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Original Research Article

MEDICATION ADHERENCE IN TYPE 2 DIABETES MELLITUS AND ITS ASSOCIATION WITH CLINICAL OUTCOMES: A PROSPECTIVE OBSERVATIONAL STUDY

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ABSTRACT

Background: Medication adherence is a key determinant of glycaemic control and prevention of complications in patients with Type 2 Diabetes Mellitus (T2DM). However, non-adherence remains a significant challenge, particularly in resource-limited settings. The objective is to assess medication adherence among T2DM patients and evaluate its association with clinical outcomes in a tertiary care teaching hospital.

Materials and Methods: A prospective observational study was conducted from January 2025 to January 2026 in the general outpatient department of a tertiary care hospital. A total of 220 adult T2DM patients were included. Medication adherence was assessed using the 8-item Morisky Medication Adherence Scale (MMAS-8) and categorized as high, moderate, or low adherence. Clinical outcomes including glycated hemoglobin (HbA1c), fasting blood glucose (FBG), and diabetes-related complications were recorded. Statistical analysis was performed using SPSS, with $p < 0.05$ considered significant.

Results: Among the study population, 38.6% exhibited high adherence, 34.5% moderate adherence, and 26.9% low adherence. Patients with high adherence had significantly lower HbA1c levels (6.9 ± 0.8%) compared to those with moderate (7.6 ± 1.0%) and low adherence (8.4 ± 1.2%) ($p < 0.001$). Good glycaemic control (HbA1c < 7%) was achieved in 68.2% of highly adherent patients versus 23.7% in the low adherence group. The prevalence of complications, including neuropathy, retinopathy, and nephropathy, was significantly higher in patients with low adherence. Logistic regression analysis identified adherence as an independent predictor of glycaemic control (OR = 2.8, $p < 0.01$).

Conclusion: Medication adherence significantly influences glycaemic control and clinical outcomes in T2DM patients. Enhancing adherence through targeted interventions may reduce complications and improve overall disease management.

Keywords: Type 2 Diabetes Mellitus, Medication Adherence, HbA1c, Clinical Outcomes, Observational Study.

INTRODUCTION

Type 2 Diabetes Mellitus (T2DM) is a chronic, progressive metabolic disorder characterized by insulin resistance, relative insulin deficiency, and impaired β-cell function. The pathophysiology involves complex interactions between genetic predisposition and environmental factors, leading to persistent hyperglycaemia. T2DM has reached epidemic proportions globally. According to the International Diabetes Federation (IDF, 2023), approximately 537 million adults are living with diabetes worldwide, and this number is projected to rise to 643 million by 2030. India, often referred to as the "diabetes capital of the world," accounts for over

101 million cases, reflecting a significant and growing public health concern.[1,2]

The burden of T2DM extends beyond glycaemic abnormalities, encompassing substantial clinical, economic, and societal impacts. Chronic hyperglycaemia is associated with microvascular complications such as retinopathy, nephropathy, and neuropathy, as well as macrovascular complications including coronary artery disease, stroke, and peripheral vascular disease. These complications contribute to increased morbidity, premature mortality, and diminished quality of life. Additionally, the economic burden is considerable due to long-term treatment costs, frequent hospitalizations, and productivity loss, particularly in resource-limited settings like India.[3]

Effective management of T2DM relies on a multifaceted approach that includes lifestyle modifications and pharmacological therapy. Oral hypoglycaemic agents (such as metformin, sulfonylureas, DPP-4 inhibitors, and SGLT2 inhibitors) and insulin therapy are central to achieving optimal glycaemic control. Adequate pharmacotherapy not only helps maintain target glycated hemoglobin (HbA1c) levels but also reduces the risk of long-term complications. However, the effectiveness of these therapies is highly dependent on patient adherence to prescribed treatment regimens.[4]

Medication adherence, as defined by the World Health Organization (WHO), is "the extent to which a person's behavior—taking medication, following a diet, and/or executing lifestyle changes—corresponds with agreed recommendations from a healthcare provider." It is distinct from compliance, which implies passive following of instructions, whereas adherence emphasizes patient engagement and shared decision-making. In chronic diseases such as T2DM, sustained adherence is essential for optimal therapeutic outcomes.[5]

