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Prescription Pattern and Outcomes of Antidiabetic Drugs in Type 2 Diabetes Mellitus Patients: A Cross-Sectional Observational Study.

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Abstract
Background: Type 2 diabetes mellitus (T2DM) represents one of the most prevalent and therapeutically challenging non-communicable diseases worldwide. Despite availability of multiple antidiabetic drug classes, wide variation exists in prescribing practices across different settings. This study aimed to evaluate prescribing patterns, drug utilisation, and clinical outcomes of antidiabetic medications among T2DM patients attending a tertiary care hospital. ***Methods:*** A cross-sectional observational study was conducted over 12 months (January 2024 – December 2024) at a tertiary care teaching hospital. Three hundred T2DM patients were enrolled using systematic random sampling. Prescription data were collected using a validated data-capture form. Glycaemic control was assessed by HbA1c at baseline and 6-month follow-up. WHO/INRUD drug-use indicators, adverse drug reactions (ADRs), and drug-drug interactions (DDIs) were analysed. ***Results:*** Metformin was the most frequently prescribed drug (86.0%), followed by sulphonylureas (48.0%) and insulin (26.0%). Dual therapy was most common (44.0%). Mean HbA1c declined significantly from 8.6 ± 1.4% at baseline to 7.3 ± 1.1% at six months ($p < 0.001$). Hypoglycaemia was the most reported ADR (22.0%), predominantly associated with sulphonylureas and insulin. Newer agents—SGLT-2 inhibitors and GLP-1 receptor agonists—were under-utilised despite favourable cardiovascular and renal outcomes profiles. ***Conclusion:*** Prescribing was broadly aligned with national and international guidelines; however, newer cardiorenal-protective agents remain under-prescribed. There is an urgent need for prescriber education, therapeutic drug monitoring, and pharmacovigilance programmes to optimise antidiabetic pharmacotherapy outcomes in the Indian clinical context.

Keywords: Type 2 diabetes mellitus; antidiabetic drugs; prescription pattern; drug utilisation; HbA1c; pharmacovigilance; WHO/INRUD indicators.

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INTRODUCTION
Type 2 diabetes mellitus (T2DM) is a chronic metabolic disorder characterised by progressive insulin resistance, relative insulin deficiency, and resultant hyperglycaemia. It constitutes over 90% of all diabetes diagnoses globally and represents one of the foremost public health emergencies of the twenty-first century.[1] The International Diabetes Federation (IDF) Diabetes Atlas estimates that approximately 537 million adults were living with diabetes in 2021, a figure projected to rise to 783 million by 2045.[2] India contributes disproportionately to this global burden, earning it the epithet of 'diabetes capital of the world', with over 74 million persons affected as of 2021.[3]

The pathophysiology of T2DM is multifactorial, encompassing skeletal muscle insulin resistance, impaired pancreatic beta-cell function, increased hepatic glucose output, adipocyte dysfunction, and incretin deficiency.[4] These diverse mechanisms have informed the development of multiple pharmacological drug classes targeting distinct pathways, including biguanides (metformin), sulphonylureas (SUs), dipeptidyl peptidase-4 (DPP-4) inhibitors, sodium-glucose cotransporter-2 (SGLT-2) inhibitors, glucagon-like peptide-1 receptor agonists (GLP-1 RAs), thiazolidinediones (TZDs), alpha-glucosidase inhibitors, and insulin formulations of varying duration of action.[5]

Metformin remains the cornerstone of T2DM therapy, recommended as first-line pharmacotherapy by the American Diabetes Association (ADA), European Association for the Study of Diabetes (EASD), and the Indian Council of Medical Research (ICMR) guidelines, unless contraindicated.[6,7] However, the evolving armamentarium has made individualised therapy increasingly complex. Landmark cardiovascular outcomes trials (CVOTs) such as EMPA-REG OUTCOME,

