Research Article

Correlates of non-compliance to follow up sputum examination and treatment outcomes among tuberculosis patients under RNTCP in tribal area of Thane district

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Abstract

Background: Revised National Tuberculosis Control Program (RNTCP) has a robust recording and reporting system in place along with multiple internal/external checks to ensure good quality data generation which forms the basis for existing supervision and monitoring strategy. However, in view of the expansion in program activities this strategy needs to be more comprehensive.

Objective: To assess response and outcome of treatment, various demographic factors associated with treatment outcome and to find out reasons for non-compliance to Directly Observed Treatment Short-course (DOTS).

Materials and Methods: A cross-sectional observational study was undertaken at designated microscopy and treatment center from May 2014 to October 2014. Tuberculosis (TB) cases registered for treatment under RNTCP in all four quarters of year 2013 were included in the study. Information collected by reviewing records with the help of predesigned and pretested schedule. Of these cases, defaulters of treatment and those cases not reported to follow up sputum examination were contacted through local health volunteers and home visits and interviewed.

Result: Of the total 126 patients, 84.9% and 15.1% were registered for Category 1 and Category 2, respectively. Pulmonary and extra-pulmonary TB accounted for 77.8% and 22.2% cases, respectively. Sputum conversion rate was 96.1%. Highest proportion of non-reporting to follow up sputum examination found in continuation phase (55.6%). Lack of awareness (23.1%) and work commitments (18.9%) were commonly given reasons for non-compliance. Treatment success rate was 85.8%. Defaulters were 3.2% and 2.4% cases were switched to multidrug-resistant TB (MDR TB) treatment.

Conclusion: Though many of performance indicators were satisfying norms of RNTCP but still significant number of cases was not reported for follow up sputum examination. Lack of awareness was the most common reason. This underlines the need of intensive IEC activity which will improve their compliance toward DOTS.

KEY WORDS: Millennium development goals (MDG), directly observed treatment short-course (DOTS), multi-drug resistant (MDR) TB, designated microscopy and treatment centre (DMC), treatment outcomes

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Introduction

The Revised National Tuberculosis Control Program (RNTCP) has successfully completed 15 years of implementation till 2013. Since its inception more than 15.8 million patients are initiated on treatment with more than 2.8 million lives saved. The program has been consistently achieving its objectives of treatment success rate >85% and case

detection rate (CDR) >70% among the new smear positive patients, since 2007, which is in alignment with the global targets. RNTCP is well on track to achieve the Millennium Development Goal (MDG) of halting and beginning to reverse the spread of the disease.[1] The program is now looking toward achieving "universal access," reaching out to the unreached and ensuring that all TB patients receive the highest quality diagnostic and treatment facilities. This therefore now urges to look beyond the objectives of 85/70. The program is also facing the challenge of multidrug resistant TB (MDR TB) and that of human immunodeficiency virus (HIV) coinfection with TB. It is recognized that management of TB control program has relatively complex diagnostics, treatment, and follow-up dimensions. The Joint Monitoring Mission (2009) has also recommended a need to have transition from target-focused monitoring of performance to analysis of key process and outcome indicators.[2]

Also it is need of a time to figure out reasons behind treatment interruption and non-compliance to follow up sputum examinations. Keeping this aspect in mind, this study was planned to assess response and outcome of treatment, various demographic factors associated with treatment outcome and to find out reasons for non-compliance to Directly Observed Treatment Short-course (DOTS) in a tribal area of Thane district of Maharashtra.

Materials and Methods

This study was a cross-sectional observational study undertaken at Designated Microscopy and Treatment Centre in Ganeshpuri, a tribal area in Thane district of Maharashtra state which is also a rural field practice area of institution from May 2014 to October 2014. A total of 126 patients registered for treatment under RNTCP in all four quarters of year 2013 (i.e., 1 January 2013 to 31 December 2013) were included in the study. Though performance indicators ideally should be calculated at tuberculosis unit (TU) level but here we applied it for study purpose. Detailed information on chest symptomatic attending OPD, proportion of sputum positivity in chest symptomatic, proportion of sputum positive in all registered TB cases, sputum conversion rate, treatment outcome about those 126 registered TB cases were collected by reviewing records with the help of a predesigned and pretested schedule. Of these 126 cases, defaulters of treatment and those cases not reported to any one of follow-up sputum examination were contacted through local health volunteers and home visits. After taking an informed consent they are interviewed with the use of pretested proforma for reasons for not attending follow-up sputum examination and treatment interruption. Outpatient registers, various registers maintained under RNTCP and TB treatment cards of patients were reviewed to collect secondary data about TB patients. Permission for study was obtained from concerned authorities under RNTCP and ethical approval was obtained from institutional ethics committee. Operational definitions from RNTCP module issued by Government of India were used for data collection and calculating various proportions.[3,4] Data were entered using Microsoft Excel 2013 version and analyzed with SPSS-v.16.

