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# **Original Research Article**

# Analysis of antidiabetic drug utilization patterns in type 2 diabetes patients: a perspective on real-time prescribing practices

Bashir Surajo<sup>1</sup>, Ziyaurrahman Khan<sup>2</sup>, M. Shadab<sup>1</sup>, Naureen Khan<sup>1</sup>, Mudassir Sada<sup>1</sup>, Mohammad Ahmad<sup>2</sup>\*, M. Sohel Akhter<sup>2</sup>, Ayasa Parveen<sup>3</sup>

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### \*Correspondence:

Dr. Mohammad Ahmad, Email: ahmadkhan@iul.ac.in

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#### **ABSTRACT**

**Background:** Type 2 diabetes is a most common health problem associated with significant morbidity and mortality worldwide, evaluation of drug utilization pattern is very crucial and significant in order to promote the rational use of drugs in treatment of diabetes, and offer insights in to the actual patterns of drug use. The objective is to evaluate drug utilization pattern of antidiabetic drugs among type 2 diabetic patients at Integral Institute of Medical Science & Research.

**Methods:** This is a prospective observational study involving 100 subjects conducted for a period of 6 months after approval by Institutional Ethics Committee (IEC) of Integral University at IIMS and R Hospital. Informed consent was obtained from all the participants. Data gathered was examined using descriptive statistics and compared to the standard guidelines. Drug utilization pattern was studied and evaluated to analyse the pattern of drug therapy among type 2 diabetics.

**Results:** Antidiabetic drugs were given 198 times among the 100 participants, averaging 2 antidiabetic drugs per prescription, Insulin therapy (58.58%) and Metformin (20.20%) were the most prescribed medications, combination therapy was common, with 66% of patients particularly with Glimepiride (DPP4 Inhibitor) at 10.61%. Most prescriptions were given by generic name (55%) and 90% of the drugs prescribed were from the WHO essential medicines. Most patients were aged 51-60 years, with a nearly equal gender distribution.

**Conclusion:** The study highlights the prescribing patterns and characteristic use of antidiabetic medications. These findings provide valuable insights into the current prescribing practices in type-2 DM treatment and can contribute to optimizing treatment strategies for better patient outcomes.

Keywords: Type-2 diabetes, Drug Utilization, Prescribing Practice, Antidiabetic drugs, Prescription pattern

#### INTRODUCTION

Drug utilization patterns refer to the manner in which drugs are prescribed, dispensed, and used by patients or populations. This includes studying prescribing practices, adherence to prescribed regimens, and medication patterns across different patient populations. Such studies are essential for healthcare providers, policymakers, and investigators to evaluate the appropriateness, safety, and effectiveness of drug therapy. Prescribing patterns may vary based on factors such as the patient's condition, age, comorbidities, and regional guidelines. Diabetes mellitus

<sup>&</sup>lt;sup>1</sup>Department of Pharmacy Practice, Integral University, Lucknow, Uttar Pradesh, India

<sup>&</sup>lt;sup>2</sup>Faculty of Pharmacy, Integral University, Lucknow, Uttar Pradesh, India

<sup>&</sup>lt;sup>3</sup>Department of General Medicine, Integral Institute of medical science and research Hospital, Uttar Pradesh, Lucknow, Uttar Pradesh, India

a group of metabolic diseases characterized by persistent hyperglycemia, resulting from either insufficient production of insulin or the body's inability to effectively use insulin. Common symptoms include increased thirst (polydipsia), frequent urination (polyuria), unexplained weight loss, fatigue, blurred vision, and recurrent infections.

Diagnosis is typically confirmed using the oral glucose tolerance test, fasting plasma glucose levels, and HbA1c levels. The global prevalence of diabetes has been steadily rising over the past few decades, reaching alarming proportions. In 2021, it was estimated to affect 10.5% of the adult population (536.6 million people), which is expected to rise up to 12.2% (783.2 million) by 2045.<sup>3</sup>

Type 2 diabetes (T2DM) typically develops in adults over the age of 40 years and is closely related to lifestyle factors such as sedentary behaviour, poor diet, and obesity. It is primarily characterized by insulin resistance, where the body's cells become less responsive to insulin, leading to elevated blood glucose levels. The Etiology of T2DM is multifactorial, involving a complex interplay of genetic, environmental, and lifestyle factors.<sup>4</sup>

Its treatment is complex, requiring the management of not only blood sugar levels but also commonly associated risk factors and comorbidities such as hypertension, dyslipidemia, obesity, chronic kidney disease, depression, and non-alcoholic fatty liver diseases and to also to prevent further complications like the neuropathy, nephropathy, retinopathy and the risk of cardiovascular diseases. The treatment must be individualized based on the severity of the condition, patient age, lifestyle, and present complications.

