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ORIGINAL ARTICLE



Impact of Counselling on Knowledge, Attitude & Practices and Medication Adherence and Health-Related Quality of Life of Diabetes Mellitus patients- A pre-post study design

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ABSTRACT

Poor medication adherence and inadequate satisfaction with treatment in type 2 diabetes patients lead to end-organ damage and result in poor health-related quality of life. The aim is to assess the influence of structured patient education on knowledge, attitudes, and practices (KAP), medication adherence behaviour, treatment satisfaction, and health-related quality of life in type 2 DM patients. A prospective interventional study was conducted at a tertiary care teaching hospital. All the enrolled type 2 diabetes patients meeting the eligible criteria were randomised into control and test groups. Structured patient education and information leaflets were only offered to the test group patients. A suitably designed KAP questionnaire was used to assess the enrolled patients' knowledge, attitudes, and practices. The MARS questionnaire was used to assess medication adherence, and DTSQ was applied to assess diabetes treatment satisfaction. Finally, DQOL was administered to study the influence of patient education on diabetes's health-related quality of life. About 400 eligible type 2 diabetes patients were randomised into control (200) and test (200) groups. Among them, 57.5% were male, and 42.5% were female. The minimum age of the patients was 31 years, and the maximum was 75 years. The mean (±SD) age of test group patients was 52.35±10.82 years, and that of the control group patients was 57.05±12.75 years. Most enrolled patients were literate (58,75%), with primary school education (22.75%). Most were farmers, daily wage labourers, and small businesses by profession. At the end of the study, a significant (p<0.01) improvement was observed in the scores of KAP, medication adherence behaviour, treatment satisfaction and health-related quality of life in test group patients. Structured patient education has demonstrated a significant improvement in the scores of KAP, medication adherence behaviour, treatment satisfaction and health-related quality of life in type 2 diabetes patients in the test group. Keywords: Diabetes, Therapeutic outcome, Knowledge, attitude, and practice, Medication adherence behaviour and Health-related quality of life.

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INTRODUCTION

Diabetes is a chronic metabolic disease characterised by consistently elevated blood glucose levels likely to damage the heart, blood vessels, eyes, kidneys, and nerves. (1) The International Diabetes Federation (IDF) 2021 estimated that 537 million adults have diabetes, i.e., 1 in 10 and may reach 643 million by 2030 and 783 million by 2045. Most diabetics, i.e., 3 in 4 patients, live in low and middle-income countries. Diabetes caused 6.7 million deaths across the globe in 2021, i.e., 1 in every 5 seconds. Diabetes led to USD 966 billion in expenditure globally and rose to 316% over the last 15 years.

In Asia, 90 million people are living with diabetes, and expected to reach 113 million by 2030 and 151 million by 2045. Due to poor awareness, 1 in 2 adults are living with diabetes undiagnosed, and 0.747 million deaths due to diabetes in 2021. In Asia, USD 10 billion was spent on diabetes. (2)

Poor management of diabetes increases complications and health problems. Unawareness about the disease and its management and non-adherence to medication complicates and lowers the therapeutic outcomes. Various studies opined that pharmacists' mediated education on knowledge attitude and practice (KAP), medication adherence, and lifestyle modifications have significantly impacted better prognosis. (3-4) Empowering patients responsible for disease management ensures fewer diabetes

complications and improved clinical outcomes. People with diabetes willing to maintain healthy lives should understand their illness and strategies to control the disease, which ratifies the importance of awareness of disease management among diabetics. (5)

The research findings of a rural South Indian study on the assessment of pharmacist-mediated education on KAP in type 2 DM patients suggest that patient education showed a significant impact (p<0.05) on KAP and lowering blood glucose levels in test group patients. (6)

A Kerala-based study on the effect of patient counselling on the quality of life in Type 2 DM patients in community pharmacy settings suggests that structured patient education enhanced better knowledge, attitude, and practices (KAP). Improved health-related quality of life among test group patients suggests pharmacist-mediated education significantly en patients' KAP. (7)

R Adepu et al. assessed medication adherence behaviour using Brief Medication Questionnaire (BMQ) and Adherence Risk Scale (ARS) in type 2 DM patients. Pharmacist-led structured education demonstrates a significant improvement in medication adherence and final CBG values. (8)