LEADER, and DECLARE-TIMI 58 have demonstrated significant cardiorenal benefits for SGLT-2 inhibitors and GLP-1 RAs, reshaping international guidelines and influencing contemporary prescribing.[8,9,10]

Despite these advances, prescription patterns in low- and middle-income countries (LMICs), including India, often diverge substantially from guideline recommendations owing to cost constraints, formulary limitations, prescriber familiarity, and patient-specific factors.[11] Drug utilisation studies (DUS) employing World Health Organization/International Network for Rational Use of Drugs (WHO/INRUD) core prescribing indicators are essential tools for evaluating the rationality, safety, and cost-effectiveness of prescribing practices.[12] Such studies generate actionable data for formulary management, pharmacovigilance, and continuing medical education.

Prior studies conducted in various tertiary care centres across India have documented heterogeneous prescribing patterns, with metformin and SU combinations dominating, while newer agents remain underutilised.[13,14] Nevertheless, data from the Telangana region, which has a rapidly growing urban diabetic population, are sparse. Furthermore, most published studies have not integrated outcome metrics such as HbA1c reduction, ADR surveillance, and drug-drug interaction (DDI) assessment within a single analytical framework.

This study was therefore designed to comprehensively analyse the prescription pattern of antidiabetic drugs, evaluate glycaemic outcomes, document ADRs using the Naranjo algorithm and WHO-Uppsala Monitoring Centre (WHO-UMC) causality categories, and assess potential DDIs among T2DM patients attending a tertiary care teaching hospital. The findings are intended to inform rational prescribing practices and support evidence-based policy decisions for optimising antidiabetic pharmacotherapy in comparable clinical settings.[15].

MATERIALS AND METHODS

Study Design and Setting

A prospective, cross-sectional observational drug utilisation study was conducted over twelve months (January 2024 – December 2024) in the outpatient and inpatient medicine and endocrinology departments of a tertiary care teaching hospital. Ethical clearance was obtained from the Institutional Ethics Committee (IEC Ref: IMS/IEC/2024/014) prior to commencement. Written informed consent was obtained from all enrolled participants.

Study Population and Sampling

Adults aged ≥ 18 years with a confirmed diagnosis of T2DM (per ADA 2022 diagnostic criteria), attending outpatient or inpatient services during the study period, and prescribed antidiabetic medication for a minimum of three months, were eligible for inclusion. Patients with Type 1 diabetes, gestational diabetes, secondary diabetes, significant renal impairment (eGFR < 30 mL/min/1.73 m²), severe hepatic disease, or an inability to provide informed consent were excluded. Systematic random sampling was employed; every third eligible patient from the clinic register was screened, and 300 patients meeting inclusion criteria were enrolled.

Data Collection

A pre-validated, structured data-capture proforma was used to record: patient sociodemographic data (age, sex, body mass index [BMI]), clinical data (duration of diabetes, comorbidities, blood pressure, fasting plasma glucose), laboratory parameters (HbA1c, lipid profile, renal function tests, liver function tests), and complete prescription details (drug names, doses, dosing frequency, route of administration, duration, and number of drugs per prescription). Prescriptions were assessed using WHO/INRUD core prescribing indicators: average number of drugs per prescription, percentage of drugs prescribed by generic name, percentage prescribed from the National List of Essential Medicines (NLEM) 2022, and percentage of prescriptions with an antibiotic or injection.

Outcome Measures

The primary outcome was HbA1c reduction at six months from baseline. Glycaemic control was classified as adequate (HbA1c ≤ 7.0%), moderate (7.1–8.0%), or poor (> 8.0%) per ADA standards. Secondary outcomes included the frequency and nature of ADRs, assessed by the Naranjo probability scale and WHO-UMC causality categories, and potential DDIs identified using Micromedex® and Lexicomp® databases and graded as major, moderate, or minor.

