



Drug Utilization Patterns in Type 2 Diabetes Mellitus: A Hospital-Based Observational Study in Central India

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Abstract

Background Type 2 Diabetes Mellitus poses a major challenge to the Indian healthcare system due to its rising prevalence, early onset, and long-term pharmacological requirements. Evaluating drug utilization patterns is essential to promote rational prescribing, improve glycemic control, and ensure adherence to the guidelines.

Methods A prospective exploratory study was conducted from January 2022 to December 2024 at Index Medical College, Indore, including 964 type 2 diabetes mellitus patients aged ≥ 20 years attending opd. demographic details, comorbidities, and prescription data were collected using a structured case report form. Statistical analysis was performed using SPSS version 30, applying descriptive statistics and inferential tests (Chi-square, Pearson's correlation, and ANOVA), with $p < 0.05$ considered statistically significant.

Results The mean age of patients was 46.91 ± 12.42 years, with significant male predominance (56.33%, $p = 0.002$); most patients belonged to the 41–50-year age group (32.57%). Metformin was the most commonly prescribed drug (48.03%), followed by glimepiride (36.41%), sitagliptin (17.43%), and dapagliflozin (13.07%). Combination therapy was more frequent (66.29%) than monotherapy (33.71%). The most common fixed-dose combination was metformin with glimepiride (15.98%). Polypharmacy (≥ 5 drugs) was observed in 34% of patients and was significantly associated with hypertension (11.31%, $p < 0.0001$) and dyslipidemia (6.95%). A strong positive correlation was noted between BMI and HbA1c ($r = 0.997$, $p = 0.003$), with significantly higher HbA1c levels in obese patients ($p < 0.001$).

Conclusion The study indicates a predominant use of metformin-based combination regimens in line with standard treatment protocols. The high prevalence of polypharmacy and its association with comorbidities highlights the need for regular prescription audits and individualized therapy to ensure rational drug use and improved patient outcomes.

Keywords Combination therapy, Drug utilization, Metformin, Polypharmacy, Prescribing patterns, Type 2 diabetes mellitus

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1 Introduction

Type 2 Diabetes Mellitus (T2DM) is a progressive metabolic condition marked by persistent hyperglycemia resulting from inadequate insulin production and/or insulin resistance. It is associated with multisystem complications, particularly affecting cardiovascular, renal, and neurological systems, and is a primary factor in worldwide morbidity and mortality. India bears one of the highest burdens of T2DM worldwide, with a prevalence exceeding 14% among adults and substantial regional variation in disease awareness and management strategies.^[1]

Rational pharmacotherapy is central to achieving optimal glycemic control and preventing complications. However, real-world evidence in India has revealed significant deviations from standard treatment guidelines, including irrational polypharmacy, low utilization of cost-effective generics, and inconsistent incorporation of newer agents with cardiovascular and renal benefits.^[2] Inappropriate prescribing practices contribute to suboptimal outcomes, especially in resource-limited settings with high rates of comorbidities such as hypertension, dyslipidemia, and obesity.^[3]

Drug utilization studies (DUS) are essential for monitoring prescription patterns, evaluating adherence to clinical guidelines, and informing interventions to promote rational and cost-effective medication use.

^[1] In India, where therapeutic decision-making is often influenced by economic, demographic, and healthcare access disparities, DUS play a crucial role in guiding clinical practice and policy reforms.^[2]

The present study evaluated the prescribing trends of antidiabetic medications among patients with T2DM at a tertiary care hospital in Central India. The objective was to analyze drug class preferences, monotherapy versus combination regimens, and associations with demographic variables and comorbidities, to identify areas for improving pharmacological care in diabetic patients.

2 Methods

Study Design

A prospective exploratory study was performed at the outpatient department (OPD) of Index Medical College Hospital and Research Centre, Indore, Madhya Pradesh, India. The facility operated as a tertiary care teaching hospital, catering to a diverse population from urban, semi-urban, and rural areas in Central India. The research was carried out over a 3-year duration from January 2022 to December 2024.

