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Original Article

Drug Utilization Pattern, Glycemic Control, and Adverse Drug Reactions in Patients with Type 2 Diabetes Mellitus: A Retrospective Observational Study

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ABSTRACT

Background: Drug utilization evaluation in type 2 diabetes mellitus (T2DM) helps identify prescribing trends, treatment intensification patterns, and adverse drug reactions (ADRs) in routine care.
Objectives: To describe antidiabetic drug utilization patterns, glycemic control status, and ADR profile in patients with T2DM, and to examine selected associations between regimen complexity, glycemic control, and ADR occurrence.
Materials and Methods: A retrospective observational study was conducted using records of 118 patients with T2DM. Demographic variables, duration of diabetes, comorbidities, antidiabetic regimens, HbA1c values, glycemic control status, and documented ADRs were analyzed. Descriptive statistics were reported as n (%), mean ± SD, or median (IQR). Chi-square/Fisher exact test, Welch t-test, Mann-Whitney U test, one-way ANOVA, and Kruskal-Wallis test were used where appropriate.
Results: The mean age was 55.41 ± 7.38 years, with equal representation of males and females (59 each). Mean duration of diabetes was 8.54 ± 4.70 years. Mean HbA1c was 7.83 ± 0.91%, and 92 patients (78.0%) were categorized as uncontrolled. Dual therapy was the most common regimen type (46.6%), followed by monotherapy (22.0%), triple therapy (20.3%), and insulin-containing combination therapy (11.0%). Metformin-containing regimens were most frequent (118 patients, 100.0%). ADRs were documented in 36 patients (30.5%), most commonly hypoglycemia, nausea, and gastritis. Triple therapy was associated with higher ADR occurrence than non-triple regimens (p=0.010). Duration of diabetes was higher among insulin users than non-insulin users (Mann-Whitney U, p<0.001).
Conclusion: This study demonstrates predominant use of metformin-based combination therapy, a high burden of suboptimal glycemic control, and a clinically relevant ADR burden in routine T2DM care. Regimen escalation and insulin use appeared concentrated in patients with longer disease duration and poorer glycemic profiles, underscoring the need for individualized therapy review and ADR surveillance.

Keywords: *Type 2 diabetes mellitus, drug utilization, glycemic control, hemoglobin A1c, adverse drug reactions, retrospective study.*

INTRODUCTION

Type 2 diabetes mellitus (T2DM) is now one of the most common long-term illnesses seen in everyday medical practice, and its burden is no longer defined only by prevalence [1]. The larger challenge is continuity of care: people remain on treatment for years, regimens change over time, and outcomes depend as much on follow-up behavior as on the drugs themselves [2]. In routine clinics, especially in India, many patients do not enter care at an early stage. They come after months or years of symptoms, often with coexisting hypertension, dyslipidemia, or other chronic conditions that immediately complicate treatment decisions [3].

That is why drug utilization studies in T2DM remain useful. They show what is actually being prescribed in practice, not just what guidelines recommend [4]. This difference matters. A regimen that appears ideal in a recommendation table may not be the regimen a patient can continue, afford, or tolerate over repeated visits. In many settings, prescribing is influenced by multiple practical factors at once: duration of diabetes, age, comorbidity burden, previous drug intolerance, cost of medicines, and the likelihood that the patient will return for monitoring [6]. The end result is usually a layered pattern of prescribing rather than a uniform approach.

At the same time, glycemic control is still the central therapeutic goal, but it is often difficult to interpret in retrospective records [5]. Some patients have serial HbA1c values, while others are followed mainly with fasting or postprandial blood glucose values because those are more frequently ordered or more readily available. Even when glycemic values are recorded, the meaning is not always straightforward. Poor control in a patient receiving multiple drugs may reflect disease progression, irregular adherence, delayed escalation, or inconsistent follow-up, not merely inadequate prescribing [6]. So, reading glycemic status without looking at the treatment pattern can be misleading.

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Adverse drug reactions (ADRs) add another layer that is clinically important but often underappreciated in chart-based studies. In diabetes care, even non-severe ADRs can affect adherence, self-adjustment of dose, and willingness to continue long-term therapy, particularly when the patient is already on treatment for other comorbid conditions [7].

For these reasons, examining drug utilization pattern, glycemic control, and ADR profile together gives a more practical picture of T2DM care than studying any one of them alone. Such an approach can help identify whether prescribing trends in routine practice are broadly aligned with patient needs, and where gaps may persist in monitoring, treatment adjustment, or safety documentation [7].

