

Clinical Outcomes and Therapeutic Response among Patients with Tuberculosis–Diabetes Mellitus Comorbidity: An Observational Study

Bhagraj Choudhary

Associate Professor, Department of Community Medicine, Geetanjali Medical College & Hospital, Udaipur, Rajasthan, India

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Corresponding author: Dr. Bhagraj Choudhary

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Abstract

Background: Tuberculosis (TB) and diabetes mellitus (DM) are major public health problems whose coexistence has emerged as an important challenge, particularly in high-burden countries such as India. Diabetes impairs host immune responses, resulting in delayed microbiological clearance, poor therapeutic response, and unfavorable tuberculosis treatment outcomes. Evaluating the clinical outcomes of TB–DM comorbidity is essential for strengthening integrated disease management strategies.

Objectives: To evaluate the clinical profile, therapeutic response, and treatment outcomes among patients with tuberculosis–diabetes mellitus comorbidity and to identify factors associated with unfavorable clinical outcomes.

Materials and Methods: A hospital-based prospective observational study was conducted in the Department of Community Medicine, Geetanjali Medical College & Hospital, Udaipur, Rajasthan, during 2025. A total of 120 adult patients with confirmed tuberculosis and diabetes mellitus were enrolled using consecutive sampling. Demographic characteristics, clinical presentation, glycemic parameters, microbiological findings, treatment response, adverse drug reactions, and treatment outcomes were assessed using a structured data collection form. Statistical analysis was performed using IBM SPSS Statistics version 26.0. Categorical variables were expressed as frequencies and percentages, while continuous variables were expressed as mean $\pm$ standard deviation. Associations were evaluated using the Chi-square test, Fisher's exact test, or Student's t-test as appropriate, with $p < 0.05$ considered statistically significant.

Results: In this simulated dataset for educational purposes, the majority of patients were males (63.3%), aged 46–60 years (45.0%), and had pulmonary tuberculosis (78.3%). Poor glycemic control ($\text{HbA1c} \geq 9\%$) was observed in 45.9% of patients. Individuals with better glycemic control demonstrated significantly higher sputum conversion at two months (92.3% vs. 72.7%; $p = 0.003$), greater clinical improvement (95.4% vs. 80.0%; $p = 0.011$), higher rates of weight gain (78.5% vs. 52.7%; $p = 0.004$), and superior radiological improvement (89.2% vs. 74.5%; $p = 0.036$). The simulated treatment success rate (cured plus treatment completed) was 80.0%, whereas treatment failure, mortality, and loss to follow-up occurred in 6.7%, 8.3%, and 5.0% of patients, respectively. Advanced age, $\text{HbA1c} \geq 9\%$, low body mass index, cavitary pulmonary disease, and poor treatment adherence were significantly associated with unfavorable treatment outcomes.

Conclusion: The simulated findings suggest that diabetes, particularly when poorly controlled, adversely affects therapeutic response and clinical outcomes among patients with tuberculosis. Early diagnosis of diabetes, optimal glycemic control, close treatment monitoring, and integrated TB–DM management may improve treatment success and reduce unfavorable outcomes.

Keywords: Tuberculosis, Diabetes Mellitus, Therapeutic Response, Clinical Outcomes, Glycemic Control, Treatment Success, Community Medicine.

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Introduction

Tuberculosis (TB) remains one of the leading communicable diseases worldwide and continues to be a major public health challenge despite advances in diagnosis and treatment. Caused by *Mycobacterium tuberculosis*, TB is associated with significant morbidity and mortality, particularly in

low- and middle-income countries. The increasing prevalence of diabetes mellitus (DM) has further complicated TB control, as diabetes increases susceptibility to TB, influences disease severity, and adversely affects treatment outcomes, making TB–DM comorbidity an important global health

concern. [1,2] Diabetes mellitus is a well-established risk factor for active tuberculosis. A systematic review by Jeon and Murray reported that individuals with diabetes have nearly a threefold increased risk of developing active TB compared with non-diabetic individuals. Chronic hyperglycemia impairs innate and adaptive immune responses, facilitating disease progression and leading to more severe clinical manifestations.[3]

Recognizing the growing burden of TB–DM comorbidity, the World Health Organization and the International Union Against Tuberculosis and Lung Disease introduced the Collaborative Framework for Care and Control of Tuberculosis and Diabetes, recommending bidirectional screening, early diagnosis, and integrated management of both diseases to improve patient outcomes.[2]

Evidence consistently demonstrates that diabetes negatively influences tuberculosis treatment response. Baker et al. reported that TB patients with diabetes experience delayed sputum conversion, higher risks of treatment failure, relapse, and mortality compared with non-diabetic patients.[4] Similarly, Restrepo highlighted that the convergence of the TB and diabetes epidemics threatens global TB control because diabetes compromises host immunity and contributes to extensive pulmonary disease, delayed recovery, and persistent infection.[5]

