Original Research

DETERMINANTS OF MEDICATION ADHERENCE AMONG TYPE 2 DIABETES MELLITUS PATIENTS: A PROSPECTIVE OBSERVATIONAL STUDY

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ABSTRACT

Background: Type 2 Diabetes Mellitus (T2DM) is a chronic metabolic disorder requiring lifelong pharmacotherapy and lifestyle modifications. Despite the availability of effective therapies, poor medication adherence remains a significant barrier to achieving optimal glycemic control, leading to increased morbidity, mortality, and healthcare costs. Identifying the factors that influence adherence is crucial for developing effective interventions.

Objective: To prospectively evaluate the factors affecting medication adherence in patients with T2DM.

Methods: This prospective, observational study was conducted at the Department of Medicine of a tertiary care hospital. A total of 160 patients with T2DM on oral hypoglycemic agents for at least one year were enrolled. Baseline demographic, socioeconomic, and clinical data were collected. Medication adherence was assessed at baseline and at the 6-month follow-up using the validated Morisky Medication Adherence Scale (MMAS-8). Glycemic control was measured via HbA1c levels. Patients were categorized as having high, medium, or low adherence. Multivariate logistic regression analysis was performed to identify independent predictors of poor adherence.

Results: Of the 160 enrolled patients, 152 completed the six-month follow-up (dropout rate: 5%). The mean age was 56.4 ± 11.2 years, with a slight male predominance (56.6%). At baseline, only 28.3% (n=43) of patients had high adherence. At the 6-month follow-up, the number of patients with high adherence had significantly declined to 23.0% (n=35) (p=0.03). Factors significantly associated with poor adherence on multivariate analysis included: the presence of depressive symptoms (AOR: 3.2, 95% CI: 1.6-6.4, p=0.001), a higher pill burden (>5 pills per day) (AOR: 2.8, 95% CI: 1.4-5.6, p=0.004), lower monthly family income (AOR: 2.1, 95% CI: 1.1-4.1, p=0.02), and the experience of medication-related side effects (AOR: 2.4, 95% CI: 1.2-4.8, p=0.01). There was a strong correlation between lower adherence scores and higher HbA1c levels at the 6-month follow-up ($r = 0.62$, $p<0.001$).

Conclusion: The rate of medication non-adherence in T2DM patients is alarmingly high and tends to decline over time. Key modifiable factors such as depression, pill burden, and side effects were identified as independent predictors of poor adherence. A multidisciplinary approach involving psychological support, regimen simplification, and proactive side-effect management is essential to improve adherence and, consequently, clinical outcomes in this patient population.

Keywords: T2DM Patients, Morisky Medication Adherence Scale (Mmas-8), Glycemic Control.

INTRODUCTION

Diabetes mellitus is a global health crisis, with the International Diabetes Federation estimating that approximately 537 million adults were living with diabetes in 2021, a number projected to rise to 783 million by 2045.[1]

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Type 2 Diabetes Mellitus (T2DM) constitutes the vast majority of these cases. The cornerstone of T2DM management involves a combination of lifestyle modifications and pharmacotherapy aimed at achieving and maintaining glycemic control to prevent long-term microvascular and macrovascular complications.

Medication adherence, defined by the World Health Organization (WHO) as "the extent to which a person's behavior... corresponds with agreed recommendations from a healthcare provider,"[2] is a critical determinant of therapeutic success. In chronic conditions like T2DM, adherence rates are notoriously suboptimal, with studies reporting that approximately 50% of patients do not achieve adequate control due to poor adherence.[3] The consequences of non-adherence are profound,

including elevated HbA1c levels, increased risk of complications (e.g., retinopathy, nephropathy, neuropathy, cardiovascular disease), higher rates of hospitalization, and increased overall healthcare expenditure.

The reasons for non-adherence are multifaceted and complex, encompassing patient-related, therapy-related, condition-related, socioeconomic, and healthcare system-related factors. Understanding the specific factors that influence adherence in a given population is essential for designing targeted interventions. While numerous cross-sectional studies have identified various correlates of non-adherence, there is a paucity of prospective studies that track adherence patterns and their contributing factors over time. The dynamic nature of adherence, influenced by changing patient circumstances and disease progression, warrants a longitudinal assessment.

