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Survey Based Report on Widely Prescribed Sitagliptin Drug for Treatment of Diabetes Mellitus

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Abstract: *Sitagliptin is an effective and well-tolerated oral antidiabetic medication that enhances pancreatic islet cell sensitivity to glucose. Clinical studies involving over 22,000 patients confirm its ability to improve glycaemic control in type 2 diabetes (T2DM) with minimal risk of hypoglycaemia, weight gain, edema, or lipid abnormalities. It is weight- and lipid-neutral, making it a strong option for monotherapy or combination therapy. When combined with metformin, sitagliptin provides glycaemic benefits comparable to thiazolidinediones. It also improves β-cell function and may positively influence disease progression in individuals with impaired glucose tolerance*

Keywords: Diabetes, Sitagliptin, incretin metformin, add-on treatment, hypoglycaemia

I. INTRODUCTION

According to the 2023 ICMR INDIAB study, about 10.1 crore Indian adults (aged 20–79) have type 2 diabetes, a number projected to reach 430 million by 2030. Although many antidiabetic medications exist (such as sulfonylureas, metformin, α-glycosidase inhibitors, thiazolidinediones, prandial glucose regulators, and insulin), a new treatment approach targets incretin hormones like GLP-1 and GIP. These hormones, released after meals, promote insulin secretion in a glucose-dependent manner but are quickly inactivated by the enzyme DPP-4. By inhibiting DPP-4, the activity of incretins increases, offering an effective strategy for diabetes control. Several DPP-4 inhibitors—such as sitagliptin, vildagliptin, and linagliptin—have been thoroughly evaluated for their pharmacokinetics, efficacy, safety, and tolerability.

Key points of this statement include:

Glycaemic goals and treatments for type 2 diabetes should be individualized, with lifestyle changes—diet, exercise, and education—forming the foundation. Metformin is generally the first-line therapy unless contraindicated. If HbA1c targets aren't met within about three months, adding a sulfonylurea, thiazolidinedione, DPP-4 inhibitor, GLP-1 receptor agonist, or basal insulin is advisable. Research does not consistently support the benefit of a third non-insulin agent when two-drug combinations fall short. If basal insulin plus another agent fails after three to six months, more advanced insulin strategies combined with non-insulin drugs may be needed.

Sitagliptin, a potent and selective DPP-4 inhibitor, works by preventing the rapid breakdown of GLP-1 and GIP, thereby enhancing α- and β-cell responsiveness to glucose. Its strong binding and long half-life allow it to suppress glucagon effectively and reduce glycemic fluctuations. This paper reviews the efficacy, safety, and acceptability of sitagliptin in managing type 2 diabetes.

Definition

Hyperglycaemia, or high blood sugar, is common in individuals with diabetes and can be triggered by various factors such as dietary choices, physical activity levels, illness, or inadequate use of glucose-lowering medications. Managing high blood sugar is crucial because if left untreated, it can escalate to dangerous levels—potentially leading to emergencies like a diabetic coma. Over time, even moderately elevated blood sugar can cause long-term complications affecting the eyes, kidneys, and nerves.

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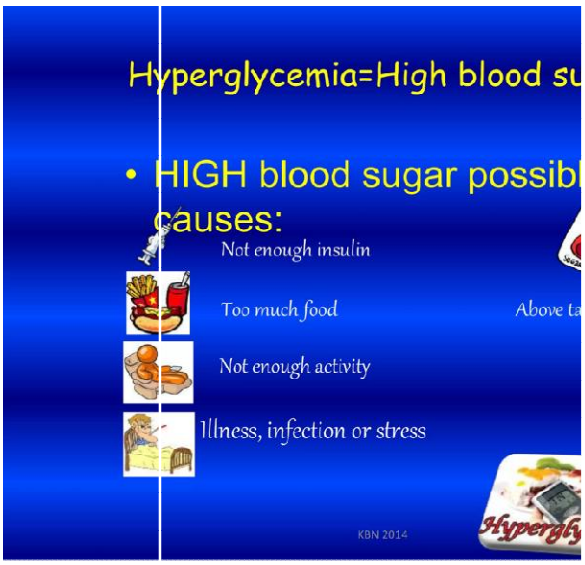

Fig.1 Hyperglycemia

Causes:

During digestion, your body breaks down carbohydrates from foods such as bread, rice, and pasta into various sugar molecules. One of these sugar molecules is glucose, a primary energy source for your body. Glucose is absorbed directly into your bloodstream after you eat, but it cannot enter most of your cells without the help of insulin, a hormone secreted by your pancreas. When your blood glucose levels rise, your pancreas releases insulin. Insulin allows glucose to enter your cells, providing them with the energy they need to function properly. Any excess glucose is stored in the liver and muscles as glycogen or converted into fat for long-term storage.