Despite its importance, medication non-adherence remains a pervasive issue. Global estimates suggest that nearly 30–50% of patients with T2DM do not adhere adequately to their prescribed medications. Indian studies report similar or even higher rates of non-adherence, often exceeding 50%. Poor adherence has been consistently associated with inadequate glycaemic control (elevated HbA1c levels), increased risk of complications, higher hospitalization rates, and increased mortality.[6,7]

Medication adherence is influenced by multiple factors, including patient-related aspects (age, literacy, beliefs, forgetfulness), therapy-related factors (polypharmacy, adverse effects, regimen complexity), healthcare system factors (accessibility, physician–patient communication), and socioeconomic determinants (cost of medication, social support). These multifactorial influences make adherence a challenging yet critical target for intervention.[8]

Improved adherence has been shown to significantly enhance clinical outcomes, including better glycaemic control, reduced incidence of complications, improved quality of life, and decreased healthcare utilization. However, there remains a paucity of real-world data, particularly from tertiary care teaching hospitals in India, examining the relationship between medication adherence and clinical outcomes. Furthermore, region-specific observational studies exploring this association are limited.

Therefore, this study was undertaken to assess medication adherence among patients with T2DM and to evaluate its association with clinical outcomes in a tertiary care teaching hospital. The findings of this study are expected to provide valuable insights into adherence patterns and inform strategies to improve diabetes management and patient outcomes in similar healthcare settings.

MATERIALS AND METHODS

Study Design and Setting: This study was conducted as a prospective observational study to evaluate medication adherence and its impact on clinical outcomes among patients with Type 2 Diabetes Mellitus (T2DM). The study was carried out in the general outpatient department (OPD) of a tertiary care teaching hospital, which caters to a large and diverse patient population, including both urban and rural communities. The observational design was chosen to reflect real-world clinical practices without any intervention or alteration in patient management.

Study Duration: The study was conducted over a period of 12 months, from January 2025 to January 2026, allowing adequate time for patient recruitment and data collection across different follow-up visits.

Study Population: The study population consisted of adult patients diagnosed with T2DM attending the outpatient department for routine follow-up and management. Patients were approached consecutively during OPD visits and screened for eligibility based on predefined criteria.

Sample Size Determination: A total of 220 patients were included in the study using a convenience sampling technique. Although no formal sample size calculation was performed, the sample size was considered adequate to achieve the study objectives based on similar observational studies reported in the literature. The sample ensured sufficient representation of different adherence categories for meaningful statistical analysis.

Inclusion Criteria

Patients fulfilling the following criteria were enrolled:

- Age ≥ 30 years
- Confirmed diagnosis of Type 2 Diabetes Mellitus for at least 6 months
- Currently receiving one or more antidiabetic medications (oral or insulin)
- Regular follow-up in the outpatient department
- Willingness to participate and provide written informed consent

Exclusion Criteria

Patients were excluded if they met any of the following conditions:

- Diagnosis of Type 1 Diabetes Mellitus
- Gestational diabetes mellitus
- Critically ill patients or those requiring emergency hospitalization
- Patients with cognitive impairment or psychiatric illness affecting reliable response
- Patients unwilling to participate

Ethical Considerations: The study protocol was reviewed and approved by the **Institutional Ethics Committee (IEC)** of the hospital. Written informed consent was obtained from all participants prior to enrolment. Confidentiality of patient data was strictly maintained, and the study adhered to the ethical principles outlined in the Declaration of Helsinki.

Data Collection Procedure: Data were collected using a pre-validated structured data collection form through patient interviews and review of medical records.

All clinical and adherence-related data, including HbA1c and fasting blood glucose values, were recorded at the end of the 12-month study period to ensure uniformity in outcome assessment.

The following information was recorded:

- Demographic data: age, gender, body mass index (BMI), and socioeconomic status
- Clinical characteristics: duration of diabetes, comorbid conditions (e.g., hypertension, dyslipidaemia)
- Laboratory parameters: glycated haemoglobin (HbA1c) and fasting blood glucose (FBG)
- Medication details: type and number of antidiabetic drugs

Assessment of Medication Adherence: Medication adherence was assessed using the 8-item Morisky Medication Adherence Scale (MMAS-8), a validated self-reported questionnaire widely used in chronic disease research.