Study Objectives

The main aim of the study was to assess the drug use patterns of antidiabetic drugs in adult patients with T2DM. Secondary objectives included analyzing prescribing trends based on demographic variables and assessing adherence to rational drug use principles as outlined by the World Health Organization (WHO).

Study Population

The study population comprised adult patients attending the OPD who had been previously diagnosed with T2DM and were on active pharmacological management.

Inclusion Criteria

Participants were eligible if they were aged 20 years or older and had a confirmed diagnosis of T2DM according to the standards of the American Diabetes Association (ADA) or the WHO. Eligible individuals must have been on antidiabetic pharmacotherapy for at least three consecutive months prior to enrollment and provided voluntary, written informed consent to participate in the study.

Exclusion Criteria

Individuals were excluded if they had a diagnosis of type 1 diabetes mellitus, gestational diabetes, or other specific types of diabetes. Patients with acute medical illnesses, terminal conditions, or those requiring emergency care were also excluded. Additionally, individuals with cognitive impairment, psychiatric conditions, or language barriers that prevented obtaining informed consent or a reliable medical history were not eligible. Finally, participants who were unwilling or unable to comply with study procedures were excluded.

Sample Size and Sampling Technique

A total of 964 patients were recruited by convenience (non-probability) sampling. The sample size was sufficient to identify common prescribing trends with a 95% confidence level and a margin of error of less than 5%, based on regional outpatient volume and T2DM prevalence.

Data Collection Tools and Procedure

Patient data were collected at the time of consultation through direct patient interviews and medical record review using a pre-designed, pre-tested, structured Case Report Form (CRF). The CRF captured the following domains:

- Demographics: age, gender, residence, socioeconomic status, education level.
- Clinical profile: duration of diabetes, comorbidities (e.g., hypertension, dyslipidemia), height, weight, BMI, glycated hemoglobin (HbA1c).

- Prescription data: drug name, class, dose, frequency, route, formulation, and duration of therapy.

Prescriptions were evaluated for completeness, rationality, and adherence to established guidelines using the WHO Core Drug Use Indicators. The assessment included the mean number of medications per prescription, the percentage of medications prescribed by their generic name, the proportion of prescriptions containing fixed-dose combinations, and the percentage of prescriptions conforming to the essential medicines list.

Statistical Analysis

All data were entered into Microsoft Excel and later analyzed using IBM SPSS Statistics for Windows, Version 30.0 (IBM Corp., Armonk, NY, USA). Descriptive statistics (mean, standard deviation, frequency, and percentage) were employed to describe patient demographics and prescribing customs. The Chi-square test was utilized to ascertain relationships between categorical variables, including gender and therapy type (monotherapy versus combination therapy). Pearson's correlation coefficient was employed to evaluate the association between BMI and HbA1c levels. A one-way analysis of variance (ANOVA) was utilized to examine mean HbA1c levels across various BMI groups. A p-value of less than 0.05 was deemed statistically significant.

The study protocol received approval from the Institutional Ethics Committee of Malwanchal University on 23 November 2021, before the initiation of patient recruitment. Written informed consent was obtained from all participants after explaining the study objectives, procedures, potential risks, and benefits in their native language. Participant anonymity and data confidentiality were rigorously upheld during the research process. This study was aligned with the principles of the Declaration of Helsinki and subsequently followed the Good Clinical Practice guidelines as established by the International Council for Harmonisation.^[4,5]

3 Results

Demographic and Clinical Characteristics

Among 964 enrolled patients with T2DM, the average age was 46.91 ± 12.42 years. The predominant age group was 41–50 years ($n = 314$; 32.57%), followed by 51–60 years ($n = 213$; 22.10%) and 31–40 years ($n = 179$; 18.57%). A statistically significant difference in age group distribution was observed ($p < 0.0001$), confirming the predominance of middle-aged patients in this study. Figure 1 depicts the age distribution of the study population, highlighting the concentration of cases in the 41–60-year range, consistent with known T2DM epidemiology in India.

