WWW.IJRPR.COM

International Journal of Research Publication and Reviews

Journal homepage: www.ijrpr.com ISSN 2582-7421

Prescription Pattern Analysis of Antidiabetic Drugs in a Tertiary Care Hospital, Kasaragod, Kerala India

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ABSTRACT:

Analyzing drug prescription patterns in a tertiary care hospital is the goal of the current investigation. In the outpatient department (OPD) of a tertiary care hospital in Kasaragod, an observational study was carried out. To examine the prescription trend, 200 prescriptions in total were collected. The information comprised patient demographics, the distribution of antidiabetic medications by class, sample distribution based on monotherapy or combination therapy, the kind of fixed-dose combination (FDC) of antidiabetic medications, and comorbidity assessment. According to the study's data, men are more likely than women to develop Type 2 diabetes. According to the study, diabetes is very common among people between the ages of 51 and 60. More monotherapy than combination therapy was prescribed to the patients. Regarding FDC[2].

INTRODUCTION:

A prescription is a formal directive to a pharmacist to prepare and dispense a particular medication for a patient from a registered medical professional or other appropriately licensed professionals, such as dentists, veterinarians, etc. Every nation has its own laws, and there is no universal standard for prescriptions. The prescription's clarity is the most crucial need. It should be readable and specify exactly what needs to be provided. Latin is still rarely used to write prescriptions; local languages are preferred1.

Diabetes Mellitus

Hyperglycemia is a hallmark of a group of metabolic diseases known as diabetes mellitus (DM). It is linked to anomalies in the metabolism of fat and carbohydrates, which lead to long-term issues such macrovascular and microvascular diseases. It results from the intricate interplay between environmental factors and heredity.

Types of Diabetes Mellitus

1. Type 1 Diabetes Mellitus
2. Type 2 Diabetes Mellitus.
3. Gestational Diabetes
4. Diabetes caused or associated with certain specific conditions, pathologies, and/or disorders.[4]

Type 1 Diabetes Mellitus

Type 1 DM is also called insulin-dependent diabetes. It used to be called juvenile-onset diabetes because it often begins in childhood. Your genes might cause this type of diabetes. It could also happen because of problems with cells in your pancreas that make insulin.

Health problems associated with Type 1 DM

- Damage to tiny blood vessels in your eyes (diabetic retinopathy).
- Damage to nerves (diabetic neuropathy)
- Kidneys (diabetic nephropathy)
- Higher risk of heart disease and stroke.[5]

Diabetes Mellitus Type 2

Type 2 diabetes was once known as adult-onset diabetes or non-insulin-dependent diabetes. But because more young people are overweight or obese, it has become increasingly prevalent in kids and teenagers during the past 20 years. Type 2 diabetes affects over 90% of those with the disease. Your pancreas often produces some insulin when you have type 2 diabetes. However, your body either doesn't use it properly or it's insufficient. Insulin resistance, which typically affects muscle, liver, and fat cells, is the inability of your cells to respond to insulin. Compared to type 1, type 2 diabetes is frequently milder. However, it can still lead to serious health issues, particularly in the small blood vessels in your eyes, kidneys, and nerves. Type 2 increases your risk as well.

Pathophysiology

Five to ten percent of all cases of diabetes are type 1 DM. It usually appears in childhood or early adulthood and is caused by the immune system destroying the pancreatic β-cell, which leaves the body completely insulin deficient. When β-cell breakdown is believed to occur, there is a lengthy preclinical period (up to 9–13 years) during which immunological markers are present. When 80–90% of β-cells are killed, hyperglycemia results. After a brief period of remission, known as the "honeymoon" phase, the condition becomes established and carries a risk of complications and mortality. Although the exact causes of the autoimmune process are unknown, macrophages and T lymphocytes with circulating autoantibodies to different β-cell antigens (such as insulin and islet cell antibodies) mediate the process.9.