Symptoms:

Early signs and symptoms:

Recognizing early symptoms of hyperglycemia can help you treat the condition promptly. Watch for:

Increased thirst

Blurred vision

Fatigue

Headache

Later signs and symptoms:

If hyperglycemia goes untreated, it can cause toxic acids (ketones) to build up in your blood and urine (ketoacidosis). Signs and symptoms include:

Nausea and vomiting

Dry mouth

Weakness

Confusion in your liver and muscles in the form of glycogen.

This process lowers the amount of glucose in your bloodstream and prevents it from reaching dangerously high levels. As your blood sugar level returns to normal, so does the secretion of insulin from your pancreases.

Treatments and drugs

Engaging in regular physical activity is an effective way to manage blood sugar levels. However, if ketones are present in your urine, exercising can cause blood sugar levels to rise even further, so it should be avoided. Monitoring blood sugar is also crucial, and you should follow your doctor's recommendations on how often to check your glucose levels. More frequent monitoring is necessary if you are ill or concerned about severe hyperglycemia or hypoglycemia. In

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cases of severe hyperglycemia, emergency treatment may be required. Fluid replacement, either orally or intravenously, helps rehydrate the body, replace fluids lost due to excessive urination, and dilute the excess sugar in the blood. Electrolytes may also be replenished to restore essential minerals needed for proper bodily functions. Additionally, insulin therapy is typically administered through a vein to help regulate blood sugar levels effectively.

Prevention:

The following strategies can help maintain your blood sugar within the desired range. Stick to your diabetes meal plan, especially if you take insulin or oral diabetes medication. Consistency in meal timing and portion sizes is crucial to ensure that the food you consume aligns with the insulin activity in your body. Regular blood sugar monitoring is also essential. Depending on your treatment plan, you may need to check and log your blood sugar levels multiple times a day or several times a week. Monitoring closely is the most effective way to ensure your blood sugar stays within the target range. Be sure to take note of any readings that fall above or below your ideal range.

Complications of Diabetes:

When a person has a high blood sugar level and it isn't controlled timely, it might lead to severe health issues. The following might be the complications of diabetes:

- Kidney failure
- Heart problems
- Damage blood vessels
- Distort brain and nerve functioning
- Affect vision and damages the eyes
- Lead to Depression
- Increase foot problems Complications

Diabetes complications develop gradually, with risks increasing the longer blood sugar remains uncontrolled. If unmanaged, these complications can become severe, disabling, or even life-threatening. Additionally, prediabetes can progress to type 2 diabetes if not properly managed.

One major complication is cardiovascular disease, as diabetes significantly raises the risk of heart-related conditions such as coronary artery disease, angina, heart attacks, strokes, and atherosclerosis. Individuals with diabetes are more prone to developing heart disease or experiencing a stroke. Nerve damage (diabetic neuropathy) is another serious issue, occurring when excess sugar harms the small blood vessels that supply the nerves, particularly in the legs. This can cause tingling, numbness, burning sensations, or pain, often starting in the toes and fingers and spreading upward. If the nerves responsible for digestion are affected, individuals may experience nausea, vomiting, diarrhea, or constipation. In men, it may lead to erectile dysfunction.

Diabetes can also damage the kidneys (diabetic nephropathy) by harming the filtering system responsible for removing waste from the blood. Similarly, it can affect the eyes (diabetic retinopathy), potentially leading to vision loss or blindness. Poor circulation and nerve damage in the feet increase the risk of foot complications, while bacterial and fungal infections can affect the skin and mouth. Additionally, hearing loss is more common in people with diabetes. Type 2 diabetes has also been linked to an increased risk of dementia, including Alzheimer's disease. Furthermore, both type 1 and type 2 diabetes are associated with a higher likelihood of depression, which can negatively impact overall well-being and diabetes management.

Types of Diabetes:

1. Type 1 Diabetes

Popularly known as auto-immune disease or juvenile diabetes, this condition is dependent on insulin and is an immune system disorder. According to the CDC, 5-10% of total diabetic patients have Type 1 diabetes.

In type 1 diabetes, the person's immune system attacks insulin-producing cells, thereby hindering the production of insulin, and therefore, you'll need to take insulin dosage regularly to live. It is a hereditary disorder that generally occurs at an early age and is most probably observed in children and young adults.

