*Original Research Article*

# Effect of Diabetes Mellitus on Clinical, Radiological Characteristics and Treatment Outcomes in Patients with PTB

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## ABSTRACT

**Aim & Objective:** To study the impact of glycemic status on clinical, radiological characteristics and treatment outcomes of pulmonary tuberculosis patients with Diabetes mellitus.

**Materials & Methods:** This is a hospital based prospective study. 100 consecutive patients with pulmonary tuberculosis and Diabetes mellitus were taken into the study and various clinical characteristics, radiological patterns; glycemic status, sputum grading and conversion at the end of intensive phase and treatment outcomes were recorded.

**Results:** Most of the diabetics are above the age of 40 years (91.66%) with peak incidence in age group of 40-60 years with mean age was 50.35 years. Male preponderance observed in the study with a total of 62 males. New cases are more than relapses accounting for 65% and 35% respectively. Mean HbA1C of the study population was 9.77 with 71 patients having HbA1C>9. Radiologically, infiltrates are the most common finding accounting for 88%. Cavitatory lesions are seen in 56%, lower lung field involvement in 38%. 26 cases were diagnosed with Diabetes mellitus de-novo and remaining 74 cases were already on treatment for previously diagnosed diabetes mellitus. Sputum smear conversion at the end of intensive phase was observed in 87.77%. Successful treatment outcome was observed in 90 cases of which 78 were cured and 12 completed the treatment and unfavourable outcomes in10 cases.

**Conclusion:** Diabetes affects the clinical and radiological characteristics of PTB patients significantly. The glycemic status of the patient has significant impact on the bacillary load of the patient. But the glycemic status at the initiation of the treatment has no impact on the sputum conversion at the end of intensive phase and on the treatment outcomes.

*Keywords:* DM- Diabetes mellitus, PTB- pulmonary tuberculosis, glycemic status, sputum grading & conversion.

## I. INTRODUCTION

One among the top ten causes of the death and leading cause from a single infectious agent (above HIV/AIDS) worldwide is tuberculosis. As per the estimates in 2017, among HIV negative people, TB caused about 1.3 million (range 1.2 -1.4 million) deaths and an additional 3,00,000 deaths from TB (range 2,66,000-3,35,000) among HIV positive people. Globally,10 million people (range 9.0 million -11.1 million) developed TB disease

in 2017 in which 5.8 million are men,3.2 million are women and 1.0 million are children. Worldwide TB incidence is falling at about 2 % per year. The number of TB deaths among HIV negative people has fallen to about 1.3 million in 2017. The TB mortality rate is falling at about 3% per year, and overall reduction in period of 2000-2017 was 42%. [1] The coexistence and synergistic role of tuberculosis and diabetes in a human in causing disease and suffering was known for decades and many prospective and retrospective studies were conducted in this regard. [2]

The incidence of tuberculosis in India including the HIV is about 27,90,000 people and the mortality due to TB (excluding HIV) is about 4,23,000 people. The incidence of HIV-TB co-infection is about 87,000 people and the mortality due to HIV-TB comorbidity is about 12,000 people. The incidence of MDRTB/RR is about 1,47,000 people. [3]

WHO projects that the seventh leading cause of death will be diabetes in 2030.Globally an estimated 422 million adults who were living with diabetes in 2014 as compared to 108 million in 1980.The global prevalence of diabetes has nearly doubled since 1980 which increased from 4.7% to 8.5% in adult population. Over the decades, the prevalence of diabetes has risen in low and middle-income countries than in high income countries. Diabetes caused about 1.5 million deaths in 2012. An additional 2.2 million deaths were caused by higher than optimal blood glucose, by increasing the risks of cardiovascular and other diseases. About 43% of these 3.7 million deaths occur before the age of 70 years. Majority of people with diabetes are affected by type 2 diabetes. This used to occur entirely among adults only, but now it occurs in children too. The percentage of deaths due to high blood glucose or diabetes which occurs prior to age 70 is higher among low and middle-income countries than in high income countries. [4]

The rate of diabetes in patients with TB is 2.0-4.6 times higher than in general population. Among all the cases of DM in TB, new cases of DM accounts for about 64%. [5] 10% of people with TB are linked to diabetes. There is 2-3 fold high risk of developing TB and relapse during and after anti tubercular therapy in people with diabetes. [2] The stress of the severe chronic infection may enhance the existing insulin resistance and may unmask the underlying beta cell deficiency which leads to hyper glycemia which possibly increase the risk of DM among people with TB, especially in the presence of the other underlying predisposing factors.