Another study was conducted by Sai Pawan AR et al. to assess pharmacist-mediated education on medication adherence behaviour in rural south Indian type 2 DM patients. The research findings suggest that patient counselling has a significant impact (p<0.05) on the Morisky Medication Adherence Scale (MMAS-8) score and lowering of blood glucose levels in test group patients. (9)

Another study by Ramanath and Santhosh used the WHO-BREF QOL to assess the influence of pharmacistmediated patient education on health-related QOL. The study findings conclude a significant increase in QOL, KAP, and medication adherence scores (p<0.05) was observed in patients who have diabetes. A significant change in glycaemic control was also seen. (10) Another study conducted by Adepu SPR et al. on the assessment of pharmacist-mediated education on health-related quality of life in rural south Indian type 2 DM patients, findings corroborated that health-related quality of life had a significant impact (p<0.05) on Diabetic health profile (DHP-18) scale and lowering blood glucose in test patients. (11) R C Puvvada and V A Muthukumar's study confirms that improvement in knowledge of the disease and its management demonstrated a positive impact on treatment outcomes and quality of life, indicating the positive influence of patient counselling. (12)

MATERIAL AND METHODS

This prospective interventional study approved by the institutional human ethics committee was carried out in the general medicine department of a teaching hospital in North Telangana, India. Type DM patients of both genders who met the inclusion criteria were enrolled in the study using the block randomisation technique. Type 2 DM patients with a disease duration of less than four years were enrolled. Gestational diabetics, patients with psychiatric illnesses and paediatrics' were excluded from the study. Before the study was initiated, the knowledge level of the surrounding community was evaluated to help select suitable patients and determine the level of awareness that needed to be provided.

Enrolled patients' demographics, educational status, social habits, socioeconomic status, stress levels, medical history, past medication history, family history, previous surgeries, allergies, body mass index (BMI), diet, marital status, smoking, and alcohol was recorded in a suitably designed data collection form. A suitable and validated Knowledge Attitude and Practice questionnaire was administered to assess the entry and exit level knowledge, attitudes and practices among test and control group patients at baseline, first, second, and final follow-up. A medication adherence reporting scale (MARS) was used to assess the medication adherence behaviour of both groups at baseline, first, second, and final follow-up. Diabetes treatment satisfaction was assessed by an 8-item Diabetes Treatment Satisfaction Questionnaire (DTSQ) questionnaire at baseline, first, second, and final follow-up. HRQOL was assessed using the Diabetes Quality of Life (DQOL) on both groups at baseline, first, second, and final follow-up.

Glycosylated haemoglobin (HbA1C) was performed at baseline to assess the diabetic status of the enrolled patients. All the enrolled patients were followed for three months from baseline with an interval of 30 days between the follow-ups. BP and capillary blood glucose (CBG) were recorded at every follow-up visit. At the end of 3 months, again, HbA1C was performed to check three months' diabetic profiles to assess the influence of patient counselling. The test group patients received pharmacist-mediated structured education regarding the disease, medication, diet, and lifestyle modification at baseline, further follow-ups, and a patient information leaflet (PIL). The control group patients received detailed education only at the final follow-up visit.

Statistical analysis

Results were analysed using JMP Statistical software for Macintosh Version 17. The significance of the change in CBG at each follow-up visit compared to the first follow-up was assessed using an independent t-test. The importance of the shift in KAP scores, MARS scores and DQOL scores from baseline to final follow-up was also assessed using a one-way ANOVA and student t-test. P value <0.05 is considered as significant.

The significance of the change in HbA1C values for the baseline and last follow-up was assessed using an independent t-test.

RESULTS

Four hundred eligible Type 2 Diabetes Mellitus patients meeting the inclusion criteria were enrolled after taking the written informed consent and randomised into the control and test groups. Two hundred patients each were from the test and the control group. Among them, 57.5% were male, and 42.5% were female. The minimum age of the patients was 31 years, and the maximum age of the enrolled patients was 75 years. The mean (±SD) age of test group patients was 52.35±10.82 years, and that of the control group patients was 57.05±12.75 years. Most enrolled patients were literate (58.75%), with most having completed primary school education (22.75%). They were farmers, daily wage labourers, and small businesses by profession since they belonged to the rural population.

