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The role of counseling in maintaining blood sugar control in patients with pulmonary tuberculosis and diabetes mellitus

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Abstract

Diabetes mellitus (DM) has emerged as an important comorbidity associated with tuberculosis (TB). Both diseases are known to affect each other's course. There has not been much data on the impact of frequent blood sugar monitoring and counseling in patients with TB and DM. A study was therefore conducted to assess the effects of these measures on glycemic control, radiological improvement, and treatment outcomes.

A total of 50 sputum-positive pulmonary TB and DM patients were enrolled and divided into 2 groups (A and B) of 25 patients each. Blood sugar monitoring in both groups was done at the initiation of treatment, at the end of the intensive phase (IP), and at the end of the continuation phase (CP), and they were counseled for glycemic control. Additionally, group A patients were counseled weekly in the IP and biweekly in the CP for glycemic control. Group B patients were provided with glucometers and told to record blood sugars weekly during the IP and biweekly in the CP. The radiological improvement was measured using the TIMIKA score, and treatment outcome was assigned based on end-CP sputum conversion.

The mean age of groups A and B was 52.96±11.06 years and 51.6±13.05 years, respectively. The differences between the mean fasting blood sugar (FBS) and TIMIKA scores of the two groups at treatment initiation, end IP, and end CP were statistically non-significant (p=0.986, 0.70, and 0.650, and p=0.190, p=0.156, and p=0.214, respectively). When the two groups were compared for changes in mean FBS status and TIMIKA score from start to end IP, end IP to end CP, and start to end CP, the changes were again statistically non-significant (p=0.171, p=0.076, p=0.541, p=0.892, p=0.691, and p=0.461, respectively). The final treatment outcomes of the two groups were also similar (p=1.000)

Counseling of patients with TB and DM was found to be similar to frequent blood glucose monitoring, as no statistically significant differences in the two groups concerning improvement in blood sugar levels, radiological changes, and treatment outcomes were found. It is hence proposed that dedicated counseling sessions are effective and should be a part of routine care in TB patients with DM.

Key words: tuberculosis, glycemic control, treatment outcome.

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Introduction

The coexistence of tuberculosis (TB) and diabetes mellitus (DM) poses a significant challenge in global TB elimination efforts. Diabetics are at much higher risk of acquiring TB than non-diabetics. India is the diabetic capital of the world, with around 11.4% of Indians suffering from diabetes and 15.3% having a pre-diabetic condition [1]. The presence of DM has a poor impact on the treatment of TB, with delayed sputum conversion and higher chances of treatment failure [2,3]. In addition, complex treatment regimens for DM lead to further nonadherence in patients with both TB and DM. Continuous motivation and regular counseling are required to ensure compliance with therapy.

Incorporation of bi-directional screening of TB-DM under the National Tuberculosis Elimination Program in India has been an effective initiative for improving treatment outcomes. It has been suggested that any patient with RBS[3] 140 mg/dL at the time of treatment initiation should be followed up with fasting blood sugar (FBS) the next day and treated as per need [4]. Thereafter, repeat blood sugar sampling should be done at the end of the intensive phase (IP).

The impact of patient education for treatment adherence in patients with TB and DM has been studied at the global level in the past [5-7]. However, the impact of counseling sessions in patients with both TB and DM has not been studied in the Indian context extensively. Thus, this study was planned to find out the role of dedicated counseling sessions in diabetic control and final TB treatment outcomes.

In previous studies, glycosylated hemoglobin (HbA1c) has been used as one of the important investigations for assessing glycemic control. However, since we followed up with our patients at more frequent intervals, we preferred to use FBS for monitoring purposes. HbA1c has the limitation of not giving an estimate of blood sugar fluctuations during the follow-up period, as it assesses diabet-

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ic control during the last 2-3 months [8]. By knowing the current blood sugar levels during follow-up, patients and medical personnel can adjust the dose of insulin or other anti-diabetic drugs promptly and improve daily glycemic control. In addition, direct monitoring can detect fluctuations in blood sugar levels throughout the day, including episodes of hypoglycemia (low blood sugar) or hyperglycemia (high blood sugar), which are not seen by the HbA1c test.

