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Comparative Study of TB Treatment Outcomes Among Non-Diabetics, Controlled Diabetics, and Uncontrolled Diabetic Patients

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ARTICLE INFO **ABSTRACT** **ORIGINAL RESEARCH ARTICLE**

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Objectives: This study was done to compare the clinical characteristics, bacteriological pattern and treatment outcomes, among non-diabetics, controlled and uncontrolled diabetics. Theoretical Framework: TB continues to be a major global public health concern, with millions of cases reported annually. While there are treatment regimens with high cure rates, achieving optimal outcomes can be significantly challenged by the presence of co-morbidities like DM. Methods: This study was an observational type of analytical study conducted in the Department of Respiratory Medicine, SNMC Agra. Patients who were sputum positive and registered under NTEP were included in this study, PTB patients were screened for DM using Fasting and 2 hour Post Prandial Blood glucose test and Hba1c. Results and Discussion: Patients with DM both controlled and uncontrolled experienced more severe clinical manifestations, delayed sputum conversion, and poorer treatment outcomes as compared to non-diabetics . There were higher cases of drug resistance, treatment failure, loss to follow-up cases and mortality in uncontrolled diabetics while best Treatment outcomes were observed in Non-Diabetics. Research Implications: Given the growing epidemic of DM worldwide it is necessary to add DM prevention and control strategies to TB control programmes during the course of TB treatment, Proper management of DM with improved glucose control and regular monitoring can affect the treatment outcomes in TB patients, as evidenced in our study. Originality: By meticulously evaluating treatment success rates, and exploring potential influencing factors, this study aims to establish a clearer picture of the link between diabetes control and TB treatment.

INTRODUCTION

India has the greatest number of TB patients worldwide and the second highest number of diabetic cases globally, the country confronts a serious health crisis[1,2]. An estimated 24.2 million cases of TB were reported in India in 2022 [1]. A study conducted by ICMR in 2023 estimated over 100 million people in India have diabetes.[2] As per the latest data from the global burden of diseases in 2019, [3] TB continues to be the leading causes of disability-adjusted life years (DALYs). This infectious disease not only poses a significant threat on its own but also has a synergistic relationship with diabetes. This creates a vicious cycle between the two diseases. While TB can disrupt blood sugar management in diabetics, diabetes itself triples the likelihood of contracting TB and makes the course of infection and its outcome significantly worse. Even though treatment plans have been developed with high percentages of cure, co-morbidities like DM make it very difficult to achieve the best results.

Uncontrolled diabetes induces a chronic hyperglycemic condition that impairs immunity and makes it more difficult for the body to fight TB, So diabetics have a larger chance of getting active TB than people without the disease.[4] Moreover, alarming clinical findings indicate that uncontrolled diabetes may considerably complicate the course of TB treatment. Uncontrolled hyperglycemia may be linked to higher rates of failure of treatment, recurrence, and even death during the treatment course, according to studies.[4] These findings underscore the necessity for a more thorough comprehension of this intricate interaction and pose important issues about how glycemic control affects therapy success.

This research work addresses this pressing issue by conducting a comparative study specifically designed to analyse TB treatment outcomes across three distinct patient groups:

Non-diabetic individuals: This group serves as the baseline for comparison, representing patients without the confounding factor of diabetes.

Diabetics with controlled blood sugar levels: This cohort enables us to observe the effects of well-controlled DM on the course of tuberculosis treatment.

Diabetics with uncontrolled blood sugar levels: This group is central to the study, enabling us to investigate the potential detrimental effects of uncontrolled diabetes on treatment success.

This study was done to compare the clinical characteristics, bacteriological pattern and treatment outcomes, among non-diabetics, controlled and uncontrolled diabetics.

THEORETICAL FRAMEWORK

In the present study 240 patients were taken from the Department of Respiratory Medicine of S.N Medical College, Agra.