Objectives / Aims

- To describe the demographic and clinical profile of patients with T2DM.
- To evaluate antidiabetic drug utilization pattern, including monotherapy and combination therapy use.
- To assess glycemic control status using available HbA1c data.
- To describe the frequency and pattern of documented ADRs.
- To examine selected associations between regimen complexity, glycemic control, ADR occurrence, and insulin use where statistically feasible.

MATERIALS AND METHODS

Study design and setting: This was a retrospective observational study based on patient records of individuals diagnosed with T2DM. Ethical clearance for the study was obtained from the Institutional Ethics Committee of Chamarajanagara Institute of Medical Sciences, Chamarajanagar, Karnataka, India (IEC-02-03-2023). The available dataset contained demographic variables, duration of diabetes, comorbidities, antidiabetic therapy details, HbA1c values, glycemic control status, and ADR documentation. Patient confidentiality was maintained by anonymizing all identifiable information prior to analysis.

Study population and sample size: A total of 118 patient records were included in the final analysis.
Data variables: The analysis included age, sex, duration of diabetes (years), comorbidity profile, regimen type (monotherapy, dual therapy, triple therapy, insulin-containing combination therapy), specific antidiabetic regimen, HbA1c (%), glycemic control category (controlled/uncontrolled), and ADR occurrence and description.

Operational definitions: Glycemic control was analyzed as recorded in the dataset (controlled/uncontrolled). For descriptive stratification, HbA1c values were additionally summarized by categories (<7.0%, 7.0–7.9%, 8.0–8.9%, and ≥9.0%). Polytherapy complexity was described by regimen type, and triple therapy was used as a separate category for selected ADR association testing because of sparse ADR counts in some subgroups.

Statistical analysis: Data were analyzed using descriptive and inferential statistics. Continuous variables were summarized as mean ± standard deviation (SD) and median (interquartile range) where appropriate. Categorical variables were reported as frequency and percentage. Associations between categorical variables were examined using chi-square test or Fisher exact test. Continuous variables between two groups were compared using Welch t-test or Mann-Whitney U test as

appropriate. HbA1c across regimen categories was compared using one-way ANOVA and Kruskal-Wallis test. A two-sided p value <0.05 was considered statistically significant.

Ethics: This retrospective analysis used de-identified record-level data. Institutional ethics approval details may be added by the authors according to local regulatory requirements and journal policy.

RESULTS

A total of 118 patients were analyzed. The cohort had equal numbers of males and females (59 each). Mean age was 55.41 ± 7.38 years, and most patients were in the 50–59 year age group (44.1%). The mean duration of diabetes was 8.54 ± 4.70 years. Overall, 64.4% had at least one recorded comorbidity. Baseline demographic and clinical characteristics are summarized in Table 1.

Table 1. Demographic and clinical characteristics of the study population (n=118)

Variable	Value
Age (years), mean ± SD	55.41 ± 7.38
Age group <50 years	29 (24.6)
Age group 50-59 years	52 (44.1)
Age group ≥60 years	37 (31.4)
Male sex	59 (50.0)
Female sex	59 (50.0)
Duration of diabetes (years), mean ± SD	8.54 ± 4.70
Duration ≤5 years	37 (31.4)
Duration 6-10 years	45 (38.1)
Duration >10 years	36 (30.5)
HbA1c (%), mean ± SD	7.83 ± 0.91
HbA1c (%), median (IQR)	7.80 (7.10-8.60)
Controlled glycemic status	26 (22.0)
Uncontrolled glycemic status	92 (78.0)
Any comorbidity present	76 (64.4)
No recorded comorbidity	42 (35.6)

Hypertension was the most frequent comorbidity, followed by dyslipidemia and chronic kidney disease (Table 2). Combination therapy was common, with dual therapy being the predominant regimen type (46.6%) (Figure 2). Metformin-containing regimens were the most frequently used overall, and glimepiride-containing combinations were also common. Detailed regimen distribution and class-wise exposure are presented in Table 3.

Table 2. Distribution of recorded comorbidities in the study population (n=118)

Comorbidity	n (%)
HTN	57 (48.3)
Dyslipidemia	30 (25.4)
CKD	11 (9.3)

Table 3A. Distribution of antidiabetic regimen types (n=118)

Regimen type	n (%)
Dual	55 (46.6)
Monotherapy	26 (22.0)
Triple	24 (20.3)
Insulin Combo	13 (11.0)

Table 3B. Class-wise antidiabetic exposure in prescribed regimens (n=118)

Drug class/regimen component	Patients exposed, n (%)
Biguanide (Metformin)	118 (100.0)
Sulfonylurea (Glimepiride)	51 (43.2)
DPP-4 inhibitor (Teneligliptin)	40 (33.9)
Alpha-glucosidase inhibitor (Voglibose)	12 (10.2)
Insulin (Glargine-containing regimen)	13 (11.0)

