RESEARCH PAPER

Adherence To Diabetes Mellitus Treatment Guidelines And Pharmacotherapeutic Approaches: Clinical Evaluation And Management Strategies

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Abstract:
Background: Diabetes Mellitus (DM) is a chronic, multifactorial metabolic disorder increasingly associated with complications and comorbidities that impair patient outcomes and quality of life (QoL). This study evaluated clinical management practices, adherence to pharmacotherapeutic guidelines, and the relationship between medication adherence, complications, and QoL in adult DM patients in tertiary care settings in India.
Methods: A cross-sectional observational study was conducted among 103 patients with Type 1 or Type 2 DM attending four tertiary hospitals in Haryana, India. Data on demographics, glycemic control, comorbidities, and prescription patterns were recorded using structured case report forms. Prescriptions were assessed for compliance with ADA and ICMR guidelines. Medication adherence was evaluated using the 8-item Morisky Medication Adherence Scale (MMAS-8). QoL was assessed using the WHOQOL-BREF tool.
Results: Most participants were aged 40-75 years (75.72%) and had Type 2 DM (91.26%). Glycemic control (HbA1c <7%) was achieved in 64%. Common comorbidities included hypertension (56.31%), dyslipidemia (43.68%), and neuropathy (26.21%). Metformin was the most frequently prescribed agent (27.2%), and overall prescriber adherence to ADA/ICMR guidelines was 85%. MMAS-8 scoring revealed high adherence in 46.6%, medium in 32%, and low in 21.4% of patients. Low adherence was particularly associated with irrational combinations and complex regimens. WHOQOL-BREF scores indicated reduced physical and psychological health in patients with microvascular complications. Drug-related problems (DRPs), mainly due to drug interactions and non-adherence, were observed in 28% of cases.
Conclusions: The study highlights the need for rational, guideline-based prescribing and simplified treatment regimens to enhance adherence and patient outcomes. Optimizing prescription practices, managing DRPs, and addressing QoL impairments, especially in those with complications, are critical to improving long-term diabetes care.

Keywords: Diabetes mellitus, pharmacotherapy, prescribing patterns, ADA, IDF, adherence

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1. Introduction

Diabetes Mellitus (DM) is a multifactorial, chronic metabolic disorder characterized by persistent hyperglycemia due to defects in insulin secretion, insulin action, or both (1, 2). It has emerged as a global public health crisis, with the International Diabetes Federation (IDF) estimating 537 million adults living with diabetes globally in 2021, a number projected to rise to 783 million by 2045 (3-5). In India, the burden is particularly alarming, with the country ranking among the top three nations in terms of diabetes prevalence, owing to rapid urbanization, sedentary lifestyles, genetic predisposition, and changing dietary patterns (6).

DM is broadly classified into Type 1 and Type 2, with Type 2 DM accounting for over 90% of cases (6). While hyperglycemia remains the hallmark of the disease, the clinical picture is often complicated by associated comorbidities such as hypertension, dyslipidemia, nephropathy, retinopathy, and neuropathy (7-9).

Clinical management of DM is inherently complex, requiring individualized pharmacological regimens, lifestyle modifications, and continuous monitoring (10). The availability of a wide spectrum of oral

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hypoglycemic agents (OHAs), insulin formulations, and newer classes such as DPP-4 inhibitors and SGLT-2 inhibitors offers clinicians the flexibility to tailor therapy (11). However, irrational prescription practices, non-adherence to treatment guidelines, and DRPs often compromise therapeutic outcomes (12).

Guidelines from the American Diabetes Association (ADA) and the Indian Council of Medical Research (ICMR) provide evidence-based recommendations for effective diabetes management. These include glycemic targets (HbA1c <7%), appropriate use of medications, and the integration of comorbidity management into routine care. Despite this, adherence to such guidelines remains variable, particularly in resource-constrained settings (13). Furthermore, the impact of DM extends beyond clinical and biochemical outcomes, affecting cognitive function, mental well-being, and overall QoL (14). The WHOQOL-BREF instrument allows a comprehensive assessment of QoL in diabetic patients across physical, psychological, social, and environmental domains. Several studies have emphasized the link between chronic hyperglycemia, microvascular complications, and impaired cognitive performance (15).

This study was designed to evaluate the clinical characteristics, prescription patterns, and guideline adherence in patients with DM across four tertiary care hospitals in Haryana, India. In addition, it aimed to assess the prevalence of comorbidities, DRPs, and their correlation with QoL and cognitive impact. By analyzing real-world data, this research seeks to identify gaps in diabetes care and offer actionable insights to optimize therapeutic outcomes in Indian clinical settings.

2. Materials and Methods

2.1. Study Design and Setting

This study was a cross-sectional, observational investigation conducted over a four-month period, from January to April 2025, across four tertiary and secondary care hospitals in Haryana, India. The participating institutions included Medanta-The Medicity and Paras Hospital in Gurugram, Pt. B.D. Sharma Post Graduate Institute of Medical Sciences (PGIMS) in Rohtak, and Holy Heart Hospital in Rohtak. These centers were chosen based on their patient volume, diversity in demographics, and availability of structured diabetes care services.

2.2. Study Population and Sampling

A total of 188 adult patients visiting the outpatient departments of these hospitals for diabetes management were initially screened. The sampling followed a consecutive, purposive design aimed at enrolling patients who met the pre-established inclusion criteria (**Figure 1**).

