Original Article

Prospective 1-year follow-up study of all cured, new sputum smear positive tuberculosis patients under the Revised National Tuberculosis Control Program in Hyderabad, Telangana State, India

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ABSTRACT

Background: Tuberculosis (TB) is one of the leading causes of mortality in India. The Revised National Tuberculosis Control Program (RNTCP) is a robust public health system to deal with TB in India. Unless the treated patient comes back to the system with signs and symptoms of TB due to relapse or re-infection, there is no mechanism of follow-up or any method to know the relapse rate in the population. We attempted to follow the patients declared as "Cured" as per the RNTCP guidelines for 1–2 years to identify the health status of the index cases and their household contacts in posttreatment phase. **Materials and Methods:** In this prospective cohort study, 187 index cases, who were declared "Cured" in six randomly selected TB units of Hyderabad district, were followed up for 1–2 years through home visits by trained staff with structured data collection forms. Data were analyzed using SPSS v20.0. **Results:** The mean age of the index cases was 33.64 (±16.10) years, and there were 75 females and 112 males. The study sample was homogenous for gender, age, smear grade, religion, marital status, smoking status, alcohol consumption, and human immunodeficiency virus status, etc., At 1-year posttreatment follow-up of 187 index cases, 143 (76.47%) were healthy and working without any symptoms of TB. Symptoms of TB were present in 26 (13.90%) cases, and seven index cases (4.06%) were re-diagnosed with TB. The 2-year posttreatment survival was 92%. **Conclusion:** Long-term follow-up of cured, new smear-positive TB cases reinforce the effectiveness of anti-TB treatment under the RNTCP as assessed by improved health outcomes in more than two-thirds of cases and posttreatment survival of 92% of index cases. We recommend continuing such follow-up for all TB cases treated under the RNTCP for effective end-TB strategy.

KEY WORDS: Follow-up, health status, new sputum smear positive (NSP), posttreatment survival, Revised National Tuberculosis Control Program, tuberculosis

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INTRODUCTION

Tuberculosis (TB) continues to be India's severest health crisis and kills an estimated 480,000 Indians every year and more than 1400 every day.[1] The Revised National Tuberculosis Control Program (RNTCP) was launched nationwide in 1997, and control of TB in India has since shown a remarkable progress, with more than 10 million TB patients treated under the Directly Observed Treatment, Short-course (DOTS) chemotherapy strategy of the RNTCP.[1,2]

Treatment success under the DOTS concerns two outcomes – cured and treatment completed. Despite assessed as cured, patients can develop recurrent disease sometime after completing treatment either due to relapse of the same infection or reinfection with a different strain of *Mycobacterium tuberculosis* (MTB).[3,4]

Recurrent disease is still considered to be an important measure of the efficacy of TB treatment, and it also has a major impact on patients. Recurrence rate is high in countries of high TB incidence[5,6] and reinfection is the principal cause,[7] especially in the presence of high prevalence of coexisting human immunodeficiency virus (HIV).[8,9] However, recurrence rate is low in countries with a low TB incidence and is mainly caused by relapse of a previously cured TB episode.[10,11]

Among TB patients who had successfully completed treatment, varying mortality rates have been reported,[12-14] and it has been suggested that the treatment outcome may not reflect final status of the patient.[15]

Household contacts of TB patients are at an increased risk of exposure to the disease-causing organism than the general population.[16,17] Several studies from high-burden countries have also shown that active case finding among household contact yields significantly more TB cases than passive case detection.[17-19]

According to the Standards of TB Care in India, after completion of TB treatment, the patients should be followed up with clinical and/or sputum examination at the end of 6 months and 12 months.[20] Long-term follow-up of cured TB patients will be useful for assessing health outcomes, which enables early detection of recurrence and mortality among these patients.

There is relatively little data about prospective long-term follow-up of cured TB patients. Thus, our study aims to prospectively follow cured new smear-positive pulmonary TB cases under the RNTCP for 1–2 years and assess their general health status and status of TB among them.

