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Original Research Article

# Outcome of tuberculosis and diabetes mellitus coinfection: A study in a tertiary care centre in semiurban India

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ABSTRACT

**Introduction:** Tuberculosis has for a very long time been one of the major causes of morbidity and mortality globally. Diabetes mellitus is another disease which is growing into another major global challenge. Presence of diabetes increases the risk of tuberculosis by 2 to 3 times.
**Materials and Methods:** 2 sputum samples were collected from all the 202 patients for Zeihl Neelson's staining to screen the Mycobacterium tuberculosis bacillus. Venous blood was taken for blood glycated hemoglobin and other biochemical and hematological tests.
**Results:** Out of these 41.6% had diabetes and 58.4% were non diabetic. The chest X-rays were severe in 51.2% patients among the TB and DM comorbid patients and 33.9% among the non diabetic patients. Poor outcome was seen in 54.8% of the cases among the DM and TB patients which in only TB patients with no diabetes, the number of cured patients was far more.
**Conclusion:** There was a high incidence of diabetes among the patients with TB, which increases the morbidity and mortality among these patients. Smoking and alcoholism are preventable risk factors. So proper counselling and health education is necessary so that the patients would be able to monitor their blood sugar levels.



## 1. Introduction

Tuberculosis has for a very long time been one of the major causes of morbidity and mortality globally. This disease is caused by a bacteria called Mycobacterium tuberculosis and affects 1/3$^{rd}$ of the population. 9 million people are infected with this disease and 2 million die every year.[1,2] Nearly 70% of the new cases are seen in the developing countries, with the maximum number seen in the African countries.[3] South East Asia, Africa and Western Pacific are the major regions which have a prevalence of 30%, 28% and 19% respectively.[4] There is a strategy put up by the World Health Organization to end the global menace of TB by 2035. This includes a reduction of the deaths due to TB by 90% and incidence by 80% by 2030.[3]

Diabetes mellitus is another disease which is growing into another major global challenge.[5] The present burden of Diabetes is estimated to be 415 million cases worldwide and is expected to reach 642 million by 2040.[6] By 2030, the 7$^{th}$ leading cause of death in the world will be Diabetes, and 90% of this will be due to Diabetes mellitus Type 2.[7] 80% of the adult cases of diabetes would be seen in the developing or in the newly developed countries.[6]

Presence of diabetes increases the risk of tuberculosis by 2 to 3 times.[8] Incase of active TN, the risk is increased 3.11 times and incase of latent TB it is 1.18 times.[9,10] Diabetics also are prone to other lung physiological abnormalities such as diminished bronchial reactivity.[11,12] Treatment of TB is also affected by DM and the outcome is poor.[13,14] The physiological abnormality is due to the delayed removal of the microorganisms from the lungs which may result in the spread of the infection. The older foci of TH may be reactivated due to this immunocompromised state leading

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to TB rather than due to fresh infection. [15,16]

In order to analyze the association of Diabetes mellitus and tuberc Davanagerekaour geographical area, the present study was undertaken.

## 2. Materials and Methods

This study was done at Kamineni academy of medicalsciences and research institute in the department of Pulmonary Medicine. 202 patients during the period Jan 2016 to April 20 over 18 years of age who were diagnosed for the first time to be sputum positive for tuberculosis were enrolled into the study. Since our hospital is an RNTCP centre, all these patients were first enrolled into RNTCP.

For the detection of tuberculosis, all the patients were asked to give 2 sputum samples – one spot and one early morning samples as per the RNTCP protocols. All these samples were subjected to Ziehl Neelson's staining method and observed under microscope. In case they were positive, the samples were graded as per the RNTCP protocols. All these patietns were enrolled into the study.

This study was cleared by the Institutional Ethical Committee. To all the new TB positive patients, the nature of the study was explained in detail and an informed consent was collected from all of them. This who refused to five consent were not enrolled into the study. They were all subjected to complete and thorough medical examination. Sputum negative patients, patients with other underlying pulmonary problems, pregnant women, HIV reactive patients, liver or renal disease were all excluded from the study. Those who were previously treated with antitubercular drugs for tuberculosis were also excluded from the study.

