



Effect of diabetes on treatment outcome of smear-positive pulmonary tuberculosis—A report from South India[☆]

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ABSTRACT

Aim: To assess the effect of diabetes on tuberculosis (TB) treatment outcome and sputum conversion among new smear-positive (NSP) cases registered under Directly Observed Treatment Short Course in South India. **Methods:** Details on sputum conversion and TB treatment outcome were collected from case records of NSP cases ($N = 332$; M/F 247:85) registered at TB units of three districts in Tamil Nadu. Subjects were screened for diabetes and categorized as diabetic (TBDM) ($n = 96$; 73:23) and non-diabetic (TBnonDM) ($n = 149$; 109:40). **Results:** Among 245 selected TB patients, 93.5% were cured, 1.6% completed TB treatment, 2% had TB treatment failure (TF), and 0.4% had treatment default (TD), 0.4% with MDR-TB and 2% death rate. At the end of intensive phase of TB treatment, 14.7% remained sputum positive in the TBDM group, whereas it was 3.5% in the TBnonDM group. Mean duration (days) for sputum conversion was higher in the TBDM group (64.2 ± 10.5) compared to the TBnonDM group (61.5 ± 7.5) ($p < 0.001$). TF rate was higher (4.2% vs 0.7%) and MDR-TB (1%) was also seen in the TBDM group. No death and TD were seen among DM whereas it was 3.4 and 0.7% in TBnonDM. **Conclusions:** Delayed sputum conversion and high TB treatment failure rates were common in NSP cases with diabetes.

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1. Introduction

Diabetes mellitus (DM) is a known risk factor for tuberculosis (TB). Several studies conducted across the world have elucidated an association between DM and TB (Alisjahbana, Sahiratmadja, Nelwan, Purwa, Ahmad, 2007; Baker, Harries, Jeon, et al., 2011; Dooley, Tang, Golub, Dorman, & Cronin, 2009). India is one among the countries with a high burden of both diseases. There were 3.1 million people living with TB and the number of new TB cases was 2.3 million during the year 2011 (Global TB Report 2012). Similarly, there is a dramatic increase in the prevalence of diabetes in India (Anjana, Pradeepa, Deepa, Datta, Sudha, 2011). The high rates of diabetes in countries like India, which is already endemic to tuberculosis, enable a suitable substratum for incidence and recurrence of TB cases.

In 2007, Stevenson, Forouhi, Roglic, Williams, and Lauer simulated a model and reported that 20% of smear-positive TB and 15% of total burden of pulmonary TB in India in the year 2000 were attributed to the prevalence of diabetes, which was then around 21 million in the

country. Recent studies conducted in south India revealed a high prevalence of diabetes among TB patients registered under the Revised National Tuberculosis Control Programme (RNTCP) (Balakrishnan, Vijayan, Nair, et al., 2012; Viswanathan et al., 2012). A nationwide study highlighted that nearly 13% of TB patients were with diabetes and 5% of them were diagnosed during the screening (Indian Diabetes Mellitus–Tuberculosis study Group, 2013).

All the above findings showed that the association of DM and TB was greater than that expected and needs increased attention for better treatment outcomes of both diseases. The impact of DM is relatively large on treatment outcomes of patients with active TB. DM increases the risk of poor outcomes of TB therapy (Alisjahbana et al., 2007; Dooley et al., 2009; Zhang, Xiao, & Sugawara, 2009). A systematic review of multiple studies conducted globally highlighted that the coexistence of DM and TB was associated with increased rates of TB treatment failures and deaths (Baker et al., 2011). Another report from South Texas revealed that mycobacterial clearance from sputum was delayed by 5 days during the first phase of treatment in patients with diabetes (Restrepo et al., 2008).

The present circumstances with a high number of people with both diabetes and TB, the reported higher association of smear-positive TB among these subjects (Viswanathan et al., 2012) and the possibility of occurrence of worst TB treatment outcome among subjects with diabetes imply the silent impact of the epidemic of diabetes on the control of TB in countries like India. Although there are few reports on

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poor TB treatment outcome among TB patients with diabetes, no such reports are available recently from India. Hence, the current study was planned to assess and compare the treatment outcome among new smear-positive TB patients with and without diabetes.

2. Subjects

A total of 827 TB patients registered in five tuberculosis units in the state of Tamil Nadu, South India, underwent diabetes screening in the first quarter of 2011. The details of study subjects and sites can be found elsewhere (Viswanathan et al., 2012). Among these 827 TB patients, 332 patients were new smear-positive cases, of which 96 (M/F 73:23) subjects had diabetes (TBDM), 87 (65:22) had pre-diabetes and 149 patients (109:40) were without diabetes (TBnonDM). TB patients with pre-diabetes were excluded and the remaining 245 patients were included for this analysis.

