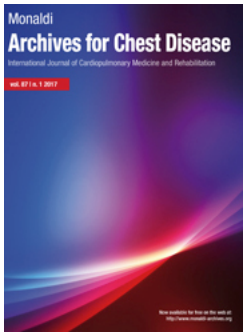

Monaldi Archives for Chest Disease

eISSN 2532-5264 https://www.monaldi-archives.org/

Monaldi Arch Chest Dis 2025 [Online ahead of print]

To cite this Article:
Chopra P, Mittal V, Girdhar N, et al. **The role of counseling in maintaining blood sugar control in patients with pulmonary tuberculosis and diabetes mellitus.** *Monaldi Arch Chest Dis* doi: 10.4081/monaldi.2025.3418

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

Preeyati Chopra, Vidhu Mittal, Nidhi Girdhar, Vishal Chopra, Kranti Garg

Department of Pulmonary Medicine, Government Medical College, Patiala, Punjab, India

Correspondence: Kranti Garg, Department of Pulmonary Medicine, Government Medical College, Patiala, Punjab, India.
Tel. +91-9914433515; +91-9646121601. E-mail: drkrantigarg@yahoo.com

Contributions: PC, concepts, design, literature search, clinical and experimental studies, data analysis, statistical analysis, manuscript preparation, editing and review; VM, NG, design, literature search, clinical and experimental studies, data acquisition and analysis, manuscript preparation, editing and review; VC, concepts, design, definition of intellectual content, clinical and experimental studies, data acquisition and analysis, manuscript preparation, editing and review; KG, concepts, design, definition of intellectual content, literature search, clinical and experimental studies, data acquisition and analysis, manuscript preparation, editing and review.

Conflict of interest: the authors declare no potential conflict of interest.

Ethics approval and consent to participate: the study was approved by the institute's Ethics committee [letter no. 9(310)2022/38577 dated 13/12/22].

Informed consent: written informed consent was obtained from all patients.

Patient consent for publication: obtained.

Availability of data and materials: all data underlying the findings are fully available.

Funding: the research work was carried out with financial assistance from the TB Association of India.

Acknowledgments: the authors acknowledge the TB Association of India for the grant of financial assistance for carrying out this research work.

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, 0.156, and 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, and p=0.892, p=0.691, 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.

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 tuberculosis 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 counselling are required to ensure compliance with therapy.

Incorporation of bi-directional screening of TB-DM under the National Tuberculosis Elimination Program (NTEP) in India has been an effective initiative for improving treatment outcomes. It has been suggested that any patient with RBS≥ 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 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 counselling 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 counselling sessions on diabetic control and final TB treatment outcomes.

In previous studies, glycosylated Hb (HbA1c) has been used as one of the important investigations for assessing glycaemic 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 the diabetic 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 antidiabetic drugs promptly and improve daily glycaemic control. In addition, direct monitoring can detect fluctuations in blood sugar levels throughout the day, including episodes of hypoglycaemia (low blood sugar) or hyperglycaemia (high blood sugar), which are not seen by the HbA1c test.

This study did a head-to-head comparison of the role of directed counselling 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 the 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 counselling 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 favourable 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, impaired glucose tolerance/pre-diabetes, with coexisting HIV infection, chronic renal failure/ chronic liver disease, and those who were critically ill were excluded from the study. After taking the 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 intensive phase (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 included insulin, biguanides, sulfonylureas, DPP-4 inhibitors, etc, and were given as per individual needs. All the patients in both the groups were counselled 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 counselling 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 fortnightly 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 start of treatment and negative at end CP) and failure (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 2 groups. Normally distributed data was presented as mean and standard deviation, and was compared with a Student t-test for 2 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=.05. Analysis was conducted using IBM SPSS STATISTICS (version 22.0).

Results

The mean age of group A was 52.96±11.06 years, and group B 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 being non-significant (p=0.986, 0.70 and 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 differences between the two groups were statistically non-significant

(p=0.190, 0.156, and 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 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 range 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 nonsignificant. At the end of CP, even this little difference in mean blood sugars was not witnessed, and the difference between the groups remained statistically nonsignificant. 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 counselling 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 counselling 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 counselling 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 counselling 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 counselling 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 'counsellors'. 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 counselling sessions can immensely help TB patients with DM, especially at the grassroots, where awareness of medication adherence is still dangerously low. Counselling 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 counselling sessions through physical and telephonic means in group A reportedly decreased apprehensions 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 counselling 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 counselling interventions, these complex issues call for integrated, patient-centred, 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 hyperglycaemia. Glycaemic 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 counselling sessions proved similar to frequent blood sugar monitoring in maintaining strict glycaemic control (in addition to anti-diabetic drugs) and

treatment outcomes in TB-DM patients. Hence, we propose that dedicated counselling 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 glycaemic 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 counselling 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 & 24 months is not available. The patients were not matched for potential confounders like gender, duration of diabetes, and type of antidiabetic treatment etc. The possibility of the Hawthorne effect could not be ruled out in both groups.

References

1. Chakaya J, Khan M, Ntoumi F, et al. Global tuberculosis report 2020—reflections on the global TB burden, treatment and prevention efforts. Int J Infect Dis 2021;113:S7-12.