PARAMETER	CONTROL		TEST		<i>p</i> value
	(n=200)		(n=200)		(<0.05)
Gender	No	%	No	%	
• Male	120	30	110	27.5	1
• Female	80	20	90	22.5	
Age					
• 30-40	62	15.5	58	14.5	0.425
• 41-50	43	10.75	46	11.5	
• 51-60	61	15.25	62	15.5	
• 61 & above	30	7.5	44	11	
Educational qualification					
Illiterate	80	20	85	21.25	1
Primary school	48	12	43	10.75	
Secondary school	35	8.75	33	8.25	
PUC	15	3.75	17	4.25	
Graduate	10	2.5	12	3	
Post Graduate	12	3	10	2.5	
Profession					
Agriculture	125	31.25	130	32.5	1
Business	35	8.75	27	6.75	
Employment	5	1.25	6	1.5	
Housewife	35	8.75	37	9.25	
Smoking status					
Yes	99	24.75	85	21.25	0.836
No	101	25.25	125	31.25	
Alcoholic status					
Yes	110	27.5	95	23.75	1
No	90	22.5	105	26.25	

The demographic details of the patients who completed all the follow-ups are presented in Table 1. **TABLE 1. DEMOGRAPHIC CHARACTERISTICS OF THE PATIENTS**

The mean BMI of the male patients was 24.23%, and that of the female patients was 25.78%. Most patients (62.5%) had an average annual income of Rs. 1,00,000 to Rs. 3,00,000, and the rest were homemakers. The percentages of smokers in the control and test groups were 24.75% and 21.25%, respectively. The alcoholic status of patients in the control group was 27.5%, and that of the test group was 23.75%.

At baseline, an HbA1c test was conducted to determine the diabetic status of the enrolled patients. The mean HbA1c value was 9±2.27% in the control group patients and 8.9±2.36% in the test group patients.

At the First follow-up and subsequent follow-ups, CBG for FBS and PPBS values were monitored to assess the influence of the educational intervention on Knowledge attitude and practice, Medication adherence behaviour (MARS), Diabetes treatment satisfaction (DTSQ), health-related quality of life (DQOL) and glycaemic control.

At the first follow-up, the mean FBS in the control group was 138 mg/dl, and the mean PPBS was 190mg/dl. In the final follow-up, the mean FBS was 136 mg/dl, and the mean PPBS was 185mg/dl. These values suggest that the glycaemic control did not change significantly in the control group patients. The findings are presented in Figure 1.

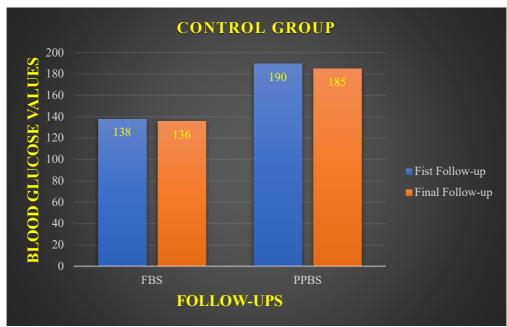


Figure 1. Mean fasting blood sugar and mean post-prandial blood sugar in the control group Meanwhile, the mean FBS during the first follow-up in test group patients was 132 mg/dl, and the mean PPBS was 185 mg/dl. In the final follow-up, the mean FBS was 98mg/dl, and the mean PPBS was 132 mg/dl. The observations are presented in Figure 2.

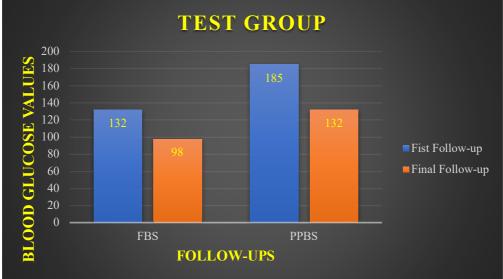


Figure 2: Mean fasting blood sugar and mean postprandial blood sugar in the test group

At the final follow-up, HbA1C was repeated to check the effect of structured patient counselling on the diabetic profile of the enrolled patients. The mean HbA1c value was 8.4±1.69% in the control group patients and 5.8±1.18% in the test group patients. The findings are presented in the figure 3.