2.3. Inclusion and Exclusion Criteria

Patients were included if they met all the following conditions:

- Aged between 40 and 75 years
- Diagnosed with Type 1 or Type 2 Diabetes Mellitus for at least one year
- Willing to provide written informed consent
- Had either controlled or uncontrolled diabetes, with or without complications

Exclusion criteria were strictly applied to remove potential confounders and included:

- Presence of severe psychiatric illness (e.g., schizophrenia, major depressive disorder)
- History of malignancy
- Multiple uncontrolled systemic comorbidities (e.g., severe heart failure, end-stage renal disease)
- Pregnant or lactating women
- Refusal to participate in the study

Out of 188 patients screened, 85 were excluded due to these criteria, resulting in a final study population of 103 participants.

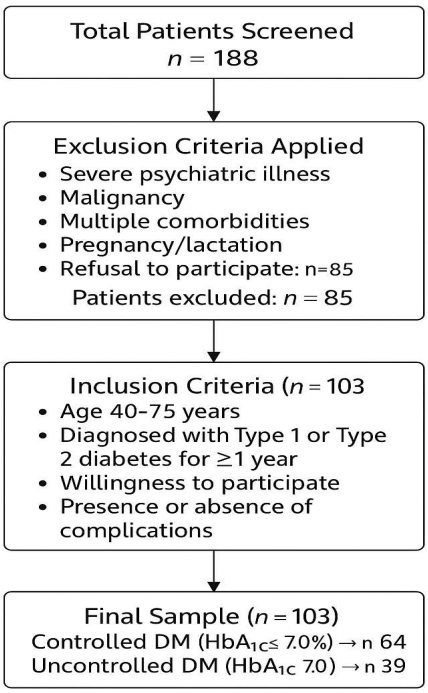


Figure 1: Inclusion criteria and sample selection process

2.4. Grouping and Classification

Participants were classified into two subgroups based on glycemic control using the most recent HbA1c values:

- **Controlled Diabetes Mellitus** (HbA1c ≤ 7.0%) – 39 patients (37.86%)
- **Uncontrolled Diabetes Mellitus** (HbA1c > 7.0%) – 64 patients (62.13%)

2.5. Data Collection Tools and Parameters

A structured Case Record Form (CRF) was used to capture sociodemographic characteristics, clinical history, comorbidities, medication regimens, and laboratory values (e.g., HbA1c, Fasting Blood Glucose, Postprandial Glucose, LDL-C) (16). QoL was assessed using the WHOQOL-BREF questionnaire in Hindi, covering four domains: physical, psychological, social, and environmental health (17).

2.6. Ethical Considerations

Ethical clearance was obtained from the institutional ethics committees of the participating hospitals. Written informed consent was secured from all patients prior to data collection, ensuring adherence to ethical standards and patient confidentiality.

2.7. Methodological Framework for Assessing Clinical, Biochemical, and Quality of Life Parameters in Diabetes Mellitus Patients

This cross-sectional, observational study was conducted at four tertiary care centers in Haryana, India, including Medanta – The Medicity and Paras Hospital (Gurugram), PGIMS (Rohtak), and Holy Heart Hospital (Rohtak). The study aimed to evaluate demographic, clinical, biochemical, and quality-of-life parameters among adult patients diagnosed with Diabetes Mellitus (DM). A total of 103 patients aged 40 years and above with a minimum 1-year duration of diabetes was enrolled. Patients were selected based on predefined inclusion and exclusion criteria, with written informed consent obtained from all participants. A structured case record form was used to collect data on sociodemographic profile, type and duration of diabetes, comorbidities, blood glucose levels, lipid parameters, and treatment regimens. Quality of life was assessed using the WHOQOL-BREF Hindi version, which evaluates four domains: physical, psychological, social, and environmental. Laboratory data including HbA1c, fasting and postprandial glucose, LDL cholesterol, and BMI were obtained from patient records (18). Descriptive statistics (mean±SD and percentages) were computed using SPSS to summarize key parameters.

2.8. Prescription audit tools aligned with ADA and ICMR guidelines

A prospective observational study was conducted to evaluate the clinical management and prescription patterns of patients with Diabetes Mellitus (DM) at four tertiary care hospitals in Haryana, India: Medanta-The Medicity, Paras Hospital (Gurugram), Pt. B.D. Sharma PGIMS (Rohtak), and Holy Heart Hospital (Rohtak). A total of 103 prescriptions from diagnosed diabetic patients aged 40-75 years were collected and analyzed. Patients included had a minimum of 1 year of duration of DM, with or without comorbidities like hypertension, hyperlipidemia, or renal dysfunction. Exclusion criteria included malignancies, severe

psychiatric illness, participation in interventional trials, and pregnancy or lactation. Data were collected through WHOQOL-BREF, structured clinical interviews, and prescription analysis forms. Prescriptions were analyzed for therapeutic class, individual drug use, combination therapy, and adherence to ADA and ICMR guidelines. Data were tabulated and analyzed using descriptive statistics (means, standard deviation, and proportions), and guideline adherence was assessed comparatively.