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2. Type 2 Diabetes:

This type is popularly known as insulin-resistant diabetes as the insulin is produced in the patient's body but either it isn't sufficient or doesn't work correctly. While Type 2 diabetes isn't as severe as Type 1, in this condition, your body doesn't make sufficient insulin or fails to use the insulin properly, and this becomes the reason for a spike in blood sugar levels.

According to the CDC, 90-95% of total diabetic patients have Type 2 diabetes. It generally develops with aging but nowadays, it is also observed in children, teens, and young adults.

Risk factors:

Risk factors for diabetes vary by type, but family history plays a role in all cases. Environmental and geographic factors may contribute to type 1 diabetes, and some individuals are tested for diabetes-related immune system cells (autoantibodies). While having these autoantibodies increases the risk, not everyone with them develops diabetes. Additionally, race and ethnicity can influence type 2 diabetes risk, with Black, Hispanic, American Indian, and Asian American populations being more susceptible.

Prediabetes, type 2 diabetes, and gestational diabetes are more common in individuals who are overweight or obese. Gestational diabetes can lead to complications for both mother and baby. In infants, excess glucose can cause overgrowth, increasing the likelihood of a difficult birth or C-section. Babies may also develop low blood sugar (hypoglycemia) due to high insulin production and have a greater risk of obesity and type 2 diabetes later in life. In severe cases, untreated gestational diabetes can result in stillbirth or infant death.

For mothers, gestational diabetes increases the risk of preeclampsia, a condition marked by high blood pressure, excess protein in urine, and swelling. Additionally, women who develop gestational diabetes during one pregnancy are more likely to experience it again in future pregnancies.

Pathophysiology:

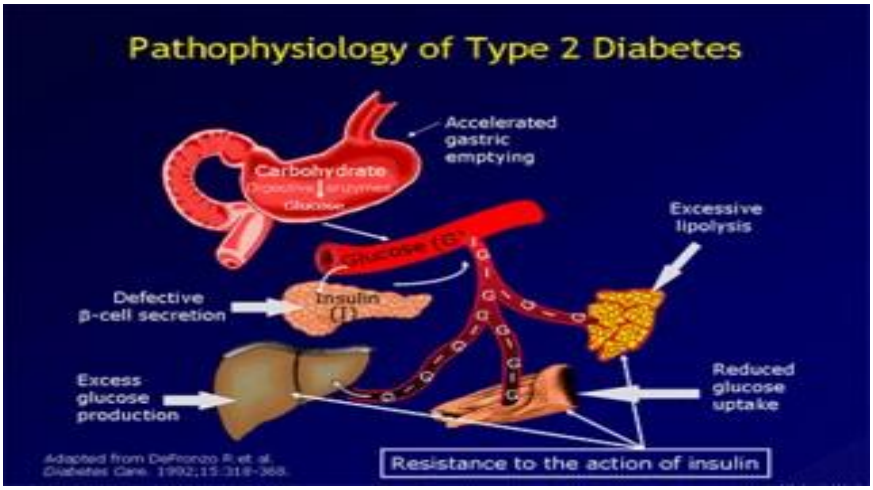

Fig 2 Pathophysiology of Type 2 diabetes

The pathophysiology of diabetes is complex and involves several different hormones (i.e., insulin, glucagons, and growth). The interaction of these hormones with the liver and their involvement in renal function make the pathological mechanisms of this disease difficult to pinpoint and widely varied among patients. More extensive reviews of this pathophysiology can be found on the American Diabetes Association Web site and in medical pathology texts.7Regardless of the cause of diabetes, the result is a decrease in the uptake of glucose. Insulin resistance is mediated by genetic predisposing factors and abdominal obesity. A strong relationship has been noted between the development of type 2 diabetes and obesity. Eighty percent of type 2 diabetic patients are obese, and excess fat is usually carried in upper body areas. The therapist should recognize that medical interventions are directed at achieving normal or near-normal glucose levels and at optimizing lipid values. Interventions vary, depending on the degree of

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control required and the level of insulin resistance and/or insufficiency noted. Resultant exercise interventions and expected outcomes vary just as widely. These variations are discussed in the "Interventions" and "Outcomes".

Equipment:

You can use a needle and syringe, an insulin pen, or an insulin pump. An artificial pancreas—also called an automated insulin delivery system—may be another option for some people.