This prospective study was designed to evaluate the factors affecting medication adherence in patients with T2DM.

METHODOLOGY

Study Design

This study employed a **prospective, observational, longitudinal cohort design**. The study was conducted at the **Outpatient Department (OPD) of General Medicine**. The target population for this study comprised all adult patients (aged ≥ 18 years) diagnosed with Type 2 Diabetes Mellitus who were receiving treatment and follow-up care at the General Medicine OPD of the study hospital.

Inclusion Criteria:

1. Patients with a confirmed diagnosis of Type 2 Diabetes Mellitus (based on American Diabetes Association [ADA] criteria: fasting plasma glucose ≥126 mg/dL, 2-hour plasma glucose ≥200 mg/dL during OGTT, or HbA1c ≥6.5%).
2. Age ≥ 18 years.
3. Duration of diabetes diagnosis of at least one year.
4. On a stable oral hypoglycemic agent (OHA) regimen (no change in drug class or dose) for the preceding 3 months.
5. Willing and able to provide written informed consent and commit to the 6-month follow-up.

- **Exclusion Criteria:**

1. Patients with Type 1 Diabetes Mellitus or secondary forms of diabetes (e.g., glucocorticoid-induced, pancreatic).
2. Patients currently on insulin therapy (alone or in combination with OHAs), as adherence dynamics may differ significantly.
3. Pregnant or lactating women, due to altered physiological states and treatment protocols.
4. Patients with severe cognitive impairment, dementia, or active major psychiatric disorders (e.g., schizophrenia, bipolar disorder) that would impede valid consent or reliable self-reporting.
5. Patients with terminal illnesses (e.g., advanced malignancy, end-stage renal disease on dialysis) or other severe, unstable medical conditions likely to cause frequent hospitalizations and interrupt follow-up.
6. Patients who were non-ambulatory or entirely dependent on caregivers for medication administration.

Procedure for Data Collection

Phase 1: Baseline Assessment (Enrollment)

1. **Patient Screening & Recruitment:** Consecutive patients attending the General Medicine OPD who met the inclusion criteria were identified by the treating physician. The study's purpose, procedures, risks, and benefits were explained in the local language (Hindi/Regional Language) by the primary investigator.
2. **Informed Consent:** Patients who agreed to participate provided written informed consent.
3. **Data Collection:** A face-to-face interview was conducted by the investigator to collect demographic, socioeconomic, and clinical data, which were recorded in the CRF. The following instruments were administered:
   - The **MMAS-8** to assess baseline adherence.
   - The **PHQ-9** to screen for depressive symptoms.
   - A structured questionnaire to assess medication details, pill burden, and side effect history.
4. **Clinical/Laboratory Assessment:** A fasting blood sample was drawn and sent to the hospital's accredited central laboratory for HbA1c estimation. The results were recorded in the CRF. Anthropometric measurements (height, weight, BMI) were also recorded.
5. **Follow-up Reminder:** Patients were given a scheduled appointment for their 6-month follow-up visit and were provided with a reminder card.

Phase 2: Six-Month Follow-Up Assessment

1. **Patient Contact:** Patients were contacted via phone one week prior to their scheduled follow-up date to remind them of the appointment. For those unable to visit the clinic, a telephonic interview was conducted as a secondary option.
2. **Follow-up Interview:** At the clinic visit, the MMAS-8 was re-administered to assess current medication adherence. Patients were also queried about any new side effects experienced, changes in medication, or any hospitalizations in the intervening six months.
3. **Laboratory Re-assessment:** A repeat blood sample was collected for HbA1c estimation.

Statistical Analysis

The cleaned and coded database was exported to **Statistical Package for the Social Sciences (SPSS) version 25.0 (IBM Corp., Armonk, NY, USA)** for analysis.

