

Sputum Conversion and Treatment Success among Tuberculosis Patients with Diabetes Treated under the Tuberculosis Control Programme in an Urban Setting in South India

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Abstract

Background: Studies from India on sputum conversion and tuberculosis (TB) treatment outcomes among TB patients with diabetes are limited. **Objective:** The objective of this study is to estimate the proportion of sputum smear conversion and successful treatment outcomes among diabetic-TB patients treated under Revised National TB Control Programme (RNTCP). **Methodology:** Information on TB disease, diabetes, sputum conversion, and treatment outcomes were collected from treatment cards of adult TB patients (age >18 years) treated in the District TB Centre TB Unit, Tiruchirappalli, Tamil Nadu from July 1, 2014, to October 31, 2015. **Results:** Diabetes was documented in 163 (14%) of 1131 TB patients. Sputum conversion was in 107 (94%) of 114 smear positive-TB patients. Successful TB treatment outcome was in 116 (85%) of 136 patients and 107 (86%) of 124 new TB patients. **Conclusion:** Sputum conversion was as per RNTCP target while treatment success rate among the new TB patients with diabetes was suboptimal.

Keywords: Diabetes, revised national tuberculosis control programme, sputum conversion, treatment success, tuberculosis

INTRODUCTION

India accounted for 2.2 million incident tuberculosis (TB) cases and 0.25 million deaths in 2014.^[1] People with diabetes have a 2–3 times higher risk of developing active TB than those without diabetes.^[2] Further, it has been documented that diabetic patients with TB have an increased risk of death and failure during anti-TB treatment and recurrent disease after successful completion of treatment.^[3] Sputum conversion and successful treatment outcomes are important to reduce the transmission of TB disease in the community. Studies from India on sputum conversion and TB treatment outcomes among diabetic-TB patients under TB Control Programme settings are limited.^[4,5] This information is important to guide the national program in planning effective interventions. The objective of this study was to estimate the proportion of sputum smear conversion at the end of intensive phase of treatment and successful treatment outcomes at the end of treatment among diabetic-TB patients treated under Revised National TB Control Programme (RNTCP).

METHODOLOGY

The study was approved by the Institutional Ethics Committee of National Institute of Epidemiology.

This retrospective cohort study was done from November 2015 to March 2016 in the District TB Centre TB Unit [DTC-TU], an urban setting in Tiruchirappalli District, Tamil Nadu. Tiruchirappalli district has 6TUs and diabetic screening for TB patients was done in DTC-TU. The study population included adult TB patients (age >18 years) with documented

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diabetes started on TB treatment in the DTC-TU from July 1, 2014, to October 31, 2015. Diabetes was documented in the TB treatment card from July 1, 2014. The TB treatment cards and register of those with documented diabetes were perused and the information available for the variables are as follows: age ($n = 163$), gender ($n = 163$), site of TB ($n = 163$), type of case ($n = 163$), sputum smear status ($n = 151$), sputum smear grading ($n = 121$), HIV status ($n = 154$), diabetes new/known ($n = 110$), diabetic treatment status ($n = 85$), details of diabetic medications ($n = 73$), random blood sugar (RBS) ($n = 79$), fasting blood sugar (FBS) ($n = 81$), postprandial blood sugar (PPBS) ($n = 82$), sputum smear status at the end of intensive phase ($n = 114$), and treatment outcomes ($n = 163$).

The definitions used to describe TB disease profile, and treatment outcomes were according to RNTCP guidelines.^[6] Under the RNTCP, new and previously treated TB patients are treated with 6 months and 8 months thrice-weekly regimen, respectively.^[6]

Sputum conversion at the end of intensive phase

Two negative sputum smears at the end of intensive phase of treatment.^[6]

Treatment success

Patients declared as cured or treatment completed.^[6]

Data were double verified, entered in Epi-Info version 7.0 and analyzed using Epi-Info version 7.0 (Centers for disease control and prevention, Atlanta, Georgia, USA). Quantitative variables were analyzed using mean and standard deviation (SD), median and interquartile range [IQR] as applicable; proportions were computed for categorical variables.

RESULTS

Of the 1157 adult TB patients started on treatment in DTC-TU from November 2015 to March 2016 at the study center, TB treatment cards of 1131 (98%) patients were perused. The treatment cards of the remaining 26 patients were not available for review. Diabetes was documented in 163/1131 (14%) of them. The median duration of diabetes in 53 patients with available information was 60 days (IQR 24–96 days). The mean \pm SD of age and body weight of 163 patients were 51.76 ± 10.97 years and 50.62 ± 10.65 Kg, respectively. Of the 163 diabetic-TB patients, 117 (72%) were male, 144 (88%) had pulmonary TB (PTB), 145 (89%) were new TB patients and 103 (63%) were new smear-positive-PTB patients. The information on sputum smear status was available for 151 patients of which 121 (80%) were smear positive. There were 121 smear positive-TB patients with information on sputum smear grading of which 66 (54%) had +2/+3 sputum smear grading. There were 151 (98%) who were HIV negative among the 154 patients with available information.

Of the 163 diabetic-TB patients, 110 had information pertaining to diabetes. Known diabetics were 97 (88%) of 110. Information on diabetic medications was available 85 patients of which 81 (95%) were on diabetic medications

at the time of starting TB treatment. The diabetic medications comprised of oral drug 37 (51%), insulin 32 (44%), and both 4 (5%) in 73 diabetic-TB patients. The mean and SD of RBS ($n = 79$), FBS ($n = 81$) and PPBS ($n = 82$) at the start of TB treatment were 259.93 ± 94.49 mg/dl, 174 ± 67.18 mg/dl, and 277 ± 92.05 mg/dl respectively.