Antidiabetic Drug:

Classification of antidiabetic:

- **Sulfonylureas – glimepiride, glipizide, glyburide.**
- **Biguanides – metformin.**
- **Thiazolidinediones (Tzd) – pioglitazone, Actos generic.**
- **Alpha-glucosidase inhibitors – Acarbose.**
- **Meglitinides – nateglinide.**

Combination of sulfonylureas plus metformin – known by generic names of the two drugs.

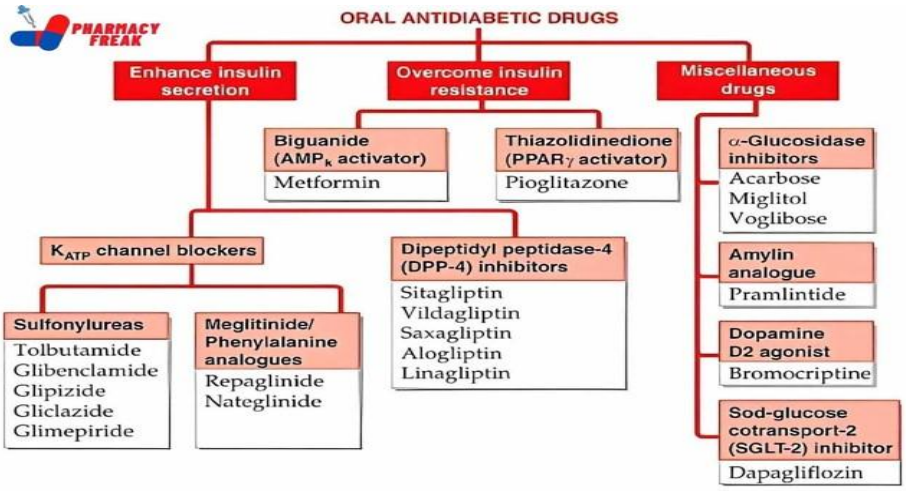

Fig.3 Classification of Antidiabetic Drug

Side Effects

HYPOGLYCEMIA

The primary side effect of sulfonylureas is hypoglycemia, which is more common and severe with long-acting forms. Studies show that severe hypoglycemia, requiring third-party assistance, occurs in 0.4–7% of patients, while non-severe cases affect a larger percentage. Continuous glucose monitoring has revealed frequent, often asymptomatic, nocturnal hypoglycemia in well-controlled type 2 diabetes patients, sometimes linked to EKG abnormalities like QTc prolongation.

Hypoglycemia is more likely after fasting or exercise. To minimize risk, treatment should start at the lowest dose and be gradually increased, especially in patients with mildly elevated A1c. Older adults and those with liver or kidney disease face higher risks, particularly if glycemic targets are too strict. Due to its greater hypoglycaemic risk, many clinicians avoid prescribing long-acting sulfonylureas like glyburide in these high-risk groups.

1. **WEIGHT GAIN**

In the UKPDS, sulfonylurea treatment caused a net weight gain of approximately 3 kg, which occurred during the first 3-4 years of treatment and then stabilized. Other studies have similarly observed weight gain with sulfonylurea treatment.

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2. **FIRST GENERATION SIDE EFFECTS**

Chlorpropamide can induce hyponatremia and water retention due to inappropriate secretion of antidiuretic hormone (ADH) . In addition, tolbutamide and chlorpropamide, in certain susceptible individuals, is associated with alcohol-induced flushing. Because of an increased risk of side effects 1st generation sulfonylureas are seldom used.

3**. RARE SIDE EFFECTS**

Intrahepatic cholestasis and allergic skin reactions, including photosensitivity and erythroderma may rarely occur.

Contraindications and Drug Interactions

Sulfonylureas should be avoided in patients with a severe sulfa allergy, though cross-reactivity with other sulphonamides is rare. In renal failure, dosage adjustments are necessary to prevent hypoglycaemia, with glipizide being the preferred option due to its liver metabolism and lack of active metabolites.

Long-acting sulfonylureas like glyburide, glimepiride, and chlorpropamide are not recommended for elderly patients. In individuals with G6PD deficiency, sulfonylureas may cause haemolytic anaemia and should be used cautiously. Certain medications, including antifungals, MAO inhibitors, NSAIDs, coumarins, and sulfonamides, can enhance sulfonylurea effects by altering their metabolism, protein binding, or excretion.

Literature Review: The RWE study suggests that vildagliptin, both as monotherapy and in combination with metformin, is an effective and well-tolerated therapy for reducing HbA1c and achieving target glycemic control in patients with T2DM.