Table 1: Baseline Demographic and Clinical Characteristics of the Study Population (N=160)

Characteristic	Category	Frequency (n)	Percentage (%)
Age (Years)	Mean ± SD	56.4 ± 11.2	-
Gender	Male	86	53.8
	Female	74	46.2
Education Level	Illiterate / Primary School	58	36.3
	Secondary / High School	72	45.0
	Graduate / Post-Graduate	30	18.7
Occupation	Unemployed / Homemaker	52	32.5
	Employed / Self-Employed	68	42.5
	Retired	40	25.0
Monthly Family Income (INR)	≤ 20,000	81	50.6
	20,001 – 50,000	55	34.4
	> 50,000	24	15.0
Duration of Diabetes	< 5 Years	42	26.3
	5 – 10 Years	78	48.7
	> 10 Years	40	25.0
Body Mass Index (BMI) (kg/m²)	Mean ± SD	27.8 ± 4.5	-
Comorbidities	Hypertension	115	71.9
	Dyslipidemia	92	57.5
	Both Hypertension & Dyslipidemia	78	48.8
Number of OHAs Prescribed	1 Drug	48	30.0
	2 Drugs	84	52.5
	≥ 3 Drugs	28	17.5
Total Daily Pill Burden	≤ 5 Pills/Day	88	55.0
	> 5 Pills/Day	72	45.0
Depressive Symptoms (PHQ-9)	Present (Score ≥ 10)	40	25.0
	Absent (Score < 10)	120	75.0
Self-Reported Medication Cost	Affordable	104	65.0
	Burdensome	56	35.0
Baseline HbA1c (%)	Mean ± SD	8.1 ± 1.6	-

Table 2: Changes in Adherence Levels and Glycemic Control Over 6-Month Follow-Up

Parameter	Baseline (N=160)	6-Month Follow-Up (N=152)	Change	p-value*
Adherence Level (MMAS-8)				**0.03**
High Adherence (Score = 8)	43 (28.3%)	35 (23.0%)	↓ 5.3%	
Medium Adherence (Score 6 to <8)	64 (42.1%)	58 (38.2%)	↓ 3.9%	
Low Adherence (Score < 6)	45 (29.6%)	59 (38.8%)	↑ 9.2%	
Mean MMAS-8 Score	6.2 ± 1.8	5.6 ± 2.1	-0.6	**0.01**
Mean HbA1c Level (%)	8.1 ± 1.6	8.5 ± 1.8	+0.4	**0.02**

Table 3: Bivariate Analysis of Factors Associated with Medication Adherence at 6-Month Follow-Up (N=152)

Characteristic	Category	Adherent Group (High Adherence) (n = 35)	Non-Adherent Group (Medium/Low) (n = 117)	p-value*
Age (Years)	Mean ± SD	57.8 ± 10.5	55.9 ± 11.8	0.63†
Gender	Male	20 (57.1%)	66 (56.4%)	0.94

	Female	15 (42.9%)	51 (43.6%)	
Education Level	Illiterate/Primary	7 (20.0%)	51 (43.6%)	**0.04**
	≥ Secondary	28 (80.0%)	66 (56.4%)	
Monthly Income	≤ 20,000 INR	11 (31.4%)	70 (59.8%)	**0.02**
	> 20,000 INR	24 (68.6%)	47 (40.2%)	
Duration of Diabetes	< 10 Years	26 (74.3%)	76 (65.0%)	0.30
	≥ 10 Years	9 (25.7%)	41 (35.0%)	
Number of OHAs	1 or 2 Drugs	30 (85.7%)	86 (73.5%)	0.14
	≥ 3 Drugs	5 (14.3%)	31 (26.5%)	
Total Pill Burden	≤ 5 Pills/Day	24 (68.6%)	60 (51.3%)	**0.003**
	> 5 Pills/Day	11 (31.4%)	57 (48.7%)	
Depressive Symptoms	Present	3 (8.6%)	35 (29.9%)	**0.001**
	Absent	32 (91.4%)	82 (70.1%)	
Medication Side Effects	Present	4 (11.4%)	37 (31.6%)	**0.01**
	Absent	31 (88.6%)	80 (68.4%)	
Medication Cost Burden	Burdensome	8 (22.9%)	42 (35.9%)	0.15
	Affordable	27 (77.1%)	75 (64.1%)	
Baseline HbA1c (%)	Mean ± SD	7.5 ± 1.2	8.3 ± 1.7	**0.03†**