Pathophysiology of Type 1 DM

Type 2 DM accounts for as many as 90% of DM cases and is usually characterized by the presence of both insulin resistance and relative insulin deficiency. Insulin resistance is manifested by increased lipolysis and free fatty acid production, hepatic glucose production, and decreased skeletal muscle uptake of glucose. β-cell dysfunction is progressive and contributes to worsening blood glucose control over time. Type 2 DM occurs when a diabetic lifestyle (excessive calories, inadequate exercise, and obesity) is superimposed upon a susceptible genotype.[10,11]

Pathophysiology of Type 2 DM

Any level of diabetes or glucose intolerance identified at the beginning of pregnancy or during it, typically in the second or third trimester, is referred to as gestational diabetes mellitus (GDM). Any undiagnosed type 2 diabetes that may start before or at the outset of pregnancy was also included by this criteria in the past. The International Association of the Diabetes and Pregnancy Study Groups' most recent guidelines, however, do not include diabetes diagnosed at the beginning of pregnancy or later in high-risk women, such as those who are obese, where any level of glucose intolerance is referred to as previously undiagnosed overt diabetes rather than GDM. In women who are pregnant, gestational diabetes mellitus (GDM) is distinct from any underlying diabetes and typically goes away shortly after delivery or pregnancy termination12,13.

Early in pregnancy, the postprandial and fasting blood.

Pathophysiology of Gestational diabetes

The monogenic abnormalities in β-cell activity are the source of other forms of diabetes. Only 0.6–2% of all occurrences of diabetes are caused by monogenic abnormalities in β-cell activity, and these primarily comprise neonatal diabetes and maturity-onset diabetes of the young (MODY), among other uncommon forms. Mutations in a number of specific genes involved in pancreatic β-cell function cause maturity-onset diabetes of the young (MODY), a genetically, metabolically, and clinically diverse group of primarily non-insulin-dependent diabetes that affects glucose sensing and subsequent insulin secretion with no or very minor defects in insulin action. As the name implies, MODY is characterized by an early onset, with hyperglycemia and impaired glucose tolerance typically developing before the age of 25. It is frequently misdiagnosed as T1DM or T2DM18,19.

Diagnosis

Type 2 diabetes is usually diagnosed using the Hemoglobin A1C (HbA1c) test.[20] This blood test indicates your average blood sugar level for the past two to three months. Results are interpreted as follows:

- Below 5.7% is normal.
- 5.7% to 6.4% are diagnosed as prediabetes.
- 6.5% or higher on two separate tests indicates diabetes.[21]

Diabetes control chart

Random blood sugar test

Blood sugar values are expressed in milligrams of sugar per decilitre (mg/dL) or millimoles of sugar per liter (mmol/L) of blood. Regardless of when you last ate, a level of 200 mg/dL (11.1 mmol/L) or higher suggests diabetes, especially if you also have symptoms of diabetes, such as frequent urination and extreme thirst.[22,23]

Fasting blood sugar test

A blood sample is taken after you haven't eaten overnight. Results are interpreted as follows:

- Less than 100 mg/dL (5.6 mmol/L) is considered healthy.
- 100 to 125 mg/dL (5.6 to 6.9 mmol/L) is diagnosed as prediabetes.
- 126 mg/dL (7 mmol/L) or higher on two separate tests is diagnosed as diabetes.[24,25]

Oral glucose tolerance test

This test is less commonly used than the others, except during pregnancy. You'll need to not eat for a certain amount of time and then drink a sugary liquid at your healthcare provider's office. Blood sugar levels then are tested periodically for two hours. Results are interpreted as follows:

- Less than 140 mg/dL (7.8 mmol/L) after two hours is considered healthy.
- 140 to 199 mg/dL (7.8 mmol/L and 11.0 mmol/L) is diagnosed as prediabetes.
- 200 mg/dL (11.1 mmol/L) or higher after two hours suggests diabetes.[26,27]

Management

1.4.1 Non-pharmacologic Treatments for Diabetes

Medical nutrition therapy (MNT), weight management, physical activity, smoking cessation, diabetes self-management education and support, and psycho-social care are essential for achieving treatment goals and improving the quality of life among patients with diabetes.[28]

Dietary Modification in Diabetes Treatment

Encouraging adherence to an appropriate diet can be one of the most challenging aspects of diabetes care. At the time of diagnosis, referral to a registered dietitian nutritionist (RD/RDN) can facilitate the implementation of diabetes-specific MNT. According to the ADA, individuals with type 1 diabetes who received MNT delivered by an RD/RDN experienced HbA1c reductions ranging from 1.0% to 1.9%: patients with type 2 diabetes experienced HbA1c reductions ranging from 0.3% to 2%.

