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Original Research Article

Evaluating Drug Regimens and Compliance Issues in Diabetes Management: A Hospital-Based Study in North India

Sunil Kumar Singh[1], Narveer Yadav[2], Lalendra Yadav[3], Venkatanarayana[4], Amit Kumar[5]

[1]Associate Professor, Department of Surgery, Government Medical College, Badaun, Uttar Pradesh
[2]Associate Professor, Department of Psychiatry, Government Medical College, Badaun, Uttar Pradesh
[3]Assistant Professor, Department of Pharmacology, Government Medical College Badaun, Uttar Pradesh
[4]Professor, Department of Pharmacology, Government Medical College, Badaun, Uttar Pradesh
[5]Assistant professor, Department of Pharmacology, Government Medical College Badaun, Uttar Pradesh

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Corresponding Author: Dr. Amit Kumar
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Abstract:

Background: Despite the availability of various therapeutic options, achieving optimal glycemic control remains a major challenge in clinical practice. One of the primary barriers to effective diabetes management is poor medication adherence. Non-adherence is a common issue among patients with chronic illnesses and is particularly prevalent in diabetes due to the need for long-term therapy, polypharmacy, adverse effects of medications, lack of patient education, economic constraints, and complex dosing regimens.

Methodology: A cross-sectional, observational study was conducted in which Structured Case Record Form (CRF) was Used to collect data on Demographics (age, gender, socioeconomic status), Clinical details (duration of diabetes, comorbidities, complications), Current medications (drug names, dose, frequency, combination), Investigations, if available (HbA1c, fasting and postprandial glucose, renal function). The Morisky Medication Adherence Scale (MMAS-8) was used to assess adherence and Face-to-face interviews were conducted to assess factors influencing adherence such as, Awareness about diabetes, Side effects, Cost of therapy, Family and social support, Frequency of follow-up.

Results: Metformin was the most prescribed drug (65%), followed by sulfonylureas (40%) and DPP-4 inhibitors (28%). Insulin was prescribed to 18% of patients, mostly in those with poor glycemic control or long-standing diabetes. Only 28.8% of patients demonstrated high adherence. A majority had moderate (39.2%) or low adherence (32.0%).

Conclusion: Metformin was the most commonly prescribed drug, with a high prevalence of combination therapies. However, only 28.8% of patients demonstrated high adherence, while factors such as polypharmacy, low literacy, and high drug costs contributed to poor compliance.

Keywords: Pharmacological Management, Adherence, Diabetic Patients.

Introduction

Diabetes mellitus (DM) is a chronic, metabolic disorder characterized by persistent hyperglycemia resulting from defects in insulin secretion, insulin action, or both. The global burden of diabetes has been rising steadily, with an estimated 537 million adults (20–79 years) living with diabetes in 2021—a figure expected to reach 643 million by 2030 and 783 million by 2045 according to the International Diabetes Federation (IDF) [1].

India, often referred to as the "diabetes capital of the world," had over 77 million diabetic patients in 2019, making it the second-largest country globally in terms of disease burden [2]. The management of diabetes involves a combination of lifestyle modification, glycemic monitoring, and pharmacological therapy. Pharmacological treatment is the cornerstone of glycemic control and includes oral hypoglycemic agents (OHAs), such as metformin, sulfonylureas, DPP-4 inhibitors, SGLT2 inhibitors, and injectable therapies such as insulin and GLP-1 receptor agonists [3].

Rational and evidence-based pharmacological management is essential for preventing microvascular and macrovascular complications associated with diabetes, including retinopathy, nephropathy, neuropathy, cardiovascular diseases, and stroke [4]. Despite the availability of various therapeutic options, achieving optimal glycemic control remains a major challenge in clinical

practice. One of the primary barriers to effective diabetes management is poor medication adherence, which is defined as the extent to which patients take medications as prescribed by their healthcare providers [5]. Non-adherence is a common issue among patients with chronic illnesses and is particularly prevalent in diabetes due to the need for long-term therapy, polypharmacy, adverse effects of medications, lack of patient education, economic constraints, and complex dosing regimens [6].

In India, the problem is further compounded by factors such as limited access to healthcare services, regional disparities in health literacy, cultural beliefs, and affordability issues. Studies conducted in various parts of India have demonstrated that adherence to anti-diabetic medication varies widely, with reported rates ranging from 30% to 80% [7]. In the northern region of India, particularly in tertiary care settings catering to both urban and rural populations, treatment adherence poses a significant challenge that adversely affects therapeutic outcomes and quality of life.