Among the 114 patients with initial sputum positivity, 107 (94%) had smear conversion at the end of months of the intensive phase of treatment [Table 1]. There were 3 patients who had smear conversion at the end of extended intensive phase of treatment. Of the 7 patients with positive sputum smears at the end of intensive phase, 4 were declared cured, 1 failed to treatment, 1 was still on treatment, and further information was not available for one patient.

There were 116 (85%) of 136 diabetic TB patients and 107 (86%) of 124 new diabetic TB patients who were successfully treated [Table 2]. The median duration of treatment in 102 new diabetic-TB patients with treatment success was 181 days (IQR 179.5–192). There were no side

Table 1: Sputum smear conversion in diabetic-tuberculosis patients treated under tuberculosis control program in Tiruchirappalli district, Tamil Nadu, July 2014 to October 2015

Sputum conversion at end of intensive phase	New ($n=103$)		Previously treated ($n=18$)		All TB patients ($n=121$)	
	N	n (%)	N	n	N	n (%)
Negative	96	91* (95)	18	16	114	107 (94)
Positive		5		2		7 (6)

*3 patients had sputum conversion at the end of extended intensive phase. TB: Tuberculosis

Table 2: Tuberculosis treatment outcomes in diabetic-tuberculosis patients treated under tuberculosis control program in Tiruchirappalli district, Tamil Nadu, July 2014 to October 2015

Treatment outcome	New ($n=145$)		Previously treated ($n=18$)		All TB patients ($n=163$)	
	N	n (%)	N	n	N	n (%)
Cured	124	71 (57)	12	8	136	79 (58)
Treatment completed		36 (29)		1		37 (27)
Lost to follow-up		5 (4)		1		6 (4)
Died		10 (8)		1		11 (8)
Failure		2 (2)		1		3 (2)
Treatment success						
Yes	124	107 (86)	12	9	136	116 (85)
No		17 (14)		3		20 (15)

TB: Tuberculosis

effects to drugs documented in the TB treatment card. Of the 11/136 (8%) who died, 10 were new TB patients (5 smear positive PTB, 4 extrapulmonary, and 1 smear negative PTB) and 2 had newly detected diabetics.

DISCUSSION

We observed sputum smear conversion of over 90% in diabetic TB patients in our analysis which is as per requirement of the RNTCP target for sputum conversion.^[7] The results from a previous systematic review on studies done worldwide in diabetic TB patients were heterogeneous with the relative risk ranging from 0.79 to 3.25 for sputum conversion.^[3] A study from Maharashtra reported significantly lower sputum conversion rates among PTB patients with diabetes (76.5%) compared to those without diabetes (92.7%) under TB Control Programme settings.^[5] Future studies have to planned to identify sputum conversion rates under program settings in different geographical regions.

The 86% successful treatment outcomes of all new diabetic TB patients observed in our study is low compared to the 90% target of RNTCP for the 12th 5 years plan (2012–2017).^[8] This could be attributed to the 8% death rate. This finding is in conformity with the findings from the previous systematic review which documented that diabetes increased the risk of death among patients with TB.^[3] An earlier study in Tamil Nadu has reported that PTB and smear positive-PTB patients with diabetes were less likely to have successful treatment outcomes and have documented higher proportion of treatment failure among diabetic-TB patients.^[4] Diabetes impairs cell-mediated immunity, and poor diabetic control has been shown to affect *in vitro* innate and type I cytokine responses.^[9] Poor diabetic control could possibly lead to unfavorable treatment outcomes such as failure and death. Glycosylated hemoglobin, which indicates blood sugar control, is not routinely done under the program settings. Nevertheless, high mean blood sugar values observed in some of the TB patients with diabetes at the start of TB treatment indicate poor blood sugar control. Glycemic equilibrium with goals of maintaining FBS <100 mg % is essential in diabetic patients with TB.^[6] The management of diabetes among TB patients has to be reviewed under program settings, and reasons for poor treatment outcomes have to be studied.

The March 2016 technical and operational guidelines of RNTCP has outlined screening of TB patients for diabetes and management of diabetes in TB patients under program settings.^[10] According to the guidelines, all diabetic-TB patients will have to be linked for diabetic care with National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS) or with nearest health-care facility wherein NPCDCS activities are not implemented. Effective collaboration and timely feedback are important for appropriate management of diabetes in TB patients.

The limitations of the study include nonavailability of blood sugar values for diabetic TB patients to comment on blood sugar control. Moreover, all the required information was not

available in the treatment cards of 163 diabetic-TB patients. This could be attributed to the fact that the treatment card of RNTCP used in the DTC-TU did not have a structured provision for documentation of details of diabetes. We could not compare sputum conversion and treatment outcomes among diabetic and nondiabetic TB patients since nondiabetic status was not documented in the TB treatment card.

Sputum conversion in Tiruchirapalli DTC-TU was as per RNTCP target while treatment success rate among the new TB patients with diabetes was suboptimal. Research is essential for follow-up of diabetic patients during TB treatment to ensure effective diabetic control and improve successful TB treatment outcomes.

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Conflicts of interest

There are no conflicts of interest.

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