This necessitates a combination of medications and regular monitoring to effectively control the disease. The chronic nature of diabetes and its impact on multiple body systems further emphasizes the importance of drug utilization studies to assess the standard of drug therapy in management of diabetes.

Several anti-diabetic drugs are used depending on the patient's condition. Metformin (Biguanide), the first-line therapy, reduces hepatic glucose production and improves insulin sensitivity. Sulfonylureas stimulate insulin secretion, while DPP-4 inhibitors increase insulin and decrease glucagon release, SGLT2 inhibitors promote glucose excretion, and GLP-1 receptor agonists stimulate insulin secretion, suppress glucagon, and promote satiety.<sup>5-7</sup>

#### **METHODS**

### Study design

The study, employing a prospective study design, was conducted at the IPD and OPD departments of Integral Institute of Medical Science and Research, Lucknow, India. With a sample size of 100 eligible patients being treated for type 2 diabetes.

#### Study period

The duration of the study spanned over six months (January 2023 to June 2023), the study fully complied with WHO guidelines and was conducted after obtaining approval from the Institutional Research and Ethics Committee. Consent, both oral and written, was diligently obtained before subjects participated, ensuring adherence to ethical standards. Data confidentiality was maintained, with each subject's identity kept confidential.

#### Inclusion criteria

Patients willing to participate were selected based on inclusion criteria, which included all patients diagnosed with diabetes, irrespective of age and sex, including pregnant and lactating patients.

#### Exclusion criteria

Exclusion criteria encompassed mentally retarded or unconscious patients, those not treated with anti-diabetic drugs and patients with psychological condition. Data for the study were sourced from physicians' prescribing records and patients' medication profiles, Evaluation parameters were assessed using WHO drug use indicators. <sup>2,8</sup> Including the type and average number of drugs prescribed, comparison between monotherapy and combination therapy, prescription by generic and brandname antidiabetic drugs, patients demographics, mode of administration, and the percentage of medications from the essential list of medicines (NLEM). <sup>9,10</sup>

#### Statistical analysis

For data analysis, the gathered information was analyzed using Microsoft Excel software (MS Office Excel-2010). Descriptive statistics, such as percentages and mean  $\pm$  SD, were applied to derive meaningful insights into the drug utilization patterns and outcomes of T2DM management.

#### **RESULTS**

#### **Demographics**

Age distribution

The most common age range was 51-60 years, accounting for 42% of the patients. The distribution across other age groups was: 41-50 years (33%), 61-70 years (8%), 31-40 years (7%), 71 and above (7%).

#### Gender distribution

Among the 100 patients in the study, 51% were females, and 49% were males.

Table 1: Demographics distribution (age and gender).

Variables	Frequency	%
Gender		
Male	49	49
Female	51	51
Total	100	100
Age distribution (years)		
20-30	3	3
31-40	7	7
41-50	33	33
51-60	42	42
61-70	8	8
Above 70	7	7

# Types and average number of antidiabetic drugs prescribed

Antidiabetic drugs were given 198 times among the participants, making an average of 2 antidiabetic drugs per prescription. Regular Insulin, a fast-acting insulin, was the most common and was prescribed 68 times accounting for 34.34% of the total, Metformin followed at 20.20%, with insulin glargin (Lantus) at 19.19%. Glimepiride made up 10.61%, and Human mixtard 5.05%. Vildagliptin and Sitagliptin were prescribed at 4.04% and 3.03%, respectively. Tenegliptin was administered 3 times, constituting 1.52%, while both Gliclazide and Dapagliflozin were each given 2 times, representing 1.01%. (Table 2).

Table 2: Types and frequency of antidiabetic drugs prescription.