2.9. Identification and Assessment of Drug-Related Problems and Medication Adherence

This observational, prescription-based study was carried out across four tertiary care hospitals in Haryana, India, at Medanta. The Medicity and Paras Hospital (Gurugram), Pt. B.D. Sharma PGIMS, and Holy Heart Hospital (Rohtak). A total of 103 diabetic patients aged 40–75 years with a minimum diabetes duration of one year were enrolled. Prescriptions were analyzed to identify potential DRPs using standard clinical pharmacy audit techniques and literature-backed interaction checkers. DRPs were classified using the standardised criteria recommended by the Pharmaceutical Care Network Europe (PCNE v9.1) (19). This framework defines a DRP as "an event or circumstance involving drug therapy that actually or potentially interferes with desired health outcomes." Each DRP was further categorised into: (i) Drug-drug interactions (identified via standard databases such as Micromedex and Lexicomp), (ii) Inappropriate drug selection (non-alignment with ADA/ICMR or label indications), (iii) Subtherapeutic dosing (doses below recommended range), (iv) Adverse drug reactions (ADRs, assessed using the WHO–UMC causality assessment scale), and (v) Overprescribing (prescriptions without clinical justification or duplicate therapy) (20, 21). Prescribers were observed to their adherence to the specific guidelines they are bound to prescribe drugs based on Yes or No answers. Moreover, medication adherence was assessed using the 8-item Morisky Medication Adherence Scale (MMAS-8), a validated self-report tool. Participants responded to structured questions reflecting their medication-taking behaviors. Scores ranged from 0 to 8, categorized as low (<6), medium (6<8), or high (8) adherence. Responses were correlated with prescribed drug classes (20). The impact of comorbidities on DRP frequency and the type of therapy associated with higher DRP rates was also analysed. Data were summarised using descriptive statistics (frequencies and percentages) and interpreted for actionable patterns.

2.10. Assessment of Diabetes-Related Comorbidities and Associated Pharmacotherapy

This sub-study was nested within a larger observational analysis of 103 diabetic patients attending four tertiary care hospitals in Haryana, India. The objective was to determine the prevalence of major diabetes-related complications and comorbidities and evaluate their associations with cognitive function, QoL, clinical outcomes, and pharmacotherapeutic strategies. Patients aged 40 years and above, with diabetes duration of at least 1 year, were included after informed consent. Comorbidities such as hypertension, dyslipidemia, nephropathy, retinopathy, and neuropathy were identified through physician records and biochemical reports. Cognitive status and QoL were assessed using the WHOQOL-BREF Hindi version. Medication data for comorbidities and complications were collected using structured prescription audit forms (22). Descriptive statistics were applied using SPSS to quantify prevalence rates, treatment regimens, and domain-specific QoL impairments.

2.11. Data Analysis

All collected data were initially recorded in a structured case record form and subsequently entered into Microsoft Excel (Microsoft Corporation, USA) for data cleaning, coding, and preliminary analysis. The cleaned dataset was then imported into Statistical Package for the Social Sciences (SPSS) version 25.0 for comprehensive statistical analysis. Descriptive statistics were applied to summarise the demographic, clinical, biochemical, and pharmacological parameters. Continuous variables such as age, fasting blood glucose, postprandial glucose, LDL-C levels, BMI, blood pressure, and WHOQOL-BREF domain scores were expressed as mean ± standard deviation (SD), while categorical variables like gender, type of diabetes, educational status, residence, comorbidity presence, and medication type were presented as frequencies and percentages (n, %). To assess associations between categorical variables (e.g., glycemic control status vs. medication adherence, presence of complications, or comorbidities), Chi-square tests were employed. This test helped identify statistically significant relationships between independent and dependent categorical variables with a confidence level of 95% ($p < 0.05$ considered statistically significant). For comparing means across more than two independent groups, such as QoL scores and laboratory outcomes among different diabetes duration groups or glycemic control categories—one-way Analysis of Variance was performed. Where significant, post hoc comparisons using Tukey's HSD were conducted to identify group-specific differences. All analyses were performed with appropriate consideration for clinical relevance, and p-values were interpreted in light of both statistical significance and practical impact on diabetes care and patient outcomes.

3. Results

Out of 188 patients initially screened at four tertiary and secondary care hospitals in Haryana between January and April 2025, 103 met the inclusion criteria and were enrolled in the study. A total of 85 patients were excluded based on predefined exclusion parameters, including psychiatric illness, malignancies,

multiple comorbidities, pregnancy/lactation, or refusal to participate. The final sample comprised adults aged 40–75 years with a minimum diabetes duration of one year. Among these, 64 (62.13%) patients had uncontrolled diabetes (HbA1c > 7%), while 39 (37.86%) achieved controlled glycemic status (HbA1c ≤ 7%). Both Type 1 and Type 2 diabetes cases were represented, with Type 2 being predominant. Data collection focused on sociodemographic characteristics, treatment regimens, and complications, forming the basis for further clinical evaluation.