DM is one of the most important risk factor for developing the active TB disease as it weakens the immune system. Lung is the target organ in DM and pulmonary involvement is also very closely related to other vascular complications. DM causes basal membrane thickness which decrease the lung elasticity and neuropathy, which may affect basic lung function. Both the acute and the chronic lung infections including the TB are frequently seen in DM patients because of the defects in cellular and humoral immunity. The risk of treatment failure, relapse and death also increase with DM. [6]

DM is known to modify the clinical features and radiological manifestations of pulmonary tuberculosis. [7] The prevalence of DM increases so rapidly not only in the high- income countries but also in the low and the middle-income countries which are having the high burden of tuberculosis. [8]

The absolute numbers of TB cases are falling and the prevalence of diabetes is projected to be doubled. Half of the people with diabetes are undiagnosed and the vast majority of this diabetic population lives in the developing world countries which are well known to be endemic for tuberculosis. So awareness and screening for DM in the TB patients should be raised. The looming DM epidemic is a threat to the TB control, adequate knowledge on the interaction of these two old disorders is critical. [9]

## II. OBJECTIVES

- To determine the effect of DM on the clinical and radiological manifestations of pulmonary tuberculosis.
- To assess the outcomes in patients of pulmonary tuberculosis with diabetes mellitus

## III. MATERIALS AND METHODS

A hospital based prospective study was conducted. A total of 100 consecutive PTB cases were enrolled into the study according to inclusion and exclusion criteria.

### INCLUSION CRITERIA:

- All cases of pulmonary tuberculosis with proven type 2 diabetes mellitus.
- Patient aged > 18 years.
- Patients willing to participate in the study.

### EXCLUSION CRITERIA:

- Patient aged <18 years
- Non co-operative patients
- Patients with type 1 diabetes mellitus
- Patients with associated HIV.
- Other infectious diseases of lung.

## METHODOLOGY

The following data was recorded:

- ❖ A detailed history of every case was obtained including
- age, sex, socioeconomic status, rural/urban(address),
- past medical history, family history and treatment history of Diabetes mellitus,
- date of PTB and T2 DM diagnosis,
- presenting symptoms of PTB,
- date of commencement of ATT,
- Complaints after using ATT.
- ❖ Physical examination was conducted
- To find the presentation of PTB in T2 DM,
- to detect drug related adverse events.
- ❖ Investigations were carried out and recorded in all subjects (at regular intervals) are:
- Sputum for acid fast bacilli (AFB)
- Chest radiography (PA view) to study the radiological pattern

  - Atypical presentations (lower lung field involvement)
  - Pleural effusions/ cavity/ infiltrates
- Fasting blood glucose
- 2 hrs postprandial blood sugar test
- Other routine investigations like complete blood picture and complete metabolic profile.

**Data analysis:**

All the data collected was organised using Microsoft excel software and statistically analysed using Graph pad Prism software. Statistical analysis was done using paired t test, chi-square test and ANOVA test.

## IV. RESULTS

Of 100 patients included in the study, 62 were males and 38 were females. The mean age of the study population was $50.35 \pm 10.01$ years. Most common symptom in the study population was cough (98%) followed by fever (79%), breathlessness (64%), hemoptysis (18%) and chest pain (6%). The mean BMI of the study population was $21.67 \pm 4.82$ kg/m$^2$. 75% of the study population presented to hospital within 2-8 weeks duration of their symptoms.

In the present study, 65 patients were new cases of PTB, 25 patients were PTB relapse and 10 patients were treatment after loss to follow up. Among all patients with pulmonary tuberculosis, 26% are diagnosed to have diabetes mellitus denovo while 74% already diagnosed to have diabetes mellitus. Among 26 patients diagnosed denovo with diabetes mellitus, 18 patients (69.23%) are new cases of pulmonary tuberculosis. Among 74 patients who are already diagnosed to have diabetes mellitus 47 patients (63.51%) are new cases of pulmonary tuberculosis.