Height and weight of the patients were also taken and body mass index was calculated. All of them were subjected to Chest X-rays to observe the presence of opacities, cavities, pleural effusion, hilar enlargement, pneumothorax etc. Grading was also done of the X-rays as minimal or mild, moderately advanced and severely advanced. Minimal was when thee was a slight to moderate density but no cavities, with a small part of one or both lungs involved and the total involvement is not more than the volume of the lung. Moderately advanced was when there was slight to moderate lesions in one or both the lungs in the total extent of the lung. Far advanced was when the lesions were more extensive than the moderate, mostly involving both the lungs.

Venous blood was collected from all the patients for hematological and biochemical investigations such as complete blood picture, erythrocyte sedimentation rate, hemoglobin estimation, random blood sugar, lipid profile, renal profile, liver function tests. In case the RBS was above the normal range, the patient was asked to come after an overnight fast the next day. Fasting blood sugar was collected from them and they were asked to have breakfast. 2 hours after their breakfast, blood was collected once gain to estimate the post parandial sugar values. HbA1c was also estimated for all the patients for the glycated sugar levels. Those who had high hba1c levels were categorized as Group 1 (with diabetes) and theose who had normal range of hba1c were grouped under Group 2 (without diabetes).

All the patients were treated with the first line of drugs for tuberculosis i.e Pyrizinamide, Ethambutol. Rifampicin and Isoniazid. In case the patient was a known diabetic, the anti diabetic drugs were continued and incase he was a new diabetic, the drugs were prescribed.

A follow up after 2 months and then again after 6 months was done for all the patients. Sputum test, blood investigations and x-rays were performed again to check the improvement. After 6 months, if the patient was not sputum positive and had no symptoms of TB, they were considered to be successfully treated of TB.

## 3. Results

The total number of people who entered into this study were 202. Out of these 84 (41.6%) had diabetes and 118 (58.4%) were non diabetic. Out of the 84 TB patients who were diabetic, 49 (58.3%) were males and 35 (46.7% were females. Even among the non diabetic patients males were the predominant gender. 73 (61.9%) were males and 45 (38.1%) were females (Table 1).

**Table 1:** Diabetes status and gender classification of the patients

| Gender | Group I (Diabetic) | Group 2 ( Non diabetic) |
|---|---|---|
| Male | 49 (58.3%) | 73 (61.9%) |
| Female | 35 (46.7%) | 45 (38.1%) |
| Total | 84 | 118 |

Most of the cases were between 41-60 years of age in both diabetes and non diabetes patients. 24 (28.6%) of the patients were between 41-50 years of age, 23 (27.4%) were between 51-60 years, 18 (21.4%) were 61-70 years, 12 (14.3%) were between 31-40 years among the patients with diabetes. In the patients who had tuberculosis but no diabetes, 25 (21.2%) were between 41-50 years, 28 (23.7%) were between 51-60 years. Very few people in both the cases were < 30 years of age. However, the percentage of older people were b=moe among the diabetic patients than the non diabetic patients (Table 2)

Most of the people in the study were in the normal range of BMI. In the patients with TB and DM comorbidity, the BMI was 18.1 $\pm$ 4.7 kg/m$^2$and in group 2 they were 21.8 $\pm$ 2.6 kg/m$^{2\cdot}$ 32 (38.1%) among the group 1 and 46 (39%) among the Group 2 were current smokers while 34 (40.5%) in group 1 and 41 (34.7%) in Group 2 were non smokers. 23 (27.4%) in group 1 and 29 (24.5%) still consumed alcohol at the time of study while 50 (59.5%) in Group 1 and 71 (60.2%) among the Group 2 were teetotalers (Table 3).

**Table 2:** Distribution of patients based on age

| Age group (in years) | Group 1 | Group 2 |
|---|---|---|
| < 30 | 2 (2.4%) | 16 (13.6%) |
| 31-40 | 12 (14.3%) | 17(14.4%) |
| 41-50 | 24 (28.6%) | 25 (21.2%) |
| 51-60 | 23 (27.4%) | 28 (23.7%) |
| 61-70 | 18 (21.4%) | 23(19.5%) |
| >70 | 6 (7.1%) | 9 (7.6%) |
| Total | 84 | 118 |