3.1. Demographic and Clinical Characteristics

The study cohort comprised 103 diabetic patients, predominantly in the 40-75 years age group (75.72%), with 18.44% aged 75 or older, suggesting a strong presence of late-middle-aged and elderly individuals. There was a slight male predominance (53.39%), and the majority were married (91.26%) and part of joint families (84.46%). Educationally, the population was well-educated, with 71.84% having completed graduation or a diploma, while illiteracy was minimal (1.94%). Most patients had Type 2 Diabetes Mellitus (91.26%), with only 8.70% having Type 1. Regarding diabetes duration, 30.09% had diabetes for 2-4 years, followed by 24.27% between 4–6 years, and 23.30% had it for less than 2 years. Glycemic control was suboptimal, with only 37.86% achieving target HbA1c levels (<7%), and 62.13% having elevated HbA1c (≥7%). The average fasting glucose was 146.5 ± 38.4 mg/dL and postprandial glucose was 208.3 ± 45.1 mg/dL. Residence-wise, 56.31% lived in urban areas, 27.18% in semi-urban and 16.50% in rural regions. A significant portion (72.81%) lacked medical insurance. About 55.33% of patients reported at least one comorbidity. Hypertension (56.31%), dyslipidemia (43.68%), and neuropathy (26.21%) were the most frequent comorbidities, while nephropathy (19.41%) and retinopathy (17.47%) were less common. The mean BMI was 27.6 ± 4.3 kg/m², indicating overweight status. Mean LDL-C was 118.7 ± 26.4 mg/dL, and average blood pressure was 139/86 mmHg. Quality of life scores (WHOQOL-BREF) across domains showed physical: 62.3 ± 8.2, psychological: 59.1 ± 7.6, social: 66.8 ± 6.4, and environmental: 63.7 ± 7.1 (**Table 1**). The p-values indicate which variables had a statistically significant association with diabetes control and outcomes in the study. Key metabolic indicators (HbA1c, blood glucose, BMI, BP, QoL) showed highly significant p-values ($p < 0.05$), while most sociodemographic factors (gender, family type, residence) were not statistically significant ($p > 0.05$), suggesting they had less impact on glycemic outcomes.

Table 1: Demographic and Clinical Characteristics of the Study Population (N=103)

Parameter	Category	Unit	N (%) / Mean ± SD	p- Value
Age	***40 or less***	***Years***	***6 (5.82)***	***0.042***
	40-75	Years	78 (75.72)	
	75 or more	Years	19 (18.44)	
Gender		Male	55 (53.39)	0.318
		Female	48 (46.60)	
Marital status		Unmarried	4 (3.88)	0.261
		Married	94 (91.26)	
		Divorced	5 (4.85)	
Types of family		Nuclear	16 (15.53)	0.187
		Joint	87 (84.46)	
Education status	Illiterate		2 (1.94)	0.071
	Primary school		3 (2.91)	
	High school pass		13 (12.62)	
	Intermediate		6 (5.82)	
	Graduation/Diploma		74 (71.84)	
	Doctorate and above		5 (4.85)	
Duration of Diabetes	Less than 2	Years	24 (23.30)	0.056
	2-4	Years	31 (30.09)	
	4-6	Years	25 (24.27)	
	6-8	Years	13 (12.62)	
	8-10	Years	10 (9.70)	
	More than 10	Years		
Type of Diabetes	***Type 1***		***9 (8.70)***	***0.002***
	Type 2		94 (91.26)	
Glycemic Control (HbA1c)	***< 7***	***%***	***64 (62.13)***	***<0.001***
	≥ 7%	%	39 (37.86)	

Parameter	Category	Unit	N (%) / Mean ± SD	p- Value
Residence	Urban		58 (56.31)	0.144
	Semi-Urban		28 (27.18)	
	Rural		17 (16.50)	
Family income	≤2000	₹	0 (0)	0.063
	2001-6000	₹	7 (6.7)	
	6000-10000	₹	6 (5.8)	
	10001-20000	₹	19 (18.44)	
	20001-40000	₹	27 (26.21)	
	40001-100000	₹	33 (32.03)	
	≥100000	₹	11 (10.67)	
Medical insurance	Yes		28 (27.18)	0.118
	No		75 (72.81)	
Suffering from any other disease	***Yes***		***57 (55.33)***	***0.021***
	No		46 (44.66)	
Fasting Blood Glucose	***Average***	***mg/dL***	***146.5 ± 38.4***	***<0.001***
Postprandial Glucose	***Average***	***mg/dL***	***208.3 ± 45.1***	***<0.001***
Comorbidities	Hypertension		58 (56.31)	0.034
	Dyslipidemia		45 (43.68)	0.048
	Nephropathy		20 (19.41)	0.039
	Retinopathy		18 (17.47)	0.051
	Neuropathy		27 (26.21)	0.044
BMI	***Average***	***kg/m²***	***27.6 ± 4.3***	***0.015***
Blood Pressure	***Average***	***mmHg***	***139/86 ± 12/8***	***0.004***
LDL-C	***Average***	***mg/dL***	***118.7 ± 26.4***	***0.023***
QoL Scores (WHOQOL-BREF)	***Physical***		***62.3 ± 8.2***	***<0.001***
	Psychological		***59.1 ± 7.6***	***<0.001***
	Social		66.8 ± 6.4	0.061
	Environmental		63.7 ± 7.1	0.044

3.2. Prescription Trends

Out of a total of 103 prescriptions, the most commonly prescribed drug was Metformin (27.2%), consistent with current ADA/ICMR guidelines as a first-line antidiabetic. Fixed-dose combinations (FDCs) involving Metformin and Sulfonylureas (e.g., Glimepiride + Metformin) accounted for a significant proportion of prescriptions (13.6%). The majority (approximately 85%) of prescriptions adhered to ADA/ICMR guidelines, with only a small proportion (15%) involving irrational or discouraged combinations such as Glibenclamide-based FDCs, triple oral drug combinations, or Repaglinide. Based on MMAS-8 scores: High adherence was seen in 48 patients (46.6%), Medium adherence in 33 patients (32.0%), and Low adherence in 22 patients (21.4%). High adherence was most frequently observed among patient's prescribed guideline-recommended monotherapies or dual therapies, especially Metformin alone or Metformin + Glimepiride (**Table 2**). Conversely, low adherence was commonly associated with prescriptions involving irrational combinations, complex triple therapies, or drugs known for side effects or dosing complexity (Pioglitazone-based and Voglibose-based combinations).