2. Baker MA, Harries AD, Jeon CY, et al. The impact of diabetes on tuberculosis treatment outcomes: a systematic review BMC Med 2011;9:81.

3. McMurry HS, Mendenhall E, Rajendrakumar A, et al. Coprevalence of type 2 diabetes mellitus and tuberculosis in low-income and middle-income countries: a systematic review. Diabetes Metab Res Rev 2019;35:e3066.

4. India Tuberculosis-Diabetes Study Group. Screening of patients with tuberculosis for diabetes mellitus in India. Trop Med Int Health 2013;18:636-45.

5. Ruslami R, Koesoemadinata RC, Soetedjo NNM, et al. The effect of a structured clinical algorithm on glycemic control in patients with combined tuberculosis and diabetes in Indonesia: A randomized trial. Diabetes Res Clin Pract 2021;173:108701.

6. Koesoemadinata RC, McAllister SM, Soetedjo NNM, et al. Educational counselling of patients with combined TB and diabetes mellitus: a randomised trial. Public Health Action 2021;11:202-8.
7. Riza AL, Pearson F, Ugarte-Gil C, et al. Clinical management of concurrent diabetes and tuberculosis and the implications for patient services. Lancet Diabetes Endocrinol 2014;2:740-53.
8. Sherwani SI, Khan HA, Ekhzaimy A, et al. Significance of HbA1c test in diagnosis and prognosis of diabetic patients. Biomark Insights 2016;11:95-104.
9. Udaykumar P, Kumar S, Chandralekha N, et al. Daily monitoring of diabetic treatment amongst TB-DM patients under NTEP: does it improve the treatment outcomes? Clin Epidemiol Glob Health 2022;17:101118.
10. Thiel BA, Bark CM, Nakibali JG, et al. Reader variability and validation of the Timika X-ray score during treatment of pulmonary tuberculosis. Int J Tuberc Lung Dis 2016;20:1358-63.
11. Chakraborthy A, Shivananjaiah AJ, Ramaswamy S, Chikkavenkatappa N. Chest X ray score (Timika score): an useful adjunct to predict treatment outcome in tuberculosis. Adv Respir Med 2018;86:205-10.
12. WHO. Guidance for national tuberculosis programmes on the management of tuberculosis in children. 2nd edition. 2014. Available from: https://iris.who.int/bitstream/handle/10665/112360/9789241548748_eng.pdf.
13. Saalai KM, Mohanty A. The effect of glycemic control on clinico-radiological manifestations of pulmonary tuberculosis in patients with diabetes mellitus. Int J Mycobacteriol 2021;10:268-70.
14. Zhan S, Juan X, Ren T, et al. Extensive radiological manifestation in patients with diabetes and pulmonary tuberculosis: a cross-sectional study. Ther Clin Risk Manag 2022;18:595-602.
15. Reis-Santos B, Locatelli R, Horta BL, et al. Socio-demographic and clinical differences in subjects with tuberculosis with and without diabetes mellitus in Brazil--a multivariate analysis. PLoS One 2013;8:e62604.
16. Kibirige D, Andia-Biraro I, Olum R, et al. Tuberculosis and diabetes mellitus comorbidity in an adult Ugandan population. BMC Infect Dis 2024;24:242.

17. Religioni U, Barrios-Rodríguez R, Requena P, et al. Enhancing therapy adherence: impact on clinical outcomes, healthcare costs, and patient quality of life. Medicina 2025;61:153.
18. Selda C, Feride TY, Seval G, Meryem T. The effect of nursing counseling on treatment compliance: acute coronary syndrome and diabetes mellitus. J Nurs Res 2024;32:e339.
19. Dailey G, Kim MS, Lian JF. Patient compliance and persistence with antihyperglycemic drug regimens: evaluation of a Medicaid patient population with type 2 diabetes mellitus. Clin Ther 2001;23:1311-20.
20. K V N, Duraisamy K, Balakrishnan S, et al. Outcome of tuberculosis treatment in patients with diabetes mellitus treated in the revised national tuberculosis control programme in Malappuram district, Kerala, India. PLoS One 2013;8:e76275.
21. Khanna A, Lohya S, Sharath BN, Harries AD. Characteristics and treatment response in patients with tuberculosis and diabetes mellitus in New Delhi, India. Public Health Action 2013;3:S48-50.
22. Mily A, Sarker P, Taznin I, et al. Slow radiological improvement and persistent low-grade inflammation after chemotherapy in tuberculosis patients with type 2 diabetes. BMC Infect Dis 2020;20:933.
23. Tegegne BS, Mengesha MM, Teferra AA, et al. Association between diabetes mellitus and multi-drug-resistant tuberculosis: evidence from a systematic review and meta-analysis. Syst Rev 2018;7:161.

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	Male	9(36%)	16(64%)	0.048
	Female	16(64%)	9(36%)	
Diabetic status	Pre-existing	14(56%)	19(76%)	0.136
	Newly diagnosed	11(44%)	6(24%)	

Table 2. Differences in fasting blood sugar (FBS), 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	24 (96%)	80%	99%	25 (100%)	87%	100.0%	1.000
	Failure	1 (4%)						

Table 3. Mean changes in FBS 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