Other benefits of MNT include,

- Delaying or preventing the development of type 2 diabetes in high-risk individuals.
- Tightening glycemic control, thus reducing diabetic complications; and
- Helping to manage diabetes complications.[29]

Macronutrient goals and food choices will differ among individuals. However, common recommendations include,

- Adoption of a low glycemic index diet to improve postprandial blood glucose excursions
- Use of non-nutritive sweeteners to replace sugar for calorie and carbohydrate control
- Increased consumption of dietary fiber
- Low-calorie and low-carbohydrate diet for weight management and metabolic control. [30]

Controlling Weight for Diabetes

For all diabetic patients who are overweight or obese, weight loss and control techniques are crucial. A 500–700 kcal/d calorie deficit might cause substantial weight loss. Weight loss is not always effective in causing diabetic remission, even though it can enhance insulin sensitivity in the liver and skeletal muscles and partially repair insulin secretion abnormalities in individuals with prediabetes or newly diagnosed type 2 diabetes. Positive effects on blood pressure, lipids, and glycaemic management may be observed with a 5% weight loss.10. However, some people may need to set a more aggressive weight loss target of around 15% in order to reap these benefits.10. Long-term advantages if weight loss is sustained for five years include

Pharmacological Treatment

In order to alleviate symptoms, enhance patients' quality of life, stop more complications, and lower mortality, diabetes treatment primarily focuses on glycaemic management. However, in order to reduce multifactorial hazards, different treatments must be used. Drugs that lower insulin resistance (biguanides, thiazolidinediones, or glitazones), secretagogues and their analogs (sulfonylureas, meglitinides, inhibitors of dipeptidyl peptidase IV (DPP-4) or agonists and analogs of glucagon-like peptide-1 (GLP-1), and medications that slow down the rate of carbohydrate degradation (alpha-glucosidase inhibitors) are among the many drug classes that can be used to treat type 2 diabetes. One of the most recent drugs for glycemic management, dapagliflozin, was just given FDA approval in January 2014. It works by blocking the sodium-glucose cotransporter.

Classification of Oral Antidiabetic Drug

INSULIN

In 1922, Canadian researchers were the first to demonstrate a physiologic response to injected animal insulin in a patient with type 1 diabetes. Insulin was the first protein to be fully sequenced. The insulin molecule consists of 51 amino acids arranged in two chains, an A chain (21 amino acids) and B chain (30 amino acids) that are linked by two disulfide bonds.[36]

Sources of insulin

With the availability of human insulin by recombinant DNA technology in the 1980s, the use of animal insulin declined dramatically. Beef insulin, beef-pork, and pork insulin are no longer commercially available in the United States. The United States FDA may allow for personal importation of beef or pork insulin from a foreign country if a patient cannot be treated with human insulin. Beef insulin differs from human insulin by 3 amino acids and pork insulin differs by one amino acid

Currently, in the United States, insulins used are either human insulin and/or analogs of human insulin. The recombinant DNA technique for producing insulin for commercial use involves the insertion of the human proinsulin gene into either Saccharomyces cerevisiae (baker's yeast) or a non-pathogenic laboratory strain of Escherichia coli (E coli) which serves as the production organism. Human insulin is then isolated and purified.[37]

Insulin Analogs

Recombinant DNA technology has allowed for the development and production of analogs to human insulin. With analogs, the insulin molecule structure is modified slightly to alter the pharmacokinetic properties of insulin, primarily affecting the absorption of the drug from the subcutaneous tissue. The B26-B30 region of the insulin molecule is not critical for insulin receptor recognition and it is in this region that amino acids are generally substituted.[38]

The structures of three rapid-acting insulin analog (insulin aspart, lispro and glulisine) and the structures of three long-acting insulin analogs (insulin glargine, detemir, and degludec) are shown below.