Moreover, irrational prescribing practices and inadequate implementation of standard treatment guidelines also affect drug utilization patterns among diabetic patients. Polypharmacy, overuse of branded medications, and preference for newer high-cost drugs without clear cost-benefit justification can contribute to treatment burden and poor adherence [8]. Drug utilization studies help in identifying prescribing trends, potential irrational drug use, and areas for intervention in clinical practice [9]. The World Health Organization (WHO) emphasizes the need for regular drug utilization evaluations and interventions to optimize pharmacotherapy and promote rational use of medicines [10]. Coupled with adherence studies, such evaluations provide a holistic understanding of real-world challenges in managing chronic diseases like diabetes in diverse settings, including tertiary care hospitals.

The North Indian healthcare landscape presents unique challenges. The region encompasses both developed urban centers and underserved rural areas. Tertiary care hospitals here act as referral centers and are burdened with high patient loads, especially for chronic conditions like diabetes. These hospitals are often the last point of contact for patients who have already failed to achieve glycemic control through primary or secondary care interventions. Hence, assessing both pharmacological management patterns and treatment adherence in these settings is critical for identifying systemic gaps and formulating evidence-based policy interventions.

In light of these considerations, the present study aims to evaluate the pharmacological management strategies and treatment adherence among diabetic patients in a tertiary care hospital in North India. This study will also explore factors influencing adherence and analyze the rationality and appropriateness of the prescribed drug regimens in accordance with current guidelines, such as those provided by the American Diabetes Association (ADA) and Indian Council of Medical Research (ICMR) [11][12].

Material & Methods

Study Setting: A cross-sectional, observational study was conducted to evaluate the pharmacological treatment patterns and challenges related to medication adherence among patients with Type 2 Diabetes Mellitus (T2DM). The study was carried out at the Outpatient Department (OPD) and Inpatient Department (IPD) of General Medicine in collaboration with department of pharmacology at a tertiary care teaching hospital located in North India. The hospital serves a diverse population, including urban, semi-urban, and rural patients. The data collection was carried out over a period of 6 months from January 2025 to June 2025.

Study Population: The study population comprised adult patients (aged ≥18 years) who were diagnosed with Type 2 Diabetes Mellitus and were either attending regular follow-up visits or admitted for diabetes-related complications. A total of 250 patients were included in the study. The sample size was estimated based on:

- An assumed adherence rate of 50%
- Confidence interval of 95%
- Margin of error of 6.2%

Sample size calculation was done using the formula for prevalence studies:

$n = Z^2 \times p \times (1-p)/d^2$

Where $Z = 1.96$, $p = 0.5$, and $d = 0.062$

Inclusion Criteria

- Patients aged 18 years or above.
- Diagnosed with Type 2 Diabetes Mellitus for at least 6 months.
- Receiving one or more pharmacological agents for diabetes management.
- Willing to provide written informed consent for participation.

Exclusion Criteria

- Patients with Type 1 Diabetes Mellitus **or** gestational diabetes**.**
- Critically ill or unconscious patients.
- Patients with known psychiatric illness or cognitive impairment.

Data Collection Tools

a) Structured Case Record Form (CRF):

Used to collect data on:

- Demographics (age, gender, socioeconomic status)
- Clinical details (duration of diabetes, comorbidities, complications)
- Current medications (drug names, dose, frequency, combination)
- Investigations, if available (HbA1c, fasting and postprandial glucose, renal function)

b) Medication Adherence Assessment Tool:

The Morisky Medication Adherence Scale (MMAS-8) was used to assess adherence.

MMAS-8 is an 8-item validated questionnaire that classifies adherence into:

- High adherence (score = 8)
- Moderate adherence (score = 6–7)
- Low adherence (score < 6)

c) Patient Interview:

Face-to-face interviews were conducted to assess factors influencing adherence such as:

- Awareness about diabetes
- Side effects
- Cost of therapy
- Family and social support
- Frequency of follow-up

Statistical Analysis: Data were compiled using Microsoft Excel and analyzed using SPSS version 22.0. Descriptive statistics (mean, standard deviation, percentages) were used for demographic and clinical data. Chi-square tests were applied to examine associations between adherence levels and variables like gender, education, number of drugs, and cost. A p-value < 0.05 was considered statistically significant.

Results

Demographic and Clinical Profile: Out of the 250 diabetic patients enrolled, the mean age was 56.4 ± 11.2 years, with male predominance (56%). A majority (60%) belonged to lower socioeconomic backgrounds, and 65% had diabetes for more than 5 years. Comorbidities included hypertension (30%), dyslipidemia (22%), and cardiovascular disease (15%).

Pharmacological Management Patterns: Metformin was the most prescribed drug (65%), followed by sulfonylureas (40%) and DPP-4 inhibitors (28%). Insulin was prescribed to 18% of patients, mostly in those with poor glycemic control or long-standing diabetes. FDCs involving metformin + sulfonylurea or metformin + DPP-4 inhibitors were frequently prescribed.

