

## Evaluation of Antidiabetic Drug Prescription Trends in a Tertiary Care Hospital's Outpatient Department

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### Abstract:

**Background:** The main goal of treatment for preventing damage to target organs and other problems from diabetes is still glucose control. When diabetes mellitus is present, poor glycemic control can be avoided with the prudent use of oral hypoglycemic medications (OHA). Drug utilization studies are a useful tool for assessing the rational use of medications in populations.

**Approach:** Prior to starting the trial, the Institutional Ethics Committee's necessary approval was acquired. After obtaining agreement, 300 Type II diabetes mellitus patients who met the study's specific inclusion and exclusion criteria were added to the trial. These patients were given a case record form that included information about their sociodemographic profile and prescription pattern. The majority of patients (65%) were receiving combination therapy, while 35% were receiving antidiabetic monotherapy. Biguanides made up 50% of all prescribed medications, followed by sulfonylureas (26%), DPP4 inhibitors (21%), and OHA combination therapy. The most commonly prescribed medication was metformin (80%), followed by sulfonylureas (45%) and DPP4 inhibitors Teneligliptin (18%), Vildagliptin (15%).

**Conclusion:** Metformin was the most commonly prescribed medication in diabetes.

**Keywords:** HbA1c, Glycated Haemoglobin, International Diabetes Federation, International Network of Rational Use of Drugs.

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### Introduction

Diabetes has emerged as a major healthcare problem in India. According to Diabetes Atlas (DA) published by the International Diabetes Federation (IDF), there is an alarming rise in disease progression from 40 million in 2007 to 70 million by 2025 in India and every fifth person with diabetes will be an Indian. Diabetes has emerged as a major healthcare problem in India.

According to Diabetes Atlas (DA) published by the International Diabetes Federation (IDF), there is an alarming rise in disease progression from 40 million in 2007 to 70 million by 2025 in India and every fifth person with diabetes will be an Indian. Is expected to quadruple in developing nations between 2000 and 2030 [1]. According to the World Health Organisation, a 50% globally, there is a projected increase from 171 million in 2000 to

366 million in 2030. Over the next ten years, the number of deaths in metropolitan areas is expected to rise due to diabetes, which is predicted to rank as the seventh most common cause of death by 2030. Regarding the possible burden that diabetes may have on the nation, these anticipated extrapolations and projections are concerning statistics [2]. The prudent administration of insulin and oral hypoglycemic agents (OHAs) can occasionally prevent poor glucose control in diabetes mellitus [3].

"Those patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements for an adequate period of time, and at the lowest cost to them and their community" [4] is the definition of rational drug usage. Drug utilisation studies are a useful tool for

assessing the rational use of medications in communities. The marketing, distribution, prescription, and use of medications in a society, taking into account its medical, social, and economic ramifications, is what the World Health Organisation (WHO) defines as "drug utilisation" [5]. Therefore, it is crucial to conduct drug utilisation studies of anti-diabetic medications in order to encourage diabetics to use drugs sensibly and to provide the medical staff with useful information. This study evaluated the drug use pattern.<sup>8</sup>

This study examined the drug use patterns of patients with type II diabetes and examined prescriptions using the WHO core drug prescribing indicators. The study's goal was to ascertain how individuals with Type II diabetes mellitus used medications based on WHO Core prescription parameters. Dipeptidyl peptidase inhibitors, or DPP-IV Inhibitors, are a novel family of antidiabetic medications that have been on the market since 2009. This has increased the options for diabetic treatment. Given the new medications being developed and extensively used in clinical settings, the study will assist in identifying any changes, if any, in the prescription trends of antidiabetic medications as monotherapy and combination therapy [4].

**Materials & Methods:** Prior to starting the investigation, the Institutional Ethics Committee's required approval was acquired.

**Study design:** The research was descriptive, cross-sectional and observational.

**Sample size:** 300 Type II diabetes mellitus patients seeking consultation in the Medicine OPD are part of the Study population: Patients with type II diabetes mellitus who met the study's specific inclusion and exclusion criteria were accepted.