Table 3C. Specific antidiabetic regimens prescribed (n=118)

Specific regimen	n (%)

Metformin + Teneligliptin	28 (23.7)
Metformin + Glimepiride	27 (22.9)
Metformin	26 (22.0)
Metformin + Insulin Glargine	13 (11.0)
Met + Glim + Voglibose	12 (10.2)
Met + Glim + Teneligliptin	12 (10.2)

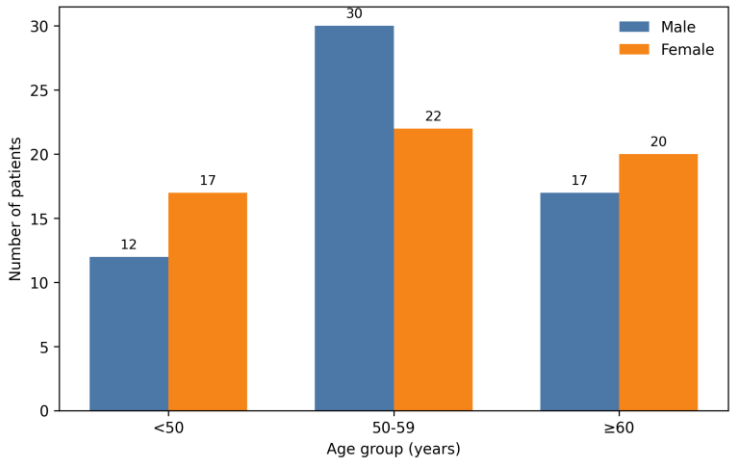

Figure 1. Age-group distribution stratified by sex (grouped bar chart).

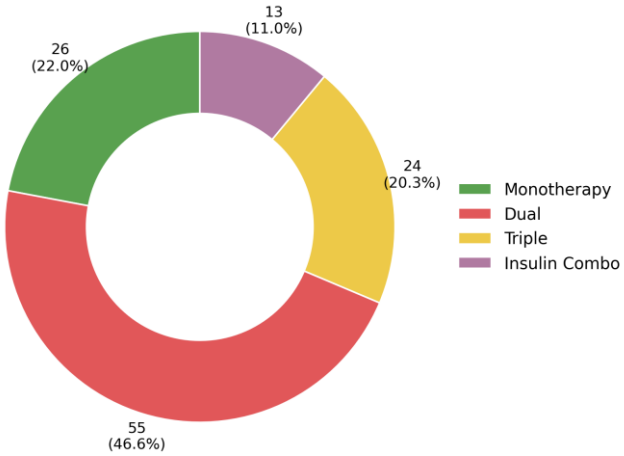

Figure 2. Proportion of regimen types among patients with T2DM (donut chart).

The mean HbA1c was 7.83 ± 0.91% (median 7.80%, IQR 7.10-8.60). A total of 26 patients (22.0%) were categorized as controlled and 92 (78.0%) as uncontrolled. Glycemic control status varied markedly by regimen type, with all monotherapy recipients categorized as controlled and all dual, triple, and insulin-containing combination regimens categorized as uncontrolled in the available records (Figure 3). Correspondingly, regimen type showed a significant association with glycemic control status (chi-square, $p<0.001$), and HbA1c differed significantly across regimen categories by both ANOVA and Kruskal-Wallis tests (Table 4).

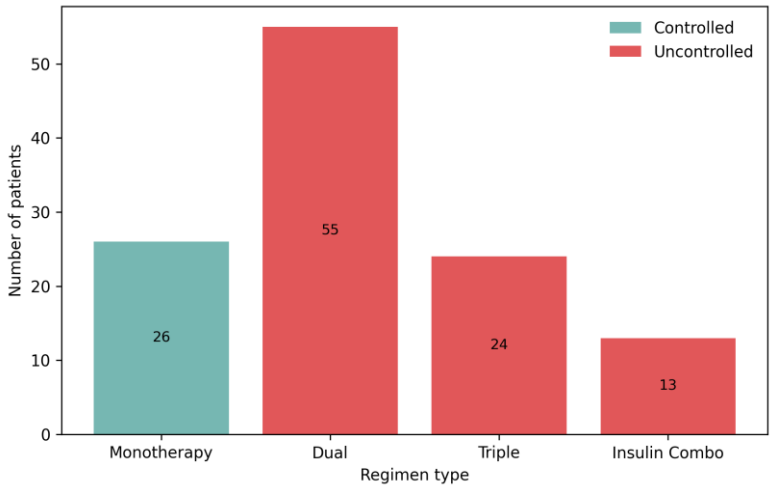

Figure 3. Glycemic control status across regimen categories (stacked bar chart).