Result

As shown in Table 1, of the total 126 patients 84.9% and 15.1% were registered for Category 1 and Category 2, respectively. Cure rate was highest (56.5) among patients aged between 45 and 54 years. As age advanced, proportion of death also increased. Treatment completion rate was high in female (50%), but cure rate was more in male (44.9%). No female was defaulter when compared 5.1% default rate in male. Mortality is more in male (10.3%) than female. Of the patients of pulmonary TB 56.1%, 27.6% and 9.2% were cured, treatment completed and died respectively whereas 3.1% were switched to MDR TB treatment. No case was found to be cured in extra pulmonary TB whereas treatment completion rate was 92.9%. The cure rate among Category 1 was

Table 1: Distribution of tuberculosis patients according to treatment outcomes (n = 126)

		Cured (%)	Treatment completed (%)	Defaulted (%)	Died (%)	Transferred out (%)	Switched to MDR TB T/t (%)	Total (%)
Sex	Male	35(44.9)	29 (37.2)	4 (5.1)	8 (10.3)	Nil	2 (2.6)	78 (100)
	Female	20(41.7)	24 (50)	0 (0)	3 (6.3)	Nil	1 (2.1)	48 (100)
Age (years)	0–14	1(11.1)	7 (77.8)	0 (0)	1 (11.1)	Nil	Nil	9 (100)
	15–24	12(42.9)	14 (50)	1 (3.6)	1 (3.6)	Nil	Nil	28 (100)
	25–34	20(52.6)	13 (34.2)	1 (2.6)	2 (5.3)	Nil	2 (5.3)	38 (100)
	35–44	5(29.4)	9 (52.9)	2 (11.8)	1 (5.9)	Nil	Nil	17 (100)
	45–54	13(56.5)	8 (34.8)	Nil	2 (8.7)	Nil	Nil	23 (100)
	>54	4(36.4)	2 (18.2)	Nil	4 (36.4)	Nil	1 (9.1)	11 (100)
Type of TB	Pulmonary	55(56.1)	27 (27.6)	4 (4.1)	9 (9.2)	Nil	3 (3.1)	98 (100)
	Extra-pulmonary	Nil	26 (92.9)	Nil	2 (7.1)	Nil	Nil	28 (100)
Treatment types	Category 1	51(47.7)	43 (40.2)	3 (2.8)	8 (7.5)	Nil	2 (1.9)	107 (100)
	Category 2	4(21.1)	10 (52.6)	1 (5.3)	3 (15.8)	Nil	1 (5.3)	19 (100)

calculated to be 47.7% as compared to 21.1% for Category 2. Treatment completed rate was more in Category 2 (52.6%) than in Category 1 (40.2%). No case of transferred out and failure was observed in this study. Proportion of defaulters and death was more in Category 2 as compared to Category 1. The observed differences were not statistically significant ($p > 0.05$).

As evident from Table 2, in new sputum positive pulmonary TB cases, cure rate was 83.6% and cure rate out of all smear positive cases was 43.7%. Ninety two percent of new smear negative patients had completed treatment. All patients with new extra pulmonary TB had completed treatment. High proportion of mortality was noted in retreatment cases (15.8%) as compared to new cases (7.5%). In new cases, cured rate was highest (47.7%) than other outcomes whereas in retreatment cases treatment completed rate was highest (52.6%).

As observed in Table 3, at pretreatment phase, of the 126 patients 76 (60.3%) were smear positive, 32 (25.4%) were smear negative, and in 18 (14.3%) patients sputum smear examination was not carried out as they were having extra-pulmonary TB without any respiratory symptoms and sign. At end of intensive phase, 83 (65.9%) became negative and 3 (2.4%) remained positive, whereas 40 (31.7%) did not reported for follow-up sputum examination. No sputum positive case was reported in continuation phase and at end of treatment. Highest proportion of non-reporting to follow-up sputum examination found in continuation phase (55.6%). At end of treatment 57.9% cases were negative and 42.1% were not reported. Sputum conversion rate among all smear positive was 96.1%. Sputum conversion rate was 96.7% and 93.3% in new smear positive and previously treated smear positive patients, respectively.