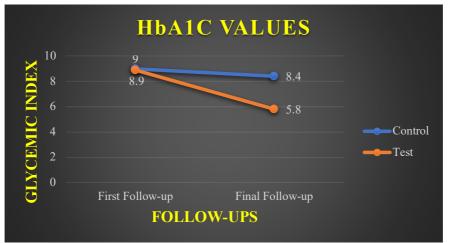
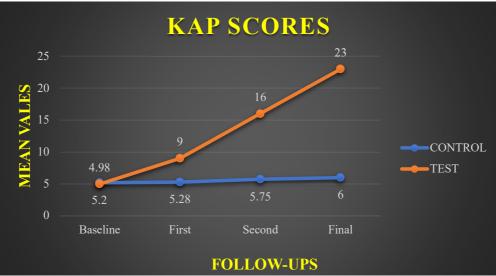
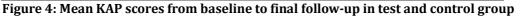


Figure 3: Mean HbA1C values from first to final follow-up in test and control group

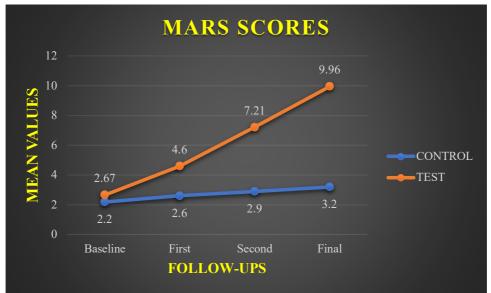
The knowledge, attitude and practices of the patients were assessed using a specially devised and validated KAP questionnaire. The scores were calculated by administering the instrument at baseline, 1st follow-up, 2nd follow-up and finally follow-up. The average score in the control group was 5.2, and in the test group, the average score was 4.98. Significant improvement was observed in the test group at the final follow-up with a score of 23, and in the control group, it was a non-significant improvement. The research findings are presented in Figure 4.

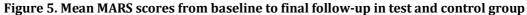




One-way ANOVA was used to calculate means for both groups from baseline to final follow-up, and a Paired t-test was used to assess the p-value. In control, KAP scores resulted in non-significant improvement and in the test group, KAP scored a significant improvement (p<0.0001).

The Medication Adherence Reporting Scale (MARS) was used to assess the medication adherence behaviour of patients in both groups at baseline, first, second, and final follow-up. A significant improvement (p<0.05) in medication adherence behaviour was observed in the test group patients compared to the control group patients. The findings are presented in Figure 5.





Satisfaction with diabetes treatment plays a major role in improving health-related quality of life. Thus, a widely used validated 8-item Diabetes Treatment Satisfaction Questionnaire (DTSQ) was applied to assess patients' treatment satisfaction in both groups at baseline, first, second, and final follow-up. The results reveal that a significant improvement (p<0.05) in satisfaction was observed in the test group patients. The findings are presented in Figure 6. ⁽¹⁹⁾

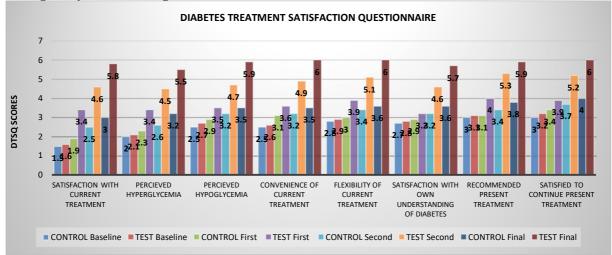


Figure 6. Treatment Satisfaction among the Diabetes Patients

The DQOL Revised 13-item questionnaire, was used to study health-related quality of life (HRQoL) in diabetes patients. A significant improvement was observed in the test group patients. ⁽²⁰⁾ The findings are presented in Figure 7.

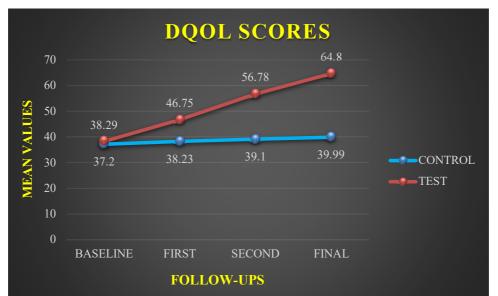


Figure 7. Mean DQOL scores from baseline to final follow-up in the test and control group.

DISCUSSION

International Diabetes Federation (IDF) findings reveal that 8.8% of the adult population has diabetes. Current global statistics indicate that 463 million and 374 million individuals suffer from diabetes and impaired glucose tolerance (IGT). By 2045, 700 million people have diabetes, and 548 million people will have IGT. (13) A systematic review indicates a large economic burden on diabetes management and directly affects patients in Low- and Middle-Income Countries. The direct cost burden is estimated at US\$ 242 to US\$ 11917, and the indirect cost burden is as low as US\$ 45 to as high as US \$ 16914, indicating a huge impact on a country's GDP. (14)

In our study, most of the enrolled subjects are illiterates, males, and in the productive age group with agriculture as the primary profession. The baseline KAP scores in both groups were the same; however, the KAP scores were significantly improved after the pharmacist-mediated educational intervention in the test group patients, confirming educational influence, which was also reflected in fasting blood glucose and glycosylated haemoglobin.