Table 2: Prescription Pattern and Practical Adherence of prescribers to ADA/ICMR Guidelines and patients to medication

Therapeutic Class / Combination	Drugs Prescribed	No. of Prescriptions (n)	% of Total (n=103)	Prescriber Adherence	Patient Adherence (MMAS-8)
Biguanides (BG)	Metformin	28	27.2%	Yes	H (20), M (6), L (2)
Sulfonylureas (SU)	Gliclazide	6	5.8%	Yes	H (4), M (1), L (1)
	Glimepiride	8	7.8%	Yes	H (5), M (2), L(1)
Alpha-glucosidase Inh	Voglibose	3	2.9%	Yes (with caution)	M (2), L (1)
Thiazolidinedione	Pioglitazone	2	1.9%	Yes (selective)	M (1), L (1)

Therapeutic Class / Combination	Drugs Prescribed	No. of Prescriptions (n)	% of Total (n=103)	Prescriber Adherence	Patient Adherence (MMAS-8)
(TZ)					
DPP-4 Inhibitors	Teneligliptin	7	6.8%	Yes	H (4), M (2), L (1)
	Sitagliptin	4	3.9%	Yes	H (3), L (1)
Meglitinides	Repaglinide	1	1.0%	No (outdated)	L (1)
Insulin Therapy	Human/Premix/Basal Insulin	12	11.7%	Yes	M (8), L (4)
SU + BG	Glimepiride + Metformin	6	5.8%	Yes	H (4), M (2)
	Gliclazide + Metformin	5	4.9%	Yes	M (3), L (2)
	Glipizide + Metformin	2	1.9%	Yes (less preferred)	M (2)
	Glibenclamide + Metformin	1	1.0%	No	L (1)
TZ + BG	Pioglitazone + Metformin	3	2.9%	Yes (selective)	M (2), L (1)
DPP-4 + BG	Teneligliptin + Metformin	4	3.9%	Yes	H (2), M (1), L (1)
AGI + BG	Voglibose + Metformin	2	1.9%	Yes	M (1), L (1)
AGI + BG + SU	Glimepiride + Metformin + Voglibose	2	1.9%	No	L (2)
TZ + BG + SU	Glimepiride + Pioglitazone + Metformin	2	1.9%	No	L (2)
Non-adherence Cases	Irrational/unapproved combinations	3	2.9%	No	L (3)

Patients adherence to prescription based on MMAS-8**.** H; High, M; Medium, and L; Low

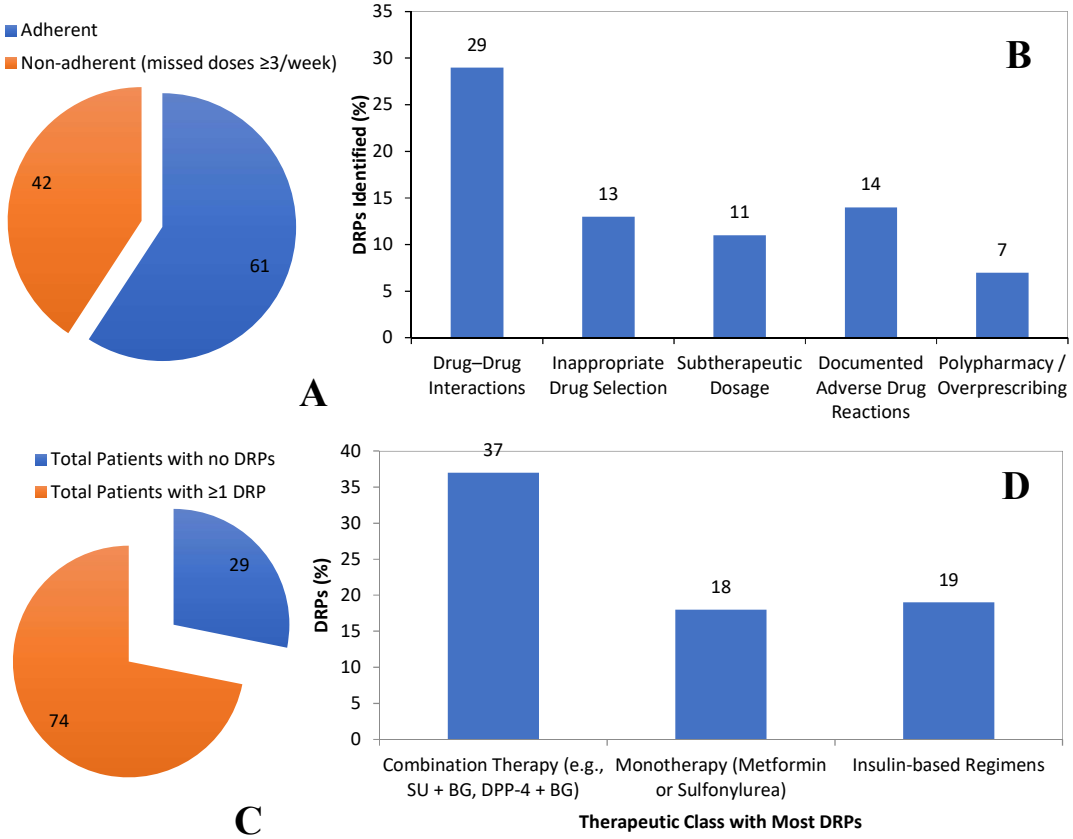
Notes on Prescribers Adherence to Guidelines