- Each item assesses patient behaviour related to medication-taking habits
- Total score ranges from 0 to 8

Adherence was categorized as:

- High adherence: Score = 8
- Moderate adherence: Score 6–7
- Low adherence: Score < 6

The questionnaire was administered in the local language when required to ensure patient understanding. Responses were recorded by trained investigators to minimize interviewer bias.

Operational Definitions

- Medication adherence: Degree to which patients follow prescribed medication regimen
- Good glycaemic control: HbA1c < 7%
- Poor adherence: MMAS-8 score < 6

Clinical Outcome Measures

Primary Outcome

- Glycaemic control, assessed using HbA1c levels
  - Good control: HbA1c < 7%
  - Poor control: HbA1c ≥ 7%

Secondary Outcomes

- Fasting Blood Glucose (FBG) levels
- Presence of diabetes-related complications:

Microvascular Complications

- Neuropathy: Assessed clinically based on symptoms (numbness, tingling) and examination findings
- Retinopathy: Based on ophthalmologic examination records
- Nephropathy: Nephropathy was assessed based on the presence of albuminuria (urinary albumin-to-creatinine ratio ≥30 mg/g) and/or reduced estimated glomerular filtration rate (eGFR <60 mL/min/1.73 m²), as documented in patient records.

Statistical Analysis

Data were entered into Microsoft Excel and analysed using SPSS version XX. Continuous variables were expressed as mean ± standard deviation, while categorical variables were presented as frequencies and percentages. The Chi-square test was used to assess associations between categorical variables, and one-way ANOVA was applied to compare mean HbA1c levels across adherence groups. Logistic regression analysis was performed to identify independent predictors of glycaemic control, with results expressed as odds ratios and 95% confidence intervals. A p-value < 0.05 was considered statistically significant.

RESULTS

1. Baseline Demographic and Clinical Characteristics: A total of 220 patients with Type 2 Diabetes Mellitus were included in the study. The mean age of the study population was 56.3 ± 10.2 years, with a slight male predominance (54% males and 46% females). The mean body mass index (BMI) was 26.8 ± 3.9 kg/m², indicating that the majority of patients were overweight.

The average duration of diabetes was 8.2 ± 4.5 years. Among the study population, 60% of patients had hypertension and 44.5% had dyslipidaemia as comorbid conditions. The overall mean HbA1c was 7.6 ± 1.2%, and the mean fasting blood glucose (FBG) level was 154 ± 38 mg/dL.

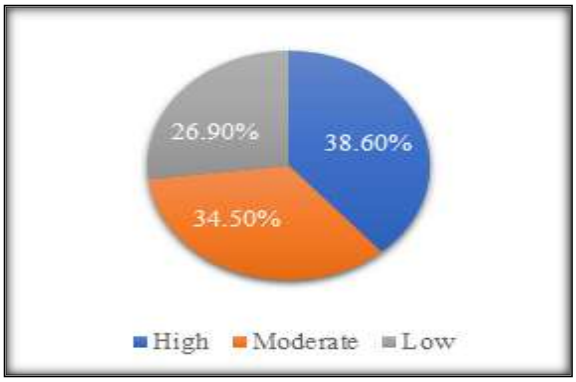

Figure 1: Distribution of Medication Adherence Levels

Table 1: Baseline Demographic and Clinical Characteristics (n = 220)

Variable	Value
Age (years)	56.3 ± 10.2
Gender (Male/Female)	119 (54%) / 101 (46%)
BMI (kg/m²)	26.8 ± 3.9
Duration of Diabetes (years)	8.2 ± 4.5
Hypertension	132 (60%)
Dyslipidaemia	98 (44.5%)
HbA1c (%)	7.6 ± 1.2
Fasting Blood Glucose (mg/dL)	154 ± 38

2. Distribution of Medication Adherence:

Medication adherence was assessed using the MMAS-8 scale. Among the study participants, 38.6% (n=85) demonstrated high adherence, 34.5% (n=76) had moderate adherence, and 26.9% (n=59) had low adherence.