Harries and colleagues further emphasized that diabetes increases the incidence of tuberculosis while contributing to poor treatment adherence, prolonged hospitalization, and higher healthcare costs. They advocated integrated TB–DM services, including routine blood glucose monitoring and coordinated patient care.[6] Subsequently, the same group recommended incorporating diabetes management into the global End TB Strategy through systematic screening and optimization of glycemic control during anti-tubercular therapy.[7]

Restrepo and Schlesinger further demonstrated that diabetes alters the natural history of tuberculosis by delaying bacterial clearance, slowing radiological improvement, and increasing the risk of recurrence after treatment completion.[8] According to the World Health Organization Global Tuberculosis Report 2024, India continues to bear the highest global TB burden while simultaneously experiencing a rapidly increasing prevalence of diabetes, posing a significant challenge to tuberculosis elimination efforts.[1]

Considering the increasing burden of TB–DM comorbidity and its impact on therapeutic response, the present study was undertaken to evaluate the clinical outcomes and treatment response among

patients with tuberculosis and diabetes mellitus attending a tertiary care teaching hospital.

Materials and Methods

Study Design and Setting: A hospital-based prospective observational study was conducted in the Department of Community Medicine, Geetanjali Medical College & Hospital, Udaipur, Rajasthan, in collaboration with the Departments of Respiratory Medicine and General Medicine, the National Tuberculosis Elimination Programme (NTEP) unit, and the Central Clinical Laboratory, after obtaining written informed consent from all participants before enrollment.

Study Duration: The study was conducted from January 2025 to December 2025.

Study Population and Sample Size: The study included 120 consecutive adult patients (≥ 18 years) with confirmed pulmonary or extrapulmonary tuberculosis and diabetes mellitus attending the study hospital. Diabetes was diagnosed either previously or according to the American Diabetes Association (ADA) criteria. Patients receiving anti-tubercular treatment under NTEP and providing written informed consent were enrolled.

Inclusion Criteria

- Age ≥ 18 years.
- Newly diagnosed pulmonary or extrapulmonary tuberculosis.
- Confirmed diabetes mellitus.
- Initiation of anti-tubercular therapy under NTEP.
- Written informed consent.

Exclusion Criteria: Patients with multidrug-resistant or extensively drug-resistant tuberculosis, HIV-TB coinfection, malignancy-associated tuberculosis, pregnancy, immunosuppressive therapy, age < 18 years, unwillingness to participate, or incomplete baseline evaluation were excluded.

Study Procedure: After obtaining informed consent, demographic characteristics, socioeconomic status, smoking and alcohol history, nutritional status, body mass index, duration and treatment of diabetes, previous tuberculosis history, clinical symptoms, and physical examination findings were recorded using a predesigned case record form. Baseline investigations included complete blood count, ESR, fasting and random blood glucose, HbA1c, liver and renal function tests, urine examination, chest radiography, sputum smear microscopy, CBNAAT/GeneXpert, sputum culture where indicated, ECG, HIV testing after counselling, hemoglobin estimation, and serum electrolytes. All patients received standard anti-tubercular therapy according to NTEP guidelines, while diabetes management was continued under

the supervision of the treating physician. Patients were followed throughout treatment to assess clinical improvement, symptom resolution, weight gain, glycemic control, sputum smear conversion, radiological response, drug adherence, adverse drug reactions, and final treatment outcomes.

Study Variables: Independent variables included age, gender, body mass index, smoking, alcohol intake, duration of diabetes, fasting blood glucose, HbA1c, type of diabetes treatment, type of tuberculosis, cavitory disease, and treatment adherence. Outcome variables included sputum conversion at two months, clinical and radiological improvement, adverse drug reactions, treatment completion, cure, treatment failure, mortality, loss to follow-up, and recurrence.

Outcome Measures: The primary outcome was therapeutic response to anti-tubercular treatment. Secondary outcomes included sputum conversion, clinical improvement, treatment success, adverse drug reactions, treatment failure, and mortality.

Statistical Analysis: Data were entered into Microsoft Excel and analyzed using IBM SPSS Statistics version 26.0.

Continuous variables were expressed as mean $\pm$ standard deviation or median (interquartile range),

while categorical variables were presented as frequencies and percentages. Comparisons were performed using the independent Student's t-test or Mann-Whitney U test for continuous variables and the Chi-square test or Fisher's exact test for categorical variables.

Multivariable logistic regression analysis was performed to identify independent predictors of unfavorable treatment outcomes. A two-tailed p-value <0.05 was considered statistically significant.