In comparison to both Controlled diabetics and Non diabetics, our study found that the UC-DM group had greater prevalence rates for symptoms such fever 87.50%, night sweats 43.75%, weight loss 57.50%, and hemoptysis 58.75%. The prevalence of cough was highest in Non-DM group, followed by C-DM group. These differences were statistically significant in many cases, highlighting the greater symptom burden among individuals with uncontrolled DM.

Anand K et al(5) found that most frequent symptoms of PTB included cough (100%), fever (78.95%), and dyspnea. According to Shaik et al. (6) cough (74.3%), fever (64.3%), and anorexia (77.1%) were the most prevalent symptoms. Similar results were found by Lata H et al. (7) who observed that the most common symptoms among PTB patients with DM were fever (75.23%), dyspnea (76.195%), and cough (87.61%). Chaya B et al. (8), who discovered that the most typical symptoms were cough (92%), fever (80%), and anorexia (58%), also noted consistent results.

Vinay Mahishale et al.'s study (4) found that patients with poorly controlled glucose were more likely to have cavitory lesions on chest X-rays. Merely 29% of the Poorly controlled group exhibited involvement in the lower lung field, 12.8% in the upper zone, and 57% in multi-lobar involvement on chest CT scan. Upper zone involvement was observed in maximum patients in optimal controlled group in contrast with those in the poorly controlled group who had reduced lung fields and multilobar involvement. The statistical significance of this difference was noted at $P<0.001$. Chiang et al.(9), found that patients with UC-DM had more number patients with cavities, cavitory lesions over the lower lung field, and multiple zone involvement. In our study the results indicate that Non Diabetic individuals, a higher prevalence of grade 1+ sputum results, while C-DM group showed more severe grades, particularly grade 3+. Grade 3+ was Found in 33.75% of UC-DM, 47.50% of C-DM, and 28.75% of Non-DM. Following a two-month period, the C-DM (67.50%) and Non-DM (83.75%) groups showed a notably greater percentage of negative AFB sputum findings than the UC-DM (37.50%) group. Overall, the Non-DM group had the largest percentage of negative AFB sputum findings, followed by the C-DM, and the UC-DM group had the lowest percentage. The UC-DM group had the largest percentage of RIF-resistant cases in their CBNAAT sputum, followed by the Controlled, and the Non-Diabetics with the lowest number.

In other previous studies also, sputum positivity rate was 62.85% in study by 58% by Hariprasad et al,(10) and 100% by Anand et al (5) .In study by Jiyami et al, the pretreatment bacillary load in category 3+ (indicated by I+,2+ & 3+) was more in those with DM than without DM. 44% of patients were sputum 1+; 40% were sputum 3+, and 16% were sputum 2+.

In terms of treatment results, this study's UC-DM group showed the highest rates of treatment failure, mortality, and loss to follow-up, along with the lowest cure rate. Although Controlled diabetes patients had better outcomes than the UC-DM group, it still showed lower cure rates and higher rates of treatment failure and loss to follow-up compared to the Non-Diabetics, which demonstrated the most favorable outcomes. Rifampicin resistance was seen in 10% of UC-DM group, 5% of Controlled diabetics, and 1% of the Non-diabetics group.

MDR-TB was seen in 11.11% of individuals with TB-DM, according to Vinay Mahishale et al. (4). In line with the severity of their clinical presentation, the study highlighted the increased risk of treatment failure, delayed mycobacterial clearance, relapse, reinfection, and drug resistance in TB-DM patients.

In comparison to patients with TB alone, Kuruva et al. (11) found that patients with TB-DM had lower rates of sputum conversion and cure, but also greater rates of treatment failure. Additionally, although the overall mortality difference was not statistically significant.

METHODOLOGY

Study Design: The proposed study is a hospital-based observational and comparative study that will be conducted at the Department of Respiratory Medicine at S.N Medical College, Agra.