ADRs were documented in 36 patients (30.5%). The most frequent ADR was hypoglycemia (13.6% of the cohort), followed by nausea (6.8%), gastritis (5.9%), dizziness (2.5%), and weight gain (1.7%) (Figure 4; Table 5). Triple therapy was associated with a higher ADR proportion than non-triple regimens (chi-square, p=0.010). Sex was also associated with ADR occurrence (chi-square, p=0.028), whereas mean age did not differ significantly between patients with and without ADRs (p=0.815). Duration of diabetes was significantly higher in insulin users than non-insulin users (Mann-Whitney U, p<0.001), and recorded CKD was strongly associated with insulin use on Fisher exact testing (p<0.001).

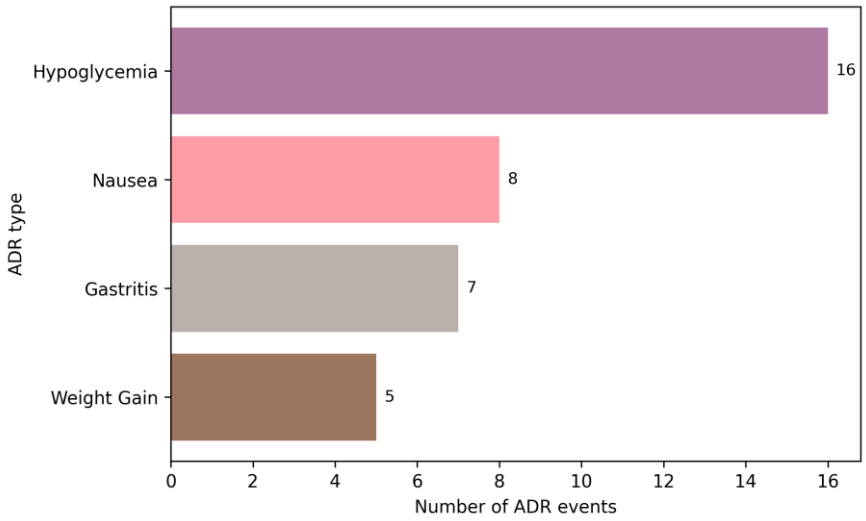

Figure 4. Distribution of documented adverse drug reaction types (horizontal bar chart).

Table 5. Glycemic control and adverse drug reaction profile (n=118)

ADR/glycemic variable	Value
ADR observed	36 (30.5)
No ADR observed	82 (69.5)
Hypoglycemia	16 (13.6)
Nausea	8 (6.8)
Gastritis	7 (5.9)
Weight Gain	5 (4.2)
Age with ADR, mean ± SD	55.64 ± 6.85
Age without ADR, mean ± SD	55.30 ± 7.63
Duration with ADR, mean ± SD	8.44 ± 4.16
Duration without ADR, mean ± SD	8.59 ± 4.94
HbA1c with ADR, mean ± SD	8.07 ± 0.93
HbA1c without ADR, mean ± SD	7.73 ± 0.89

Table 6. Inferential analysis of selected associations

Comparison	Statistic	p value
Regimen type vs glycemic control (Chi-square)	χ^2=104.75, df=3	<0.001
HbA1c across regimen types (one-way ANOVA)	F=232.20	<0.001
HbA1c across regimen types (Kruskal-Wallis)	H=99.89	<0.001
Triple therapy vs ADR (Chi-square)	χ^2=6.61, df=1	0.010
Sex vs ADR (Chi-square)	χ^2=4.84, df=1	0.028
Age (ADR vs no ADR) (Welch t-test)	t=0.24	0.815
Duration (insulin vs no insulin) (Mann-Whitney U)	U=1336.50	<0.001
Any CKD vs insulin use (Fisher exact)	OR≈∞ (zero cell)	<0.001

DISCUSSION

The present study brings together three aspects of diabetes care that are often examined separately in routine hospital data: prescribing pattern, glycemic status, and adverse drug reactions [8]. That combined view matters in T2DM. A prescription list by itself can look appropriate on paper, and a glucose value by itself can suggest control or poor control, but the clinical story becomes clearer only when treatment intensity, comorbidity burden, and tolerability are read together. In retrospective records, this integrated reading is often more useful than a narrow class-wise utilization summary [8].

