

Original Research Article

A study on co-morbidities and treatment outcome based on updated definitions among tuberculosis patients registered at a tuberculosis unit, Bangalore

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ABSTRACT

Background: Tuberculosis remains one of the world's deadliest communicable diseases and a major public health problem and is a most common opportunistic infection in people living with HIV. The treatment outcome of Tuberculosis is influenced by numerous factors of which presence of co-morbidities is one of the factors. The present study was done with following objectives, to assess the proportion of co-morbidities and treatment outcome of the Tuberculosis cases registered for DOTS treatment at the Tuberculosis unit.

Methods: A Descriptive study was conducted at a Tuberculosis Unit in Bangalore with 80 subjects selected by purposive sampling satisfying inclusion & exclusion criteria. Data was collected using a pretested semi structured proforma administered to all the study subjects by trained investigators. Data regarding socio demographic profile, profile of tuberculosis, medical co-morbidities which the subjects were suffering were collected and these patients were followed up till their treatment completion and outcome of treatment was given based on new WHO definitions.

Results: The present study showed that, 38 (47.50%) of the study subjects had one or the other comorbidities with chronic obstructive pulmonary disease being the most common 18(22.5%) followed by Diabetes 13(16.25%). On determining the treatment outcome of the study subjects the overall treatment success rate was 86.25% which included the cured and treatment completed subjects. However there was no statistically significant ($p = 0.614$) association between treatment success and presence of comorbidity.

Conclusions: The cure rate among the tuberculosis patients, following DOTS therapy was found to be slightly less than the RNTCP standards.

Keywords: Tuberculosis, Comorbidity, Treatment outcome, Tuberculosis unit

INTRODUCTION

Tuberculosis (TB) remains one of the world's deadliest communicable diseases and a major public health problem, despite the fact that, the causative organism was discovered more than 100 years ago and highly effective drugs & vaccine are available making tuberculosis a preventable and curable disease. The burden in India is

also significantly high as 24% of the global TB cases occur in India.¹

TB is the most common opportunistic infection and cause of mortality among people living with HIV, the prevalence of HIV among incident TB patients is estimated to be 5.95%. Although the elevated mortality rate in TB patients is often attributed to the presence of multidrug resistant tuberculosis (MDRTB) or

concomitant infection with the HIV but there is a need to explore other factors that are contributing to increased mortality, especially among the HIV-negative population.²

Most countries with high levels of tuberculosis face a large comorbidity burden from both non-communicable and communicable diseases.³

The treatment outcome of tuberculosis is influenced by numerous factors of which presence of comorbidity is one of the factor as indicated by a study conducted in south India, where in 25.3% of the tuberculosis patients registered for the study were suffering from Diabetes & had higher defaulters than non-diabetics in the study.⁴

Numerous studies exist on proportion of diabetes and HIV in patients suffering Tuberculosis but there is minimum data regarding presence of other co-morbidities in Tuberculosis patients.

Hence the present study was taken up with the following objectives, to assess the proportion of co-morbidities among Tuberculosis cases registered for treatment and to assess the treatment outcome of the Tuberculosis cases registered for DOTS treatment.

METHODS

A Descriptive study was conducted at a Tuberculosis Unit in Bangalore having 5 designated microscopic centers & 8 DOTS centers from January 2014 to June 2015. Patients registering for treatment during the study period till the desired sample of 80 subjects (calculated taking prevalence of Tuberculosis as 256 per 1 lakh population based on TB India 2012 report and taking an absolute precision of 10%) meeting the inclusion criteria of subjects aged above 18 years & subjects willing to participate and co-operate in the study were included by purposive sampling.⁵

Confirmed patients for MDR (multi drug resistant tuberculosis) and XDR (Extremely Drug Resistant Tuberculosis) tuberculosis and patients taking treatment under local DOTS providers like private clinics, Anganwadis, pharmacies etc were excluded.

Data was collected using a pretested semi structured proforma administered to all the study subjects by trained investigators. Data regarding socio demographic profile, profile of tuberculosis, medical co-morbidities which the subjects were suffering were collected and these patients were followed up till their treatment completion and outcome of treatment was given based on new WHO definitions.⁶

Treatment outcome for subjects of smear positive Pulmonary Tuberculosis was assessed in terms of cured, lost to follow up, not evaluated treatment failure and died. Treatment outcome for extra Pulmonary

Tuberculosis & smear negative Pulmonary Tuberculosis patients was assessed in terms of treatment completed, died, not evaluated & lost to follow up.

Data was entered in Microsoft excel 2007 and analyzed using SPSS (statistical package for social sciences) version 16 Descriptive statistics such as mean, standard deviation, percentage were used to describe the data collected in the present study.

RESULTS

The present study included 80 subjects with 51(63.75%) males and 29(36.25%) females. The mean age & standard deviation of the study subjects was 37.8 ± 14.2 years. Majority of the study subjects 27(33.75%) were employed in unskilled type of occupation. The socio economic status of most of the subjects was upper lower class according to Modified Kuppuswamy classification with updated income ranges for the year 2013.

In the present, 70 of the study subjects were receiving category I DOTS therapy; among them 40(57.14%) were cases of pulmonary tuberculosis and 30(42.86%) were extra pulmonary tuberculosis. Similarly, 10 subjects were on category II therapy, among whom, 9(90%) were cases of pulmonary tuberculosis and rest 1(10%) were extra pulmonary tuberculosis.