Drug class	Drug name	Frequency	%
	Regular Human Insulin-Short acting	68	34.34
Insulin therapy	Insulin Glargin (Lantus)- Long acting	38	19.19
	Human Mixtard*	10	5.05
Biguanide	Metformin	40	20.20
Dipeptidyl	Tenegliptin	3	1.52
peptidase-4	Vildagliptin	8	4.04
(DPP-4) inhibitors	Sitagliptin	6	3.03
Sulfonylurea	Glimepiride	21	10.61
	Gliclazide	2	1.01
Sodium- glucose co- transporter 2 (SGLT2) inhibitors	Dapagliflozin	2	1.01

<sup>\*</sup>Human mixtard-combination of regular insulin and NPH insulin

#### Classes of antidiabetic drugs utilised

Five classes of antidiabetic drugs were prescribed. Insulin Therapy constitutes 58.58% of the total prescriptions, while Biguanide metformin accounts for 20.20%. Dipeptidyl peptidase-4 (DPP-4) inhibitors make up 8.59%, sulfonylurea represents 11.62%, and sodium-glucose Co-Transporter 2 (SGLT2) Inhibitors constitute 1.01%. (Table 2)

#### Combination therapy

A notable majority of the prescriptions (66%) included a combination of two or more antidiabetic drugs. Some of the combinations observed were, Human mixtard (regular insulin+NPH insulin), Metformin+Sitagliptin, Insulin Glargine+Regular Insulin, Tenegliptin+Human Mixtard, Metformin+Glimepiride, and Metformin+Vildagliptin.

Table 3: Distribution of antidiabetic drug therapy by prescription frequency.

S. No.	Drug therapy	Frequency
1	Monotherapy	
a	Prescriptions having one antidiabetic medications	34
2	Combination therapy	
a	Prescriptions having two antidiabetic medications	60
b	Prescriptions having more than two antidiabetic medications	6

# Prescription comparison between generic and brand name

Majority of the antidiabetic drugs were prescribed by generic name 109 (55%) compared to brand name 89 (45%).

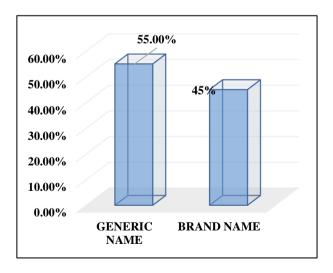


Figure 1: Comparison of drugs prescribed by generic versus brand name.

# Percentage of medicines prescribed from the essential medicines list

9 out of 10 of the prescribed antidiabetic medicines (90%), are included in the WHO 2023 essential medicines list and the CDSCO Essential Medicines List. Only sitagliptin is not currently on the essential medicines list.

#### Mode of administration

Drug prescribed by subcutaneous (SC) route are Regular Insulin, Insulin Glargin and Human mixtard which account for 58.58 % of the total prescription. Orally were Metformin, Tenegliptin, Vildagliptin, Sitagliptin, Glimepiride, Gliclazide and Dapagliflozin accounting for 41.42%.

Table 4: Mode of administration.

Drugs name	Route	%
Regular insulin Insulin glargin Human mixtard	Subcutaneous (SC)	58.58
Metformin Tenegliptin Vildagliptin Sitagliptin Glimepiride Gliclazide Dapagliflozin	Oral	41.42

### **DISCUSSION**

The demographic data showed a higher prevalence of T2DM in the age group of 51-60 years, (Table 1) accounting for 42% of the patients, consistent with global patterns indicating a higher incidence of diabetes in middle-aged adults likely due to the cumulative effect of prolonged exposure to risk factors such as obesity, sedentary lifestyle, and metabolic syndrome over time. The gender distribution was nearly equal, with 51% females and 49% males, aligning with global patterns indicating that diabetes affects both genders almost equally, though some studies suggest that TD2M is more common in males rather than females, however females often have more serious complication and a greater risk of death. <sup>11</sup>

