Bridging the Adherence Gap: Innovative Counseling Strategies and their Effect on HbA$_{1c}$ in Type 2 Diabetes Patients

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ABSTRACT

Background: Medication adherence is essential for effective Type 2 Diabetes Mellitus (T2DM) management; still, non-adherence occurs in countries with low or middle incomes like India, leading to uncontrolled glycemia and comorbidities. The study objectives were to assess adherence patterns in T2DM patients, identify non-adherence factors, evaluate the effectiveness of awareness measures, and follow HbA$_{1c}$ changes to establish adherence-related outcomes. **Materials and Methods:** The 12-month prospective observational study was conducted in the General Medicine and Endocrinology outpatient departments of a tertiary care hospital. It utilized the 8-item Morisky Medication Adherence Scale (MMAS-8) and 15-item Medication Adherence Reasons Scale (MARS-15) to measure adherence and identify non-adherence factors. The study also offered patient verbal counseling and follow-ups to assess effectiveness. **Results:** The study found that glycemic control improved, with HbA$_{1c}$ levels dropping from 61.49% to 52.17% and medication adherence dropping from 55.9% to 23.6%. Factors contributing to poor adherence included forgetfulness 89 (20.36%), medication cost 36 (8.23%), and concerns about side effects 39 (8.92%). **Conclusion:** Verbal counseling and leaflets significantly improved medication adherence and glycemic control in T2DM patients by overcoming barriers like forgetfulness, inconvenience in taking medications as prescribed, and fear of side effects, emphasizing the importance of patient-centered education strategies.

Keywords: Counseling, HbA$_{1c}$, Medication Adherence, Medication Adherence Reasons Scale (MARS-15), Morisky Medication Adherence Scale (MMAS-8), Type 2 Diabetes mellitus (T2DM).

INTRODUCTION

Medication adherence is "the degree to which a person's behavior corresponds with agreed-upon recommendations from a healthcare provider" (Parmar *et al*., 2025). However, over 50% of Type 2 Diabetes mellitus (T2DM) patients worldwide fail to take their prescribed medications, a problem that more prevalent in nations with low or middle incomes, where T2DM accounts for over 95% of cases (Sendekie *et al*., 2022). Non-adherence levels in India may exceed 50% due to high medication costs, a lack of knowledge, polypharmacy, side effects, and sociocultural beliefs (Yosef *et al*., 2023). Diabetes Mellitus (DM) is a widespread health concern, with an estimated 783 million cases projected by 2045 (International Diabetes Federation, 2024).

Diabetes therapy aims to achieve optimal glucose control to avoid complications such as cardiovascular disease, nephropathy, neuropathy, and retinopathy (Afaya *et al*., 2020). Non-adherence remains a major challenge, resulting in treatment failure, increased hospitalizations, and greater mortality and morbidity rates (Stewart *et al*., 2022). Older age, longer diabetes duration, financial restrictions, and educational background are associated with medication adherence (Huang *et al*., 2021). Adherence has a major influence on metabolic management, and understanding the factors that influence nonadherence is essential for improving outcomes (Verma *et al*., 2024). Simple strategies, including smartphone reminders and pillboxes, can enhance adherence. Clinical pharmacist-led counseling improves adherence by educating patients leading to better outcomes (Worrall *et al*., 2024).

This study aimed to assess medication adherence patterns among T2DM patients, identify factors contributing to non-adherence, and better understand the reasons behind low adherence. It also evaluates the impact of pharmacist-led patient counseling on improving adherence and emphasizes its significance.

MATERIALS AND METHODS

Study Design and Setting

The 12-month prospective observational study included T2DM patients from a tertiary care hospital's General Medicine and Endocrinology departments who complied with institutional norms.

Sample Size

The study initially enrolled 200 participants, with 186 completing the first follow-up after one month. After three months, the number reduced to 161 due to issues such as unavailability and non-responsiveness. These participants were considered in the final analysis.

Inclusion and Exclusion criteria

We included newly diagnosed T2DM patients aged 18-59, either of gender, on an antidiabetic regimen, and with at least one comorbidity. The study only included patients who provided informed consent and an in-depth explanation. The study excluded patients with type 1 diabetes, gestational diabetes, hospitalization, and major concomitant conditions such as End-Stage Liver Disease (ESLD), End-Stage Renal Disease (ESRD), malignancy, post-transplant diabetes, or recent cardiac events.