Table 2: Treatment outcomes in new and retreatment cases ($n = 126$)

Treatment outcomes			Cured (%)	Treatment completed (%)	Defaulted (%)	Died (%)	Transferred out (%)	Switched to MDR TB T/t (%)	Total (%)
Types of patients	New cases	SS*. +ve	51 (83.6)	0 (0)	3 (4.9)	5 (8.2)	0 (0)	2 (3.3)	61 (100)
		SS. -ve	NA (0)	25 (92.6)	0 (0)	3 (7.4)	0 (0)	0 (0)	28 (100)
		Extra pulmonary**	NA (0)	18 (100)	0 (0)	0 (0)	0 (0)	0 (0)	18 (100)
		Total	51 (47.7)	43 (40.2)	3 (2.8)	8 (7.5)	0 (0)	2 (1.9)	107 (100)
	Retreatment cases	SS. +ve relapses	4 (57.1)	1 (16.3)	0 (0)	0 (0)	0 (0)	1 (16.3)	6 (100)
		SS. +ve failure	0 (0)	1 (50)	0 (0)	1 (50)	0 (0)	0 (0)	2 (100)
		SS. +ve treatment after default	0 (0)	4 (57.1)	1 (14.3)	2 (28.6)	0 (0)	0 (0)	7 (100)
		Others***	0 (0)	4 (100)	0 (0)	0 (0)	0 (0)	0 (0)	4 (100)
		Total	4 (21.1)	10 (52.6)	1 (5.3)	3 (15.8)	0 (0)	1 (5.3)	19 (100)

*SS- Sputum smear

**Sputum smear negative extra pulmonary cases excluded from sample.

***In rare and exceptional cases, patients who are sputum smear-negative or who have extra-pulmonary disease can have recurrence or non-response. This diagnosis in all such cases should always be made by an MO and should be supported by culture or histological evidence of current, active TB. In these cases, the patient should be typed as 'Others' and given treatment regimen for previously treated.

Table 3: Distribution of tuberculosis patients according to their pretreatment and follow-up sputum examination results ($n = 126$)

Sputum smear results		New	Relapse	Failure	Treatment after default	Others	Total (%)
Pretreatment	Positive	61	6	2	7	0	76 (60.3)
	Negative	28	0	0	0	4	32 (25.4)
	Not done	18	0	0	0	0	18 (14.3)
	Total	107	6	2	7	4	126 (100)
End of Intensive phase	Positive	2	0	0	1	0	3 (2.4)
	Negative	73	5	1	3	1	83 (65.9)
	Not reported	32	1	1	3	3	40 (31.7)
	Total	107	6	2	7	4	126 (100)
Into Continuation phase	Positive	0	0	0	0	0	0
	Negative	51	5	0	0	0	56 (44.4)
	Not reported	56	1	2	7	4	70 (55.6)
	Total	107	6	2	7	4	126 (100)
End of treatment	Positive	0	0	0	0	0	0
	Negative	65	3	1	3	1	73 (57.9)
	Not reported	42	3	1	4	3	53 (42.1)
	Total	107	6	2	7	4	126 (100)

As seen in Figure 1, of the 169 various responses to reasons for not attending follow-up sputum smear examination, lack of awareness (23.1%) and work commitments (18.9%) were commonly given. Negligent about the role of follow-up examination (10.1%), dissatisfaction of drugs (13.6%), too far distance of institution (9.5%) and inconvenient timings (8.9%) were also reasons for non-reporting. Eleven (6.5%) cases were died during follow up.

Table 4 shows various annual performance indicators of designated microscopy and treatment center. Proportion of new smear positive cases among all new pulmonary cases was 68.5% which was satisfying the criteria (at least 50%) set by RNTCP. Ninety-six percent of registered TB patients were tested for HIV. Of these 9.1% were found HIV positive. Sputum conversion rate was 96.1% which was more than criteria (at least 90%) set by program. Proportion of cured and treatment completed were reported nearly same (43%), it might be due to not-attending follow-up sputum examination and cases of extra-pulmonary TB. Treatment failure rate was zero in that year. Defaulters of 3.2% and 2.4% cases were switched to MDR TB treatment.

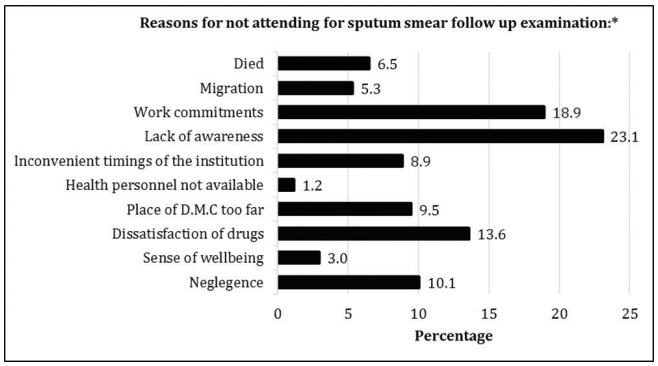

Figure 1: Reasons for not attending for sputum smear follow-up examination (*, Multiple responses; ** Designated microscopy center (DMC)).

