

Original Research Article

Reasons for default and death among tuberculosis cases treated under revised national tuberculosis control program in selected tuberculosis units of Bangalore urban district of Karnataka state

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ABSTRACT

Background: Tuberculosis (TB) is a disease of great antiquity. *Mycobacterium tuberculosis* is a formidable pathogen. Tuberculosis still remains a worldwide problem, despite the facts that proper medications are available to treat the condition. Defaulting from the treatment is a serious issue in the treatment failure. The current study was undertaken to understand the default rate, death and its reasons among the TB patients who underwent treatment in two selected DOTS centre at Bangalore Urban district of Karnataka state.

Methods: A cross-sectional study was conducted on 160 default patients treated under RNTCP at two randomly selected TB centres. The interview was conducted using a semi-structured questionnaire. Patient's relatives were interviewed in case of deaths. Appropriate statistics were used to find the significance.

Results: Among the total study subjects, the 75% of the cases were males, 71.9% were in the age group 15-44 years. More than 46% of the patients were registered in category-1. The study observed that 70% of the patients defaulted during the continuation phase and only 30% defaulting was observed in the initial phase. Migration, side effects of the drugs and alcohol addiction were the major reasons for discontinuing from therapy. Maximum death (52%) was observed among Cat-1 followed by Cat-2 and the highest death rate was observed among >45 years age group.

Conclusions: The study concludes that the default was prevalent among the study population, migration and untoward effects of the drugs were the important factors of default.

Keywords: Pulmonary tuberculosis, Treatment default, Deaths, Knowledge regarding tuberculosis

INTRODUCTION

Tuberculosis (TB) is a disease of great antiquity. Tuberculosis still remains a worldwide problem, despite the fact that its causative organism was discovered more than 100 years ago by Robed Koch and effective anti-tuberculosis drugs have been invented decades ago.¹ Tuberculosis is not only a health concern but also a complex socio-economic problem that impedes human development. In 1993, WHO took the unprecedented step of declaring tuberculosis epidemic to be a global

emergency. The dual problems of HIV epidemic and the rise in MDR-TB make the TB epidemic even more aggressive.²

Tuberculosis has been reported as one of the most important public health problems in all regions of WHO, using surveillance and survey data. More than 80% of the global TB burden lies in South East Asian region and India is been reported as the country with highest TB burden in the world. The World Health WHO-TB statistics for India for 2016 give an estimated incidence

figure of 2.79 million cases of TB for India. However, TB mortality in the country was reduced from 42/100,000 population in 1990 to 24/100,000 population in 2013.³

To curb the menace of TB and to reduce the TB load in the community, National Tuberculosis Program (NTP) was launched throughout the country in 1962. Different evaluation studies showed that NTP was not as successful as expected therefore need was there to introduce a new program. In 1992, Nation Wide Review of the National Tuberculosis Program was conducted jointly by the Government of India, WHO and World Bank.⁴ Based on the evaluation and findings, NTP was revised and new objectives were set. Accordingly, in 1993, Revised National Tuberculosis Control Program (RNTCP) was launched in the country. Initially, the project was implemented as a pilot program executed in 5 regions. Later WHO-recommended DOTS strategy (Directly Observed Treatment, Short-Course) and Government of India designed the program in 1997 with the support of World Bank. By the end of 1998, only 2% of the population of India was covered by RNTCP. Large-scale implementation started in late 1998. Later the RNTCP coverage was increased and found to be effective. The population covered by RNTCP increased from 18 million in 1998 to 851 million by the end of May 2004 covering 76% of the country's population. By the end of 2004 approximately 947 million of the population (87%) was covered under RNTCP full nationwide coverage was achieved in March 2006 covering over a billion populations.⁵

Bangalore urban district has 5 TB units which cater to the health needs of TB patients. The RNTCP status of default rate is 6.4% and the mortality rate is 4.6% in India, whereas in Karnataka default rate is 9.8% and the death rate is 6.5% which is higher than the RNTCP guidelines. Hence we undertook this research to find out the default and death cases in Bangalore Urban district and to analyze the causes of default and death among TB patients treated under RNTCP.