**Inclusion Criteria:** Those who were diagnosed with Type II Diabetes Mellitus and were at least 18 years old OHA alone, insulin alone, or OHA + insulin (monotherapy or combination therapy) for a minimum of four months in the past. The individuals who consented to sign the informed consent document

**Exclusion Criteria:** Patients with type 1 diabetes; expectant mothers, including those with gestational diabetes; and patients with diabetes brought on by other causes (such as malnourishment, illness, or surgery) are excluded.

- Patients who were unable to finish the survey
- Hospitalized and/or suffering from a mental illness at the time of data collection (due to an evaluation of diabetic self-care practices)

**Form for case records (CRF):** The following details about the Type II diabetes patients who

visited the medicine outside department were entered into a CRF.

Pattern of prescriptions based on WHO Core prescribing indicators

- Typical medications prescribed;
- Generic names prescribed;
- Antibiotics utilized;
- Injections used;
- Medications included in India's Essential Drug List (2011)

**Socio-Demographic Profile:** Using Kuppaswamy's socio-economic status scale (modified), the patients with Type II diabetes were categorised as belonging to Upper, Upper Middle, Lower Middle, Upper Lower, and Lower socio-economic classes based on their age, gender, occupation, education, and family income.

- Oral hypoglycemic medications (OHA) in combination, monotherapy, or dual therapy. The CRF recorded the use of oral hypoglycemic medications, including biguanides, sulfonylureas, alpha glucosidase inhibitors, DPP-IV inhibitors, Thiazolidinediones, and meglitinides.
- Insulin by itself (pre-mixed, long-acting, and short-acting)
- Insulin and OHA combined therapy.

#### Study Methodology:

Completed prescriptions and all of the aforementioned information were gathered using a case record form that had already been created. After being informed of the study's purpose, the type II diabetes mellitus patients who were diagnosed and present at the medical outside department were enrolled. Every patient provided written informed consent. Prior approval was acquired from the head of the medicine department, the hospital superintendent, and the Institutional Ethics Committee of Dr. D. Y. Patil Medical College, Hospital & Research Centre, Pune. The study included all patients, regardless of gender, who were using insulin, anti-diabetic medications or both. Medication that was prescribed. Drug active components are categorised using the Anatomical Therapeutic Chemical (ATC) Classification System based on their chemical, pharmacological, and therapeutic qualities as well as the organ or system they work on. It was initially published in 1976 and is overseen by the World Health Organisation Collaborating Centre for Drug Statistics Methodology (WHOC).

After the data was gathered, it was examined and the relevant statistics were used to produce insightful data.

**Primary Outcomes:** The prescribing pattern for both combination and monotherapy antidiabetic

medications. Average medications prescribed, medications by name, antibiotics administered, injections administered, and medications prescribed that are on the Essential Drug List-India

**Secondary Results:** The anthropometric, sociodemographic, and professional characteristics of individuals with Type II diabetes. Survey responses and patient demographics were compiled using descriptive statistics. Chi-square tests (categorical variables) were used to assess differences in HbA1c goals. Individual differences were evaluated using the Bonferroni function when chi-square testing revealed significant differences. The association between insufficient glycaemic control and possible influencing factors was evaluated using the independent t test (measurement data). A value of  $P < 0.05$  was deemed statistically significant. For all computations, SPSS software (version 20.0) was utilised.

### The sociodemographic profile of individuals with Type II diabetes

**Age:** The mean age (S.D.) of 300 Type 2 diabetic patients in this study, who ranged in age from 18 to 80, was 50.9 (15.5) years. 81 (30.5%) were younger than 55. 8 (38.01%) were in the 45–50 age range, and 70 (30.6%) were over 65. **Gender:** 90 (45.5%) of the 300 patients were female, and 115 (55.9%) were male. The ratio of males to females was 1.5.

**Social class:** Of the 300 patients, 35 (18%) belonged to the upper class, 98 (45.2%) to the upper middle class, 16 (5.9%) to the lower middle class, 50 (22.9%) to the upper lower class, and 24 (9%) to the lower socioeconomic level.

Patients with Type II diabetes and their treatment options of all the diabetic patients, 225 (90.5%) were taking oral hypoglycemic medications alone, and 30 (10%) were taking both insulin and oral hypoglycemic medications.