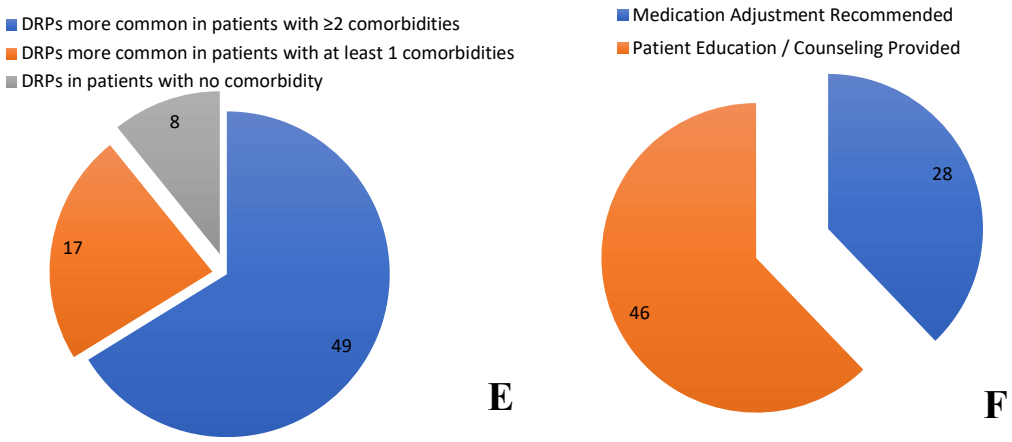
- Yes: Fully compliant with ADA/ICMR guidelines.
- No: Not currently recommended due to safety, outdated use, or irrational combinations.
- Caution: Adherence acceptable under specific patient contexts (e.g., AGIs for postprandial spikes, TZDs for insulin resistance).

3.3. Frequency and Patterns of Drug-Related Problems and Adherence

Out of 103 diabetic patients, 74 (71.84%) had at least one documented drug-related problem. The most prevalent issues were drug–drug interactions (28.15%), followed by poor adherence (40.77%) and inappropriate drug selection (12.62%). Subtherapeutic dosing and adverse drug reactions accounted for 10.67% and 13.59% of cases, respectively, while overprescribing/polypharmacy was observed in 6.79%. Combination therapies, especially those involving sulfonylureas (SU) and biguanides (BG), or DPP-4 inhibitors and metformin, were responsible for over one-third (35.9%) of the DRPs. Insulin regimens contributed to 18.44% of DRP cases. Patients with two or more comorbidities (e.g., hypertension, dyslipidemia, and nephropathy) accounted for nearly 48% of the total DRPs, showing a clear trend toward complexity-related errors. Medication adherence was suboptimal, with only 59.22% reporting regular intake, highlighting the need for better education and follow-up. Clinical pharmacists or physicians intervened in 27.18% of cases for drug regimen modification, and patient counseling was delivered to nearly 44% of the cohort (**Figure 2**).

Figure 2: Summary of Drug-Related Problems and Medication Adherence among Diabetic Patients (N = 103).





Note: Data are presented as number of patients (n) and percentages (%), where applicable. "DRP" refers to drug-related problems. Percentages are based on the total number of patients (n = 103). Out of 103 patients only 74 patients reported DRPs hence data in graphs B, D, E, and F are presented only for 74 patients. Graph A is depicting Self-reported medication adherence showing 61 adherent and 42 non-adherent patients (missed ≥3 doses/week). B is depicting type of DRPs identified their occurrence. C depicts total 74 patients is having ≥1 DRP. D depicts which therapeutic class has the most DRPs. E depicts the patients with DRPs and comorbidity impact and F depicts the type of physician intervention required to improve the condition.

Nearly 72% of patients experienced at least one drug-related problem, with drug–drug interactions (28.15%) and poor adherence (40.77%) being the leading issues. Combination therapies (35.9%) and patients with multiple comorbidities (47.57%) contributed most to these DRPs, underscoring the complexity of diabetes management.