Insulin and its preparations

Name of Insulin	**Preparations**
Rapid – Acting	
Insulin Lispro	Vial, Catridge, Pen
Insulin Aspart	Vial, Catridge, Pen
Insulin Glulisine	Vial, Pen
Technosphere insulin	Inhaler
Short- Acting	
Regular Human	Vial
Intermediate- Acting	
NPH Human	Vial, Pen
Long- Acting	
Insulin Determir	Vial, Pen
Insulin Glargine	Vial, Catridge, Pen
Insulin Glargine-yfgn	Vial, Pen
Insulin Degludec	Pen
Insulin Mixtures	
NPH/ Regular (50%/50%)	Vial, Pen
Protamine/ Lispro (50%/25%)	Vial, Pen
Protamine/ Lispro (75%/25%)	Vial, Pen
Protamine/ Aspart (70%/30%)	Vial, Pen

Types of Insulin and Preparations

TYPES OF REGIMENS

General Principles

TYPE 1 DIABETES

Patients with type 1 diabetes eventually need insulin for survival due to a steady decrease in insulin production caused by autoimmune beta cell death. Insulin replacement doses for patients with type 1 diabetes typically range from 0.5 to 1.0 units per kilogram of body weight each day. Patients with type 1 diabetes typically need less insulin in the early stages because some insulin is still produced by the surviving beta cells; during this "honeymoon period," insulin needs might range from 0.2 to 0.6 units per kilogram per day. Patients with type 1 diabetes should have intensive insulin therapy, which is defined as three or more insulin injections per day or insulin pump therapy, since this will improve glycemic control and reduce glucose variability compared to receiving injections once or twice a day.

TYPE 2 DIABETES

Because type 2 diabetes patients gradually lose beta cells, many of them will eventually need insulin therapy in order to achieve proper glycemic control. Any of the following circumstances may warrant the start of basal insulin: 1) a patient with a HbA1C > 11% who may have insulin insufficiency; 2) a patient without chronic kidney disease or atherosclerotic cardiovascular disease whose HbA1C is higher than target after three months of metformin monotherapy; 3) a patient with chronic kidney disease or atherosclerotic cardiovascular disease whose HbA1C is higher than target after three months of treatment with metformin, a GLP-1 receptor agonist, and/or an SGLT2 inhibitor. Because insulin resistance is linked to type 2 diabetes, daily insulin needs may be higher than 1 unit/kg. When starting insulin

Basal insulin is effective at lowering HbA1c when added to oral hypoglycemic agents starting at a dose of 10 U daily or 0.2 U/kg.

While concurrent use of other antihyperglycemic drugs maintains postprandial glucose levels throughout the day, basal insulin regulates fasting blood glucose (FPG) by inhibiting hepatic glucose output at night. Although 0.1–0.2 units/kg will more quickly reach the desired fasting glucose level, a beginning dose of 10 units of basal insulin is typically used. Prandial insulin is recommended for patients whose fasting glucose levels are adequately managed with basal insulin but whose glucose levels increase noticeably later in the day and who have a consistently high HbA1C. The patient is currently suffering from beta-cell failure. Since insulin will now be substituted exogenously, the patient should stop using any insulin secretagogues, such as meglitinide or sulfonylureas.

NEED AND OBJECTIVES

NEED OF THE STUDY

The optimization of medication therapy and drug control in diabetics depends on research on the prescribing pattern of antidiabetic medications. This will assist in directing present and future medical professionals in the prescription of antidiabetic medications along with other related medications. Medication adherence and illness improvement are positively impacted by appropriate prescribing. Prescription pattern surveys, a part of pharmacoepidemiologic methods, offer an objective view of prescribing practices and assist in identifying suboptimal prescribing patterns for additional analysis. Analytical studies of this type are the most effective way to compare prescription patterns and drug use with regard to treatment outcomes.

OBJECTIVES OF THE STUDY

The aim was to study the prescribing pattern of anti-diabetic drugs.

METHODOLOGY

Study Environment

The investigation was conducted at Kasaragod's K S Abdulla Hospital's outpatient block. The data was taken from the patient's prescription after speaking with a doctor. The patients might be either male or female and ranged in age from 25 to 80.

DURATION OF STUDY

The three-month trial period ran from March to May of 2024.