The mean duration of diabetes in this study was $4.71 \pm 4.03$ years. The mean HbA1C of the study population was $9.77 \pm 2.28\%$. The mean FBS value in patients with pulmonary tuberculosis and diabetes mellitus was $191.04 \pm 85.45$ with lowest

value recorded being 84 mg/dl and highest value recorded being 418 mg/dl. The mean PPBS value in patients with pulmonary tuberculosis and diabetes mellitus was 290.9 ± 103.31 with lowest value recorded being 116 mg/dl and highest value recorded being 560 mg/dl.

In this study 10 patients had negative sputum smear microscopy, 3 had scanty bacilli, 19 had 1+, 35 had 2+ and 33 patients had 3+ grading on sputum smear microscopy. 10 patients with negative sputum smear microscopy were diagnosed to have PTB through CBNAAT test and all are found to be Rifampicin sensitive.

The most common radiological presentations in patients with pulmonary tuberculosis and diabetes mellitus in this study were infiltrates (86%) and cavities (57%). Lobar consolidation was observed in 4 patients. Along with lung lesions pleural effusions are seen in 13% patients. Lung abscess is seen in 12% patients. Along with lung lesions hydro pneumothorax was seen in 4 patients. 38% of the patients with diabetes mellitus have isolated lower lung field (LLF) tuberculosis radiologically.

In the study population only 90 patients were sputum smear positive at the initiation of treatment. Of 65 patients who were on cat I ATT, 59 were smear positive at the initiation of treatment. Of 35 patients who were on cat II ATT, 31 were smear positive at the initiation of treatment.

Sputum smear conversion at the end of intensive phase was observed using florescent staining. It was done at the end of 2 months in patients receiving cat I ATT and at the end of 3 months in patients receiving cat II ATT. Sputum smear conversion in sputum smear positive patients on cat I ATT was observed in 54 patients (91.52%) and in 25(80.64%) of 31 patients who were on cat II ATT. In total, sputum smear conversion was observed in 79(87.77%) of 90 patients.

Among 65 new TB cases who used cat I ATT, 52 were cured, 5 completed treatment, 6 loss to follow up, 1 treatment failure and 1 patient died. Among 35 previously treated PTB cases who used cat II ATT, 26 were cured, 7 completed treatment, 1 was loss to follow up and 1 patient died. Overall in this study, 78% were cured and 12% completed the treatment, 7% lost to follow up, 1% failure and 2% were died. Treatment outcomes were categorized into favourable and unfavourable outcomes. Cured and treatment completed were categorized as favourable outcomes and remaining as unfavourable outcomes. Accordingly 90% favourable and 10% unfavourable outcomes were obtained.

**Relation between glycemic status and bacillary load at initiation of treatment:**

**Table 1: HbA1C vs sputum smear grading at treatment initiation**

| HbA1C | Sputum negative | Sputum scanty | Sputum 1+ | Sputum 2+ | Sputum 3+ | Total |
|---|---|---|---|---|---|---|
| <6.5 | 6 | 1 | 1 | 2 | 1 | 11 |
| 6.5-9 | 2 | 1 | 2 | 6 | 7 | 18 |
| >9 | 2 | 1 | 16 | 27 | 25 | 71 |
| Total | 10 | 3 | 19 | 35 | 33 | 100 |

In the present study, HbA1C was <6.5 in 11 patients of which 6 were sputum negative, 2 were sputum 2+, 1 each were sputum scanty, sputum 2+ and sputum 3+. HbA1C was 6.5-9 in 18 patients of which 7 were sputum 3+, 6 were sputum 2+, 2 were sputum 1+ and 2 were sputum negative and 1 was sputum scanty. HbA1C was >9 in 71 patients of which 27 were sputum 2+, 25 were sputum 3+, 16 were sputum 1+, 2 were sputum negative and 1 was sputum scanty. (p-value: 0.04) (table 1).

**Relation of glycemic status and radiological lung fields involvement:**
Of 11 patients with HbA1C < 6.5, 1 patient had isolated LLF. Of 18 patients with HbA1C 6.5-9, 5 patients had isolated LLF. Of 71 patients with HbA1C >9, 32 had isolated LLF.(p-value: 0.02), as shown in table 2.