This study did a head-to-head comparison of the role of directed counseling sessions *vs*. frequent blood sugar sampling. This novel approach aimed to provide an alternative to repeat blood sugar sampling and multiple needle pricks, thereby decreasing the laboratory load as well. Judicious use of existing human resources in this manner is believed to be highly cost-effective in resource-constrained settings.

Materials and Methods

After taking ethical clearance from the institutional ethical committee vide letter no. 9(310)2022/38577 dated 13/12/22, a prospective study was done on 50 new smear-positive pulmonary TB patients with DM (pre-existing/newly diagnosed) with a primary objective of assessing the impact of counseling on diabetic control and treatment outcomes of pulmonary TB. The sample size was estimated based on a previous study where the supervised group had a favorable outcome of 81% [9]. The formula for sample size calculation was: $n = (Z\alpha/2+Z\beta)2 * (p1(1-p1)+p2(1-p2)) / (p1-p2)2$.

Where $Z\alpha/2$ is the critical value of the normal distribution at $\alpha/2$ (for a one-sided test with 95% CI, the critical value (z-score) is approximately 1.645). $Z\beta$ is the critical value of the normal distribution at β (*e.g*., for a power of 80%, β is 0.2, and the critical value is 0.84), and p1 and p2 are the expected sample proportions of the two groups.

The sample size came out to be 23 participants per group (power of 80% and confidence interval of 95%). Considering possible attrition, it was decided to include 25 patients in each group.

Pregnant females, those with extrapulmonary TB, those with impaired glucose tolerance/pre-diabetes, those with coexisting HIV infection, those with chronic renal failure/chronic liver disease, and those who were critically ill were excluded from the study. After obtaining written informed consent in the presence of two witnesses, patients were divided into group A and group B via computer-generated random number tables, with 25 patients in each group. FBS was measured at treatment initiation, end of IP, and end of continuation phase (CP) in both groups. All the patients in both groups were either advised to continue their treatment for DM (pre-existing DM) or started on the same (newly diagnosed DM). Dose modifications in pre-existing diabetics were done as per blood sugar levels. Various types of anti-diabetic medications, including insulin, biguanides, sulfonylureas, DPP-4 inhibitors, *etc*., were given as per individual needs. All the patients in both the groups were counseled regarding adopting a healthy lifestyle, a timely and regular nutritious diet, and exercise, and timely intake of anti-diabetic medications in appropriate dosage as prescribed by the experts at these three time points. Additionally, group A patients were imparted these counseling sessions telephonically weekly during the IP phase and fortnightly during the CP phase. On the other hand, group B patients were given a glucometer, and their blood sugar recordings were noted once every week throughout IP and once every fortnight throughout the CP.

Sputum smear and radiological scoring (TIMIKA score) were done at treatment initiation, end IP, and end CP, and treatment outcomes were noted as cured (a patient who is sputum smear positive at the start of treatment and negative at end CP) and failure (a patient who remains sputum smear positive at 5 months of treatment) [10-12].

Statistical analysis

The normality of the quantitative variables was tested with the Shapiro-Wilk test and Kolmogorov-Smirnov tests of normality. Skewed values were written in the form of their mean, standard deviation, and the form of their median and interquartile range. Group comparisons of values of data were made by the Mann-Whitney test for comparisons of two groups. Normally distributed data were presented as mean and standard deviation and were compared with a Student t-test for two groups. Categorical variables were reported as counts and percentages. Group comparisons were made with the Chi-Sq test if all expected cell frequencies were more than 5 and Fisher's Exact test when expected cell frequencies were less than 5. The Spearman correlation coefficient was calculated to see the relationship between FBS and the TIMIKA score. All the statistical tests were two-sided and were performed at a significance level of α=0.05. Analysis was conducted using IBM SPSS STATISTICS (version 22.0) (IBM, Armonk, NY, USA).