Study Population: All newly diagnosed Drug Sensitive Pulmonary Tuberculosis patients (Microbiologically confirmed) registered for DSTB under NTEP during the study period, along with known cases or Newly Diagnosed cases of Diabetes Mellitus.

Study Period: The study was carried out from September 2022 to June 2024 (18 Months).

Inclusion Criteria:

1. Patients who are willingly participating in the study and give informed consent.
2. Newly diagnosed microbiologically confirmed drug-sensitive pulmonary tuberculosis patients who are >18 years of age

and registered under NTEP at the Department of Respiratory Medicine, Agra.

3. Known case or Newly diagnosed cases of Diabetes mellitus, and Patients who were screened for Diabetes during TB treatment initiation. (FBG= >126, 2HOUR PP=>200, HbA1C= >6.5)

Exclusion Criteria:

1. Patients who are not willingly giving consent.
2. Known cases of drug-resistant pulmonary tuberculosis patients.
3. Patients with any comorbidities (hepatic, renal, or cardiac)
4. Patients with any other immunocompromised states(HIV, HEP-B, HEP-C)
5. Pregnant or breastfeeding females.
6. Unstable and Disseminated tuberculosis patients.

Pre-Treatment Evaluation:

All routine investigations will be carried out which include:

- Sputum – AFB, CBNAAT

Statistical Analysis:

Categorical variables were presented as frequencies and percentages (%), while quantitative data were reported as means ± SD and as medians with the interquartile range (25th and 75th percentiles). Normality of the data was assessed using the Shapiro-Wilk test. Statistical analysis included:

1. For quantitative variables, Independent t-tests (for two groups) and ANOVA (for more than two groups) were conducted, followed by Post Hoc tests with Bonferroni correction.
2. For qualitative variables, the Chi-Square test was employed. Fisher's exact test was used if any expected cell count was less than 5.

Data entry was performed using Microsoft Excel, and Statistical Package for Social Sciences (SPSS) software version 25.0 by IBM, Chicago, USA, was used for final analysis.

A p-value less than 0.05 was considered as statistically significant.

Study Design:

240 recently diagnosed smear-positive patients with TB were enrolled in this prospective observational study between September 2022 and March 2023. In the Department of Respiratory Medicine, the patients were registered for DOTS under NTEP. The National Tuberculosis Elimination Program (NTEP) criteria. were followed in the diagnosis of smear-positive TB. Patients were followed up for 2, 4 and 6 months for their clincal profile, microbiological status,and finally treatment outcomes were compared at 6 months in the three categories

Three categories were created for the patients based on their HbA1c status: non-diabetics, controlled DM, and uncontrolled DM.

A DM screening was done according to ADA guidelines where DM is indicated by FBG>126 mg/dl, impaired fasting glucose is indicated by FBG≥110 mg/dl to <126 mg/dl, and normal is FBG<110 mg/dl.

Patients who had RBS more than 200 mg/dl, fasting and postprandial blood sugars (FBS and PPBS) were used to further assess the patient. When FBS or PPBS levels exceeded 126 mg/dl or 200 mg/dl, respectively, the individuals were diagnosed with diabetes mellitus. Individuals with HbA1c values less than 7% were classified as controlled diabetics, whereas those with levels >7% were thought to have uncontrolled diabetes mellitus. A Hba1c of less than 5.6% was also used to rule out diabetes.

Patient's clinical profile and microbiological status were monitored for two, four, and six months. Treatment outcomes were compared among all the 3 groups at the end of 6 months.

Ethical Consideration: Ethical clearance was taken from the Thesis Review Board and the Institutional Ethics Committee.

RESULTS AND DISCUSSIONS

Table 1: Comparison of symptoms between UC-DM, C-DM and non DM.