MATERIALS AND METHODS

The present study was a prospective cohort study conducted from June 2016 to June 2018 in six randomly selected RNTCP TB units (TUs) among 16 TUs in Hyderabad district, Telangana state, India. The 6/16 randomly selected TUs were (1) Secunderabad, (2) Cantonment, (3) Osmania, (4) Nampally, (5) Barkas, and (6) Dabeerpura. The study population was all cured, new sputum smear positive (NSP) (RNTCP category 1) TB cases who were declared "Cured" as per the RNTCP definition during June 2016–April 2017 and are referred to as index cases. These index cases were diagnosed as NSP cases, were initiated treatment during 2016 (66.3%) and 2017 (33.7%), and were declared "Cured" as per the RNTCP definitions.

Sample size

Expecting a relapse rate of 10% in India,[21] the minimum sample size required to detect the relapse rate within 95% confidence limits was calculated to be 139. The adjusted sample size with an expected 80% response rate was 174, and the study finally included 187 patients from the designated cohort.

Approval was obtained from the institutional ethics committee prior to the commencement of the study. Written informed consent was obtained from all index cases.

Data collection was done by specially recruited, trained program assistants for the project with the support of RNTCP field staff. Letter of support from District TB Control Officer was obtained to facilitate home visits to the index cases which were conducted at the beginning of the data collection, followed by 6-monthly visits until the end of the study. During the home visits, the following symptoms of TB were explored through interactions with the index cases: chronic cough of >2 weeks' duration, production of sputum and blood-streaked sputum, unexplained weight loss, fever, fatigue/tiredness, night sweats, breathlessness, and chest pain. An index case or a family member of an index case was noted even with any one of the above symptoms either alone or in combination.

In addition, the index cases were asked about their current health status and whether they were currently working and, if not working, it was further inquired if it was due to poor health after TB treatment or some other reason.

The index cases were also followed up through phone calls every 3 months. Special home visits were also done if any information on phone call needed visit in person to the index case. Oral consent of the index cases was obtained for data collection.

Statistical analysis

Data collected in specially designed formats were collated into SPSS Statistics Version 20.0.0 (IBM) for further analysis. Continuous variables were expressed as mean (± standard deviation [SD]). Mortality rate was calculated as number of deaths per 1000 person-years. Test for statistical significance of demographic characteristics for mortality and recurrence was applied using Pearson's

Chi-square or Fisher's exact test, as applicable, for analyzing the difference between the two proportions ($P < 0.05$ was considered statistically significant). Kaplan–Meier survival analysis was used to plot posttreatment survival of index cases.

RESULTS

A total of 187 index cases were contacted from six randomly selected TUs of Hyderabad district in Telangana state, India. The mean (±SD) age of the index cases was 33.64 (±16.10) years; it was 29.63 (±15.38) years and 36.32 (±16.09) years among females and males, respectively (range: 7–105 years). There were 75 (40.11%) females and 112 (59.89%) males among a total of 187 index cases. There were 42% of unmarried index cases, which was little higher among women than men. However, the sample was homogenously distributed (χ^2 P = 0.411). Alcoholism and smoking were prevalent at around 30% among male index cases, whereas none reported among women index cases. Sputum smear (SS) grading was not statistically significantly different among men and women index cases (χ^2 P = 0.203). HIV as a comorbidity was present in seven (3.7%) cases. Proportion of Muslim women index cases was observed to be higher but was not found to be statistically significant (χ^2 P = 0.193). Nuclear family setup was observed among the index cases but was not statistically significant with respect to the gender of patients (χ^2 P = 0.104). Sociodemographic characteristics of the index cases are depicted in Table 1.

Health status of index cases during posttreatment follow-up

At 1-year posttreatment follow-up of 187 index cases, 143 (76.47%) were healthy and working without any symptoms of TB. Of the remaining, 19 (10.16%) cases were healthy but not working due to reasons other than TB and 15 (8.02%) were unable to work due to TB morbidity. At 18th-month posttreatment follow-up of 183 index cases, 146 (79.78%) cases were healthy and were working without any symptoms of TB and 11 (6.01%) were unable to work due to TB morbidity. At 1-year posttreatment follow-up, symptoms of TB were present in 26 (13.90%) cases and 161 (90.96%) patients were asymptomatic.