### Research on the use of antidiabetic medications:

The overall use of antidiabetic medications: As diabetes worsens, beta cell activity typically declines, necessitating combination therapy. As a result, combination modalities are now a crucial component of diabetes care. Combination therapy's main justification is to enable lower dosages for illness control while offering cumulative effects with various modes of action. Accordingly, the majority of patients in this study (75%) were receiving combination medication, whereas 25% were receiving monotherapy.

Biguanides made up 38% of all prescription medications among all hypoglycemic medicines, followed by sulfonylureas (19%), and insulin was administered in 3% of instances. The most often

given medications were biguanides (Metformin), which accounted for 203 (90%) of all prescriptions, followed by sulfonylureas (Glimepiride) in 87 (45%), and DPP4 inhibitors (Teneligliptin, Vildagliptin).

Insulin encounters were 20 (9%), in 100 (40%) of Type II diabetic patients.

• **Monotherapy:** Biguanides were the most often given oral hypoglycemic medication among 65 patients receiving monotherapy, with 40 (55%), followed by sulfonylureas 32 (40%), meglitinide (4, 7%), and thiazolidinediones (2, 5%). Insulin encounters did not occur.

• **Combination therapy:** Among the 300 total encounters, 157 (96%), biguanides (Metformin) were the most frequently prescribed medication. Sulfonylureas (Glimepiride) came in second, with 20 (10%), prescriptions for combination therapy including insulin and an oral hypoglycemic agent.

Short-acting insulin was the most often prescribed kind of insulin therapy, as seen in Figure 3. The most often administered insulin (80%) is insulin lispro.

• Prescriptions for fixed medication combinations accounted for 145 (72%) of all prescriptions. There were two kinds of it.

### Discussion:

In India, diabetes is a serious medical issue. "A chronic, metabolic disease characterised by elevated levels of blood glucose (or blood sugar), which over time leads to serious damage to the heart, blood vessels, eyes, kidneys, and nerves," is how the World Health Organisation defines diabetes mellitus [6]. According to a population survey conducted in India, 4% of adults had diabetes mellitus in 2000, and by 2025, that number is predicted to increase to 6% [7].

In contrast to industrialised nations where diabetes is most common in people over 65, the majority of diabetics in developing nations like India are between the ages of 40 and 65 [8]. By 2025, there will be 70 million diabetics in India, up from 40 million in 2007; every fifth diabetic worldwide will be an Indian, according to the International Diabetes Federation's (IDF) Diabetes Atlas (ADA) [9]. As a result, research on many facets of diabetes mellitus and how to control it is crucial. The current study focused on the drug use patterns of Type II diabetic patients and was a hospital-based cross-sectional study carried out in the tertiary care hospital's diabetes clinic. The study's main goal was to evaluate the prescription patterns for antidiabetic medications among diabetic patients who visited the medicine outpatient department.

### Type II diabetes mellitus patient profile

The current study included 300 patients as participants. The age group under 50 years old accounted for the majority of responders (42%), followed by the age group over 65 (46.3%). This result contradicts research by Jambu Jain et al. [11].

Similar to a study by Mamata Sharma et al. [15], the majority of the patients in this study were from the upper middle socioeconomic level. These findings contradict those of Shah et al. [16], who discovered that almost 60% of patients came from low socioeconomic backgrounds. 7.7% of diabetes patients were receiving insulin and oral hypoglycemic agent (OHA) combination therapy, whereas the majority of patients (92.3%) were using oral hypoglycemic agents alone. No patient attending the outpatient department was administered insulin alone, however according to a study by Gopinath B et al. [17], in 66.4% of the instances, OHA alone,

Similar studies have been reported by various authors in literature. Khushali G. Acharya et al. [18], Jambu Jain et al. (2016) [11] have also reported that OHA is the most commonly prescribed therapy. Drug utilization study This study focused on the prescription pattern among diabetic patients attending the outpatient departments in the hospital the principal aim of drug utilization research is to facilitate the rational use of drugs in populations.

For the individual patient, the rational use of a drug implies the prescription of a well-documented drug at an optimal dose, together with the correct information, at an affordable price. Knowledge of how drugs are being prescribed and used, will help to identify issues if any addressing rational drug.

According to the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, the MCI circular reaffirmed that all registered medical practitioners must adhere to them. Despite these rules, brand-name prescriptions are still a concern. These findings are consistent with those made, in particular, by Dev Priya et al. [23] and Kumar Raj et al. [25]. Parenteral preparation (injection) encounters were 12.27% in our study, compared to 17.04% in a study by V. Karthikeyan et al. [22].