METHODS

It was a cross-sectional study conducted among the TB patients who visit the 2 TB units which include Anekal, Abbigere, under Bangalore urban district during 2010 January to December. All the cases of default and death in selected TB units of Bangalore Urban district. In case of non-availability for at least 3 visits during the study period were excluded from the study. Based on previous studies, the sample size was calculated and 157 subjects were recruited into the study. The cases were chosen by simple random sampling. The required data was collected by using a semi-structured questionnaire based on the objectives and variables of the study. After collecting the basic information from the treatment register and treatment card, the patients were interviewed at their residences. In case of death, the interview was elicited from a first degree relative to the treatment and whether

they had defaulted during the treatment and reasons for the death. The term default was defined as "Any TB patient who has not taken anti-tuberculosis drugs for two months or more consecutively after starting treatment". The death is defined "the patient who died during the course of treatment, regardless of the cause of death". The authors obtained ethical committee approval from Vydehi Institute of Medical Science ethical committee and permission was obtained from District Tuberculosis officer (DTO), Bangalore urban district to perform the research.

Descriptive statistics were used to assess the demographic parameters. Chi-square and Fisher Exact test was used to find out the significance of study parameters on a categorical scale between two or more groups. The continuous values were expressed in Mean $\pm$ SD and categorical measurements were expressed in percentage (%).

RESULTS

In the current study, we examined 160 default cases during the study period. During the study, we collected data such as gender, age, religion, socioeconomic status, the category of the treatment, type of DOT provider, place of DOT, number of missed doses and default retrieval action. Out of 160 cases, we could analyze only 126 cases as remaining 34 cases were migrated to different places. Out of 160 cases, 120 cases (75%) were males and 40 (25%) were females. The mean $\pm$ SD age was 36.81 $\pm$ 13.09 and the majority of the patients were in the productive age group of 21-40 years. The study also pointed out that 74 (46.3%) of defaulters belonged to CAT-I, 64 (40%) to CAT-II and 22 (13.8%) to CAT-III. Out of the 160 cases, 45.2% (n=57) did not have even primary school education and 19.8% (n=25) had an only primary education. Among the total cases, 74 males and 23 females (76.98%) were found to be married. The study also pointed out that majority of the patients (58.9%) were employed in several areas and 29.3% patients were not going for any job. Nearly 11% of the patients went outstations for employment-related works. Out of the employed patients, 34.2% (41 males and 2 females) patients reported that the disease affected their profession.

The detailed evaluation of the treatment card revealed that 60.3% (n=76) patients were visited by health centre staff and 20.6% (n=26) patients were visited by senior treatment supervisors as part of the initial home visit before the commencement of the treatment course. We could not retrieve any data regarding the initial home visit in 13.4% (n=17) cases. The information regarding the DOT providers pointed out that 75% of the patients were catered by a pharmacist, Anganwadi teachers, junior health assistant and Tuberculosis health visitor whereas the remaining patients were catered by medical officers, nurses, field health workers and social workers. The information about the places of DOT delivery revealed

that 88% (n=140) of the patients obtained treatment from PHCs and Anganawadis. Others obtained the treatment

from Nirashitra Parihara Kendra (NPK), private clinics, community health centres and other healthcare providers.

Table 1: Distribution of study subjects according to reason for stopping treatment.

Reason for stopping treatment	Male		Female		Total	
	Total	Percentage (%)	Total	Percentage (%)	Total	Percentage (%)
Migration/out of station	30	25.00	8	20.00	38	23.75
Side effects	23	19.17	5	12.50	28	17.50
Alcohol addiction	15	12.50	1	2.50	16	10.00
Treatment else where	7	5.83	8	20.00	15	9.38
Symptoms disappeared	9	7.50	2	5.00	11	6.88
Felt better or cured	7	5.83	4	10.00	11	6.88
Too many tablets	4	3.33	3	7.50	7	4.38
Stigma	4	3.33	3	7.50	7	4.38
No Improvement	4	3.33	2	5.00	6	3.75
Centre timing not suitable	4	3.33	1	2.50	5	3.13
Patients too sick	5	4.17	0	0.00	5	3.13
Personal problems	4	3.33	1	2.50	5	3.13
No faith in treatment	2	1.67	1	2.50	3	1.88
No money to travel	1	0.83	1	2.50	2	1.25
Rude behaviour of staff	1	0.83	0	0.00	1	0.63
Total	120	100.00	40	100.00	160	100.00

Table 2: Default retrieval action.