Symptoms	UC-DM(n=80)	C-DM (n=80)	Non DM (n=80)
Couh	52 (65%)	64 (80%)	69 (86.25%)
Fever	70 (87.50%)	59 (73.75%)	55 (68.75%)
Night sweats	35 (43.75%)	28 (35%)	14 (17.50%)
Anorexia	32 (40%)	19 (23.75%)	40 (50%)
Weight loss	46 (57.50%)	20 (25%)	14 (17.50%)
Hemoptysis	47 (58.75%)	37 (46.25%)	2 (15%)

The Uncontrolled diabetics generally exhibited higher prevalence rates for symptoms such as fever, night sweats, weight loss, and hemoptysis as compared to the controlled and non diabetics groups. These differences were statistically significant in many cases, highlighting the greater symptom burden among individuals with uncontrolled diabetes mellitus as compared to other groups.

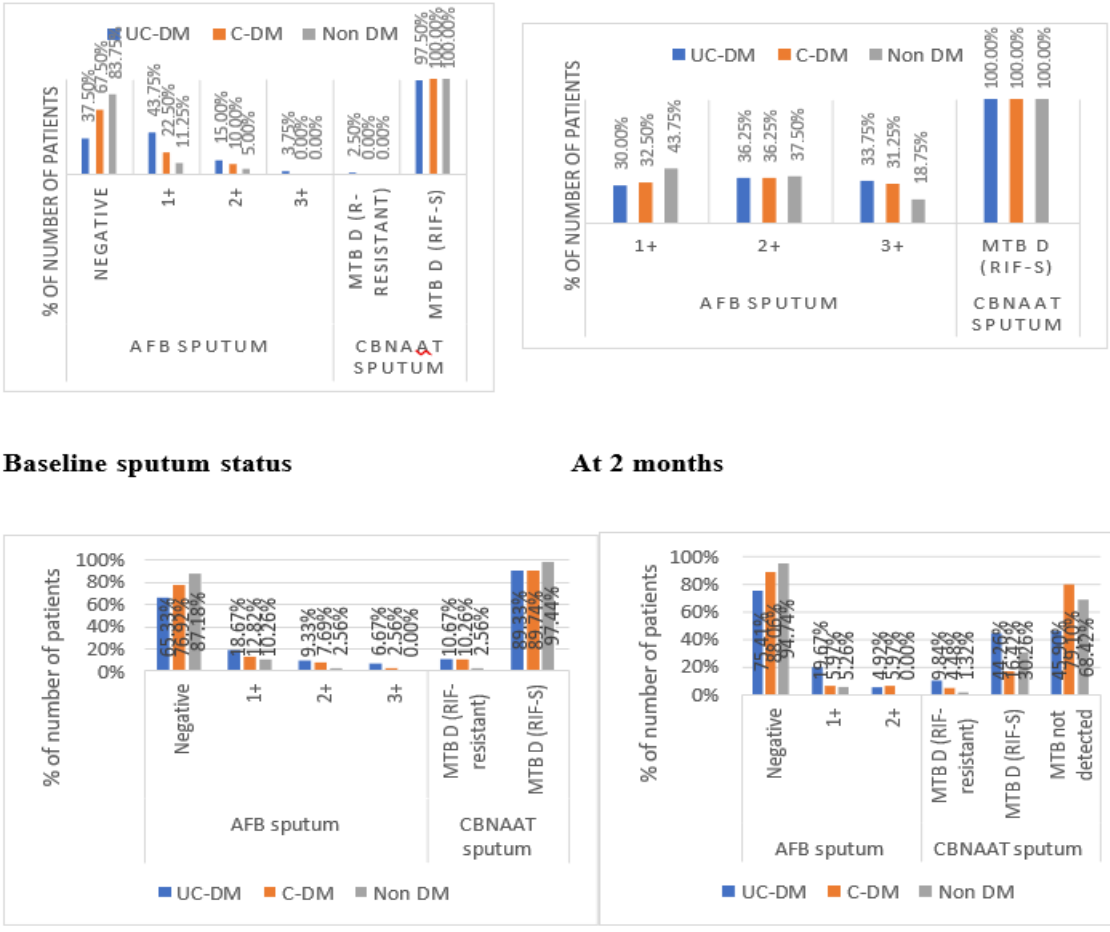

Figure 1:-Comparison of sputum between UC-DM, C-DM and non DM.