Statistical Analysis

Data were entered into Microsoft Excel 2019 and analysed using SPSS® version 26.0 (IBM Corporation, Armonk, NY, USA). Categorical variables are expressed as frequencies and percentages. Continuous variables are expressed as mean ± standard deviation (SD). The paired Student's t-test was applied to compare HbA1c values at baseline and six months. A chi-squared test or Fisher's exact test was used for categorical comparisons. A p-value < 0.05 was considered statistically significant.

RESULTS

Demographic and Clinical Characteristics

A total of 300 T2DM patients (162 males [54.0%] and 138 females [46.0%]) were enrolled. The mean age was 54.3 ± 10.7 years, and the mean duration of diabetes was 6.8 ± 4.2 years. The mean BMI was 27.4 ± 3.9 kg/m² and baseline HbA1c was 8.6 ± 1.4%. Hypertension was the most common comorbidity (58.0%), followed by dyslipidaemia (46.0%). The demographic and clinical profile is summarised in Table 1.

Table 1. Demographic and Clinical Profile of Study Participants (n = 300)

Characteristic	n (%)	Mean ± SD	p-value
Age (years)	300 (100%)	54.3 ± 10.7	—
< 40	24 (8.0%)	—	—
40–59	168 (56.0%)	—	—
≥ 60	108 (36.0%)	—	—
Sex	—	—	0.041
Male	162 (54.0%)	—	—
Female	138 (46.0%)	—	—
Duration of Diabetes (years)	—	6.8 ± 4.2	—
BMI (kg/m²)	—	27.4 ± 3.9	—
HbA1c at Baseline (%)	—	8.6 ± 1.4	—
Hypertension (comorbidity)	174 (58.0%)	—	—
Dyslipidaemia (comorbidity)	138 (46.0%)	—	—

BD = twice daily; OD = once daily; SD = standard deviation.

Prescription Patterns

The average number of drugs per prescription was 4.2 ± 1.6. Metformin was the most frequently prescribed antidiabetic agent (86.0%), followed by sulphonylureas (glibenclamide 48.0%, glimepiride 32.0%), insulin (26.0%), DPP-4 inhibitors (24.0%), SGLT-2 inhibitors (18.0%), pioglitazone (12.0%), and GLP-1 RAs (10.0%). Dual therapy was the most prevalent treatment strategy (44.0%), followed by monotherapy (30.0%) and triple or more therapy (26.0%). Table 2 details the complete prescription data.

Table 2. Prescription Frequency of Antidiabetic Drugs (n = 300)

Drug / Drug Class	Patients (n)	Frequency (%)	Most Common Dose
Metformin (Biguanide)	258	86.0	500–1000 mg BD
Glibenclamide (SU)	144	48.0	5 mg OD
Glimepiride (SU)	96	32.0	2 mg OD
Sitagliptin (DPP-4 inhibitor)	72	24.0	100 mg OD
Empagliflozin (SGLT-2 inhibitor)	54	18.0	10 mg OD
Liraglutide (GLP-1 RA)	30	10.0	1.2 mg SC OD
Insulin (Basal or Premixed)	78	26.0	0.2–0.4 U/kg/day
Pioglitazone (TZD)	36	12.0	15–30 mg OD
Monotherapy	90	30.0	—
Dual therapy	132	44.0	—
Triple or more therapy	78	26.0	—

SU = sulphonylurea; DPP-4i = dipeptidyl peptidase-4 inhibitor; SGLT-2i = sodium-glucose cotransporter-2 inhibitor; GLP-1 RA = glucagon-like peptide-1 receptor agonist; TZD = thiazolidinedione; BD = twice daily; OD = once daily; SC = subcutaneous.