Defaulter retrieval action (DRA)	Number of patients responded (n=160)	Percentage (%)
Taken	133	83.1
Not taken	13	8.1
Not recorded/stated	12	7.5
Not applicable	2	1.3

Table 3: Distribution of deaths due to tuberculosis according to category of treatment.

Category	Male		Female		Total	
	Total	Percentage (%)	Total	Percentage (%)	Total	Percentage (%)
CAT I	10	52.63	4	80.00	14	58.83
CAT II	4	21.05	0	0.00	4	16.67
CAT III	5	26.32	1	20.00	6	25.00
Total	19	100.00	5	100.00	24	100.00

Table 4: Distribution of deaths according to age group.

Age group	Male		Female		Total	
	Total	Percentage (%)	Total	Percentage (%)	Total	Percentage (%)
<15	0	0.00	1	20.00	1	4.17
15-29	2	10.53	0	0.00	2	8.33
30-44	7	36.84	3	60.00	10	41.67
≥45	10	52.63	1	20.00	11	45.83
Total	19	100.00	5	100.00	24	100.00

Mann-Whitney test was used to analyze the difference in default rate in the different phases of the DOT management. Even though there was the mean rank

difference in both in males and females in phase-2 therapy, there was no statistically significant difference in the default rate between phase-1 and 2. The further

analysis we found that 45.6% of the patients were not informed about the treatment transfer facility in DOTS and 33% of the people were informed about the transfer facility. Remaining people were not available as they were already migrated to other places. The present study revealed that only 60% of study subjects felt the place was suitable for DOT, only 5% had responded that there was adequacy of drinking water and 22% had said that waiting area and seating provision was adequate in the DOT centre. These aspects need to be improved in order to prevent default.

In the current study, further, we analyzed the reasons for discontinuing the treatment (Table 1). The result showed that 30 patients (25%) discontinued the therapy due to migration associated with the job and other personal reasons. Untoward effects of antitubercular drugs were responsible for 19.2% of the discontinuation. Alcohol addiction, no significant improvement in symptoms and lack of motivation are the other reasons for discontinuation of the treatment. Regarding the default retrieval action, we found that in 83.1% patients, default retrieval action was taken, whereas, in 8.1% of the patients, the default retrieval action was not taken. No record was available in 7.5% cases and in 1.3% of cases the retrieval action was not applicable (Table 2).

Table 3 shows the death rate in each category of DOTS. CAT I accounted for 14 deaths (58.3%), followed by CAT II and CAT III accounting for 4 (16.6%) and 6 (25%) respectively. The age wise death rate analysis showed that age >45 years accounted for 11 deaths (45.5%) followed by 10 deaths (41.6%) in 33-40 year age group. Less than 15 year of age group had least death rate (8.3%) (Table 4). The data also showed that maximum death (66.6%) occurred among the patients who had defaulted during the course of treatment. Nearly 34% of the death cases had HIV as comorbidities and 25% had bronchial asthma.

In this study it was found that the mortality in regular treatment patients was only 1.26% whereas in default patients it was 19.51%, ($p < 0.001$).