Results

The mean age in group A was 52.96±11.06 years, and in group B, it was 51.6±13.05 years. There were more females in group A and more males in group B (Table 1). There were 14 patients in group A and 19 in group B with pre-existing diabetes, and 11 in group A and 6 in group B with newly diagnosed diabetes, as shown in Table 1. The mean FBS at treatment initiation, end IP, and end CP in group A was 177.2±67, 142.7±39.3, and 142.04±43.3 mg/dL, and in group B was 177.5±56.06, 162.53±36.11, and 147.15±35.5 mg/dL, and the differences between the two groups were non-significant (p=0.986, p=0.70 and p=0.650, respectively), as shown in Table 2. Likewise, the TIMIKA score at treatment initiation, end IP, and end CP in group A was 56.62±22.32, 43.90±20.68, and 23.74±15.8, and in group B was 49.96±28.2, 37.12±25.8, and 19.74±17.04, and the dif-

Table 1. Demographic profile of the patients in two groups.

Variable		Group A (n=25)	Group B (n=25)	p
Age (years)		52.9±11.06	51.6±13.06	0.693
Gender, n (%)	Male Female	9 (36) 16 (64)	16 (64) 9 (36)	0.048
Diabetic status, n (%)	Pre-existing Newly diagnosed	14 (56) 11 (44)	19 (76) 6 (24)	0.136

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ferences between the two groups were statistically non-significant (p=0.190, p=0.156, and p=0.214, respectively). The outcome at the end of treatment was cured in all group B patients, with 1 failure in group A (p=1.000) (Table 2). When the two groups were compared for changes in mean FBS status from start to end IP, end IP to end CP, and start to end CP, the changes were again statistically non-significant (p=0.171, p=0.076, p=0.541, respectively) (Table 3). Similarly, when the two groups were compared for changes in TIMIKA score from start to end IP, end IP to end CP, and start to end CP, the differences were statistically non-significant (p=0.892, p=0.691, p=0.461, respectively) (Table 3).

Discussion

The mean age of group A and group B was similar to previous studies [13,14]. The studies in the past have found variable gender distribution in patients suffering from both diseases, with a few having a male and others having a female predominance [15,16]. Our study had a greater number of females in group A and males in group B. The mean FBS at treatment initiation in the two groups was 177.2±67.6 mg/dL and 177.5±56.06 (p=0.986), which is in line with the fasting blood sugars observed by Udayakumar *et al*. [9]. At follow-up, FBS levels improved in both groups at the end of IP, with a slightly better improvement in group B than group A, but it was statistically non-significant. At the end of CP, even this little difference in mean blood sugars was not witnessed, and the difference between the groups remained statistically non-significant. However, when the two groups were compared for changes in mean blood sugars at end IP and end CP, both groups showed similar improvement. These results thus showed that dedicated counseling sessions at frequent intervals in group A were able to maintain control of blood sugars at end IP as well as end CP, and the effect was as good as frequent blood sampling (p=0.171 and 0.541). The positive impact of counseling on treatment adherence and outcome has already been highlighted in the past [5,6,17,18]. In patients with TB and DM, pill burden may cause treatment non-adherence for one or both diseases. This phenomenon of default has previously been noticed by Dailey *et al.*, who found that only 15% of the patients with type 2 DM were taking regular treatment for control of blood sugars at the end of one year [19]. Focused counseling of such patients, hence, helps them to remain compliant with treatment, thereby maintaining the bioavailability of drugs.

The radiological scoring was done using the TIMIKA score [16,20-22]. Both groups were similar at baseline concerning TIMIKA score and showed improvement at end IP and end CP. The degree of improvement in TIMIKA score at end IP and end CP was similar in both groups, with no statistically significant differences.

Our study thus found that the impact of frequent counseling is similar to actual blood sugar sampling and monitoring while the patients of TB are on ATT, as is reflected in similar treatment outcomes and radiological improvements at both follow-ups. Dedicated counseling sessions should hence be incorporated under the program as a part of routine care. Health care workers (HCWs), ancillary staff, relatives of the patients, and TB champions can all be trained to play the role of such 'counselors'. The program is already narrowing down to an individualized approach. There is a provision for referral for super-specialist care as per need. Addition of dedicated counseling sessions can immensely help TB patients with DM, especially at the grassroots, where awareness of medication adherence is still dangerously low. Counseling sessions also provide psychological support, which leads to a sense of well-being and positivity, necessary for the success of any kind of polypharmacotherapy, especially when the treatment duration is prolonged.