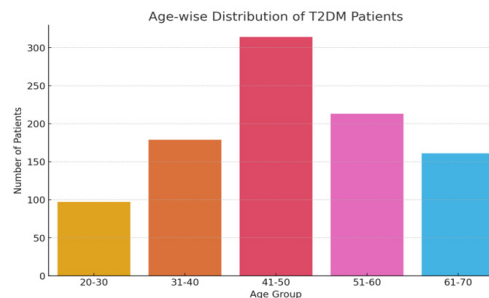


Figure 1 Age-wise distribution of T2DM patients

A gender-wise breakdown revealed that 549 (56.33%) patients were male and 415 (43.67%) were female. The gender distribution was statistically significant ($p = 0.002$), suggesting a higher proportion of T2DM detection or reporting among males. Figure 2 shows the gender distribution, where males constitute a significantly larger proportion of the study population, possibly due to higher health-seeking behavior or greater risk factor exposure in men.

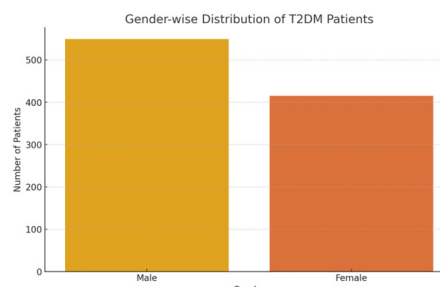


Figure 2 Gender-wise distribution of T2DM patients

Patterns of Antidiabetic Therapy

Among all prescriptions analyzed:

- 325 (33.71%) patients received monotherapy,
- 523 (54.25%) received dual drug therapy,
- 116 (12.03%) received triple drug therapy.

This distribution was statistically significant ($p < 0.0001$), indicating that dual therapy is the predominant prescribing pattern, potentially reflecting progressive disease or attempts at tighter glycemic control. Figure 3 presents the relative proportions of patients on each regimen, demonstrating the shift away from monotherapy toward combination regimens in contemporary practice.

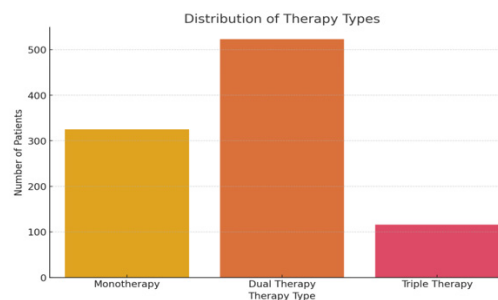


Figure 3 Distribution of therapy types

Drug Utilization Profile

Metformin was the most commonly prescribed medication (n = 463; 48.03%), after glimepiride (n = 351; 36.41%) and sitagliptin (n = 168; 17.43%). Dapagliflozin (n = 126; 13.07%) and vildagliptin (n = 166; 17.22%) showed moderate usage, reflecting growing but cautious adoption of newer antidiabetic agents. Insulin use was reported in 47 patients (4.88%), indicating its reserved use for patients with poor glycemic control or contraindications to oral agents. Figure 4 shows the number of prescriptions for each antidiabetic drug. The dominance of metformin aligns with global and national guidelines recommending it as first-line therapy, while sulfonylureas (glimepiride) remain common due to cost and accessibility.

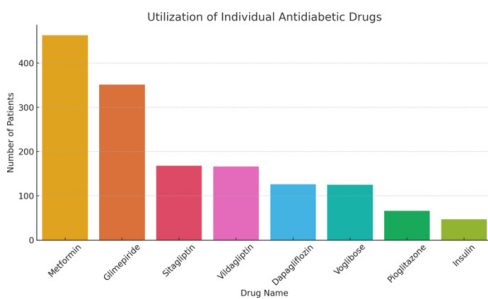


Figure 4 Utilization of individual antidiabetic drugs

HbA1c Levels Across BMI Categories

To evaluate the effect of body weight on glycemic control, HbA1c values were analyzed across three BMI categories (normal, overweight, and obese) utilizing a one-way ANOVA test. The findings indicated a statistically significant difference between the groups ($F(2, 87) = 199.34, p < 0.001$). As shown in Table 1, the mean HbA1c levels increased progressively with BMI, measuring $6.21 \pm 0.31\%$ in patients with normal BMI, $7.13 \pm 0.42\%$ in overweight patients, and $8.20 \pm 0.50\%$ in obese patients. This indicates that glycemic control worsens as adiposity increases.