3. Antidiabetic Medications

Table 2: Distribution of Antidiabetic Medications (n = 220)

Medication Type	Frequency (n)	Percentage (%)
Metformin	180	81.8%
Sulfonylureas	120	54.5%
DPP-4 inhibitors	95	43.2%
SGLT2 inhibitors	70	31.8%
Insulin	85	38.6%
Combination therapy	150	68.2%

The majority of patients were on combination therapy, with metformin being the most commonly prescribed medication.

4. Association Between Medication Adherence and Glycaemic Control

A statistically significant association was observed between medication adherence and glycaemic control. Patients with high adherence had significantly lower mean HbA1c and fasting blood glucose levels compared to those with moderate and low adherence.

Furthermore, a higher proportion of patients with high adherence achieved good glycaemic control (HbA1c < 7%) compared to those with moderate and low adherence. The glycaemic parameters presented represent values obtained after 12 months of follow-up.

Table 3: Association Between Medication Adherence and Glycaemic Parameters After 12 Months of Therapy

Adherence Level	HbA1c (%) (Mean ± SD)	FBG (mg/dL) (Mean ± SD)	Good Control (<7%) n (%)	Poor Control (≥7%) n (%)
High (n=85)	6.9 ± 0.8	132 ± 28	58 (68.2%)	27 (31.8%)
Moderate (n=76)	7.6 ± 1.0	148 ± 32	32 (42.1%)	44 (57.9%)
Low (n=59)	8.4 ± 1.2	178 ± 40	14 (23.7%)	45 (76.3%)

Values shown represent HbA1c and fasting blood glucose measurements recorded after completion of 12 months of follow-up.

Statistical analysis:

- HbA1c and FBG comparison: One-way ANOVA, $p < 0.001$
- Glycaemic control categories: Chi-square test, $p < 0.001$

5. Association Between Medication Adherence and Diabetes-related Complications

The prevalence of diabetes-related complications was found to be significantly higher among patients with low medication adherence compared to those with moderate and high adherence.

Neuropathy was the most commonly observed complication, followed by retinopathy and nephropathy. A clear increasing trend in complication rates was observed with decreasing adherence levels. Nephropathy was identified based on documented albuminuria and/or reduced eGFR values.

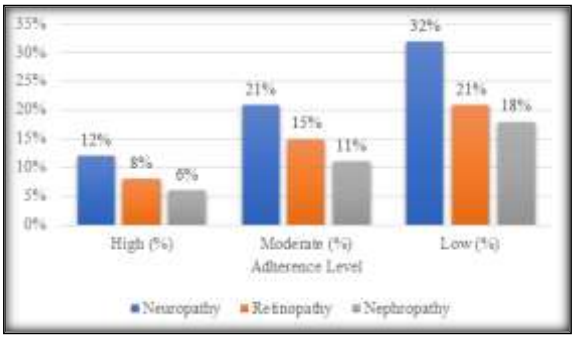

Figure 2: Prevalence of Complications According to Adherence Level

6. Logistic Regression Analysis

Multivariate logistic regression analysis was performed to identify independent predictors of good glycaemic control (HbA1c < 7%). Medication adherence was found to be a significant independent predictor.

Patients with high adherence were approximately 2.8 times more likely to achieve good glycaemic control compared to those with low adherence.

Table 4: Logistic Regression Analysis for Predictors of Good Glycaemic Control.

Variable	Odds Ratio (OR)	95% Confidence Interval	p-value
High adherence	2.8	1.6 – 4.9	<0.01
Duration of diabetes	0.9	0.8 – 1.1	0.08
Age	1.1	0.9 – 1.2	0.12
BMI	0.95	0.8 – 1.1	0.20

7. Summary of Findings

The study demonstrated that medication adherence is a critical determinant of clinical outcomes in patients with Type 2 Diabetes Mellitus. Patients with higher adherence levels showed significantly better glycaemic control, as evidenced by lower HbA1c and fasting blood glucose levels. Additionally, lower adherence was associated with a higher prevalence of diabetes-related complications. Logistic regression analysis further confirmed that medication adherence is an independent predictor of good glycaemic control.