Recurrence

Seven index cases (4.06%) were re-diagnosed with TB during the follow-up and were promptly put on treatment under the RNTCP. The months at which the seven index cases were re-diagnosed with TB were at 6th, 11th, 12th, 13th, 15th, 16th, and 19th month, respectively. All cases of recurrence were negative for HIV. The health status of index cases during posttreatment follow-up (at 3rd, 6th, 9th, 12th, 18th, and 24th month) is depicted in Table 2.

Mortality and survival among index cases

At 1-year posttreatment follow-up, ten index cases had died, and the 1-year mortality rate was 53.48 deaths per 1000 person-years; six deaths were reportedly due to TB and 94.65% cases were surviving. At 18th-month posttreatment follow-up, four more cases had died and 92.51% were surviving; at the end of 24-month follow-up, 15 cases had died. The mean age of cases who died was

Table 1: Sociodemographic characteristics of the index cases

Variable	Study population			χ^2 P
	Female (n=75), n (%)	Male (n=112), n (%)	Total (n=187), n (%)	
Age (years), mean±SD	29.63±15.38	36.32±16.09	33.64±16.10	
Marital status				
Married	41 (54.7)	68 (60.7)	109 (58.3)	0.411
Unmarried	34 (45.3)	44 (39.3)	78 (41.7)	
Alcohol				
Yes	0	34 (30.4)	38 (20.3)	Not valid
No	75 (100)	78 (69.6)	149 (79.7)	
Smoking				
Yes	0	38 (33.9)	38 (20.3)	Not valid
No	75 (100)	74 (66.1)	149 (79.7)	
SS grade at the time of diagnosis				
Scanty	8 (10.7)	9 (8.0)	17 (9.1)	0.203
1+	38 (50.7)	42 (37.5)	80 (42.8)	
2+	14 (18.7)	27 (24.1)	41 (21.9)	
3+	15 (20.0)	34 (30.4)	49 (26.2)	
HIV status				
Negative	73 (97.3)	107 (95.5)	180 (96.3)	Not valid
Positive	2 (2.7)	5 (4.5)	7 (3.7)	
Religion				
Hindu	33 (44.0)	65 (58.0)	98 (52.4)	0.193
Islam	40 (53.3)	46 (41.1)	86 (46.0)	
Christianity	2 (2.7)	1 (0.9)	3 (1.6)	
Type of family				
Nuclear	48 (64.0)	87 (77.7)	135 (72.2)	0.104
Joint	6 (8.0)	4 (3.6)	10 (5.3)	
Extended	21 (28.0)	21 (18.8)	42 (22.5)	

SD: Standard deviation, HIV: Human immunodeficiency virus, SS: Sputum smear

Table 2: Health status of the index cases during posttreatment follow-up

Follow-up months	Healthy and working	Healthy but not working due to other reasons	Not working due to poor health after TB treatment	Number of dead	Total
At 3 months					
Living status	10 (66.67)	2 (13.33)	2 (6.67)	1 (6.67)	15 (100)
Number of index cases with TB symptoms	1 (6.67)	0	2 (13.33)		3 (20)
At 6 months					
Living status	32 (65.31)	11 (22.45)	4 (8.16)	2 (4.08)	49 (100)
Number of index cases with TB symptoms	3 (6.12)	2 (4.08)	4 (8.16)		9 (18.37)
At 9 months					
Living status	64 (66.67)	18 (18.75)	8 (8.33)	6 (6.25)	96 (100)
Number of index cases with TB symptoms	4 (4.17)	2 (2.08)	8 (8.33)		14 (14.58)
At 12 months					
Living status	143 (76.47)	19 (10.16)	15 (8.02)	10 (5.35)	187 (100)
Number of index cases with TB symptoms	10 (5.35)	3 (1.60)	13 (6.95)		26 (13.90)
At 18 months					
Living status	146 (79.78)	12 (6.56)	11 (6.01)	14 (7.65)	183 (100)
Number of index cases with TB symptoms	7 (3.83)	4 (2.19)	11 (6.01)		22 (12.02)
At 24 months					
Living status	26 (59.09)	1 (2.27)	2 (4.55)	15 (34.09)	44 (100)
Number of index cases with TB symptoms	1 (2.27)	0	1 (2.27)		2 (4.55)