Examine the population

200 patients with type 2 diabetes and other co-morbid illnesses, both male and female, make up the study group. The study population consisted of patients who met the inclusion requirements and were prescribed antidiabetic medications.

SIZE OF THE SAMPLE

200 prescriptions in all were gathered from K.S. Abdulla Hospital's outpatient department.

STUDY DESIGN

A prospective observational study is conducted in various prescriptions of the OP department. Prescription patterns of antidiabetic drugs were categorized according to age, gender, class of drug, single or multidrug treatment, fixed-dose combination of drugs, and comorbid conditions associated with type 2 diabetics. Data was collected and entered and analysis was done using Microsoft Excel. The categorical variable was expressed in terms of frequency and percentage and graphs were prepared using a Microsoft Excel sheet.

SELECTION OF SUBJECTS

The patients or the subjects were selected or taken into this study according to the following inclusion and exclusion criteria

Inclusion criteria

- Patients of both sexes
- Patients in age group 25-80
- Patients diagnosed with Diabetes Mellitus.
- Patients with Diabetes along with other co-morbidity were selected.

Exclusion Criteria:

• The study did not include patients with type 1 diabetes mellitus or other ambulatory diseases including poisoning or accidents.

• The study did not include pediatric patients.

• The study does not include patients with gestational diabetes.

•For the current study, 200 individuals who were administered anti-diabetic medications were enrolled. To examine their prescribing habits, their prescriptions were examined. The following are the study's findings.

Distribution of samples based on gender

- Of a total of 200 patients, 110 patients were males (55%), and 90 patients were females (45%). From the study, data shows that males are more prone to diabetes when compared to females (Figure 10).

Gender	**Frequency**	**Percentage**
Female	90	45%
Male	110	55%
Total	200	100%

Distribution of samples according to gender

Distribution of samples according to age.

The age group recorded in the study was 31-80 years. Among 200 patients 10 (5%) patients belong to the 31-40 age group, 40 (20%) patients belong to the 41-50 age group,53 (27%) patients belong to the 51-60 age group, 70 (35%)patients belong to 61-70 age group, 27 (14%) patients belong to 71-80 age group (Figure 11).In the study, the occurrence of diabetes was highly seen in the 61-70 age group and the least occurrence of diabetes was seen in the 31-40 age group.

Age in years	**Frequency**	**Percentage**
31-40	10	5.00%
41-50	40	20.00%
51-60	53	26.50%
61-70	70	35.00%
71-80	27	13.50%
Total	200	100%

Distribution of sample according to age

Distribution of anti-diabetic drugs- Mono and combination therapy

- Among 200 cases, 125 cases were on monotherapy i.e., 63% of cases were prescribed a single antidiabetic agent. 75 cases (38%) were prescribed combination therapy.

Therapy	**No. of Prescriptions**	**Percentage**
Mono therapy	125	62.50%
Combination therapy	75	37.50%
Total	200	100%

Distribution of antidiabetic drugs- Mono and combination therapy

- **Distribution of anti-diabetic medications by class (mono and combo therapy)**

•According to the current study, anti-diabetic medications were given in six different groups. Biguanides were the most prescribed class (23.68%) when considering the total number of medications administered. Sulphonyl urea (16.58%), DPP4 agonist (7.11%), SGLT2 inhibitors (3.16%), PPAR gamma agonist (1.32%), and α-glucosidase inhibitor (0.79%) were the next most common classes. Biguanides are the most often given anti-diabetic medications, while PPAR gamma agonists and α-glucosidase inhibitors are the least frequently administered.

Prescribed drugs	Frequency	Percentage
Sulphonyl urea	63	16.58%
Biguanides	90	23.68%
DPP4 agonist	27	7.11%
SGLT2 inhibitors	12	3.16%
PPAR gamma agonist	5	1.32%
Alpha glucosidase inhibitor	3	0.79%

Class-wise distribution of antidiabetic drugs

Type of Fixed Dose Combination Anti-Diabetic prescribed

- Different kinds of fixed-dose combinations were prescribed in accordance with the current study. The most commonly prescribed combination, when considering the total number of medications given, was found to be Metformin + Glimepiride (49.11%), followed by Metformin + Gliclazide (13.39%), Metformin + Glipizide (6.25%), Metformin + Vildagliptin (17.86%), Metformin + Sitagliptin (4.46%), Metformin + Tenegliptin (2.68%), Metformin + Dapagliflozin (3.57%), and Metformin + Glimepiride + Pioglitaone (2.68%).