3. Materials and methods

The study protocol was approved by the institutional ethics committee and done with the approval of regional authorities. A retrospective analysis was planned with case records of new smear-positive cases, with and without diabetes. Trained investigators who were part of the diabetes screening program for TB patients approached the tuberculosis units and retrieved the relevant details from the case records of the selected TB patients. The sputum smear results at different time points were noted and the treatment outcomes as defined by standard RNTCP were collected from the case records. According to RNTCP, TB treatment outcomes were classified as *cured*: indicating that the TB patients had negative sputum smears on two occasions, one of which is at the end of the treatment; *completed*: TB patients who had negative smears at the end of the intensive phase but none at the end of the treatment; *died*: those who had died during the course of treatment regardless of cause of death; *failure*: those who had smear positive at 5 months or more after starting the treatment; and *defaulters*: TB patients who had not taken anti-TB drugs for 2 months or more consecutively after starting treatment (<http://www.tbcindia.nic.in/pdfs/RNTCP%20at%20a%20Glance.pdf>).

The details of type of diabetes treatment taken by the subjects with diabetes during the course of DOTS were collected from the patients through telephonic contact. At the time of registration of DOTS treatment, demographic data and anthropometric measurements were recorded and biochemical investigations were also performed. Descriptive and inferential statistical analyses were done using the statistical software package SPSS version 16.0, and the relative risk for subjects with diabetes and TB was estimated for delay in sputum conversion at the end of intensive phase. A *p*-value of <0.05 was considered statistically significant to refute the null hypothesis.

4. Results

TB patients with diabetes were older than those without diabetes; about 78.1% of TBDM patients were aged more than 40 years whereas it was only 45% in TBnonDM patients as shown in Table 1. Mean BMI was significantly higher in TBDM patients than in those without diabetes even though the mean value was within normal nutritional grade. There was a significantly higher number of TBDM patients with obesity and overweight compared to TBnonDM subjects ($p < 0.001$). A significant difference in waist circumference was noted between the men in two groups but not in women.

As expected, plasma glucose levels and HbA1c were significantly higher in TBDM patients. The proportion of subjects with positive family history of diabetes was significantly higher in TBDM patients, whereas those with positive family history of TB were equally distributed in both groups.

Table 1
Characteristics of study subjects based on their glycemic status.

Characteristics	TB patients with normoglycemia (TBnonDM), <i>n</i> = 149 (M/F 109:40)	TB patients with diabetes (TBDM), <i>n</i> = 96 (M/F 73:23)	<i>p</i> -Value
Age (years)	37.5 ± 13.6	49.9 ± 11.3	<0.001
Aged ≥40 years, <i>n</i> (%)	67 (45)	75 (78.1)	<0.001
BMI (kg/m ²)	17.2 ± 3.1	18.9 ± 4.1	<0.001
BMI category, <i>n</i> (%)			
Underweight	110 (73.8)	44 (45.8)	<0.001
Normal	34 (22.8)	40 (41.7)	
Overweight	2 (1.3)	3 (3.1)	
Obese	3 (2.0)	9 (9.4)	
Waist circumference (cm)			
Men	68.8 ± 9.2	73.9 ± 12.6	0.002
Women	67.5 ± 12.2	71.22 ± 16.6	0.312
Plasma glucose (mg/dl)			
Fasting	91.7 ± 8.6	173.7 ± 83.6	<0.001
2-h	113.8 ± 20.7	227.3 ± 76.9	<0.001
HbA1c %	5.8 ± 0.25	9.1 ± 2.7	<0.001
Positive family history of diabetes, <i>n</i> (%)	9 (6.0)	16 (16.7)	0.014
Positive family history of TB, <i>n</i> (%)	25 (16.8)	12 (12.5)	0.465

Values are mean ± SD.

4.1. Comparison of TB treatment outcome between TBDM and TBnonDM groups

Overall, TB treatment outcome among the total study subjects showed a very high cure rate of 93.5%, 1.6% completed the TB treatment, 2% had TB treatment failure, and 0.4% was treatment defaulters, 0.4% with MDR-TB and 2% death rate as shown in Table 2.

Table 2 also shows the comparison of TB treatment outcome between TBDM and TBnonDM patients. There was a significantly higher proportion of treatment failures (4.2%) among TBDM patients compared to TBnonDM patients (0.7%) ($p = 0.04$). There were no treatment defaulters and no death reported in TBDM patients. Surprisingly, it was noted that 5 (3.4%) of TBnonDM patients died during the course of DOTS. A single case of MDR-TB was seen in the TBDM group.

4.2. Rate of sputum conversion at the end of intensive phase

At the end of intensive phase of DOTS treatment, about 14.7% of TBDM patients had positive sputum smear whereas it was 3.6% in TBnonDM patients. The proportion of subjects with sputum smear positive and negative in the two groups is shown in Fig. 1, and the difference in smear conversion was statistically significant ($p = 0.02$). The estimated relative risk to remain as sputum smear positive among TBDM patients at the end of intensive phase was 3.9 (95% CI: 1.5–10.6).

Table 2
Comparison of TB treatment outcome among TB patients with and without diabetes.

	TB patients with normoglycemia (<i>n</i> = 149)	TB patients with diabetes (<i>n</i> = 96)	Total (<i>N</i> = 245)	<i>p</i> -Value
Cured	139 (93.3)	90 (93.8)	229 (93.5)	0.04
Completed the treatment	3 (2)	1 (1)	4 (1.6)	
Treatment failure	1 (0.7)	4 (4.2)	5 (2)	
Died	5 (3.4)	–	5 (2)	
Treatment defaulters	1 (0.7)	–	1 (0.4)	
MDR-TB	–	1 (1)	1 (0.4)	

Values are *n* (%).

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