Sitagliptin

Sitagliptin is a new oral anti-hyperglycemic (anti-diabetic) medication from the new dipeptidyl peptidase-4 (DPP-4) inhibitor class. The medication works by preventing DPP-4 from inactivating glucagon-like peptide-1 (GLP-1) and gastric inhibitory polypeptide (GIP). This inhibitory activity leads to a two-fold action in the pancreas' islets of Langerhans, where GLP-1 and GIP potentiate insulin secretion by beta cells while suppressing glucagon secretion by alpha cells.

Sitagliptin Uses:

The medication is used for the treatment of Type 2 diabetes mellitus. This is used along with diet and exercise to improve blood sugar control in adults with Type 2 diabetes. The medication is a type of anti-diabetic drug. It works by causing the pancreas to release more insulin and decreasing the hormones that cause blood sugar levels to rise. Fasting and post-meal sugar levels are reduced as a result of this.

Common and major side effects of Sitagliptin are:

- Headache
- cough
- Sweating
- Hypoglycaemia
- Weakness
- Excessive sweating
- Heartburn
- Swelling of face, lips and eyelids
- The common side effects don’t need any medical attention and will disappear as your body gets adjusted to the dosage. But if you are facing any kind of serious or rare side effects then immediately seek medical attention

Precautions

Before using Sitagliptin talk with your doctor if you are allergic to it or any other medications. The product can contain some inactive ingredients which will cause serious allergic reactions or other serious problems. If you are having any of the following medical histories then talk with your doctor immediately, such as skin allergy, Type I diabetes mellitus, Diabetic Ketoacidosis and Hepatic Impairments.

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Missed Dose: As soon as you remember, take the missing dose. If it's time for the next dose, skip the missed dose. Do not take a double dose to compensate for a missed dose

Overdose: Overdose of this medication can lead to some serious side effects like irregular heartbeat, trouble while breathing, severe dizziness and fainting.

Warnings for serious Health Conditions:

Pregnancy: Pregnant women should avoid taking this drug unless it is absolutely appropriate. Before taking this drug, talk to your doctor about all the complications and benefits. Depending on your health condition, your doctor can recommend a safer alternative.

Breastfeeding: The medication can pass into the breast milk and can cause some serious side effects to the infants. Avoid taking this medication without consulting your doctor while you are breastfeeding.

Storage: Direct contact with heat, air and light may damage your medicines. Exposure to medicine may cause some harmful effects. The medicine must be kept in a safe place and out of children's reach.

II. PHARMACOLOGY

Indication

Sitagliptin is indicated in the treatment of type II diabetes mellitus in adults. As monotherapy, Sitagliptin is indicated in adults inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance.6 It is also indicated as dual therapy in combination with metformin, a sulphonyl urea, or a thiazolidinedione in adults' patients with insufficient glycemic control despite maximal tolerated dose of monotherapy.

Sitagliptin is also marketed in a combination product with metformin for the treatment of adults with type II diabetes mellitus who inadequately respond to either monotherapy of Sitagliptin or metformin. This fixed-dose formulation can be used in combination with a sulphonyl urea or insulin (i.e., triple therapy) as an adjunct to diet and exercise in adults who do not achieve adequate glycaemic control with monotherapy or dual therapy.

Pharmacodynamics:

Sitagliptin works to improve glycaemic control in type II diabetes mellitus by enhancing the glucose sensitivity of beta-cells (β-cells) in pancreatic islets and promoting glucose-dependent insulin secretion. Increased GLP-1 levels leads to enhanced sensitivity of alpha cells to glucose, promoting glucagon secretion. Sitagliptin causes an increase in the insulin to glucagon ratio by increasing incretin hormone levels: this results in a decrease in fasting and postprandial hepatic glucose production. Sitagliptin does not affect gastric emptying. It also has no effects on insulin secretion or blood glucose levels in individuals with normal glycaemic control. In clinical trials, treatment with Sitagliptin 50-100 mg daily in patients with type 2 diabetes significantly improved markers of beta-cells, proinsulin to insulin ratio, and measures of beta-cell responsiveness from the frequently-sampled meal tolerance test.