**Table 3:** Demographic data of the patients

| Data | Group 1 | Group 2 |
|---|---|---|
| Body Mass Index (Mean – $kg/m^2$) | 18.1 ± 4.7 | 21.8 ± 2.6 |
| Smokers | | |
| Current | 32 (38.1%) | 46 (39%) |
| Past | 18 (21.4%) | 31 (26.3%) |
| Non smoker | 34 (40.5%) | 41 (34.7%) |
| Alcohol consumption | | |
| Current | 23 (27.4%) | 29 (24.5%) |
| Past | 11 (13.1%) | 18 (15.3%) |
| Does not drink | 50 (59.5%) | 71 (60.2%) |

The hemoglobin levels among the patients were slightly below the normal range with 11.5 ± 3.7 g/dl in Group 1 and 12.9 ± 3.1 g/dl in Group 2. The Erythrocyte sedimentation rate was quite high in both the groups. In Group 1 it was 49.4 ± 6.3mm/hr and in group 2 it was 57.2 ± 13.4 mm/hr. 58 (69%) of the patients had uncontrolled hba1c levels of >9%, 23 (27.4%) had between 7-9%. Only 3 (3.6%) of the patients had a hba1c level below 7%. TB was graded in our study and 33 (39.3%) had 3+ grade, 41(48.8%) were 2+, while in Group 2 37 (31.4%) were 3+ and 57 (48.3%) had 2+. The chest X-rays were severe in 43 (51.2%) patients among the TB and DM comorbid patients and 40 (33.9%) in Group 2 patients, while moderate X-rays were seen in 9 (34.5%) among the TB and DM comorbid patients and 62 (52.5%) in Group 2 patients (Table 4).

Among the symptoms that the patients had at the time of enrolment was cough with sputum in 83 (98.8%) TB and DM patients and 98 (83.1%) in only TB patients. 116 of the total in Group 2 had cough. Fever was seen in 79 (94%) in Group 1 and 109 (92.4%) in Gorup 2, dyspnea in 53 (63.1%) in Group 1 and 47 (39.8%) in Group 2, Weight loss in 72 (85.7%) in Group 1 and 77 (62.3%) in Group 2 (Table 5)

26 (31%) in Group 1 and 78 (66.1%) in Group 2 were completely cured of TB after 6 months of treatment while 46 (54.8%) in Group 1 and 27 (22.9%) in Group 2 were not completely cured. 4 (4.8%) in group 1 and 2 (1.7%) in Group 2 died during the treatment. However, there were 8 (9.5%) from group 1 and 11 (9.3%) from group 2 who were defaulters. 2 of them changed address and we were not able to track them and the 4 refused treatment as it made them sick. The others were not consistent in their medication and thus we labelled them in this category (Table 6).

**Table 4:** Investigations

| Investigations | Group 1 | Group2 |
|---|---|---|
| Hemoglobin (gm/dL) | 11.5 ± 3.7 | 12.9 ± 3.1 |
| ESR (mm/hr) | 49.4 ± 6.3 | 57.2 ± 13.4 |
| Hba1c levels | | |
| < 7 % | 3 (3.6%) | 117 (99.2%) |
| 7-9% | 23 (27.4%) | 1 (0.8%) |
| >9% | 58 (69%) | 0 (0%) |
| Grading of TB | | |
| Scanty | 2 (2.4%) | 1 (0.8%) |
| + | 8 (9.5%) | 23 (19.5%) |
| ++ | 41(48.8%) | 57 (48.3%) |
| +++ | 33 (39.3%) | 37 (31.4%) |
| Chest X rays | | |
| Minimal | 12 (14.3%) | 16 (13.6%) |
| Moderate | 29 (34.5%) | 62 (52.5%) |
| Severe | 43 (51.2%) | 40 (33.9%) |

**Table 5:** Symptoms at the time of enrolment

| Symptoms | Group 1 | Group2 |
|---|---|---|
| Cough | 83 (98.8%) | 116 (98.3%) |
| Dyspnea | 53 (63.1%) | 47 (39.8%) |
| Night Sweats | 36 (42.9%) | 62 (52.5%) |
| Weight Loss | 72 (85.7%) | 77 (62.3%) |
| Hemoptysis | 25 (%29.8) | 13 (11%) |
| Fever | 79 (94%) | 109 (92.4%) |
| Sputum production | 83 (98.8%) | 98 (83.1%) |