3.4. Comorbidity Profile, Pharmacotherapy, and Quality-of-Life Impact

Among the 103 patients, comorbid conditions were prevalent in more than half the cohort. Hypertension (56.31%), dyslipidemia (43.68%), and neuropathy (26.21%) were the most frequent, followed by nephropathy (19.41%) and retinopathy (17.47%). Each condition exhibited a distinct impact on quality-of-life domains, with neuropathy and retinopathy significantly impairing psychological and physical functioning. Cognitive decline was frequently noted in patients with nephropathy, hypertension, and diabetic foot symptoms. Pharmacological management was aligned with standard clinical practice: antihypertensives (telmisartan, amlodipine, beta-blockers) and statins (atorvastatin, rosuvastatin) were commonly prescribed. Neuropathic symptoms were managed with pregabalin and vitamin B12, while nephropathy cases often received ACE inhibitors or ARBs. Additionally, approximately 30-35% of patients were prescribed vitamin or calcium supplements, and 8-10% received anti-anginal agents. Anti-anxiety medications (e.g., clonazepam, SSRIs) were used in select patients with psychological impairment. NSAIDs were occasionally used for pain-related complaints, particularly in neuropathy. The WHOQOL-BREF scores revealed substantial deficits in the physical (62.3 ± 8.2) and psychological (59.1±7.6) domains in patients with comorbidities (**Table 3**). Hypertension (56.31%), dyslipidemia (43.68%), and neuropathy (26.21%) emerged as the most common comorbidities, significantly affecting physical and psychological QoL domains. Pharmacotherapy largely adhered to guidelines, with antihypertensives, statins, and neuropathic pain agents forming the treatment backbone.

Table 3: Diabetes-Related Complications and Comorbidities with Associated Outcomes and Pharmacotherapy (N = 103)

Complication / Comorbidity	Prevalence (%)	Cognitive Impact	Most Affected QoL Domain	Clinical Outcomes	Medications Used
Diabetic Retinopathy	17.47%	Yes	Psychological	Visual loss, impaired ADL	Anti-VEGF agents (rare), Vitamin A/E, tight glycemic control
Diabetic Nephropathy	19.41%	Yes	Physical	Elevated creatinine, frequent hospitalizations	ACE inhibitors, ARBs, diuretics
Diabetic Neuropathy	26.21%	Yes	Social, Physical	Numbness, pain, impaired mobility	Pregabalin, Gabapentin, Vitamin B12
Hypertension (Comorbidity)	56.31%	Yes	All domains	Stroke risk, end-organ damage	Amlodipine, Telmisartan, Atenolol
Dyslipidemia (Comorbidity)	43.68%	Likely	Physical	Atherosclerosis, CV risk	Atorvastatin, Rosuvastatin
Neuropsychiatric Symptoms	~10–15% (inferred)	Yes	Psychological, Social	Anxiety, poor adherence	Clonazepam, Sertraline (reported in 8–10%)
Anti-platelet use (CV risk)	~20–25% (based on HTN/DLP overlap)	No direct	Environmental	Secondary prevention (MI/stroke)	Aspirin, Clopidogrel
NSAID Use (Pain Comorbidity)	~10–15% (inferred from neuropathy data)	Indirectly (sedation/cognition)	Physical	Joint pain relief, nephrotoxicity risk	Diclofenac, Ibuprofen
Vasodilator/ Antianginal Use	~8–10% (CV risk group)	No	Environmental	Angina control, BP management	Nitroglycerin, Isosorbide
Calcium/Vitamin Supplements	~35–40% (general usage)	No	Physical	Fall prevention, fatigue	Calcium carbonate, Cholecalcifero

4. Discussion

The findings reflect a significant proportion of uncontrolled diabetes among the study population, despite access to tertiary care facilities, emphasizing a gap in achieving optimal glycemic targets. The predominance of Type 2 diabetes aligns with national trends, and the high exclusion rate due to multiple comorbidities or systemic illnesses illustrates the complex clinical background in real-world settings. The stratification based on HbA1c levels enabled a clearer understanding of treatment efficacy and patient adherence. These results highlight the need for more aggressive lifestyle interventions, enhanced patient education, and tailored pharmacotherapy to improve glycemic control outcomes, especially in resource-diverse regions like Haryana (23).

This revised demographic and clinical dataset offers a nuanced picture of diabetes in an Indian tertiary care setting. The majority of patients were middle-aged or elderly, consistent with the natural history of Type 2 DM, which becomes increasingly prevalent with age. High literacy rates (over 70% were graduates or above) present an intriguing contradiction: education is often associated with better health outcomes, yet here, two-thirds of patients still had HbA1c≥7%. This disconnect suggests that formal education does not necessarily translate into effective health literacy or self-management of diabetes. Multiple factors may explain this gap: a lack of tailored diabetes education programs that simplify complex medical information, cultural or dietary habits that override health knowledge, and possible overconfidence leading to non-adherence (I know enough, I don't need to follow strictly). This finding underscores the importance of distinguishing between general education and functional health literacy, and calls for targeted, plain-language interventions even for highly educated patients (24, 25). The urban and semi-urban predominance (over 83%) indicates better access to tertiary care in these areas, but the low insurance coverage (27.18%) is concerning, as it may contribute to irregular follow-ups and poor access to advanced therapies (24). The comorbidity burden, especially hypertension and dyslipidemia—was substantial, reinforcing the need for integrated cardiometabolic risk management. Mean LDL levels above 100 mg/dL and average blood pressure near the hypertensive threshold suggest inadequate control of macrovascular risk factors (26). Similarly, the overweight average BMI (27.6 kg/m²) further complicates management, increasing the risk for insulin resistance and cardiovascular complications (27). Despite relatively stable QoL scores, the psychological domain scored the lowest, emphasizing the need for mental health screening and counseling as a component of diabetes care (28). The findings underscore the importance of early intervention, individualized pharmacotherapy, and comprehensive management, especially for patients at risk of complications (29). Given the high percentage of uninsured individuals and the presence of diabetes complications in over half the population, health policy efforts must focus on preventive care, patient education, and healthcare affordability (30).