Mechanism of action

Glucagon-like peptide-1 (GLP-1) and glucose-dependent insulinotropic peptide (GIP) are incretin hormones that regulate blood glucose levels and maintain glucose homeostasis. It is estimated that the activity of GLP-1 and GIP contribute more than 70% to the insulin response to an oral glucose challenge. They stimulate insulin secretion in a glucose-dependent manner via G-protein-coupled GIP and GLP-1 receptor signalling. In addition to their effects on insulin secretion, GLP-1 is also involved in promoting islet neogenesis and differentiation, as well as attenuating pancreatic beta-cell apoptosis. Incretin hormones also exert extra-pancreatic effects, such as lipogenesis and myocardial function.3 In type II diabetes mellitus, GLP-1 secretion is impaired, and the insulinotropic effect of GIP is significantly diminished.2 Sitagliptin exerts its blood glucose-lowering effects by selectively inhibiting dipeptidyl peptidase-4 (DPP-4), an enzyme that rapidly truncates and inactivates GLP-1 and GIP upon their release from the intestinal cells. DPP-4 cleaves oligopeptides after the second amino acid from the N-terminal end. Inhibition of DPP-4 substantially prolongs the half-life of GLP-1 and GIP, increasing the levels of active circulating incretin hormones.3 The duration of DPP-4 inhibition by Sitagliptin is dose-dependent.5Sitagliptin reduces fasting and prandial glucose and HbA1c. It enhances the glucose sensitivity of alpha- and beta-cells and augments glucose-dependent insulin secretion. Fasting and postprandial glucose levels are decreased, and postprandial lipid and lipoprotein metabolism are also improved.

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Here are some of the standard and significant side effects of using Sitagliptin:

- Excessive sweating.
- Headache.
- Constipation.
- Hypoglycaemia.
- Heartburn.
- Cough.
- Swelling of eyelids, lips, and face.
- Weakness.

Toxicity:

The oral Lowest published toxic dose (TDLO) is 0.3 mg/kg in rats and 1 mg/kg in mice. There is limited information regarding overdose with Sitagliptin. In one study, patients experienced muscle pain, mild and transient paraesthesia, fever, edema, and a transient increase in lipase levels at a dose of 400 mg.

Method of Administration:

When used in dual combination with a sulphonyl urea, the recommended dose of Sitagliptin is 50 mg once daily administered in the morning. In this patient population, Sitagliptin 100 mg daily was no more effective than Sitagliptin 50 mg once daily.

Uses:

Sitagliptin (LAF237) is an orally active antihyperglycemic agent that selectively inhibits the dipeptidyl peptidase-4 (DPP-4) enzyme. It is used to manage type II diabetes mellitus

Aim and Objective:

Aim: To have a Survey on widely prescribed drug for hypertension.

Objective:

1. To conduct a survey on Enalapril most prescribed drug for hypertension.
2. Discuss the contraindication for Enalapril therapy.

III. RESULT

When we do 50 medical surveys that time, we found that most of doctor prescribed the generic medicine like jankey M 500, Sltawok 50

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But also, most of doctor prescribed standard medicine like Sitazit M,Siqrez M-500In treatment of hyperglycaemia**.**

IV. DISCUSSION

At the Chikhali area, I conducted a survey at about fifty medical supply stores. When antidiabetic medications were surveyed, we discovered that the most often prescribed medication was Vildagliptin, sitagliptin dapagliflozin and Zita DM Among which Vildagliptin is widely prescribed because, when combined with metformin, it had greater efficacy and fewer side effects than other medications.

Apart from which we also visited Manipal hospital to have a survey on most commonly prescribed Oral Hypoglycemics Drugs. We have discussed with Diabetic specialist that why metformin and Vildagliptin is widely prescribed in Hyperglycaemia. The discussion comes with the end that metformin and Vildagliptin are synergistic and have high efficiency in low dose with very few side effects.

V. CONCLUSION

The introduction of DPP-4 inhibitors has expanded treatment options for managing hyperglycemia in type 2 diabetes. Sitagliptin is highly effective in improving glycaemic control across various stages of the disease, from impaired glucose tolerance to advanced cases requiring insulin. Its ability to lower HbA1c is comparable to thiazolidinediones and acarbose, with sustained efficacy for up to two years. Sitagliptin also helps regulate postprandial and fasting glucose levels, providing a valuable alternative for managing post-meal glucose spikes.

Diabetes mellitus includes multiple metabolic disorders, primarily characterized by insulin resistance or pancreatic beta-cell failure. Type 1 diabetes results from beta-cell destruction, leading to insufficient insulin production, while type 2 diabetes is linked to insulin resistance, obesity, and lack of physical activity. The goal of diabetes management is to restore normal carbohydrate metabolism, often requiring insulin therapy through injections or oral medications. Sitagliptin is particularly effective when combined with metformin for better glucose control.

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