Data Collection and Procedures

Demographic Profile

Details on the patient's age, gender, educational background, employment, marital status, and social history were documented.

Clinical characteristics of patients with type 2 diabetes

Patient data includes medical and medication history, family history, and diabetes duration (<5, 5-10, or >10 years). HbA$_{1c}$ levels were used to assess glycemic management in three categories: 6.5-7.0%, 7.1-10%, and >10%. Complications related to diabetes were documented.

Adherence Measure

Medication adherence was evaluated using the 8-item Morisky Medication Adherence Scale (MMAS-8), which coordinates subjective self-reports with objective data to provide reliable adherence evaluation. The MMAS-8 was translated into Marathi utilizing a rigorous forward-backward procedure to assure its precision and clarity, with bilingual experts reviewing both versions to preserve the scale's original meaning.

The MMAS-8 includes eight questions intended specifically to assess medication adherence. It consists of seven "yes/no" questions and one 5-point Likert scale item. The Score depends on response accuracy: most questions award one point for each accurate response, except of question 5, where a "No" answer obtains one point. A "never/rarely" response receives 0 points on the Likert-scale questions, whereas other replies score one point for each. Adherence is divided into three categories: low (≥2 points), medium (1-2 points), and high (0 points).

Factors associated with medication adherence

The 15-item Medication Adherence Reasons Scale (MARS-15), which evaluates causes for medication non-adherence across five domains: Management Issues, Multiple Medication Concerns, Belief Issues, Availability Issues, and Forgetfulness/Inconvenience. To ensure linguistic authenticity, the scale was translated into Marathi using the same rigorous forward-backward procedure used for MMAS-8. This technique highlights specific factors to adherence, allowing for better management plans.

Patient counseling (verbal) with leaflet

The leaflet effectively counsels patients regarding medication adherence, addressing common issues like forgetfulness, side effect concerns, medication costs, and the difficulties of managing polypharmacy. Patients were counseled on practical strategies such as using pill boxes, setting reminders, reaching out to healthcare providers for prescription issues, and asking their healthcare team before changing or discontinuing their medications. The leaflet aimed to improve medication adherence and provide practical advice, which was then distributed to patients after counseling.

Study Procedure

Initially, after obtaining consent, we conducted a 10-15 min interview with patients to collect their demographic, clinical, and HbA$_{1c}$ values, along with details about their glucose-lowering therapy. Participants were categorized based on low, medium, or high medication adherence using the MMAS-8 scale. The MARS-15 scale determined non-adherence factors in the low and medium adherence categories. All patients received verbal counseling along with a leaflet featuring adherence suggestions. A one-month follow-up via phone call or in-person interview evaluated MMAS-8 and advised patients to check their HbA$_{1c}$ levels before the next follow-up. At the final three-month follow-up, the MMAS-8 questionnaire was re-administered to assess medication adherence patterns, and HbA$_{1c}$ levels were recorded again to compare with the initial values to evaluate the impact of counseling, followed by data analysis.

Statistical methods and data analysis

The data was collected using Google Forms and analyzed using Microsoft Excel 2013. A paired *t*-test was used to compare mean values from three phases: initial, first follow-up, and second follow-up, and also compare initial and final HbA$_{1c}$ values. A *p*-value <0.05 was considered statistically significant.

Ethical considerations

The Institutional Ethics Committee approved the study (DMHRC Code: PharmD_2023_NJ_14, dated 03-11-2023). The study follows the Helsinki Declaration's guidelines.

RESULTS

Demographic Profile of Patients

The evaluation of 161 patients revealed a predominance of males, 103 (63.97%). A majority of patients were 46-59 years old, 127 (78.88%). Regarding risk factors, 18 (11.18%) consumed alcohol, and 6 (3.72%) were smokers. The majority of patients, 156 (96.89%), were married, with 108 (67.08%) being graduates and 118 (73.29%) employed, see Table 1.

Clinical profile of patients with T2DM

Diabetes duration varied across individuals, with 65 (40.37%) having it for 5-10 years, 52 (32.30%) for <5 years, and 44 (27.33%) for >10 years. Hypertension was the most common comorbidity among T2DM patients, accounting for 60 (37.27%), see Table 2.

87 (54.04%) individuals had a positive family history of T2DM, whereas 74 (45.96%) had no such history. There were 27 complications, with neuropathy becoming the most prevalent 13 (8.07%), followed by retinopathy 6 (3.72%) and nephropathy 4 (2.48%), demonstrating a widespread prevalence of neuropathy, see Table 3.