The Non-diabetics had the highest proportion of sputum negative AFB, followed by the C-DM group. The UC-DM group also showed higher percentages of 3+ and 2+ AFB sputum, indicating higher sputum positivity. In terms of CBNAAT sputum results, the UC-DM group had the highest proportion of RIF-resistant cases, followed by the Controlled diabetics, while the Non-Diabetics had the lowest proportion. At follow up, a slower conversion was observed in uncontrolled diabetics, than controlled and non diabetic TB patients.

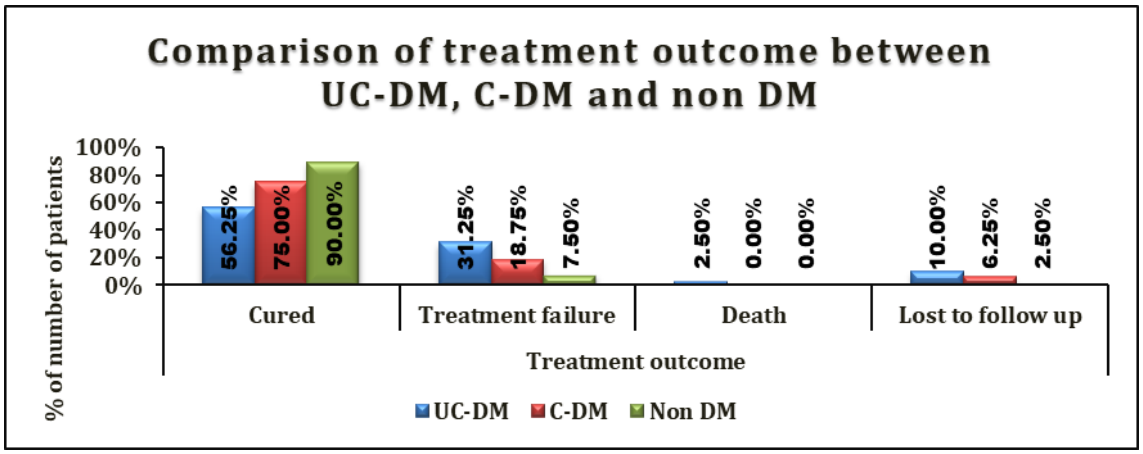

Figure 2:-Comparison of treatment outcomes between UC-DM, C-DM and non DM.

Overall, the UC-DM group exhibited the poorest treatment outcomes with the lowest cure rate and the highest rates of treatment failure, drug-resistant cases, mortality, and loss to follow-up. Drug Resistance was seen highest among uncontrolled diabetics, followed by Controlled Diabetics contributing significantly to treatment failures. The Controlled diabetics somewhat had better outcomes compared to the UC-DM group but still had a lower cure rate and higher rates of treatment failure and loss to follow-up than the Non- Diabetics. In contrast, the Non diabetics demonstrated the highest cure rate and the lowest rates of treatment failure, mortality, and loss to follow-up, indicating the most favorable treatment outcomes in NON-DM among the three groups.

CONCLUSION:

In summary, both patients with uncontrolled and controlled diabetes show a significantly high risk of developing advanced and severe TB disease, characterized by severe clinical manifestations, positive sputum tests, and slower conversion of sputum tests after starting treatment. Poor management of blood sugar levels in patients with TB and diabetes significantly impairs treatment completion, reduces cure rates, and raises mortality rates. Uncontrolled diabetics are more likely to experience symptoms like hemoptysis, fever, night sweats, and weight loss than either controlled or non-diabetic populations, fever, night sweats, and weight loss than either controlled or non-diabetic populations.

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