**Table 2: HbA1C at treatment initiation vs radiological lung fields**

| HbA1C | LLF | Other than LLF | Total |
|-------|-----|----------------|-------|
| <6.5  | 1   | 10             | 11    |
| 6.5-9 | 5   | 13             | 18    |
| >9    | 32  | 39             | 71    |

## Relation of glycemic status and radiological distribution of lesions:

Of 11 patients with HbA1C < 6.5, 7 had unilateral lesions. Of 18 patients with HbA1C 6.5-9, 12 had unilateral lesions. Of 71 patients with HbA1C >9, 39 had unilateral lesions.(p-value :0.008) (table 3).

**Table 3: HbA1C at treatment initiation vs radiological distribution**

| HbA1C | Unilateral | Bilateral | Total |
|-------|------------|-----------|-------|
| <6.5  | 7          | 4         | 11    |
| 6.5-9 | 12         | 6         | 18    |
| >9    | 39         | 32        | 71    |
| Total | 58         | 42        | 100   |

## Effect of glycemic status of the patients on sputum smear conversion:

In this study, of 69 patients with HbA1C >9 at the time of treatment initiation, 60 had sputum smear conversion and 9 were sputum positive at the end of intensive phase. Of 15 patients with HbA1C 6.5-9 at the time of initiation of treatment, 14 had sputum smear conversion and 1 was sputum positive at the end of intensive phase. Of 6 patients with HbA1C <6.5 at the time of initiation of treatment, 5 had sputum smear conversion and 1 was sputum positive at the end of intensive phase.(p-value: 0.40) (table 4).

**Table 4: Glycemic status vs sputum smear conversion**

| HbA1C | Sputum smear converted | Sputum smear not converted | Total |
|-------|------------------------|----------------------------|-------|
| <6.5  | 5                      | 1                          | 6     |
| 6.5-9 | 14                     | 1                          | 15    |
| >9    | 60                     | 9                          | 69    |
| Total | 79                     | 11                         | 90    |

## Effect of bacillary load on sputum smear conversion: (table 5)

In the present study, 29 patients with sputum for AFB 3+, 29 with 2+, 18 with sputum 1+ and 3 with sputum for AFB scanty at the time of diagnosis had sputum smear conversion at the end of intensive phase. (p-value: 0.03)

**Table 5: sputum smear grading vs sputum smear conversion at the end of intensive phase**

| Sputum grading | Sputum smear converted | Sputum smear not converted | Total |
|----------------|------------------------|----------------------------|-------|
| scanty         | 3                      | 0                          | 3     |
| 1+             | 18                     | 1                          | 19    |
| 2+             | 29                     | 6                          | 35    |
| 3+             | 29                     | 4                          | 33    |
| Total          | 79                     | 11                         | 90    |

## Effect of glycemic status over treatment outcomes: (table 6)

In 71 patients with HbA1C >9 at the time of initiation of treatment, 63 had favourable and 8 had unfavourable outcomes. In 18 patients with HbA1C 6.5-9 at the time of initiation of treatment, the final treatment outcomes were 17 had favourable and 1 had unfavourable outcome. Likewise in 11 patients with HbA1C < 6.5 at the time of treatment initiation, 10 had favourable and 1 had unfavourable outcomes.(p-value:0.34)

**Table 6: Glycemic status vs treatment outcomes**

| HbA1C | Favourable outcome | Unfavourable outcome | Total |
|-------|--------------------|----------------------|-------|
| <6.5  | 10                 | 1                    | 11    |
| 6.5-9 | 17                 | 1                    | 18    |
| >9    | 63                 | 8                    | 71    |
| Total | 90                 | 10                   | 100   |

## Relation of sputum smear conversion over treatment outcomes: (table 7)

Among the 79 patients who had sputum smear conversion at the end of intensive phase, final outcome was favourable in 74 and unfavourable in 5 patients. Among the 11 patients whose sputum was still positive for AFB at the end of intensive phase, final treatment outcome was found to be favourable in 7 and unfavourable in 4 patients. (p-value: 0.0116)

**Table 7: sputum smear conversion vs treatment outcomes**

|                     | Favourable outcome | Unfavourable outcome | Total |
|---------------------|--------------------|----------------------|-------|
| Smear converted     | 74                 | 5                    | 79    |
| Smear not converted | 7                  | 4                    | 11    |
| Total               | 81                 | 9                    | 90    |

## V. DISCUSSION

Pulmonary tuberculosis and diabetes mellitus may occur in same individuals frequently, particularly in a population with a high risk of acquiring tuberculosis. The clinical features of tuberculosis have been

reported to be modified by the presence of diabetes mellitus.