Table 1 Comparison of mean HbA1c levels across BMI categories

BMI category	Mean HbA1c (%)	Standard deviation (SD)	n
Normal	6.21	0.31	30
Overweight	7.13	0.42	30
Obese	8.20	0.50	30

Figure 5 presents a boxplot illustrating the HbA1c distribution across BMI categories, with clear separation between groups. The upward trend strongly supports the known pathophysiologic association between obesity and insulin resistance.

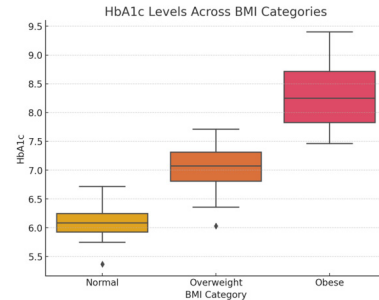


Figure 5 HbA1c levels across BMI categories

Therapy Distribution Across Age Groups

The distribution of therapy types was assessed across different age categories using a chi-square test, which revealed a statistically significant association ($\chi^2 = 62.34, p < 0.001$). Younger patients (particularly those aged 20–30 years) were more frequently managed with monotherapy, whereas combination therapy (dual and triple) became increasingly common in older age groups. Table 2 details this variation in prescribing practices by age group, reinforcing the concept of personalized therapy intensification with increasing age and disease duration.

Table 2 Distribution of therapy types across age groups

Age group (years)	Monotherapy (n)	Dual therapy (n)	Triple therapy (n)	Total (n)
20–30	71	28	24	123
31–40	48	114	113	275
41–50	52	106	96	254
51–60	74	86	61	221
61–70	42	89	34	165

Figure 6 provided a stacked bar chart representing the proportions of therapy types within each age group. The figure demonstrates a clear shift from monotherapy to triple therapy as patient age advances, likely driven by progressive β -cell dysfunction and higher comorbidity burden in older individuals.

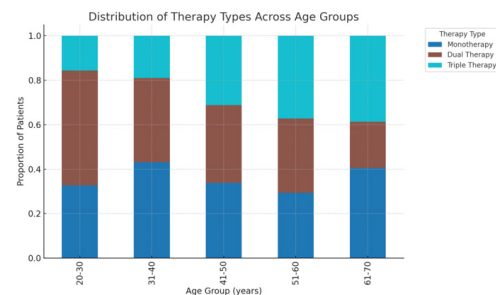


Figure 6 Distribution of therapy types across age groups

4 Discussion

This observational study investigated prescribing patterns in patients with T2DM within a tertiary care setting in Central India. The results demonstrate a strong preference for metformin-based combination therapy, a high burden of polypharmacy due to comorbidities, and an age-related increase in treatment intensity.

The demographic characteristics revealed that T2DM predominantly affects middle-aged adults, particularly those between 41 and 60 years, consistent with data from the ICMR-INDIAB study, which showed similar age clustering across Indian states.^[2] Male predominance in this study (56.33%) is also in line with national trends and may reflect differences in healthcare-seeking behavior or metabolic risk exposure between genders.^[6,7]

Metformin was the most frequently prescribed drug (48.03%), reinforcing its role as the first-line therapy recommended by both national and international guidelines for its safety, cost-effectiveness, and cardiovascular benefits.^[8] Its dominance was also reported in the Chennai Urban Population Study and other Indian studies, which found metformin use ranging from 45% to 60% among diabetic patients.^[9]

The frequent use of glimepiride (36.41%) reflects persistent reliance on sulfonylureas in Indian practice, likely due to affordability and clinical familiarity. Although newer agents such as Dipeptidyl Peptidase-4 (DPP-4) inhibitors (e.g., sitagliptin) and sodium-glucose transport-2 (SGLT-2) inhibitors (e.g., dapagliflozin) showed moderate use (17.43% and 13.07%, respectively), their uptake was lower compared to global patterns. For example, studies from Europe and the USA report SGLT-2 inhibitor use exceeding 25–30%, supported by cardiovascular outcome trial (CVOT) evidence.^[10] The lower use in India may be attributed to higher cost, lack of insurance coverage, and limited access to public healthcare systems.