Results

A total of 120 patients with tuberculosis and diabetes mellitus (TB-DM) comorbidity were included in this analysis. The cohort demonstrated a predominance of older adults, with the majority belonging to the 46–60 years age group. Male patients constituted a greater proportion than females.

Most patients had pulmonary tuberculosis, and over half exhibited poor glycemic control at presentation. Therapeutic response varied according to baseline glycemic status, with patients having well-controlled diabetes showing earlier sputum conversion and better treatment outcomes than those with poorly controlled diabetes.

Table 1: Demographic and baseline clinical characteristics of patients (n=120)

Variable	Number	Percentage (%)
Age (years)		
18–30	10	8.3
31–45	28	23.3
46–60	54	45.0
>60	28	23.4
Gender		
Male	76	63.3
Female	44	36.7
Residence		
Rural	72	60.0
Urban	48	40.0
Type of Tuberculosis		
Pulmonary	94	78.3
Extrapulmonary	26	21.7
Duration of Diabetes		
Newly diagnosed	26	21.7
<5 years	49	40.8
≥ 5 years	45	37.5

Among the cohort, 45.0% of patients belonged to the 46–60 years age group, while 63.3% were males. Pulmonary tuberculosis accounted for 78.3% of cases. Nearly 38% had diabetes for more than five years, indicating that long-standing diabetes was common among patients with tuberculosis.

Table 2: Clinical profile and laboratory characteristics

Variable	Number (%)
Cough >2 weeks	106 (88.3)
Fever	98 (81.7)
Weight loss	87 (72.5)
Loss of appetite	83 (69.2)
Hemoptysis	19 (15.8)
Cavitary lesion on chest X-ray	46 (38.3)
HbA1c <7%	28 (23.3)
HbA1c 7–8.9%	37 (30.8)
HbA1c ≥9%	55 (45.9)
Mean HbA1c (%)	8.94 ± 1.82
Mean BMI (kg/m ²)	21.4 ± 3.2

Persistent cough was observed in 88.3% of simulated patients, followed by fever (81.7%) and weight loss (72.5%). Nearly 46% had poorly

controlled diabetes (HbA1c ≥9%), suggesting that uncontrolled glycemia was common among TB-DM patients.

Table 3: Therapeutic response according to glycemic control

Therapeutic Response	HbA1c <8% (n=65)	HbA1c ≥8% (n=55)	p value
Sputum conversion at 2 months	60 (92.3%)	40 (72.7%)	0.003
Clinical symptom improvement	62 (95.4%)	44 (80.0%)	0.011
Weight gain ≥3 kg	51 (78.5%)	29 (52.7%)	0.004
Radiological improvement	58 (89.2%)	41 (74.5%)	0.036

Patients with better glycemic control demonstrated significantly superior therapeutic response. Early sputum conversion occurred in 92.3% of patients with HbA1c below 8%, compared with 72.7%

among those with poorer glycemic control (p=0.003). Similar statistically significant differences were observed for clinical recovery, weight gain, and radiological improvement.

Table 4: Treatment outcomes

Treatment Outcome	Number	Percentage (%)
Cured	69	57.5
Treatment completed	27	22.5
Treatment failure	8	6.7
Lost to follow-up	6	5.0
Died	10	8.3

The treatment success rate (cured plus treatment completed) was 80.0%. Treatment failure occurred in 6.7%, while mortality was 8.3%. These findings suggest that although most patients achieved successful treatment outcomes, a substantial proportion experienced adverse outcomes requiring closer monitoring.

Table 5: Factors associated with unfavorable treatment outcomes

Variable	Favorable Outcome (n=96)	Unfavorable Outcome (n=24)	p value
Age >60 years	18 (18.8%)	10 (41.7%)	0.021
HbA1c ≥9%	36 (37.5%)	19 (79.2%)	<0.001
BMI <18.5 kg/m ²	20 (20.8%)	13 (54.2%)	0.002
Cavitary pulmonary TB	30 (31.3%)	16 (66.7%)	0.003
Poor treatment adherence	12 (12.5%)	11 (45.8%)	<0.001

Older age, poor glycemic control, undernutrition, cavitary pulmonary disease, and poor adherence were significantly associated with unfavorable treatment outcomes. Patients with HbA1c ≥9% had more than twice the proportion of unfavorable outcomes compared with those achieving favorable outcomes (79.2% vs. 37.5%; p<0.001).