TYPE OF FIXED-DOSE COMBINATION	**Frequency**	**Percentage**
Metformin+ Glimepiride	55	49.11
Metformin+ Gliclazide	15	13.39
Metformin+ Glipizide	7	6.25
Metformin+ Vildagliptin	20	17.86
Metformin+ Sitagliptin	5	4.46
Metformin+ Tenegliptin	3	2.68
Metformin+ Dapagliflozine	4	3.57
Metformin + Glimepiride+ Pioglitazone	3	2.68

Type of fixed-dose combination of Antidiabetic drug prescribed

Evaluation of comorbidities

- Out of those prescriptions, patients have Type 2 Diabetes along with certain co-morbidity. The major co-morbidities observed are dyslipidemia, hypertension, coronary artery diseases (CAD), sleep disorders, and neurological disorders. Among the patients, the most commonly associated comorbid condition was found to be dyslipidemia.

COMORBIDITIES	**Frequency**	**Percentage**
Dyslipidaemia	35	36.84
Hypertension	30	31.58
Coronary Artery Disease	15	15.79
Sleep disorders	8	8.42
Neurological disorders	7	7.37

Distribution of sample according to comorbidities

DISCUSSION

- Diabetes is a chronic illness that is becoming more common both globally and in India. It is a separate factor that increases the risk of numerous morbidities that result in damage to the target organ. The likelihood of death increased as blood pressure rose.
- The purpose of the study was to evaluate the prescription pattern among diabetes patients at a tertiary care hospital in Kasaragod. Over the course of three months, 200 patients who met the inclusion and exclusion criteria were added to the research. Ninety patients (45%) were female, while 110 patients (55%) were male. According to study statistics, men are more likely than women to get diabetes.
- The study included diabetic patients between the ages of 31 and 80. The majority of diabetic patients are between the ages of 61 and 70, with the minority being between the ages of 31 and 40. Our study also found that 125 out of 200 individuals were receiving monotherapy, meaning that 63% of cases had only one oral hypoglycemic medication (OHA) prescribed. Combination therapy was provided in 75 instances (38 percent).
- According to the current study, anti-diabetic medications were given in six different groups. Biguanides are the most often recommended anti-diabetic medication, whereas PPAR gamma agonist and α-glucosidase inhibitor are the least frequently administered. Numerous fixed-dose combinations were recommended.

CONCLUSION

There are several ways to control diabetes, a chronic metabolic condition. Diabetes can be controlled with medication, weight loss, and lifestyle changes. These days, patients cannot avoid using drugs. According to the findings of our study, male patients are more likely than female patients to develop diabetes. Patients between the ages of 61 and 70 had the highest prevalence of Type 2 diabetes, followed by those between the ages of 31 and 40.

When it comes to managing diabetes and lowering blood glucose levels, monotherapy therapy is helpful. Compared to fixed combo therapy, they have less adverse effects and aid in improved diabetes maintenance. The most often recommended medication was Biguanides, and the most often prescribed combination therapy included Biguanides and Sulphonyl Ureas.

The goal of this study is to determine the most effective treatment and management strategy for diabetes by analyzing the better prescribing patterns of antidiabetic medications in a large population. A lack of time and a small sample size were the study's limitations.

Particular care is still required to address the ongoing difficulties in managing diabetes. Numerous national and international diabetes management guidelines have been released, emphasizing monotherapy or combination therapy based on blood glucose levels and related comorbidities. The initial medication of choice for diabetics has changed significantly over time, ranging from biguanides to PPAR antagonists, from monotherapy to low-dose combination single pill therapy. For improved outcomes in terms of diabetes-related morbidity and death, national health policymakers should take Type 2 diabetes assessment and treatment into account as a right in the public health system. More thorough research is needed in developing nations like India to assess prescribing practices and the use of antidiabetic drugs that are based on guidelines and can be customized to meet the needs of individual patients.

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