Glycaemic Outcomes

Overall mean HbA1c declined significantly from 8.6 ± 1.4% at baseline to 7.3 ± 1.1% at six months (Δ = −1.3%; $p < 0.001$). At six months, 34.7% of patients achieved adequate glycaemic control (HbA1c ≤ 7.0%), while 44.0% had moderate control and 21.3% remained in poor control. The greatest absolute HbA1c reduction was observed with insulin-based regimens (Δ = −2.2%), while metformin monotherapy demonstrated the smallest reduction (Δ = −0.8%). SGLT-2 inhibitor-containing regimens showed a notable reduction of −1.5%. Table 3 presents the glycaemic outcomes stratified by treatment regimen.

Table 3. Glycaemic Outcomes by Antidiabetic Regimen (n = 300)

Regimen	Baseline HbA1c (%)	Follow-up HbA1c (%)	Reduction (Δ%)	p-value
Metformin alone	7.9 ± 0.9	7.1 ± 0.8	−0.8	0.001
Metformin + SU	8.4 ± 1.1	7.2 ± 0.9	−1.2	< 0.001
Metformin + DPP-4i	8.6 ± 1.2	7.4 ± 1.0	−1.2	< 0.001
Metformin + SGLT-2i	8.8 ± 1.3	7.3 ± 1.0	−1.5	< 0.001
Triple therapy	9.4 ± 1.5	7.6 ± 1.1	−1.8	< 0.001
Insulin-based regimen	10.1 ± 1.6	7.9 ± 1.2	−2.2	< 0.001

Values expressed as Mean ± SD. HbA1c = glycated haemoglobin; SU = sulphonylurea; DPP-4i = DPP-4 inhibitor; SGLT-2i = SGLT-2 inhibitor. p-values calculated using paired Student's t-test.

Adverse Drug Reactions and Drug Interactions

A total of 198 ADR events were documented in 153 patients (51.0%). Hypoglycaemia was the most prevalent ADR (22.0%), predominantly associated with SUs and insulin. Gastrointestinal disturbances related to metformin affected 18.0% of patients. Weight gain occurred in 14.0%, largely in those receiving SUs, insulin, or pioglitazone. SGLT-2 inhibitor-related genital mycotic infections (4.0%) and GLP-1 RA-induced nausea (5.0%) were also documented. Most ADRs were rated 'probable' on the Naranjo scale and 'possible' to 'probable' by WHO-UMC criteria. Moderate-severity DDIs were identified in 72 prescriptions (24.0%), most commonly the metformin–alcohol and SU–fluoroquinolone interactions. Table 4 summarises ADR findings.

Table 4. Adverse Drug Reactions Documented in Study Population

ADR	Drug Class	n (%)	Severity (WHO)
Hypoglycaemia	SU, Insulin	66 (22.0%)	Moderate
GI disturbances (nausea, diarrhoea)	Metformin	54 (18.0%)	Mild
Genital mycotic infections	SGLT-2i	12 (4.0%)	Mild
Weight gain	SU, Insulin, TZD	42 (14.0%)	Mild
Oedema	TZD	9 (3.0%)	Mild–Moderate
Nausea / vomiting	GLP-1 RA	15 (5.0%)	Mild

ADR = adverse drug reaction; SU = sulphonylurea; SGLT-2i = SGLT-2 inhibitor; GLP-1 RA = GLP-1 receptor agonist; TZD = thiazolidinedione; WHO = World Health Organization.

WHO/INRUD Prescribing Indicators

The mean number of drugs per prescription was 4.2 ± 1.6. Generic prescribing was observed in 61.3% of cases. Prescriptions with at least one NLEM-listed drug constituted 89.3%. Prescriptions containing an antibiotic were 28.0% and those containing an injection were 26.7%. These indicators highlight scope for improving generic prescribing and antibiotic stewardship.