Our extensive counseling sessions through physical and tele-

Table 2. Differences in fasting blood sugar, TIMIKA score and treatment outcome between the two groups.

Parameter		Group A	95% confidence interval for mean		Group B	95% confidence interval for mean		p
			Lower bound	Upper bound		Lower bound	Upper bound	
FBS (mean)	At start	177.2±67.6	149.299	205.101	177.5±56.06	154.377	200.663	0.986
	End IP	142.7±39.3	126.499	158.941	162.53±36.11	147.624	177.436	0.070
	End CP	142.04±43.3	124.167	159.913	147.15±35.5	132.497	161.803	0.650
TIMIKA score	At start	56.62±22.32	47.409	65.842	49.96±28.2	38.310	61.611	0.190
	End IP	43.90±20.68	4.136	35.366	37.12±25.8	5.158	26.480	0.156
	End CP	23.74±15.8	3.157	17.229	19.74±17.04	3.409	12.703	0.214
Treatment outcome (in numbers)	Cured Failure	24 (96%) 1 (4%)	80%	99%	25 (100%)	87%	100.0%	1.000

FBS, fasting blood sugar; IP, intensive phase; CP, continuation phase.

Table 3. Mean changes in fasting blood sugar and TIMIKA score between the two groups.

Parameter		Change between group A and group B (p-value)
Fasting blood glucose	From start to end IP	0.171
	From end IP to end CP	0.076
	From start to end CP	0.541
TIMIKA score	From start to end IP	0.892
	From end IP to end CP	0.691
	From start to end CP	0.461

IP, intensive phase; CP, continuation phase.

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phonic means in group A reportedly decreased apprehension of the patients and provided the support mechanism necessary for successful treatment outcomes. Previous literature suggests that the chances of poor treatment outcomes, including the development of drug-resistant TB, are higher in patients with uncontrolled DM [23].

Although counseling is essential for managing TB-DM co-infection, several factors, such as knowledge gaps, psychosocial barriers, limitations in the healthcare system, drug interactions, and socioeconomic difficulties, may limit its ability to lower blood sugars. To improve the efficacy of counseling interventions, these complex issues call for integrated, patient-centered, and culturally sensitive approaches. Execution of such an approach under the program, within the existing infrastructure and without utilization of additional resources, is practically feasible and is expected to bring an appreciable change in our efforts to eliminate TB.

It should be noted that for effective management in a TB-DM co-infected patient, it is essential to comprehend the reciprocal relationship between inflammation and hyperglycemia. Glycemic control and inflammatory marker monitoring can help determine how the disease is progressing and customize treatment plans to reduce immunological dysfunction and enhance patient outcomes.

Conclusions

Our study found that frequent counseling sessions proved similar to frequent blood sugar monitoring in maintaining strict glycemic control (in addition to anti-diabetic drugs) and treatment outcomes in TB-DM patients. Hence, we propose that dedicated counseling sessions along with strict diabetic control through drugs (as per individual needs) are mandatory for successful treatment outcomes. There is a pressing need for longitudinal research in this aspect. In addition, the role of various other point-of-care biomarkers that can predict inflammation and indicate glycemic control should be explored, with a larger sample size and closer monitoring.

Strengths of the study

No similar study focusing on the role of dedicated counseling sessions in maintaining diabetic control in patients with TB has been done in the past in the Indian context. The study has taken care of selection bias during data collection and incorporated validated radiological scores and blood sugar monitoring for outcome assessments.

Limitations of the study

The sample size was small. Long-term follow-up of our patients was not done; hence, the status of the patients at 6, 12, 18 and 24 months is not available. The patients were not matched for potential confounders like gender, duration of diabetes, type of anti-diabetic treatment, *etc*. The possibility of the Hawthorne effect could not be ruled out in both groups.

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