Discussion

This study showed that pulmonary TB accounted for 77.8% cases whereas the extra-pulmonary TB accounted for 22.2% cases. The ratio between the two was 3.5:1 as compared to the expected RNTCP criteria of 10:1.[2,4] This relatively higher caseload of extra-pulmonary cases points towards its over-diagnosis. Of the total 126 cases, 107 (84.9%) were new cases and 19 (15.1%) were retreatment cases. the ratio between two was 5.6:1. Treatment success rate (cured and treatment completed) for Category 1 and Category 2 in this study were 87.9% and 73.7%, respectively. Slightly higher proportions were noted in study done by Verma et al.[5] in Lucknow [Category 1 (89.8%) and Category 2 (84%)]. Death during treatment was reported more in men than women. In men maximum death were reported in cases more than 54 years of age. No female case was defaulter whereas 4 (5.1%) of male defaulted treatment. Reasons given by defaulter were side-effects of drugs, sense of

Table 4: Performance indicators

Performance Indicators	Percentage
Case finding indicators	
Proportion of new smear positive cases among all new pulmonary cases	68.5
Proportion of new extra pulmonary TB cases among all new TB cases	16.8
Proportion of smear positive previously treated cases among all smear positive cases	19.7
Proportion of new pediatric cases among all new cases	7.5
TB-HIV status indicators	
Proportion of registered TB patients with known HIV status	96.0
Proportion of registered TB patients found to be HIV-positive	9.1
Sputum Conversion indicators	
Sputum Conversion rate among all smear +ve	96.1
Sputum Conversion among new smear +ve	96.7
Sputum Conversion among previously treated smear +ve	93.3
Treatment outcome indicators	
Cured	43.7
Treatment completed	42.1
Died	8.7
Failure	Nil
Default	3.2
Transferred out	Nil
Switched to MDR TB treatment	2.4

well-being, lack of faith in treatment center, and having faith in traditional healing methods.

Sputum conversion rate at end of intensive phase was 96.1% and failure rate was 3.9%. This satisfied criteria set by RNTCP (i.e., at least 90%).[4] Dembele et al.[6] found that conversion rate was 82.9%. Lack of awareness and work commitments were commonly given reasons for not reporting for follow-up sputum examination. Similar findings were noted in study carried out by Kizito et al.[7]

This study showed that sputum positive rate among chest symptomatic was equal to norm of RNTCP, which indicates good quality of sputum microscopy. Sputum conversion rate was at par with norm of RNTCP indicating toward satisfactory quality of treatment. Proportion of defaulters also satisfied norms by RNTCP (maximum 5%). Success rate of treatment was 85.8% which satisfied set criteria (at least 85%) by RNTCP.[4] Cure rate and treatment completed rate were nearly equal. This might be due to not-attending follow-up sputum examination and cases of extra-pulmonary TB.

Conclusion

Though many of performance indicators were satisfying norms of RNTCP but still study showed one-third of the cases did not reported for follow-up sputum examination at the end of intensive phase and half of the cases at end of the treatment. Lack of awareness was the most common reason. This finding underlines the need of health education and counselling in current TB case management. So health educating and counselling of patients and their families about various aspects of tuberculosis and its management will improve their compliance toward treatment and follow-up sputum examinations. This ultimately improves the performance of program.

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References

1. TB India 2013, RNTCP status report. New Delhi: Central TB division, Ministry family of health and family welfare, Nirman Bhawan, 2013. pp. 11–15.
2. Supervision and Monitoring strategy in RNTCP. New Delhi: Central TB division, Ministry family of health and family welfare, Nirman Bhawan, 2012. pp. 1–5.
3. Managing the Revised National Tuberculosis Control Programme in your area. A Training Course—modules (1–4). New Delhi: Central TB Division, Ministry of Health and Family Welfare, Nirman Bhavan, New Delhi, 2010. pp. 1–195.
4. Managing the Revised National Tuberculosis Control Programme in your area. A Training Course—modules (5). New Delhi: Central TB Division, Ministry of Health and Family Welfare, Nirman Bhavan, 2010. pp. 1–71.
5. Verma SK, Kant S, Kumar S, et al. A Five-Year Follow-up Study of Revised National Tuberculosis Control Programme of India, Lucknow. Indian J Chest Dis Allied Sci 2008;50:195–8.
6. Dembele SM, Quedraogo HZ, Combary A, Saleri N, Macq J, Dujardin B. conversion rate at two month follow-up of smear positive TB patients in Burkina Faso. Int J Tuberc Lung Dis 2007;11:1339–44.
7. Kizito KW, Dunkley S, Kingori M, Reid T. Lost to follow up from tuberculosis treatment in an urban informal settlement (Kibera), Nairobi, Kenya: what are the rates and determinants? Trans R Soc Trop Med Hyg 2011;105:52–7.

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