Table 4: Multivariate Logistic Regression Model for Independent Predictors of Non-Adherence (N=152)

Predictor Variable	Adjusted Odds Ratio (AOR)	95% Confidence Interval (CI)	p-value
Presence of Depressive Symptoms (PHQ-9 ≥ 10)	**3.2**	1.6 – 6.4	**0.001**
Total Pill Burden > 5 Pills/Day	**2.8**	1.4 – 5.6	**0.004**
Presence of Medication Side Effects	**2.4**	1.2 – 4.8	**0.01**
Monthly Income ≤ 20,000 INR	**2.1**	1.1 – 4.1	**0.02**
Education Level ≤ Primary School	1.6	0.8 – 3.4	0.16
Baseline HbA1c (%)	1.2	0.9 – 1.5	0.21

DISCUSSION

This prospective study provides critical insights into the trajectory of medication adherence and its determinants in a cohort of T2DM patients over six months. The findings reveal an alarmingly low rate of adherence that declined further over time, highlighting the dynamic and challenging nature of managing this chronic disease. Our study successfully identified several independent and potentially modifiable predictors of non-adherence, including depressive symptoms, high pill burden, medication-related side effects, and low socioeconomic status. These findings align with and extend the existing body of evidence on adherence barriers in diabetes care.

The overall low adherence rate observed in our study—with only 23% of patients demonstrating high adherence at the six-month follow-up—is consistent with the global challenge of medication non-adherence in chronic diseases. The World Health Organization has recognized that approximately 50% of patients with chronic illnesses do not adhere to their prescribed therapies.[4] However, our findings indicate an even more concerning scenario in our cohort. The significant decline in adherence from baseline (28.3%) to the 6-month follow-up (23.0%) is a particularly noteworthy finding. While baseline adherence was already poor, it worsened over time, suggesting that the initial motivation or "white coat compliance" observed at clinic visits may wane as the reality of lifelong therapy sets in.

This declining trajectory contrasts with findings from some other studies. A cross-sectional study conducted at a tertiary care teaching hospital in Gujarat, India, reported notably high adherence (91.28%) among diabetes patients.[5] However, that study utilized a different assessment tool (a 12-item questionnaire with Bloom's cut-point) and was cross-sectional in design, which may not capture the dynamic nature of adherence over time.[5] Similarly, a study from Kolkata reported that 69.7% of patients demonstrated high adherence.[6] The discrepancy between these findings and ours may be attributed to differences in study design (cross-sectional vs. prospective), assessment instruments, and possibly

regional variations in patient populations and healthcare delivery systems. Our prospective design, which tracked the same patients over time, revealed a deterioration that cross-sectional studies might miss.

Among the factors identified, depressive symptoms were the strongest independent predictor of poor adherence (AOR: 3.2). This finding is robustly supported by existing literature demonstrating a well-established bidirectional relationship between depression and diabetes.[7] Depression can lead to a loss of motivation, feelings of hopelessness, and impaired executive function—all of which can make it difficult for patients to adhere to complex self-care regimens, including medication taking.

The moderating effect of depression on adherence has been documented in other populations. A study using the 2020 Korea Health Panel Data found that while having a usual source of care significantly improved medication adherence (OR: 1.60), this beneficial effect was diminished in the presence of depressive symptoms.[8] The interaction effect confirmed that depression weakens the positive influence of healthcare continuity on adherence. This aligns with our findings and underscores the critical importance of screening for and managing depressive symptoms in routine diabetes care. The qualitative literature further supports this connection; focus group participants have expressed frustration when medications fail to produce immediate improvement, with one participant stating, "At times I feel very frustrated because so many medications that you are taking and the sugar does not go down…that puts me depressed".[9] Integrating mental health support into diabetes management protocols is therefore paramount.