In order to prove the above fact, a number of studies have been conducted previously. The present study was done with an objective to find out the clinical and radiological presentation and to assess the treatment outcome in the pulmonary tuberculosis patients with associated diabetes mellitus.

In the present study, a total of one hundred patients with pulmonary tuberculosis and associated diabetes mellitus have been evaluated. The clinical history of these patients was recorded. Blood sugars comprising FBS and PPBS were estimated. Sputum smear for microscopy was done with fluorescent staining and grading was done for the smears according to the number of bacilli present. Chest X-rays were done and interpreted for the presence of cavitary and non- cavitary lung lesions, observed for the presence of unilateral or bilateral involvement. Chest X-rays were also observed for the lower lung field tuberculosis. All the observations were tabulated and analysed. In the present study both new and retreatment cases of pulmonary tuberculosis with diabetes mellitus were considered.

The proportion of PTB patients with DM was more in men compared to women, which may be due to the synergistic effect of other risk factors such as smoking, tobacco use and alcohol consumption, which impact both TB and DM. The mean BMI was found to be low in patients with PTB and DM when compared to those PTB patients without DM as observed in the study done by S. Kumpatla et al., [11] Under nutrition, smoking, diabetes and alcohol consumption can increase the risk of developing active tuberculosis two to threefold.

In the present study 65% were new cases of pulmonary tuberculosis and 35% were retreatment cases. In the present study, sputum smear for AFB was positive in 90% patients whereas it was 62.5% in the study by Jovana M Pavlovic et al., [6] and 47.6%

in the study by Chi. C. Leung et al., [8] and 59.6% in the study by A. A. Viswanathan et al., [10] In the present study 78% of cases have smear grading ≥ 2+. It implies that high bacillary load is seen in pulmonary tuberculosis patients with diabetes. This observation is also in agreement with the observations of many earlier authors.

Localization of the radiological lesions was interpreted using two different classifications. First, commonly upper-mid and lower zones are separated by a horizontal line passing at the level of second and fourth ribs respectively. The lower lung field (LLF) was separately defined as the area below an imaginary line traced across the hila and including the parahilar regions on a standard posteroanterior chest roentgenogram. This was to allow comparisons to be made with previous reports that used the same definition. The lower lung field included middle lobe and the lingula in addition to the lower lobes. [12] In the present study, 38% of the patients with diabetes mellitus had isolated lower lung field tuberculosis radiologically while 62% of patients have lesions in other than lower lung fields tuberculosis. In the present study 57% of patients had cavitary lesions radiologically. In the study conducted by R. Singla et al., [7] 23.5% patients had lower lung field involvement and 50.8% had cavitary lesions radiologically. In the study conducted by Park SW et al., they observed more number of cavitary lesions and higher positive smear rates in diabetics with uncontrolled sugar levels when compared to non-diabetics [14]

## Sputum conversion at the end of intensive phase

Sputum smear conversion in sputum smear positive patients on cat I ATT (59 patients) was observed in 54 patients (91.52%) and in 25(80.64%) of 31 patients who were on cat II ATT(35 patients). In total, sputum smear conversion was observed in 79(87.77%) of 90 patients. Similar findings were observed in the study conducted by R. Singla et al., [7] in which sputum smear conversion at the end of 2

months was present in 83.8% and at the end of 3 months in 98.9% patients. In the study conducted by Chi. C. Leung et al., [8] sputum smear conversion at the end of 2 months in PTB with DM patients was 81.6%.