Table 1: Distribution of Antidiabetic Drug Classes Prescribed

Drug Class	Number of Patients	Percentage (%)
Metformin	163	65.2
Sulfonylureas	98	39.2
DPP-4 Inhibitors	71	28.4
Insulin	44	17.6
SGLT2 Inhibitors	19	7.6
Others	17	6.8

***Combination of drugs was also prescribed**

Table 2: Distribution of Antidiabetic Therapy Regimens

Regimen Type	Number of Patients	Percentage (%)
Monotherapy	90	36
Dual Therapy	110	44
Triple Therapy	50	20

Therapy Regimens: Analysis of therapeutic combinations revealed that dual therapy was the most common (44%), followed by monotherapy (36%), and triple therapy (20%). Monotherapy was generally prescribed for newly diagnosed patients, while dual or triple therapies were more common in patients with longer disease duration.

Table 3: Medication Adherence Levels Based on MMAS-8

Adherence Level	Number of Patients	Percentage (%)
High (MMAS ≥ 8)	72	28.8
Moderate (MMAS 6–7)	98	39.2
Low (MMAS < 6)	80	32.0

Medication Adherence: Adherence was assessed using the MMAS-8 scale. Only 28.8% of patients demonstrated high adherence. A majority had moderate (39.2%) or low adherence (32.0%).

Table 4: Factors Associated with Low Medication Adherence (n=80)

Factor	Number of Patients	Percentage (%)
Polypharmacy	50	62.5
Low Literacy	45	56.3
No Family Support	40	50.0
High Drug Cost	42	52.5
Side Effects	38	47.5

Factors Influencing Low Adherence: Low adherence (MMAS <6) was significantly associated with multiple behavioral, socioeconomic, and therapeutic factors. The most common contributor was polypharmacy (62.5%), followed by low literacy (56.3%) and high drug cost (52.5%).

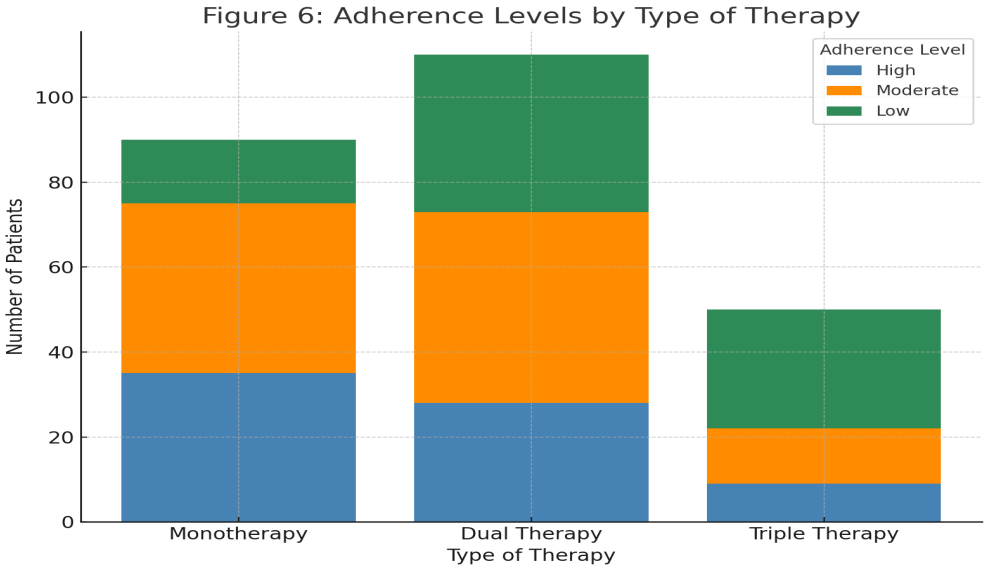

Figure 1:

Discussion

The present study aimed to evaluate the pharmacological management practices and treatment adherence among diabetic patients in a tertiary care hospital in North India. The findings of the study provide important insights into real-world prescribing trends, adherence behavior, and associated challenges faced by patients and healthcare providers in this region.

Pharmacological Management Patterns: In our study, metformin emerged as the most frequently prescribed oral hypoglycemic agent, consistent with national and international guidelines recommending it as the first-line treatment for Type 2 Diabetes Mellitus (T2DM) [13]. This finding aligns with prior Indian studies, such as the one by Dutta and Beg in 2021 which reported that metformin was included in nearly 80% of prescriptions across tertiary care hospitals [14]. Sulfonylureas, particularly glimepiride and gliclazide, were the second most common agents used, especially among patients with longstanding diabetes or inadequate glycemic control with monotherapy. Their widespread use is attributed to low cost, availability, and physician familiarity. However, it is important to note that sulfonylureas carry a higher risk of hypoglycemia, particularly in elderly patients, and should be prescribed judiciously [15]. The increasing prescription of DPP-4 inhibitors (e.g., sitagliptin, teneligliptin) observed in our study reflects a shift towards newer, more tolerable medications, albeit at a higher cost. Despite their favorable safety profile and cardiovascular neutrality, their use may not always be cost-effective in low-resource settings, unless justified by comorbid conditions or intolerance to older agents [16]. Insulin therapy was observed in approximately 15–20% of patients, mostly among those with uncontrolled diabetes, long disease duration, or complications. Initiating insulin remains a clinical challenge due to patient resistance, fear of injections, and need for regular monitoring. Studies such as Asche et al. (2011) have shown that delayed insulin initiation contributes to prolonged periods of poor glycemic control and worsened outcomes [17].