**Table 6:** Outcome of treatment

| Outcome | Group 1 | Group 2 |
|---|---|---|
| Cured | 26 (31%) | 78 (66.1%) |
| Failed | 46 (54.8%) | 27 (22.9%) |
| Defaulted | 8 (9.5%) | 11 (9.3%) |
| Died | 4 (4.8%) | 2 (1.7%) |

## 4. Discussion

There is substantial evidence that diabetes mellitus is associated with Tuberculosis and its poor outcome.[17,18] There is a high chance of the smear positive patients with diabetes to not have a conversion to smear negative within 2 months of treatment than those patients who do not have diabetes mellitus.[19,20]

In the present study, males were predominantly more affected with tuberculosis than females. In both the groups, the number of males were more than the females. However, no significant difference was found among the males and females. Similar results were observed in other studies.[21,22] Sharma et al and Damtew et al also found males in more in number to be affected with tuberculosis as in our study.[23,24]

More number of patients who were affected were in 40-60 years age group, which accounted for more than 50% in

both the groups. There were very few patients below the age of 30 and above 70 in both the groups. However, the age of the people with diabetes was more than those without diabetes. This was observed in a study by Agarwal et al, where they also found the ages of the patients to be more among the diabetic group than the non diabetic group.[25] A study by Nair et al reported that people above the age of 50 years are at higher risk to have a TB infection with DM.[26]

A prevalence of 41.6% of diabetes mellitus was seen in the present study among the tuberculosis sputum positive patients. In a study by Balakrishnan et al, a prevalence of 44% was seen in Kerala.[27] But another study by Agarwal et al in Gwalior saw a prevalence of 15.5%.[25] Similar pattern was found in yet another study by Ahmed et al, where they found a strong association between pulmonary TB and uncontrolled hba1c.[28] In our study also there was a strong association with uncontrolled hba1c (>9) in 69% of the patients with DM. A study by Bokam and Pujitha states that there was an increase in hba1c with increase in duration of diabetes. The patients may not know that they have diabetes because there is and elevation of hba1c in TB.[29]

Though the mean BMI was within the normal range in our study, in the patients with DM and TB, the BMI was in the upper range, and many of the patients in this group were overweight. The opposite was seen in the group 2, where the BMI was on the lower end of the normal range. This higher BMI is also said to be associated with a poor outcome as observed by Agarwal et al and Vishwanathan et al.[30] In another similar study, Raghuraman et al found that family history current alcohol consumption were also risk factors for poor outcome.[31] However, in our study we were not able to correlate the same.

The chest X-rays in our study showed severe lung involvement in diabetic patients rather than the non diabetic patients. Studies by Chiang and Avuthu et al also stated that in diabetic patients, the lungs were more involved and there were multiple cavities and lesions in the lungs.[32,33]

The outcome of the treatment in our study also showed that the number of failed cases were significantly higher among the TB patients with DM, while in the TB patients without DM, the number of cured cases was far higher. This shows that DM is associated with the poor outcome of TB. This similar pattern was observed in a study by Agarwal et al, who also observed that the outcome of o comorbidity of TB and DM was poor compared to only TB.[25] A study by Vishwanathan and Gawde showed that there was a poorer outcome as diabetes increases the risk in TB patients.[34] A large cohort study by Alisjahbana et al also found DM to be strongly and independently associated with the poor outcome of the Tb treatment. Even after 6 months of treatment, they found sputum positive smears in these patients.[20] Although most of the patients with DM were not defaulters and stuck to the treatment regimen, the failure for the medication could be attributed to the development of multidrug resistance in these patients. Another explanation was the pharmacokinetics of the treatment. It is said that rifampicin is associated with the maximum amount of exposure to the drug or drug concentrations received. Exposure to rifampicin in the TB patients with DM was twice lower than those patients without DM.[35,36] There was a difference in the maximal plasma concentrations of rifampicin also, which was found to be lesser that the required 8mg/L in TB patients with diabetes.[37]

## 5. Conclusion

There was a high incidence of diabetes among the patients with TB, which increases the morbidity and mortality among these patients. Smoking and alcoholism are preventable risk factors. Therefore, it is imperative that there must be screening of blood sugar among all the patients with TB. The smokers and alcoholics, who have TB should be counselled about the ill effects of their vices should they get diabetes also. Health education must be given to the TB patients to monitor their glucose levels regularly and monitor their glycemic index, to prevent deleterious effects.

## 6. Source of Funding

None.

## 7. Conflict of Interest

None.

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