DISCUSSION

The present study evaluated medication adherence among patients with Type 2 Diabetes Mellitus (T2DM) and its association with clinical outcomes in a tertiary care setting. The findings demonstrate that medication adherence is a significant determinant of glycaemic control and complication burden, reinforcing its central role in diabetes management.

In this study, only 38.6% of patients exhibited high adherence, while nearly one-quarter demonstrated low adherence. These findings are consistent with global literature reporting adherence rates ranging between 30% and 70% in T2DM populations.[1,2] Similar adherence patterns have been observed in Indian cohorts, where socioeconomic constraints, limited health literacy, and healthcare access disparities contribute to suboptimal adherence.[3] The persistence of moderate-to-low adherence levels despite advances in pharmacotherapy highlights the complexity of adherence behaviour.

A key finding of this study is the strong association between adherence and glycaemic control, as evidenced by significantly lower HbA1c levels in the high-adherence group (6.9 ± 0.8%) compared to the low-adherence group (8.4 ± 1.2%). This aligns with previous large-scale observational and meta-analytic studies demonstrating that improved adherence is directly associated with better glycaemic outcomes.[4,5] A systematic review has reported that adherence rates above 80% are associated with clinically meaningful reductions in HbA1c and improved metabolic control.[6] The gradient observed across adherence categories in the present study further supports a dose–response relationship between adherence and glycaemic outcomes.

The study also demonstrated a significant association between adherence and diabetes-related complications, with higher prevalence of neuropathy, retinopathy, and nephropathy among patients with low adherence. These findings are consistent with evidence indicating that poor adherence accelerates the progression of both microvascular and macrovascular complications.[7,8] Chronic hyperglycaemia resulting from inadequate adherence contributes to endothelial dysfunction, oxidative stress, and inflammatory pathways, thereby increasing complication risk.[9]

Multivariate analysis identified medication adherence as an independent predictor of good glycaemic control, with highly adherent patients being nearly three times more likely to achieve target HbA1c levels. This observation is supported by real-world studies demonstrating that adherence remains a stronger predictor of outcomes than many demographic or clinical variables.[10] The lack of significant association with variables such as age, BMI, and duration of diabetes in this study further underscores the dominant influence of adherence.

Medication adherence in T2DM is inherently multifactorial. Consistent with prior literature, adherence behaviour is influenced by patient-related factors such as forgetfulness and beliefs about medication, therapy-related factors including regimen complexity and side effects, and healthcare system factors such as accessibility and physician–patient communication.[11,12] In low- and middle-income countries, economic constraints and healthcare access barriers further exacerbate non-adherence.[13]

The findings of this study have important clinical implications, as improving adherence has the potential to reduce complications, healthcare utilization, and overall disease burden. Interventions such as patient education, simplified treatment regimens, and digital or pharmacist-led adherence programs have been shown to improve adherence and clinical outcomes.[14,15]

This study has several strengths. It provides real-world evidence from a tertiary care teaching hospital, reflecting routine clinical practice. The use of the validated MMAS-8 scale enhances the reliability of adherence assessment. Furthermore, the study comprehensively evaluated both biochemical parameters and clinical outcomes, and the application of multivariate analysis strengthens the validity of the findings. Additionally, it contributes region-specific data from India, addressing a gap in the existing literature.

However, certain limitations should be acknowledged. Medication adherence was assessed using a self-reported tool, which may introduce recall and social desirability bias. The single-centre design and convenience sampling may limit the generalizability of the findings. Although prospective in design, the study's outcome assessment was largely observational, restricting causal inference.

Moreover, factors such as lifestyle behaviours, psychological status, and medication cost were not extensively evaluated. The absence of objective adherence measures and a moderate sample size may also influence the precision of the results.

CONCLUSION

Medication adherence is a critical and modifiable determinant of clinical outcomes in patients with Type 2 Diabetes Mellitus. The present study demonstrates a clear association between higher adherence and improved glycaemic control, along with a lower burden of diabetes-related complications. Despite advances in pharmacotherapy, suboptimal adherence remains prevalent, underscoring the need for targeted, patient-centred interventions. Strategies such as education, simplified regimens, and integrated care approaches are essential to enhance adherence. Strengthening adherence-focused practices in routine clinical care can significantly improve disease management, reduce complications, and ultimately lessen the overall healthcare burden of diabetes.

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