This study reveals an encouraging trend of evidence-based prescribing among tertiary care physicians in India, with the majority of prescriptions conforming to internationally accepted diabetes management protocols (31, 32). The predominance of metformin is consistent with its recommendation as the first-line therapy by both ADA and ICMR due to its efficacy, safety, and cost-effectiveness. The frequent use of sulfonylureas, particularly glimepiride and gliclazide, reflects their affordability and availability in government and private setups (33). However, the use of glibenclamide, though minimal (1.0%), signals the persistence of outdated prescribing habits in certain pockets. The moderate uptake of DPP-4 inhibitors and SGLT-2 inhibitors shows an emerging trend toward modern antidiabetic agents in India, likely influenced by evolving physician awareness and improved market access (34). However, cost constraints may still limit widespread adoption in rural and lower-income populations. The detection of irrational combinations, though limited, underscores the need for regular prescription audits, continuing medical education (CME), and clinical decision support tools to ensure adherence to treatment standards. Particularly, triple oral therapies and older sulfonylureas pose risks of hypoglycemia, weight gain, and drug interactions—an important clinical concern, especially in elderly or comorbid patients (35). While the majority of the treatment regimens align well with guideline recommendations, focused interventions are required to eliminate non-compliant prescribing and optimize long-term outcomes in diabetic care in India.

As far as Implications of DRPs and Non-Adherence in Diabetes Management, the findings of this study underscore the significant burden of drug-related problems in the pharmacotherapy of diabetes mellitus, particularly in multi-drug regimens and patients with comorbidities (36). High rates of drug–drug interactions and inappropriate prescribing highlight the need for routine prescription audits and greater integration of clinical pharmacists in diabetes care. Poor medication adherence, observed in over 40% of patients, reflects gaps in patient education, health literacy, and follow-up mechanisms. These issues, if unaddressed, may compromise glycemic control and elevate risks for complications. The concentration of DRPs in patients on combination therapy suggests that while such regimens may improve glycemic outcomes, they also increase complexity and risk. Interventions such as regular medication reviews, digital reminders, and patient-centered counselling could significantly reduce DRPs and improve therapeutic adherence (37). These findings advocate for a multi-disciplinary approach aligned with ADA and ICMR guidelines to ensure safer, more effective diabetes management in tertiary care settings. Patient adherence, as assessed by the MMAS-8 scale, reveals encouraging trends: nearly 47% of patients demonstrated high adherence, which is positively associated with simple regimens and guideline-compliant prescriptions. These findings are consistent with existing literature, which emphasizes that simpler, safer, and evidence-based regimens are associated with better medication-taking behaviour (38-40). In contrast, low adherence was significantly higher in patients on irrational combinations or multi-drug regimens, likely due to increased pill burden, side effects, or patient confusion. Notably, prescriptions involving Glibenclamide or triple oral therapies showed 100% low adherence, underscoring the need to discourage such combinations in practice. The study supports the need for continued adherence to national and international guidelines, alongside patient education and periodic adherence assessments using

tools like MMAS-8, to improve long-term diabetes outcomes.

Clinical Implications of Comorbid Burden and Pharmacological Alignment reveals that the high prevalence of diabetes-associated comorbidities reflects the multifactorial burden typical of middle-aged to elderly diabetic cohorts in India (41). Hypertension and dyslipidemia, occurring in over 50% and 40% of patients, respectively, have well-documented synergistic effects on cardiovascular morbidity. Neuropathy and nephropathy further compromised physical functioning, with downstream effects on treatment adherence, mobility, and daily living activities (42). The data suggest strong adherence to pharmacological guidelines, with prescriptions largely conforming to ADA and ICMR recommendations. The inclusion of mental health medications and supplements also indicates a growing awareness of holistic diabetes care. Importantly, the linkage between specific comorbidities and impaired QoL domains underscores the need for integrated care strategies (43). Targeted interventions addressing not just glycemic control but also renal, cardiovascular, and neurocognitive health are vital to improving long-term outcomes in Indian diabetic populations.

5. Conclusion

This study highlights critical gaps and opportunities in the clinical management of Diabetes Mellitus in Indian tertiary care settings. Despite widespread use of metformin, sulfonylureas, and evidence-based combinations, over 60% of patients exhibited poor glycemic control, compounded by high rates of comorbidities and associated complications impacting quality of life. Although adherence to ADA and ICMR guidelines was generally strong, instances of irrational combinations and non-adherence point to the urgent need for structured prescription audits and continuous medical education for prescribers. Optimizing prescription practices in line with clinical guidelines and simplifying regimens can significantly enhance patient adherence and overall diabetes management outcomes. Strengthening national diabetes programs with clear frameworks for patient counselling, adherence monitoring, and pharmacovigilance could significantly reduce drug-related problems and prevent avoidable complications. Importantly, these findings support a policy shift from glucose-centric targets to integrated, patient-centered care models that incorporate mental health, lifestyle interventions, and social support. Implementing these strategies through state and national health initiatives will be key to improving outcomes and reducing the long-term economic and healthcare burden of diabetes in India.

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