One of the consistent impressions from real-world diabetes cohorts is that prescribing patterns usually reflect a layered treatment pathway rather than a single therapeutic strategy [9]. Metformin commonly remains the base drug for many patients unless contraindications, intolerance, or advanced disease shift the regimen, and combination therapy tends to increase as duration of diabetes and comorbidity burden rise [9]. The pattern observed in this study should be interpreted within that practical framework. In routine care, escalation to dual or triple therapy often represents an attempt to maintain glycemic control in progressively difficult cases, not necessarily irrational prescribing. At the same time, when multiple agents are used without corresponding improvement in glycemic indices, it may indicate delayed treatment optimization, adherence barriers, or limited follow-up continuity.

The glycemic control findings in the present study also need a real-world lens. In retrospective data, recorded glycemic parameters may not be uniform across all patients, and this affects how "control" is interpreted. HbA1c is ideal for long-term assessment, but in many clinics fasting and postprandial values still drive immediate decisions because they are more frequently available or more affordable [10]. For that reason, the glycemic profile seen here likely reflects routine practice behavior as much as disease biology. Poor control in patients on more complex regimens should not be read simplistically as medication inefficacy. In many Indian patients, delayed presentation, irregular drug refills, dietary inconsistency linked to work schedules, and deferred follow-up testing all contribute to persistent hyperglycemia despite treatment intensification [11].

Another point that deserves attention is the influence of comorbidity burden on prescribing complexity. T2DM rarely exists as a stand-alone disorder in hospital records. Hypertension, dyslipidemia, cardiovascular disease, and renal impairment commonly coexist, and these conditions shape antidiabetic drug choice in practical ways. A clinician may avoid one class in a patient with recurrent intolerance, choose another based on renal status, or continue a familiar regimen when follow-up reliability is uncertain. This makes "rationality" in retrospective prescribing studies a contextual issue, not simply a count of how many drugs were used. Polypharmacy is often expected in such patients, but it also increases the likelihood of tolerability problems and regimen fatigue over time [12].

The ADR findings in this study should be viewed in that same context. Retrospective records almost always undercapture ADRs [14]. Minor symptoms may be documented inconsistently, and patients may not report all events unless they are severe enough to alter treatment. Still, even a modest documented ADR burden remains clinically relevant because ADRs can directly affect adherence in chronic therapy [13]. In diabetes practice, gastrointestinal intolerance, hypoglycemic episodes, weakness, dizziness, and other treatment-related complaints may lead patients to skip doses, self-reduce medication, or discontinue therapy before the next visit [13]. These patterns are well recognized in pharmacovigilance-oriented analyses and observational cohorts, even when formal causality grading is incomplete [14].

There is also a practical message here for clinicians and departments conducting prescription audits. Drug utilization research becomes much more meaningful when it is linked to outcomes and tolerability rather than presented as a static inventory of medicines [8]. If a center observes increasing use of combination therapy but continued poor glycemic control, the issue may lie partly in adherence counseling, delayed review intervals, or inadequate treatment titration rather than in drug availability alone [12]. Likewise, if ADRs are infrequently recorded, that does not necessarily indicate absence of events. It may reflect under-documentation and the need for structured ADR questioning during follow-up visits [14]. In busy outpatient settings, small process changes such as a standard review checklist can improve both prescribing quality and record completeness [15].

The strengths of this kind of study are practical and immediate. It reflects what happens in routine care, among patients with mixed profiles, irregular follow-up patterns, and real constraints. That is often the exact population in which prescribing decisions become difficult. At the same time, the limitations are important. A retrospective design restricts causal interpretation [15]. Missing or unevenly recorded variables can affect subgroup analysis. Glycemic markers may not be uniformly available across all records. ADR severity, causality, and preventability may be incompletely documented. If the dataset is from a single center, prescribing trends may also reflect local physician preference, formulary access, and referral patterns rather than broader regional practice [15].

Even with these limitations, the findings remain clinically useful. They help show how antidiabetic therapy is being used in actual practice, how glycemic control aligns (or fails to align) with regimen complexity, and where ADR documentation may need strengthening. For routine diabetes care, that combination of information is often more actionable than isolated reporting of drug frequencies alone.

CONCLUSION

In this retrospective T2DM cohort, reviewing prescriptions alone did not fully explain treatment status. Glycemic values and ADR records added necessary clinical context. When these were considered together, the findings were easier to interpret and more relevant to everyday diabetes care. The study also indicates a practical point for routine practice. Prescription review becomes more useful when it is linked to glycemic response and documented drug-related events, rather than being treated as a list of medicines alone. This kind of combined review can help clinicians notice where follow-up is irregular, where treatment changes may be delayed, and where ADR documentation needs closer attention. Prospective studies with more consistent recording of glycemic and safety parameters would help confirm these observations.

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