Treatment Profile

According to the treatment profile, most patients received Oral Hypoglycemic medications (OHA) alone, followed by insulin therapy separately, and combined OHA and insulin as shown in Figure 1.

Adherence measurement

Medication adherence was assessed utilizing MMAS-8 in three stages: initially (before counseling), at the first follow-up (after counseling), and the second follow-up. Initially, 90 (55.90%) were low adherent, 32 (19.87%) were medium adherent, and 39 (24.22%) were high adherent. Following the first counseling, low adherence dropped to 58 (36.02%), medium adherence increased to 47 (29.19%), and high adherence increased to 56 (34.78%). By the second follow-up, poor adherence had dropped to 38 (23.60%), medium adherence to 50 (31.05%), and high adherence had risen to 73 (45.34%) as shown in Figure 2.

The mean adherence score increased considerably from the initial phase (1.654±0.709) to the first follow-up (1.931±0.718, $p<0.001$), followed by the second follow-up (2.037±0.707, $p<0.001$). The statistically significant improvement ($p=0.021$) between the first and second follow-ups demonstrates that the positive benefits of adherence were sustained after post-counseling, see Table 4.

In terms of individual behaviors, 77 (47.77%) reported forgetting to take their medication when traveling, which improved to 51 (31.68%) at the first follow-up but significantly increased to 58 (36.02%) at the second. Initially, 96 (59.75%) felt that taking medicine every day was a real inconvenience, which dropped to 72 (44.72%) at the first follow-up and rose to 77 (47.83%) at the second. Furthermore, 58 (36.04%) discontinued taking medicine when symptoms were under control, which decreased to 46 (28.57%) at the first follow-up and 45 (27.95%) at the second. Furthermore, 34 (21.12%) admitted to forgetting to take their medication, which improved to 33 (20.50%) at the first follow-up and 30 (18.63%) at the second, indicating an improving pattern in adherence, see Table 5.

Factors Associated with Low and Medium Adherence in T2DM Patients

The MARS-15 identified factors that contribute to non-adherence. Management issues include uncertainty over administration of 32 (7.32%) patients. Patients also expressed concerns regarding the long-term effects in 38 (8.69%) patients. Fears of side effects 39 (8.92%) patients were included among the belief-related issues. Patients highlighted availability concerns due to busy schedules

Table 1: Demographic data of the respondents (*n*=161).

Patients Characteristics	Number of Participants (%)
Gender	
Male	103 (63.97%)
Female	58 (36.02%)
Age range	
18-31	3 (1.86%)
32-45	31 (19.25%)
46-59	127 (78.88%)
Social history	
Smoker	6 (3.72%)
Alcoholic	18 (11.18%)
Both	15 (9.31%)
None	122 (75.77%)
Marital status	
Married	156 (96.89%)
Single	5 (3.11%)
Education	
Uneducated	6 (3.72%)
Primary/Secondary	47 (29.19%)
Graduate	108 (67.08%)
Employment/Occupation	
Retired	13 (8.07%)
Employed	118 (73.29%)
Unemployed	30 (18.63%)

32 (7.32%) patients. The predominant issue was forgetfulness, affecting 89 (20.36%) patients, see Table 6.

The impact of leaflet distribution and verbal patient counseling on glycemic control

During the initial interview, 99 (61.49%) had moderately raised HbA$_{1c}$ (7.1%-10%), 41 (25.47%) had effectively managed diabetes (6.5%-7.0%), and 21 (13.04%) had poorly managed diabetes (HbA$_{1c}$>10%). At the three-month follow-up, 20 (12.42%) had poorly managed diabetes (HbA$_{1c}$>10%), 6 (3.72%) had well-controlled glucose (HbA$_{1c}$ 5.7%-6.4%), 51 (31.67%) maintained excellent glucose control (HbA$_{1c}$ 6.5%-7.0%), and 84 (52.17%) had moderately increased (HbA$_{1c}$ 7.1%-10%), indicating improvement in glycemic control.

A *t*-test comparing the beginning and final HbA$_{1c}$ values revealed a *t*-statistic value of 3.93 and a *p*-value of 0.0001, indicating a statistically significant decrease in HbA$_{1c}$ levels post-counseling, confirming that the observed improvement is not due to random variation. The positive t-statistic indicates a general decrease in HbA$_{1c}$ values, demonstrating overall improvements.