The use of fixed-dose combinations (FDCs), especially metformin with sulfonylureas or DPP-4 inhibitors, was prevalent in over half of the prescriptions. While FDCs improve convenience and potentially adherence, irrational or uncustomized use can complicate dose titration and obscure the contribution of individual agents to side effects or efficacy [18]. Rational prescribing based on individualized patient profiles is essential for optimizing outcomes.

Adherence to Therapy: Our study revealed that a significant proportion of patients demonstrated low to moderate adherence to antidiabetic therapy, as assessed using the MMAS-8 scale. These findings are consistent with previous Indian data, where adherence rates typically range from 40% to 70%, depending on the region and population characteristics [19]. Non-adherence is a multifactorial problem and was strongly associated in our study with polypharmacy, higher pill burden, low literacy levels, and financial constraints.

A particularly concerning finding was that many patients did not understand the purpose of each medication or the consequences of skipping doses. This reflects the lack of structured diabetes education and counseling, an issue highlighted in the WHO report on long-term therapy adherence [20]. Patients in rural and semi-urban areas, which constitute a significant share of our hospital's catchment area, often receive limited information about their disease and therapy.

In line with other studies, we observed better adherence among patients with family support, regular follow-up visits, and those who experienced symptomatic relief [21]. Conversely, side effects such as gastrointestinal upset (from metformin) or hypoglycemia (from sulfonylureas) were significant contributors to non-adherence, underscoring the importance of early side effect management and patient communication.

Impact of Socioeconomic and Demographic Factors: Socioeconomic status played a pivotal role in both drug selection and adherence behavior. Lower-income groups were more likely to be prescribed older and cheaper agents (metformin, sulfonylureas) and also showed higher rates of therapy discontinuation or dose skipping due to cost. The economic burden of diabetes, as highlighted in a study by Kumpatla et al. (2013), remains a major barrier to long-term disease control in India [22]. Educational level and age were also significant predictors. Elderly patients, especially those living alone or with limited health literacy, exhibited poorer adherence. Younger patients with professional backgrounds showed better adherence, possibly due to better disease awareness and access to resources.

Guideline Adherence and Rationality: An analysis of prescription rationality in this study revealed that while a majority of prescriptions followed ADA/ICMR guidelines in terms of drug class selection and initiation sequence, dose titration and patient-specific customizations were often lacking. For example, many overweight patients were prescribed sulfonylureas despite weight gain being a known adverse effect. Similarly, renal function was not consistently documented before prescribing metformin or SGLT2 inhibitors. This raises concerns about limited use of risk stratification tools and individualized therapeutic planning in routine practice. Adherence to updated clinical guidelines, routine use of laboratory investigations (e.g., HbA1c, eGFR), and involvement of clinical pharmacists can substantially improve therapeutic outcomes.

Recommendations

The findings of this study suggest a pressing need for multifaceted interventions to improve pharmacological management and adherence in diabetic patients. These could include:

- Patient education programs to increase awareness about diabetes and the importance of adherence.
- Medication counseling sessions delivered by clinical pharmacists or diabetes educators.
- Development of adherence-support tools such as reminder charts, SMS alerts, or mobile apps, especially in urban populations.
- Subsidized drug programs or public-private partnerships to make newer antidiabetic agents more accessible.
- Incorporation of structured treatment algorithms and monitoring tools into clinical workflows to ensure rational drug use.

Strengths and Limitations: One strength of our study lies in its setting—a tertiary care hospital catering to both urban and rural populations, which allowed for broad representation of demographic and clinical diversity. Additionally, the use of a validated adherence scale (MMAS-8) adds credibility to the adherence analysis.

However, the study is limited by its cross-sectional design, which precludes causal inference. Self-reported adherence may also be influenced by recall or social desirability bias. Furthermore, clinical outcome data such as HbA1c levels were not consistently available, which limits the correlation of adherence with glycemic control.

Conclusion

This study highlights significant gaps in the pharmacological management and medication adherence among diabetic patients in a tertiary care hospital in North India. Metformin was the most commonly prescribed drug, with a high prevalence of combination therapies. However, only 28.8% of patients demonstrated high adherence, while factors

such as polypharmacy, low literacy, and high drug costs contributed to poor compliance. Patients on simpler regimens had better adherence.

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