In this study, ten antidiabetic medications from five classes were prescribed to the 100 Patients, Among the classes: Insulin Therapy was the most common, constituting 58.58% of the total prescriptions, from which regular human Insulin was frequently prescribed at 34.34%, followed by insulin glargin at 19.19% and Human mixtard at 5.05%. The use of insulin therapy in type-2-diabtes, particularly in a hospital setting, is attributed to the need for tighter glycemic control, and the need to quickly bring down blood sugar levels in acute hyperglycemia, it is commonly used in combination with other oral antidiabetics especially when oral medications are not enough. Biguanide (metformin) was the second most

prescribed antidiabetic drug at 20.20%, reflecting its status as the first-line therapy for type 2 diabetes. Its widespread use is highlighted in many studies, it is preferred for improving insulin sensitivity and having a favourable safety profile. <sup>13,14</sup> The use of sulfonylureas, particularly Glimepiride, accounted for 10.61% of prescriptions, Sulfonylureas are established as the second-line oral hypoglycemic agents for T2DM after metformin, and are often used in combination with metformin as an ad-on therapy. 15 A study conducted by Tanwar S et al, 2021 reported a 97% use of metformin and 65.5% sulfonylureas for T2DM treatment. <sup>13</sup>

Less prescribed classes are dipeptidyl peptidase-4 (DPP-4) Inhibitors including Vildagliptin and Sitagliptin (8.59%), and sodium-glucose co-transporter 2 (SGLT2) Inhibitor Dapagliflozin (1.01%). DPP-4 inhibitors and SGLT2 inhibitors are preferred in patients with renal impairment and cardiovascular comorbidities respectively. <sup>16</sup> especially since metformin is contraindicated in patients with renal dysfunction, congestive heart failure (CHF), and hepatic impairment. <sup>17</sup>

Combination therapy was prevalent, with 66% of the patients receiving two or more antidiabetic drugs. The observed combinations, such as metformin with Sitagliptin, metformin with glimepiride or insulin glargine with regular insulin, reflect the contemporary practice aimed at optimizing glycaemic control by targeting different pathways to enhance efficacy, delay progression and address different pathophysiological defects. The current treatment guidelines recommend combination therapy for patients who do not achieve glycaemic targets with monotherapy.<sup>18</sup>

The prescription of drugs by Generic name (55%) was slightly more common than by Brand name (45%), However, this is less than the ideal goal of 100% prescription by generic name recommended by WHO indicating a potential area for improvement. On a positive note, the high percentage (90%) of drugs prescribed from the WHO and CDSCO essential medicines list indicates adherence to guidelines for the prescription of essential drugs. 9,10

The mode of administration data showed that 58.58% of the antidiabetic drugs were given subcutaneously, primarily insulin therapies, while 41.42% were orally. This is because insulin therapy is often needed for immediate blood glucose control, while oral medications are typically used for ongoing management in stable patients. <sup>12</sup> Drug Utilisation Evaluation studies are imperative in gauging prescription patterns in comparison with commonly applied guidelines and to assess the quality of drug therapy provided to patients, to monitor, evaluate and suggest necessary modifications in the methods of prescribing to attain rational and cost-economical pharmacotherapy.<sup>2,19</sup>

It is important to recognize the study's limitations. Firstly, the research focused on evaluating drug prescribing

patterns, excluding other non-pharmacological therapies, laboratory reports, and medication adherence. Secondly, the research was conducted at a single institution with a small sample size, limiting generalizability. Furthermore, the inability to follow up with patients after discharge prevents a comprehensive assessment of the long-term outcomes of the treatment. Relying on prescription records and patient medication profiles may also overlook the use of over-the-counter drugs.

#### CONCLUSION

The study provides valuable insights into real time prescribing patterns of antidiabetic drugs in a hospital setting, revealing the majority of patients (66%) to be receiving combination therapy with an average of 2 drugs per prescription, metformin, as expected, remained the most frequently used oral antidiabetic (20.20%), reflecting its status as the first-line therapy and insulin therapy being most commonly prescribed class (58.58%), The data also highlighted a slightly higher prescribing by generic names and a high adherence to the use of WHO essential medicines list (90%).

The study advances our understanding of current prescribing trends and underscores the importance of combination therapy in managing type 2 Diabetes, especially in achieving tighter glycaemic control. The findings can help healthcare professionals and relevant authorities refine treatment guidelines, promote rational drug use, and emphasize the need for broader adherence to prescribing guidelines. Additionally, these insights can assist in improving patient outcomes by encouraging the integration of comprehensive drug utilization reviews in prescribing practice.

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