DISCUSSION

This study revealed a male predominance, consistent with studies emphasizing that males had more significant diabetes rates (Mnif *et al.*, 2022). The majority of patients were adults from age 46 to 59, which is similar to Diabetes Control and Complications Trial (DCCT) findings highlighting older people suffer from

greater diabetes complication risks (ElSayed *et al.*, 2023). Majorly participants had diabetes for 5-10 years, which has been linked to increased complications due to a reduction in medication adherence (Olickal *et al.*, 2021). In this study, lifestyle factors such as social habits had a substantial impact on diabetes control (Sahoo *et al.*, 2022). The majority of patients had spouses, which has been associated with increased adherence as a result of partner support (Otanga *et al.*, 2022). Higher levels of education can increase health literacy, which is necessary for understanding diabetes treatment plans and adhering to prescription regimens effectively (Diabetesjournals.org, 2024). Stable employment improves diabetes management by ensuring access to healthcare, medications, and health insurance, while unemployed individuals may face financial constraints, emphasizing the importance of socioeconomic factors in diabetes care and adherence. (Hellebo *et al.*, 2024).

Hypertension, a prevalent comorbidity in T2DM, affects 37.27% of patients. A similar study found that hypertension affects roughly 39.5% of T2DM patients. The high prevalence emphasizes the significance of managing both illnesses

Table 2: Prevalence of Comorbid Conditions in Study Participants (*n*=161).

| Comorbidities	Number of Participants (%)
Hyperlipidemia	3 (1.86%)
Hypertension	60 (37.27%)
Alzheimer's	1 (0.62%)
Dyslipidemia	8 (4.96%)
Asthma	2 (1.24%)
Angina	2 (1.24%)
Spondylitis	1 (0.62%)
Coronary Artery Bypass Grafting	2 (1.24%)
Parkinson's Disease	3 (1.86%)
Chronic Kidney Disease	3 (1.86%)
Major Depressive Disorder	1 (0.62%)
Stroke	1 (0.62%)
Hypothyroidism	2 (1.24%)
Coronary Artery Disease	1 (0.62%)
Epilepsy	1 (0.62%)
None	70 (43.47%)
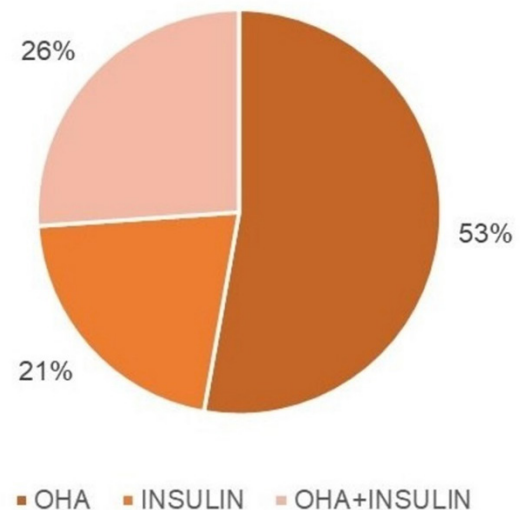
Figure 1: Treatment Profile.

Table 3: Prevalence of Diabetic Complications in Study Participants (*n*=161)

Diabetic Complications	Number of Patients (%)
Diabetic Neuropathy	13 (8.07%)
Diabetic Nephropathy	4 (2.48%)
Diabetic Retinopathy	6 (3.72%)
Diabetic Foot	3 (1.86%)
Peripheral Vascular Disease	1 (0.62%)
None	134 (83.23%)

concurrently to optimize patient outcomes (Haile *et al.*, 2022). Lipid disorders and CKD are common comorbidities in T2DM patients, displaying the significance of integrated medication to reduce health risks and improve outcomes (Zhang *et al.*, 2022). A family history of diabetes had a substantial impact on the study findings, underlining genetic and lifestyle factors as major factors in T2DM risk (Vassou *et al.*, 2023). Diabetic neuropathy is the most prevalent comorbidity (48.1%), similar to a study revealing that it affects almost half of all T2DM patients. The findings

also emphasized diabetic retinopathy and nephropathy. Regular screenings, comprehensive treatment strategies, and family history consideration are essential for patient risk assessment and care planning. (Basebaa *et al.*, 2024). Patients receiving combined insulin and OHA treatment were at more risk of uncontrolled hyperglycemia (Rajan *et al.*, 2024).