DISCUSSION

The study was conducted to assess the rate of default and deaths in Bangalore Urban district and to analyze the causes of default and death among TB patients treated under RNTCP. We have evaluated patient and treatment-related aspects in detail. The study showed that majority of the patients was males and belongs to productive age group. (21-40 year) The findings were at par with the observations of Chatterjee, et al.⁶ The initial home visit by the healthcare workers is very important to induce the confidence in the patients. The current study revealed that 14% of the patients did not have or not recorded the home visit by any of healthcare providers. A home visit is an important step to trace the defaulters and bring back

them to the treatment course. In the study done by Vijay et al observed that the lack of home visit was one of the major reasons for the default from treatment.⁷

In the current study, we observed that majority of the patients were catered by pharmacist followed by Anganwadi teachers. Usually, the exclusive DOT workers like volunteers are trained to serve and motivate the TB patients. A study done on treatment compliance in 2 tuberculosis units in Gujarat, revealed that patients who were observed by Government DOT workers defaulted twice more than that catered by volunteers.⁸

The current study revealed that 70% of the default happened in continuation phase (75%). In the continuation phase, the major symptoms may be disappeared and the patient may be symptomatically better. This could be the reason for the maximum default in the continuation phase. In the study conducted by Vijay et al, found that the rate of default was maximum in continuation phase in an urban area.⁷ Khans, et al also observed the similar outcome where they found that maximum default happened in 3rd and 4th month of the treatment course.⁹

In this study, it was found that only less than 40% of the patients were informed about transfer facility, and the majority was not aware of the treatment transfer facility and few were already migrated to different places. It is important to inform the patients about transfer facility so that the number of defaults can be reduced and patients can be redirected when they migrate to different places. The present study revealed that only 60% of study subjects felt the place was suitable for DOT. Some patients even commented about the availability of drinking water and other amenities in the DOT centres. These aspects need to be improved in order to prevent default. More studies should be taken up in future regarding patient satisfaction which would promote patient retention during the course of treatment.

In the current study, we observed that the major reasons for the discontinuation of therapy were migration, adverse effects of drugs and alcohol addiction. These three factors are responsible for more than 50% the total discontinuation. The selected location of the study contains a large proportion of the mobile population who comes to the area for job purpose. People frequently migrate to different places which may affect the course of treatment. The adverse effects of the drugs like orange discolouration of urine, hepatotoxicity, neuropathy, etc can badly affect the patient compliance. Alcohol addiction is a serious issue and the person may deviate from normal life and forget to take the antitubercular medicine regularly. All these factors can significantly contribute to the default rate. The study conducted by Vijay et al found that the major reason for default were side effects account for 37% and unsuitable DOT timings in 14%.⁷ Chatterjee et al revealed various reasons for

defaulting and important ones were indifference after an improvement in symptoms, distance from the treatment centre, lack of motivation, intolerance to drugs and temporary illness.¹⁰ Whereas, Chandrasekhar et al, reported in their study that major reasons for default were migration, work-related issues, adverse effects and alcohol addiction. In this study, it was found that the default retrieval action was not there in more than 80% the cases which contribute the high incidence of default in the treatment course.¹¹

In the present study, it was found that CAT I accounted for more than 50% death during the treatment followed by CAT II and CAT III. We also observed that the age greater than 45 years accounted for 46% deaths followed by 30- 45 year age group. Least death rate was observed among less than 5 year age group. According to Gopi et al, 70% of death among TB patients occurred after the age of 60 years.¹² Vasantha et al also observed similar findings in their study. In this study, it was found that the number of deaths occurred more among patients who had defaulted treatment than those on regular treatment.¹³ The observation was similar to the study conducted by Santha et al; they found that the maximum death rate was observed in the default group. In this study, it was found that HIV infections were the most important comorbidities followed by bronchial asthma.¹⁴ Vasantha et al found the same observation in a study conducted among the urban population.¹³ Whereas Kartalogu, et al found a different observation in their study.¹⁵ Alcoholism and diabetes were the major comorbidities in their study. Hence, we can assume that the pattern of comorbidities may vary from place to place.

CONCLUSION

The study concludes that the default was prevalent among the study population. We also found that migration and untoward effects of the drugs were important factors of default. HIV infection was the important comorbidity among the selected patient population. Majority of the default was observed in the continuation phase. Lack of awareness, motivation and information about transfer facilities are also contributed to the default rate. We also found that mortality rate was higher among defaulters than the patients on regular treatment. The highest mortality was noted among the >45 age group.

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