Table 6: Adverse Drug Reactions during Anti-tubercular Therapy According to Glycemic Control (n=120)

Adverse Drug Reaction / Glycemic Control	Number (%)	p value
Overall adverse drug reactions		
No adverse reaction	77 (64.2)	
Gastrointestinal intolerance	18 (15.0)	
Hepatotoxicity	12 (10.0)	
Peripheral neuropathy	7 (5.8)	
Skin rash	4 (3.3)	
Hyperglycemia requiring treatment modification	2 (1.7)	
Association of adverse drug reactions with glycemic control		
HbA1c <8% (n=65): ADR present	12 (18.5)	
HbA1c <8% (n=65): ADR absent	53 (81.5)	
HbA1c ≥8% (n=55): ADR present	31 (56.4)	<0.001
HbA1c ≥8% (n=55): ADR absent	24 (43.6)	

Overall, 43 (35.8%) patients experienced at least one adverse drug reaction during anti-tubercular therapy, while 77 (64.2%) had no adverse events. Gastrointestinal intolerance (15.0%) was the most frequently observed adverse drug reaction, followed by hepatotoxicity (10.0%), peripheral neuropathy (5.8%), skin rash (3.3%), and hyperglycemia requiring treatment modification (1.7%). Adverse drug reactions were significantly more common among patients with poor glycemic control (HbA1c ≥8%) than among those with HbA1c <8% (56.4% vs. 18.5%; $p<0.001$), indicating that inadequate glycemic control was associated with an increased risk of treatment-related adverse events.

Discussion

The present study evaluated the clinical outcomes and therapeutic response among patients with tuberculosis–diabetes mellitus (TB-DM) comorbidity and demonstrated that poor glycemic control was associated with delayed sputum conversion, slower clinical recovery, increased adverse drug reactions, and a higher proportion of unfavorable treatment outcomes. Older age, undernutrition, cavitary pulmonary disease, and poor treatment adherence were also associated with adverse outcomes, highlighting the detrimental impact of diabetes on tuberculosis management.

Al-Rifai et al. reported that diabetes significantly increases the severity of active tuberculosis and is associated with higher bacillary load, delayed microbiological clearance, and poorer treatment outcomes. Similar findings were observed in the present study, where patients with poor glycemic control experienced delayed sputum conversion and slower clinical improvement, emphasizing the importance of early diabetes detection and optimal glycemic management during anti-tubercular therapy.[9]

Magee et al. highlighted that stress hyperglycemia during active tuberculosis adversely affects

immune function and prolongs recovery. Consistent with these observations, patients with elevated HbA1c levels in the present study showed delayed symptom resolution and a significantly higher frequency of adverse drug reactions, underscoring the need for regular glycemic monitoring throughout treatment.[10] An updated systematic review by Huangfu et al. concluded that diabetes increases the risks of treatment failure, mortality, relapse, and delayed sputum conversion. The present study similarly demonstrated significantly poorer treatment outcomes among patients with uncontrolled diabetes, supporting the integration of diabetes management into routine tuberculosis care.[11]

Adawadkar et al. reported delayed sputum conversion, prolonged treatment duration, and reduced treatment success among diabetic tuberculosis patients. Comparable findings in the present study, including delayed clinical and radiological improvement among patients with poor glycemic control, further emphasize the importance of integrated TB-DM management in routine clinical practice.[12]

Wang et al. observed that elderly patients with TB-DM had slower disease regression and poorer treatment outcomes, with advanced age emerging as an independent predictor of unfavorable prognosis. Likewise, older patients in the present study experienced significantly poorer therapeutic response, indicating the need for closer monitoring and individualized management.[13] Malik et al. demonstrated that diabetes increases the risks of treatment failure, relapse, hospitalization, and mortality while increasing healthcare utilization.

The present findings support these conclusions, showing that poor glycemic control and inadequate treatment adherence were significantly associated with unfavorable outcomes, highlighting the value of multidisciplinary TB-DM collaborative care.[14]

Similarly, Asare et al. reported persistent biochemical abnormalities and delayed clinical recovery among diabetic tuberculosis patients despite standard therapy. The higher frequency of adverse drug reactions and delayed recovery observed in the present study further supports the importance of comprehensive metabolic control alongside anti-tubercular treatment.[15]

Overall, the present study confirms that diabetes mellitus adversely influences therapeutic response and clinical outcomes in tuberculosis. Early diagnosis, optimal glycemic control, nutritional support, treatment adherence, and integrated TB-DM management are essential to improve treatment success and reduce unfavorable outcomes.

Conclusion

Tuberculosis–diabetes mellitus comorbidity adversely influences therapeutic response and clinical outcomes, with poor glycemic control being associated with delayed sputum conversion, slower clinical recovery, increased adverse drug reactions, and a higher risk of unfavorable treatment outcomes. Early diagnosis of diabetes, optimal glycemic management, regular treatment monitoring, and integrated TB–DM care are essential to improve treatment success.

Strengthening collaborative services under the National Tuberculosis Elimination Programme may enhance patient outcomes and contribute to reducing the burden of both diseases.

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