Thirty percent of patients in the current study were receiving oral hypoglycemic medication alone, while seventy percent were receiving combination therapy.

A research by Soumya Mary Alex et al. [13] in Kerala revealed similar findings (58.4% polytherapy). Monotherapy and two-drug combination therapies were prescribed to 21.7% and 78.3% of patients, respectively, in a Tamil Nadu study by Sivasankari V et al. [4]. Biguanides (Metformin) were the most often given class of

anti-diabetic medications, either alone or in combination. Metformin made up 85% of all prescriptions, followed by sulfonylureas (glimepiride) (41%), and DPP4 inhibitors (teneligliptin, Vildagliptin). Similar findings for biguanides and sulfonylureas have been reported in studies by Akshay A. Agarwal et al. and Soumya Mary Alex et al. [13].

In contrast to insulin, thiazolidinediones, and sulfonylureas, metformin is weight neutral, making it a desirable option for obese individuals. Moreover, hypoglycemia can significantly hinder the goal of glycaemic control, making Type II diabetes care more difficult. Since metformin reduces excess hepatic gluconeogenesis without increasing insulin levels, it rarely causes significant hypoglycemia when taken alone. Metformin is therefore frequently regarded as the best first-line medication for the management of Type 2 diabetes. Furthermore, people in economically disadvantaged nations like India can purchase metformin due to its extremely low cost [13].

Remarkably, the results did not support the DPP4 inhibitor usage trend. Jambu, Akshay A. Agarwal et al. [12], Soumya Mary Alex et al. [13], Fewer usage patterns than those revealed in the current study were documented. The findings highlight how this relatively new family of antidiabetic medications is being used more often in clinical settings. Potential advantages of DPP-4 inhibitors include a favourable adverse-effect profile, a neutral effect on weight, and a complimentary mechanism of action with other antidiabetic drugs. For individuals who consistently have increased glucose levels after meals but are near their target HbA1c, DPP-4 Inhibitors are beneficial due to their minimal risk of hypoglycemia.

Among the two medication combinations, metformin + vildagliptin (37%) and metformin + glimepiride (34%), respectively, were the most frequently given fixed dose combinations. Biguanide + sulfonylureas + alpha glucosidase inhibitor was the most commonly recommended fixed dose combination among the three medication combinations.

Similar outcomes were demonstrated by various articles using the for-metformin combination. The most often recommended combinations, were metformin and DPP4 inhibitor (62%) as second-line treatments and metformin + sulphonylureas + DPP4 inhibitor (44%) as third-line agents. In the current trial, patients with a higher body mass index and glycated haemoglobin levels above 9% were started on DPP4 inhibitors.

The current investigation encountered three different forms of insulin, according to the results. Lispro (8.70%), insulin glargine (0.7%), Regular Human Insulin, and NPH Human Insulin combo

(2%) were among the insulin formulations that were prescribed.

In summary, biguanides made up 50% of all prescribed hypoglycemic medications, followed by sulfonylureas (26%), DPP4 inhibitors (22%), meglitinide (10%), glucosidase inhibitors (6%), and thiazolidinediones (4%), after insulin (3%). The most frequently prescribed fixed medication combination was metformin with Vildagliptin. We were unable to assess the suitability of treatment or examine the dosages of antidiabetic medications that were prescribed. The current study demonstrated the prescription pattern in practice for a significant number of patients with type 2 diabetes in spite of these constraints. In summary, the trend in the prescription of antidiabetic medications has shifted from sulphonylurea monotherapy to combination treatments, which employ Biguanides and DPP-4 inhibitors more frequently to improve glycaemic control.

### Conclusion:

Sulfonylureas (glimepiride) were the next most commonly recommended medication for diabetes, behind Metformin. Biguanides and sulfonylureas were the most often used pharmacological class among antidiabetic medications used as monotherapy. Glimpiride and metformin together were the most commonly given combination treatment. The most often prescribed combination of fixed drugs was metformin plus vildagliptin. The majority of medications were prescribed from the list of national essential pharmaceuticals. The average number of medications prescribed was 2.03. There were no generic names prescribed for any of the medications. Every medication had a brand name on the prescription.

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