Counseling significantly improves medication adherence by reducing low and high adherence. Key barriers like forgetfulness

Table 4: Effect of Counseling on Medication Adherence: Statistical Comparison across Study Phases.

Phase Comparison	Mean	Standard Deviation	*t*-test (Initial vs 1st)	*p*-value (Initial vs 1st)	*t*-test (1st vs 2nd)	*p*-value (1st vs 2nd)	*t*-test (Initial vs 2nd)	*p*-value (Initial vs 2nd)
Initial	1.654	0.709	-5.812	<0.001			-6.423	<0.001
1st Follow-up	1.931	0.718			-2.356	0.021		
2nd Follow-up	2.037	0.707						

Table 5: Medication Adherence Responses Over Follow-ups (*n*=161).

Question	Patient Response					
	Initial interview		First follow-up		Second Follow-up	
	Yes (%)	No (%)	Yes (%)	No (%)	Yes (%)	No (%)
1. Do you sometimes forget to take your medicine?	34 (21.12%)	127 (78.88%)	33 (20.50%)	128 (79.50%)	30 (18.63%)	131 (81.37%)
2. People sometimes miss taking their medicines for reasons other than forgetting. Think over the past 2 weeks, were there any days when you did not take your medicine?	39 (24.22%)	122 (75.78%)	33 (20.50%)	128 (79.50%)	29 (18.01%)	132 (81.99%)
3. Have you ever cut back or stopped taking your medicine without telling your doctor because you felt worse when you took it?	20 (12.42%)	141 (87.58%)	18 (11.18%)	143 (88.82%)	16 (9.94%)	145 (90.06%)
4. When you travel or leave home, do you sometimes forget to bring along your medicine?	77 (47.77%)	84 (52.23%)	51 (31.68%)	110 (68.32%)	58 (36.02%)	103 (63.98%)
5. Did you take all your medicines yesterday?	7 (4.35%)	154 (95.65%)	149 (92.55%)	12 (7.45%)	156 (96.89%)	5 (3.11%)
6. When you feel like your symptoms are under control, do you sometimes stop taking your medicine?	58 (36.04%)	103 (63.96%)	46 (28.57%)	115 (71.43%)	45 (27.95%)	116 (72.05%)
7. Taking medicine every day is a real inconvenience for some people. Do you ever feel hassled about sticking to your treatment plan?	96 (59.75%)	65 (40.25%)	72 (44.72%)	89 (55.28%)	77 (47.83%)	84 (52.17%)
8. How often do you have difficulty remembering to take all your medicine?						
A. Never/rarely	A. 50(31.06%)		A. 72(44.72%)		A. 84(52.17%)	
B. Once in a while	B. 56(34.78%)		B. 36(22.3%)		B. 30(18.63%)	
C. Sometimes	C. 40(24.84%)		C. 38(23.60%)		C. 35(21.74%)	
D. Usually	D. 14(8.73%)		D. 14(8.70%)		D. 12(7.45%)	
E. All of the time	E. 1(0.62%)		E. 1(0.62%)		E. 0(0.00%)	

Table 6: Factors Contributing to Medication Non-Adherence (*n*=161).