TB: Tuberculosis

40.93 (±13.48) years. The cause of death as reported by the family members of six of the ten index cases was TB before death. All the 15 cases who died were negative for HIV. The survival graph of index cases 2 years after treatment completion is depicted in Figure 1.

Contact tracing

Among the total 692 family members of the index cases, four (0.58%) had symptoms of TB, of which two (0.29%) were confirmed with TB diagnosis through RNTCP laboratory network.

DISCUSSION

Health outcomes of patients at 1-year posttreatment follow-up

In the present study, 86.63% of the index cases were healthy and were either working/not working due to reasons other than TB and 15 (8.02%) were unable to work due to TB morbidity. The 1-year posttreatment disease-free survival was 94.65%, which reinforces the effectiveness of DOTS and anti-TB treatment.

Relatively few prospective studies have reported the health outcomes of cured patients. In a retrospective study by Joseph *et al.*,[14] 73.6% of cases were healthy. A systematic review by Cox *et al.*[21] has also identified that when quality of services is good, effectiveness of DOTS is very high.

In the present study, symptoms of TB were present in 26 (13.90%) cases. Banu Rekha *et al.*[22] from TRC Chennai had reported 29% of residual respiratory problems 14–18 years after treatment with short-course regimens. In the retrospective study by Joseph *et al.*,[14] 29.87% patients were symptomatic.

In the present study, 161 (90.96%) patients were asymptomatic. In their prospective cohort study, Vijay

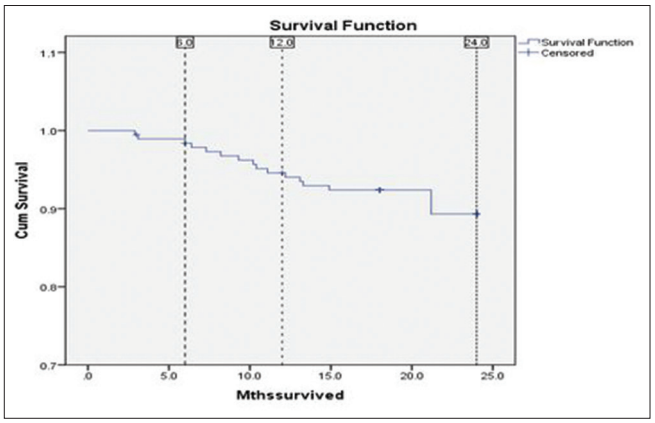

Figure 1: Survival graph 2 years after treatment completion

et al.[23] followed up patients for 2.5 years and reported that 79.6% of new SS-positive patients were asymptomatic. In their retrospective 5-year follow-up study of patients who had completed treatment under the RNTCP, Verma *et al.* [24] revealed that 73 (91.2%) were asymptomatic.

Mortality

In the present study, at 1-year posttreatment follow-up, ten (5.34%) index cases had died and the 1-year mortality rate was 53.48 deaths per 1000 person-years. Of the ten deaths, six were reportedly due to TB.

The mortality in the present study was higher than the national mortality due to TB of 32/100,000 population but was comparable with mortality rates reported by similar studies. In the study by Joseph *et al.*,[14] the overall mortality was 42.7/1000 person-years. In a prospective study among successfully treated new smear-positive pulmonary TB patients by Vree *et al.*[13] in Vietnam, 19 (6%) patients had died. In the study by Kolappan *et al.*,[25] the general mortality rate for the study cohort was 61.0/1000 person-years, which is higher than the present study,

probably due to the inclusion of all patients registered under the RNTCP.