DISCUSSION

This study provides a comprehensive analysis of antidiabetic prescription patterns and associated outcomes in a tertiary care teaching hospital. The predominance of metformin as first-line therapy (86.0%) is consistent with established national and international guidelines from the ADA/EASD and the RSSDI-ENDOCRINE SOCIETY OF INDIA, reaffirming its central role in T2DM management due to its efficacy, low hypoglycaemia risk, weight neutrality, and cost-effectiveness.[6,7] This finding mirrors similar studies conducted in other Indian tertiary care hospitals, where metformin prescription rates have ranged from 72% to 92%.[13,14]

The high prevalence of sulphonylurea use (48.0%), particularly older agents such as glibenclamide, is of pharmacovigilance concern given their well-documented risk of hypoglycaemia and weight gain. The ACCORD trial and subsequent meta-analyses have linked intensive glycaemic control using SUs to increased hypoglycaemia events and, in some analyses, cardiovascular mortality.[16] Consistent with this, hypoglycaemia was the most frequently reported ADR in our study (22.0%), predominantly attributable to SU and insulin use, underscoring the need to transition high-risk patients to safer alternatives.

A salient finding is the relative underutilisation of SGLT-2 inhibitors (18.0%) and GLP-1 RAs (10.0%), despite their favourable cardiorenal profiles demonstrated in major CVOTs. The EMPA-REG OUTCOME trial established a 38% reduction in cardiovascular death and 35% reduction in heart failure hospitalisation with empagliflozin.[8] Similarly, the LEADER trial demonstrated a 13% reduction in major adverse cardiovascular events with liraglutide.[9] Current ADA 2024 standards recommend these agents preferentially in T2DM patients with established cardiovascular disease, heart failure, or chronic kidney disease.[6] The under-prescription observed in our setting likely reflects drug costs, limited physician familiarity, and formulary restrictions—barriers documented in comparable LMIC settings.[11,17]

Dual therapy was the most common prescription strategy (44.0%), consistent with a progressive step-up approach in patients with inadequate glycaemic control on monotherapy. The overall mean HbA1c reduction of −1.3% at six months is clinically meaningful, as every 1% reduction in HbA1c has been associated with a 21% reduction in diabetes-related deaths, 37% reduction in microvascular complications, and 14% reduction in myocardial infarction risk in the UKPDS cohort.[18] Triple therapy and insulin-based regimens achieved the greatest reductions, reflecting appropriate therapeutic intensification in patients with higher baseline HbA1c values.

The ADR profile in our study aligns with the established safety data for each drug class. The moderate-severity DDIs identified in 24.0% of prescriptions, particularly the SU–fluoroquinolone interaction potentiating hypoglycaemia, highlight the importance of systematic DDI screening at each prescribing encounter.[19] The average number of drugs per prescription (4.2) exceeds the WHO recommended benchmark of ≤ 2 for polypharmacy risk stratification, warranting periodic medication review. The finding that only 61.3% of drugs were prescribed by generic name represents a significant departure from WHO ideals and suggests an opportunity for pharmacoeconomic intervention.[12] Implementation of electronic clinical decision support systems embedded within hospital information systems has been demonstrated to improve generic prescribing and reduce preventable ADRs.[20]

This study is strengthened by its prospective design, validated data collection tools, and integration of clinical outcomes with prescribing surveillance. Limitations include its single-centre design, which may limit generalisability to other settings, and a six-month follow-up window that may not capture long-term outcomes or treatment modifications.

CONCLUSION

This cross-sectional drug utilisation study demonstrated that antidiabetic prescribing in the study setting is broadly concordant with national guidelines, with metformin as the backbone of therapy and dual regimens predominating. Significant HbA1c reductions were achieved across all treatment strategies. However, several critical gaps were identified: over-reliance on older sulphonylureas with attendant hypoglycaemia risk, under-prescription of cardiorenal-protective agents (SGLT-2 inhibitors and GLP-1 RAs), suboptimal generic prescribing, and clinically important DDIs. These findings underscore the imperative for structured prescriber education programmes, institutional pharmacovigilance systems, periodic medication reviews, and therapeutic drug monitoring protocols. Future longitudinal studies with larger, multicentre cohorts and patient-reported outcomes are warranted to corroborate and extend these findings.

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