**Treatment outcomes**

In the present study successful outcome (cured and treatment completed)

was observed in 90% of patients and unfavorable outcomes were seen in 10% of patients. In the study conducted by R. Singla et al., [7] successful outcome was observed in 97.1% of patients and in the study by Chi. C. Leung et al., [8] it was observed in 73.9% patients and in the study by A. A. Viswanathan et al., [11] it was observed in 89.3% patients**.**

| | Cured and treatment completed | failure | Death | Lost to follow up |
|---|---|---|---|---|
| Present study | 90% | 1% | 2% | 7% |
| A.A. Viswanathan et al., | 87.9% | 7.9% | 1.1% | 1.1% |
| Chi C. Leung et al., | 73.9% | 0% | 9.9% | 3.3% |
| R. Singla et al., | 97.1% | 0% | 0.7% | 2.2% |

Similar results were obtained by Rani Balasubramanian et al 2007 in their study to evaluate the effect of intermittent regimen in new pulmonary tuberculosis cases with diabetes mellitus. 94% of their patients were cured and 4% relapsed. They also reported good response to anti tubercular treatment by majority of their patients in spite of poor diabetic control. [13] This was in contrary to the previous studies which stated that the success of antitubercular treatment among TB-DM patients requires strict glycaemic equilibrium. [15]

**Glycemic status vs sputum smear grading:**

In the present study among 71 patients who had poorly controlled diabetes i.e. HbA1C >9, 52 patients had high bacillary load i.e. sputum for AFB 2+ and 3+.So, it is inferred that 73.2 % of poorly controlled diabetes had high bacillary load which was statistically significant.

**Glycemic status vs radiological zone involvement**

In the present study, only lower lung field lesions were observed in 45.07%, 20.68% of patients with HbA1C >9 and <9 respectively. So, in this study lower lung field opacities were more in patients with poorly controlled diabetes, which was statistically significant. In the study conducted by L. K. Huang et al., only lower lung field lesions were seen in 10.9% patients with HbA1C ≤ 8% and in 10.6% patients with HbA1C >8%.

In this study, 50% of the patients with sputum for AFB scanty and 1+ had unilateral lesions radiologically. 60.29% of the patients with sputum for AFB 2+ and 3+ had unilateral lesions radiologically. This show that even in patients with high bacillary load, predominantly unilateral lesions were observed radiologically.

In the present study, 85.29% of the patients with sputum for AFB 2+ and 3+ had sputum conversion at the end of intensive phase. 95.45% of the patients with sputum for AFB 1+ and scanty also had sputum conversion at the end of intensive phase. So there was good proportion of sputum conversion at the end of intensive phase among sputum positive PTB patients with diabetes.

Among 29 patients with HbA1C <9, 21 patients were sputum positive at the initiation of treatment and were followed up with sputum microscopy at the end of intensive phase. Sputum smear conversion was observed in 90.47% (19 out of 21 patients). Amongst 71 patients with HbA1C >9, 69 patients were sputum positive at the initiation of treatment and were followed up with sputum microscopy at the end of intensive phase. Sputum smear conversion was observed in 86.95% (60 out of 69 patients). So, it is inferred from this study that glycaemic status had no significant impact of on smear conversion (effect of glycemic status at the initiation of treatment on smear conversion at the end of intensive phase is statistically not significant).

Amongst 71 patients with HbA1C > 9, 63 had successful treatment outcome which is 88.73%. Amongst 29 patients with HbA1C < 9, 27 had successful treatment which is 93.1%. So, it is inferred from this study that glycemic status of the patient at the time of diagnosis had no significant influence on the treatment outcomes.

This shows that the glycemic control during the treatment will have impact on the sputum smear conversion and treatment outcomes rather than the glycemic status at the initiation of treatment.

Amongst 22 patients with sputum for AFB scanty and 1+,21 had successful treatment outcomes, which is 95.45%. Amongst 68 patients with sputum for AFB 2+ and 3+,60 had successful treatment outcomes which is 88.23%.So, it is inferred from this study that higher proportion of patient with low bacillary load associated with successful treatment outcomes compared to those with high bacillary load though it was not statistically significant. This means even though the bacillary load is high at the initiation of treatment, successful outcomes can be achieved with good compliance and adherence to the anti-tubercular therapy.

## VI. CONCLUSION

Diabetes has significant impact on PTB patients in the form of high bacillary load, predominant lower lung field involvement but the glycemic status of the patient at the initiation ATT has no impact on smear conversion or the treatment outcome. It is the glycemic control throughout the treatment that is important for treatment outcome.

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