Our findings also indicated that dual therapy was the most common treatment regimen (54.25%), followed by monotherapy (33.71%) and triple therapy (12.03%). This is consistent with evolving clinical practices promoting early combination therapy to achieve glycemic targets efficiently. The study supported this approach by demonstrating the long-term durability of early dual therapy over monotherapy.^[11]

Importantly, we observed a statistically significant association between therapy complexity and age group ($p < 0.001$), with older patients more likely to receive combination therapies. This trend reflects longer disease duration, worsening β -cell function, and the presence of comorbidities. Such age-related intensification of therapy has also been reported in North Indian studies evaluating guideline adherence.^[12]

Polypharmacy was seen in 34% of patients, primarily

due to coexisting hypertension, dyslipidemia, and microvascular complications. Although necessary in many cases, polypharmacy increases the risk of drug interactions, non-adherence, and financial burden. This is particularly important in elderly or low-income populations, where appropriate medication review and deprescribing are essential for safe diabetes care.^[13]

A significant finding was the strong positive correlation between BMI and HbA1c ($r = 0.997$, $p < 0.001$). This aligns with well-established evidence linking obesity with insulin resistance and poor glycemic control. Our results support lifestyle-based interventions in conjunction with pharmacotherapy, especially for overweight and obese patients.^[14]

Overall, the prescribing patterns identified in this study reflect both adherence to standard practices and gaps that require attention, especially the limited use of newer agents with proven cardiovascular and renal benefits. Cost, accessibility, and physician training are critical areas that must be addressed to ensure equitable and guideline-based diabetes care across all patient populations.

5 Conclusion

This study highlights critical trends in the pharmacological management of T2DM in a tertiary care centre in India. Metformin-based regimens remain the cornerstone of therapy, while dual combination treatments are increasingly favored. However, the low uptake of newer antidiabetic agents and the significant prevalence of polypharmacy suggest a need for policy interventions to improve rational drug use.

The positive correlation between BMI and HbA1c reinforces the importance of weight management in diabetes care. The findings underscore the necessity for individualized, evidence-based treatment protocols that consider patient-specific factors such as age, BMI, and comorbidities.

Regular prescription audits, adherence to treatment guidelines, and continuous education for healthcare providers are essential to optimize diabetes care and improve long-term outcomes in the Indian population.

Declarations

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Artificial Intelligence Disclosure

AI tools were not used in the generation, analysis, or interpretation of data, and all conclusions are those of the authors.

Authors' Contributions

Rajveer Singh Rathore, Dr. Akash Vishwe, and Dr. Susheel Kumar contributed to the concept and design of the study. Data

were collected by Rajveer Singh Rathore, Dr. Akash Vishwe, and Dr. Alka Bansal, while data analysis and interpretation were carried out by Rajveer Singh Rathore, Dr. Susheel Kumar, Dr. Lokendra Sharma, and Dr. Punam Jakhar. The manuscript was drafted by Rajveer Singh Rathore, Dr. Akash Vishwe, Dr. Alka Bansal, and Dr. Punam Jakhar, and critically revised by Rajveer Singh Rathore, Dr. Susheel Kumar, and Dr. Lokendra Sharma. All authors reviewed and provided final approval of the version to be published.

Availability of Data and Materials

The datasets generated and analyzed during the current study are not publicly available due to institutional regulations and confidentiality agreements with the participating patients. All data were anonymized before analysis to ensure participant privacy and compliance with ethical standards.

Conflict of Interest

The authors declare that there is no conflict of interest.

Consent for Publication

Not applicable.

Ethical Considerations

The protocol was approved by the Institutional Ethics Committee of Malwanchal University on 23.11.2021 (MU/Research/EC/Ph.D./2021/93a). Written informed consent was obtained from all participants. Confidentiality was maintained. The study conformed to the Declaration of Helsinki (2013) and ICH-GCP guidelines.

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