	Cured	Treatment completed	Defaulted	Died	Transferred out	Total
Illiterate	12 (30.0)	20 (50.0)	7 (17.5)	1 (2.5)	Nil	40 (100)
Up to high school	26 (36.6)	26 (36.6)	16 (22.5)	2 (2.8)	1 (1.40)	71 (100)
Above high school	6 (42.9)	4 (28.6)	2 (14.3)	1 (7.1)	1 (7.1)	14 (100)
Total	44 (35.2)	50 (40)	25 (20.0)	4 (3.2)	2 (1.6)	125 (100)

Figure in parenthesis denotes percentage. $P = 0.54$

Table 6: Distribution of treatment outcome among the patients of tuberculosis according to type of tuberculosis

Type of TB	Cured	Treatment completed	Defaulted	Died	Transferred out	Total
Pulmonary	44 (41.1)	41 (38.3)	17 (15.9)	3 (2.9)	2 (1.9)	107
Extra-pulmonary	Nil	09 (50.0)	8 (44.4)	1 (5.6)	Nil	18
Total	44 (35.2)	50 (40.0)	25 (20.0)	4 (3.2)	2 (1.6)	125 (100)

Figure in parenthesis denotes percentage. $P < 0.01$, TB: Tuberculosis

Table 7: Status of TB patients during follow-up visit after completion of DOTS treatment

Status of patient	Number	Percentage
Live	103	82.4
Dead	22	17.6
Total	125	100

DOTS: Directly observed treatment short-course, TB: Tuberculosis

Table 8: Weight of the tuberculosis patients after completion DOTS during follow-up visit

Weight	Total	Percentage
Increased	85	86.7
Constant	10	10.2
Decreased	3	3.1
Total	98	100

DOTS: Directly observed treatment short-course

and not the patient. Although DOTS treatment regimens were found to be effective, intensive efforts are required to educate and create awareness of importance of regular treatment among the patients. During follow-up visit, 86.7% (85/98) of the patients revealed increase in their weight. Improvement in the patients' general condition after DOTS treatment was observed. Majority of the patients left treatment due to feeling well. This can be tackled by effective counseling.

The present study is community based study with maximum coverage of study subjects. The patients and household contacts of TB patients were also evaluated for chest symptoms and treated accordingly. This was the strength of our study. Though, many of these deaths were reported to be due to TB and its sequelae, corresponding records including death certificates to confirm the cause of death were not available for ten out of 22 patients who died. The available records were incomplete and hence, had not documented co-morbid conditions leading to death among these patients. The reasons for the death among ten patients were assessed by only verbal autopsy. This was limitation of our study.

The RNTCP is on the right path and steadily working toward achieving TB control. The follow-up results of a DOTS regimen in the form of a cohort study for a longer duration are necessary to know the fate of TB patients after DOTS treatment. In the present study, 18 patients were symptomatic and out of those 4.8% patients were again put on DOTS treatment during follow-up visit. In future, studies are required to find out reasons for those who did not return for retreatment at DOTS center and evolve methods to ensure their return to treatment.

Conclusions

Treatment success rate was observed to be high among DOTS patients. The cure rate was low in the old age group. Extra pulmonary TB patients had revealed low cure rate and high death rate as compared to pulmonary TB patients. The proportion of defaulters was higher in the present study and the default rate is high among male patients as compared to female patients.

Older patients had revealed high tendency of discontinuation of treatment. The literacy had inverse relation with treatment continuation. The majority of patients left treatment due to feeling well. This can be tackled by effective counseling and providing sufficient time for counseling of importance of regular treatment and side-effects. Higher percentage of the patients showed improvement in their weight after completion of DOTS treatment. DOTS are an effective treatment strategy for cure of TB patients. More emphasis is to be given toward existing TB patients to get results of RNTCP. Six of the patients again put on DOTS treatment during the follow-up visit. The cure of TB patients is considered only as responsibility of DOTS, but patients should also take responsibility of their own health by early detection of TB and treatment adherence. This can be achieved by increasing awareness through effective and sufficient counseling. Improper treatment further creates the problem of a multi-drug resistant TB. Thus, missionary zeal of self-care by the individual, community participation and health system can definitely tackle this issue.

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How to cite this article: Karanjekar VD, Lokare PO, Gaikwad AV, Doibale MK, Gujrathi VV, Kulkarni AP. Treatment outcome and follow-up of tuberculosis patients put on directly observed treatment short-course under rural health training center, Paithan, Aurangabad in India. *Ann Med Health Sci Res* 2014;4:222-6.

Source of Support: Nil. **Conflict of Interest:** None declared.