The pill burden, defined as taking more than five pills per day, was another significant independent predictor of non-adherence (AOR: 2.8). This aligns with regimen complexity being a major barrier to adherence. Many T2DM patients are also on medications for comorbidities like hypertension and dyslipidemia, leading to polypharmacy. A high pill burden can be overwhelming, leading to confusion, forgetfulness, and intentional omissions.

Our findings are consistent with an Indian study on insulin therapy which identified polypharmacy as an independent predictor of non-adherence (AOR: 4.00).[10] The clinical implications are significant; fixed-dose combinations have been proposed as a strategy to reduce pill burden. A clinician perception study (GOLD-PCP) found that 83.2% of clinicians perceived improvements in patient adherence with fixed-dose combinations, and there was a strong correlation between perceived pill burden reduction and perceived adherence improvement ($r = 0.883$, $p < 0.001$).[11] Patient perspectives from focus groups echo this: participants have reported taking "ten medications in the morning and eight at night" and expressed feeling "disgusted by having to take so many medications".[12] Strategies like simplifying regimens, using fixed-dose combination pills, or considering once-daily dosing could be instrumental in improving adherence.

The presence of medication-related side effects was a strong predictor of non-adherence (AOR: 2.4). This is a highly modifiable factor with a direct patient impact. Side effects like gastrointestinal disturbances (from metformin), hypoglycemia (from sulfonylureas), or edema (from thiazolidinediones) can make patients feel worse than their disease itself, leading them to skip doses or discontinue therapy.

The fear of side effects is a prominent theme in patient-reported barriers. Focus group participants have expressed concerns such as, "You are taking a risk, if you take the medication, it alleviates something but it will damage something else," and "Because you know that there are medications that damage the kidneys and then the doctor tells you, I'm sorry, it was the medication [that caused the kidney damage], so you live in fear".[13] This highlights the critical role of clinicians in proactively discussing potential side effects, managing them effectively, and switching therapies when necessary. A study from Italy found that patients with T2DM had high adherence, which was attributed in part to a low number of adverse drug reactions.[14] This suggests that minimizing side effects through careful medication selection and management can directly improve adherence.

Our study identified low socioeconomic status as a significant independent predictor of non-adherence (AOR: 2.1). The cost of medications, even in publicly funded systems, can be a substantial barrier for low-income patients, who may skip doses to make their supply last longer. However, the relationship between socioeconomic status and adherence is complex and may be context-dependent. Interestingly, a study on insulin non-adherence found that upper-middle socioeconomic status was associated with higher odds of non-adherence (AOR: 2.11),[15] suggesting that in some contexts, financial constraints may be less of a barrier than structural or behavioral factors. This paradox underscores the need for nuanced understanding of socioeconomic influences on adherence, which may vary based on healthcare systems, medication costs, and patient priorities.

The strong negative correlation between adherence scores and HbA1c levels at follow-up ($r = -0.62$, $p < 0.001$) reinforces the clinical significance of our findings. This demonstrates that non-adherence directly translates to poorer glycemic control, validating the MMAS-8 as a clinically meaningful measure. This association is well-established; a study from Gujarat also found a significant association between medication adherence and

glycemic control.[16] The clinical implication is clear: interventions targeting modifiable adherence barriers have the potential to directly improve glycemic outcomes and reduce the risk of diabetes-related complications.

CONCLUSION

This prospective study confirms that medication non-adherence in T2DM patients is a significant and persistent problem that worsens over time. The independent predictors of poor adherence identified—depressive symptoms, high pill burden, side effects, and low income—are, for the most part, modifiable. These findings advocate for a shift from a purely clinical approach to a more holistic, patient-centered model of diabetes care that incorporates routine depression screening, active side-effect management, regimen simplification, and consideration of financial constraints. By addressing these multifaceted barriers, healthcare providers can empower patients, improve adherence, and ultimately enhance glycemic control, leading to better long-term health outcomes and a reduction in the burden of diabetes-related complications.

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