Thus, it is essential to empower diabetic patients to manage their clinical condition confidently. This is possible only when diabetic patients are made aware of their clinical condition and safe strategies to implement and control the manifestations and the disorder. An important strategy is to improve the knowledge, attitude, and practices. Evaluation of diabetes knowledge, attitude, and practice (KAP) has become crucial for guiding behavioural changes for persons with diabetes and individuals at risk, KAPrelated studies are important in tailoring a health programme to help curb the threats caused by the disease. Adequate information helps the public understand the risks of diabetes and its complications, seek treatment for existing diseases, take preventive measures and develop a proactive attitude towards health. Worldwide, many studies have been conducted to assess the impact of education on KAP. Findings of many studies revealed that structured education had influenced diabetic patients to become more responsible in altering their diet and lifestyle modifications. Such simple strategies helped the patients to achieve their therapeutic goals. A South African-based study has observed that Lack of knowledge, poor attitude, and inadequate practice were found in their community, suggesting a need for structured educational programs to assist newly detected and uneducated diabetic patients. (14) Indian-based studies also corroborated the improved awareness about the disease, and its management alerts diabetic patients to take improved care. (4, 6, 8-11)

Non-adherence to medications continues to be a significant challenge in healthcare. World Health Organization corroborated only 50% of chronically ill patients adhere to their medication in developed countries. Many systematic reviews and intervention studies reiterated the same. Poor adherence to medications negatively influences therapeutic outcomes and treatment costs. In our study, we have observed inadequate adherence behaviour in control group patients. This might be due to a lack of awareness about medication's importance and health value. The information-motivation-behavioural skills (IMB) model (15) is a widely used social behaviour model to explain medication adherence among chronically ill patients. Face-to-face motivational interviews demonstrated a positive impact. (16) The same was applied in our study to empower the enrolled patients. Medication Adherence Rating Scale

(MARS) scores have demonstrated the positive influence of efforts on test group patients with statistically improved scores.

Type 2 diabetes patients are treated using oral hypoglycaemic agents and insulin formulations based on glycaemic levels. Several factors influence treatment satisfaction, such as hypoglycaemic episodes, insulin prick pain, and adverse drug reactions associated with oral hypoglycaemic medications. Very few studies assessed the satisfaction of type 2 DM patients with their treatment. The results of a European-based study identified the importance of diabetes education in insulin-treated patients with T2DM. In addition, they demonstrated no episodes of hypoglycaemia, and normalised HbA1c levels enhanced patient treatment satisfaction. (17) In our study, we have administered a Diabetes Treatment Satisfaction Questionnaire (8-item) to assess treatment satisfaction. Our findings reveal that counselling support and motivation to the patients in the test group increased their satisfaction scores.

Another important objective of our study is to assess the influence of patient education on Health-Related Quality of Life (HRQoL). Our findings have shown a significant improvement in quality-of-life scores in Test group patients. This is mainly due to improved medication adherence, clinical outcomes, and positive satisfaction with the treatment.

In a Palestinian-based study, the impact of treatment satisfaction on health-related quality of life was studied. The results revealed that most satisfied patients were found to be adherent to medication and had a good QOL. (18)

A significant association was observed between adherence and QoL, mainly due to treatment satisfaction. Improved awareness helps the patients understand medication adherence and the importance of suitable strategies. This has directly influenced the health-related quality of life.

CONCLUSION

Our study findings have shown a positive association between structured patient education and medication adherence behaviour, treatment satisfaction and health-related quality of life among the type 2 diabetes patients in the test group.

LIMITATIONS

The patients' literacy rate resisted perceiving the patient counselling and implementing it in daily life since patients belonged to rural backgrounds. Cultural beliefs and practices relating to health had a major impact on negative outcomes, as patients in Telangana prefer alcohol on a daily basis, which would have adverse effects on controlling diabetes. For better results, the study should be performed for a longer duration and in multiple centres.

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Conflict of Interest

None

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