Domain	No. of Items	Item Description	Patients Responded (%)
Management Issues	4	Problems opening medication	2 (0.45%)
		Embarrassment in taking medications	8 (1.83%)
		Difficulty swallowing medications	1 (0.22%)
		Uncertainty about proper medication administration	32 (7.32%)
Multiple Medication Issues	3	Concerns about the long-term effects of medications	38 (8.69%)
		Consumption of too many medications	29 (6.63%)
		Cost of medications	36 (8.23%)
Belief Issues with Medications	4	Ineffective medications	4 (0.91%)
		Side effects/fear of side effects	39 (8.92%)
		Unnecessary medications	11 (2.51%)
		Medication cessation to see if it is still needed	34 (7.78%)
Availability Issues	2	Medications unavailable in the pharmacy	2 (0.45%)
		End of medication supply due to busy schedule	32 (7.32%)
Forgetfulness and Inconvenience Issues	2	Forgetfulness in taking medications due to busy schedule	89 (20.36%)
		Inconvenience in taking medications as prescribed	26 (5.94%)
None	0	NA	54 (12.35%)
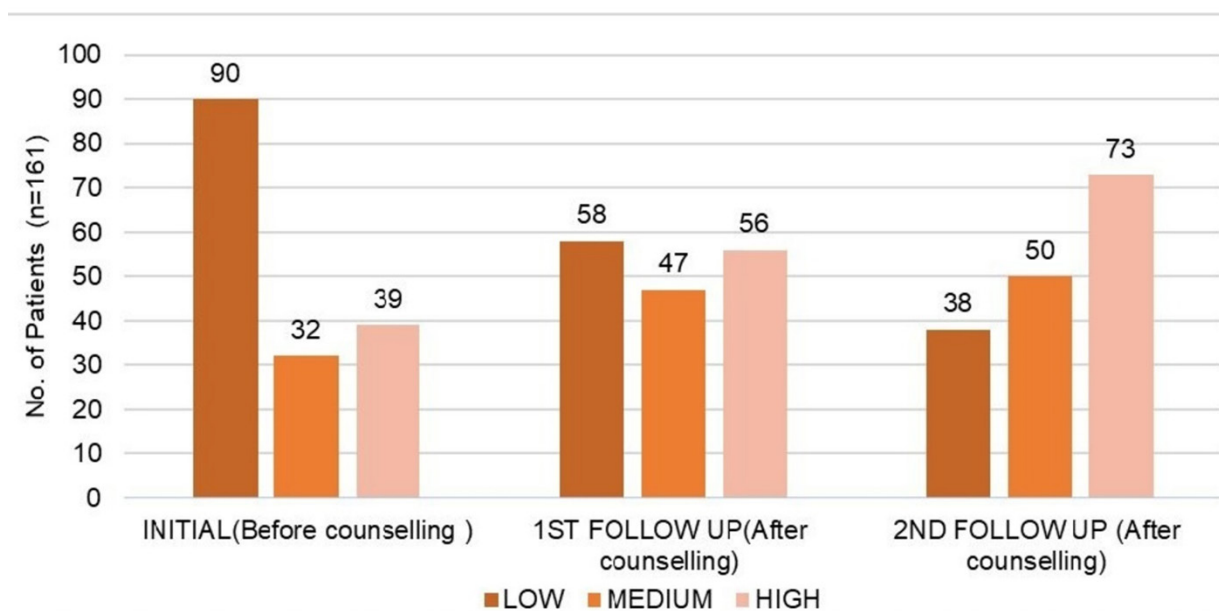
Figure 2: Adherence measurement.

while traveling and difficulty sticking to their medication every day were reduced post-counseling but slightly increased during the second follow-up. This highlights the importance of ongoing patient education and follow-up for long-term adherence. (Carratalá-Munuera *et al.*, 2022). Following counseling, there was a significant improvement in adherence ($p<0.001$), which continued at the second follow-up ($p=0.021$). A similar study found that structured counseling interventions dramatically improved long-term medication adherence in diabetic patients (Atolagbe *et al.*, 2023).

Additionally, concerns about long-term effects, medication costs, and availability further impacted adherence. These findings underscore the need for strategies that address both psychological factors (e.g., fear of side effects) and practical challenges (e.g., forgetfulness, cost), including enhanced patient education, simplified treatment regimens, and financial support to improve medication adherence (Kalaman *et al.*, 2024).

This study demonstrated that leaflet distribution and verbal counseling significantly improved glycemic control in T2DM patients, as evidenced by reduced HbA$_{1c}$ values after three months. Most patients had moderately elevated HbA$_{1c}$ at baseline, although there was a noticeable change toward better glycemic control following counseling. A paired *t*-test yielded a *t*-statistic of *3.93* and a *p*-value of 0.0001, indicating a significant drop in HbA$_{1c}$ levels post-counseling. The study found that patient education, such as verbal counseling and leaflets, significantly improved glycemic control, pointing out the importance of effective diabetes management and optimizing patient outcomes (Thanh & Tien, 2021).

CONCLUSION

The study investigated medication adherence patterns and found that verbal patient counseling significantly improved glycemic control and medication adherence in individuals with T2DM when supported by leaflet distribution. Education and follow-ups overcome the barriers influencing non-adherence. The study concluded that addressing socioeconomic variables, including education, can further enhance adherence. The study indicates the positive impacts of measures on glycemic control and HbA$_{1c}$ levels, highlighting the need for ongoing patient-centered support in overcoming physical and psychological barriers to better diabetes management.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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