It is known that mortality rates decline faster than incidence rates under an efficient control program and that they can be used as an impact indicator.

In the present study, mortality was not found to be associated significantly with age, gender, education, occupation, smoking status, alcohol consumption, SS at diagnosis, marital status, and socioeconomic status ($P > 0.05$), probably due to the inclusion of only cured new sputum smear positive (NSP) patients. Datiko and Lindtjørn[26] have reported similar findings; however, other studies have reported significant associations of mortality in cases during follow-up with the abovementioned factors.[14,25]

In the present study, the mean age of cases who died was 40.93 (±13.48) years, which is much lower than the mean age of 60.6 years of patients who died, as reported by Joseph *et al*.[14]

The cause of death in the index cases was reported to be TB in 53.33% of cases and due to causes other than TB in 46.67% of cases. A more detailed verbal autopsy to ascertain the cause of mortality in TB cases would be potential area of further research.

Recurrence

In the present study, the recurrence of TB was observed in 4.06% of cured patients at 12 months of follow-up, which was higher than the national TB incidence of 217/100,000 population in 2017.[2]

Variable findings are reported by other studies. Vree *et al*.[13] have reported relapse in 8.6% of patients. In studies conducted in South India by Thomas *et al*.,[6] 12% of patients relapsed during the 18-month follow-up period. In the study by Vijay *et al*.,[23] relapses during the intervening period were 11.4%, which is higher than that observed in the present study, probably due to the fact that they were conducted more than a decade ago and included bacteriological confirmation in all categories of patients.

Some studies have reported lower recurrence. Joseph *et al*.[14] and Millet *et al*.[27] have reported recurrences of 0.4% and 1.3%, respectively, probably due to longer period of follow-up after cure (3–7 years). In the study by Chang *et al*.,[28] the overall 30-month relapse rate was 0.9%.

The recurrence rate in the present study was 12 times higher than the incidence of TB in the general population. This reinforces the observation that TB is more frequent in persons who have had a history of TB treatment; the same is also corroborated by other studies.[4] TB recurrence in the present study was not associated with age, sex, occupation, marital status, level of education, and HIV status.

Contact tracing

In the present study, among family members of index cases, four (0.58%) had symptoms of TB of which two (0.29%) were confirmed with TB diagnosis through RNTCP laboratory network. In North Indian studies conducted by Dhingra *et al*.[18] and Singh *et al*.,[19] 6.9% and 4.3% of household contacts, respectively, were found to be MTB culture positive. In a study on household contacts of newly diagnosed SS-positive pulmonary TB (PTB) cases by Gupta *et al*.,[29] 3.45% of cases had symptoms suggestive of TB of whom six (1.15%) contacts were diagnosed to have TB.

The prevalence of TB is higher in household contacts of PTB cases than that in general population as transmission can happen from index case to the contact any time (before diagnosis or during treatment), which is reinforced by findings of the present and abovementioned studies. In the National Strategic Plan for Elimination of Tuberculosis (2017–2025), screening of close contacts of TB cases has been emphasized.

Strength

The present study was a prospective study where index cases were visited at their houses.

Limitations

One major limitation of the study is that the "cause of death" in cured TB cases was ascertained verbally from their relatives, as death reports/certificates could not be availed. Another limitation of the study is that the SS examination and X-ray were done only in symptomatic cases and household contacts only and not in the entire study cohort. Longer periods of follow-up would provide additional information on treatment efficacy. Genotyping of recurrent cases was not performed to distinguish between relapse and reinfection. The sample involved cured NSP category 1 cases from the RNTCP only and not all types of TB cases.

CONCLUSION

Long-term follow-up of cured NSP cases reinforces the effectiveness of anti-TB treatment under the RNTCP as assessed by improved health status in more than two-thirds of cases and posttreatment survival of 92% of index cases. Further follow-up studies are suggested involving all types of TB cases to better understand the posttreatment health status among TB patients and their household contacts from both public and private sectors.

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Conflicts of interest

There are no conflicts of interest.

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