The present study showed that, 38 (47.50%) of the study subjects had one or the other comorbidities with chronic obstructive pulmonary disease being the most common comorbidity followed by Diabetes 13(16.25%) as shown in Table 1.

Table 1: Distribution of the study subjects based on co-morbidities.

Co-morbidities*	Number (n = 80) *	Percentage
Chronic Obstructive Pulmonary Disease	18	22.50
Diabetes	13	16.25
HIV	6	7.50
Hypertension	4	5.00
Other**	9	11.25

*Indicates multiple responses

**Others included: Gout - 1, Thyroid disorders - 5, Coronary Artery Disease - 1, Epilepsy - 1 & Carcinoma - 1.

The treatment outcome of all 80 study subjects were assessed at the end of DOTS therapy. The overall treatment success rate was 69(86.25%) which included the cured and treatment completed subjects. Of these 69 subjects 62(77.5%) subjects belonged to Category I and 7(8.75%) belonged to category II. The total cure rate was 80.95%.

On further classification of treatment outcome based on 2013 revised WHO definitions, 34 study subjects were

labelled as cured, of them 29 belonged to category I and 5 belonged to category II DOTS therapy.

Table 2: Distribution of the bacteriologically confirmed subjects based on treatment outcome.

Treatment outcome	Number	Percentage
Cured	34	80.95
Death	3	7.14
Lost for follow up	2	4.76
Treatment failure	1	2.38
Not evaluated	2	4.76
Total	42	100.00

Table 3: Distribution of the clinically diagnosed subjects based on treatment outcome.

Treatment outcome	Number	Percentage
Treatment completed	35	92.11
Death	2	5.26
Treatment failure	1	2.63
Total	38	100.00

Similarly, subjects with smear negative pulmonary TB and extra pulmonary tuberculosis (EP-TB) were labelled as treatment completed on successful completion of prescribed treatment, which was 35 subjects, hence the treatment completion rate is 92.10%. Among them, 33 subjects were on category I DOTS therapy and rest 2 subjects were on category II DOTS therapy.

A total of 5(6.25%) subjects died during the course of therapy indicating a mortality rate of 6.25% of which 3 subjects belonged to category I and 2 subjects belonged to category II DOTS therapy.

Sputum smear was positive at the end of the therapy for 2(2.5%) subjects who were subsequently labelled as treatment failure of which 1 subject was on Category I & another subject was on category II DOTS therapy which subsequently turned out to be MDR-TB on drug susceptibility testing.

The outcome of 2 (2.5%) study subjects was not evaluated as they were transferred out to different Tuberculosis Unit of these both subjects were on category I DOTS therapy.

Lastly 2(2.5%) of the study subjects were lost for follow up and both these subjects were on category I DOTS therapy.

However on applying chi-square test, there was no statistically significant ($\chi^2 = 0.253$, $p = 0.614$) association between treatment success and presence of comorbidity.

DISCUSSION

Tuberculosis continues to be a major public health problem with India being one of the six countries accounting for 60% of global TB cases.⁷

It is important to combat all factors to reduce the tuberculosis epidemic in order to achieve the sustainable development goal 3 adopted by United nations and to achieve the objectives of end TB strategy adopted by WHO as to reduce the mortality due to tuberculosis by 95% and incidence of Tuberculosis by 90% by the year 2035.^{8,9}

Most countries with high levels of tuberculosis face a large comorbidity burden from both non-communicable and communicable diseases and coexisting communicable and non-communicable diseases augment the risk or effect of the other.³

Most of our study subjects were on category I DOTS therapy which was 87.5% but according to the study done by Dnyaneshwar et al the proportion of category I patients was 46.6% this may be because the study was done in 2005 when Category III existed.¹⁰

A total of 16.25% of the study subjects in our study were suffering from diabetes. A study done at Tamil Nadu by Balkrishnan et al revealed 23.5% of the TB patients were diabetics. Similarly a cross sectional study done by Raghuraman et al revealed a prevalence of 29% diabetes among TB patients. This difference can be attributed to cross sectional study design used in the latter.^{11,12}

5% of the study subjects in the present study were hypertensive but according to a study done by Jethani et al proportion of hypertensive subjects was 1.9%.¹³

Only 7.5% of our study subjects were HIV positive. Globally 13% of the patients diagnosed with tuberculosis are HIV positive and in India 5% of the patients diagnosed with TB were HIV positive according to WHO global tuberculosis report 2014. The large difference in the findings may be attributed to small sample size in our study. But according to a study done by Gupta et al in south India 10.6% of the TB patients were infected with HIV.^{7,14}

The cure rate in the present study was 80.9% which is less than the objective under RNTCP which is achievement of 85% cure rate.⁴ But according to the study done by Masthi et al during 1999 the cure rate achieved was 72.22%, also according to a study done by Joseph et al the cure rate was 69.6% this is again attributed to different time periods when the studies were conducted.^{2,15,16}

Treatment completion rate in the present study was 92.10% but in contrast a study conducted in Bangalore by

Masthi et al the treatment completion rate was 81.39%. This difference may be attributed to the time of study as the later was conducted in the year 1999.¹⁵

Mortality rate in the present study was 6.25% but according to the study by Masthi et al it was 1.13% which may be attributed to the different study settings.¹⁵

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