

INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES

[ISSN: 0975-4725; CODEN(USA):IJPS00] Journal Homepage: https://www.ijpsjournal.com



Research Article

Effectiveness Of Vildagliptin Versus Teneligliptin As An Add On Therapy In Type 2 Diabetes Mellitus Patients

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ARTICLE INFO

Received: 29 April 2024 Accepted: 03 May 2024 Published: 13 May 2024 Keywords: Type 2 Diabetes mellitus , Dipeptidyl peptidase -4 inhibitors , Vildagliptin, Teneligliptin DOI: 10.5281/zenodo.11183698

ABSTRACT

Background:

Diabetes is a chronic condition that develops when the body is unable to effectively utilise the insulin that the pancreas generates, or when the organ is unable to produce insulin at all. Innovative therapeutic agents are required to further advance the management of type 2 diabetes mellitus, a condition that is progressing and common. DPP-4 inhibitors offer unique advantages such as low risk of hypoglycaemia, weight neutrality, and oral administration , making them valuable options in the treatment of type 2 diabetes. Overall, their favourable safety profile and convenient once-daily dosing make DPP-4 inhibitors a valuable addition to the treatment options. In order to effectively manage type 2 diabetes, DPP-4 inhibitors are a useful complement to the therapeutic alternatives.DPP-4 inhibitors are particularly effective at targeting postprandial (after-meal) hyperglycaemia, which is a significant contributor to overall blood sugar levels in patients with type 2 diabetes.

Aim and Objectives:

To assess the effectiveness of vildagliptin versus teneligliptin as an add on therapy in type 2 diabetes patients, To compare the effectiveness on the HbA1c reduction, To assess the safety profile and tolerability

Method:

A Prospective observational study was conducted in the General Medicine department, PSG Hospital for a duration of 1 year. A total of 80 patients were selected based on the inclusion and exclusion criteria. The patients were divided into two groups Group A and Group B, where Group A were receiving the medication vildagliptin and consist a total number of 40patients where Group B where receiving the medication Teneligliptin which consist a total number of 40 patients. And both the groups were followed up to 3 months to find out the reduction difference in the HbA1c, FBS, and PPBS.

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Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.



Result

Both the drugs were found to be effective but after the 3 months follow up Group B(Teneligliptin) has shown a significant reduction in the HbA1C, and FBS where as a significant reduction in the PPBS was found in the Group A (vildagliptin) after 3 months . within the groups both the drugs has shown significant difference as an add on therapy. **Conclusion:**

The outcome of this study which was conducted to assess the effectiveness of vildagliptin v/s teneligliptin as an add on therapy in type 2 diabetes mellitus patients showed that both Vildagliptin and Teneligliptin were effective as add-on therapies in reducing HbA1c levels in type 2 diabetes mellitus patients .A significant reductions in the glycaemic parameters, including fasting blood sugar (FBS) Post prandial blood sugar (PPBS), and HbA1c levels, were observed . In this study both the drugs exhibit favourable safety profiles, characterized by fewer incidence of hypoglycaemic episodes because DPP-4 inhibitors typically have low risk of hypoglycaemia. Moreover, making them suitable for a wide range of patients with diabetes.

INTRODUCTION

Diabetes Mellitus is a group of metabolic diseases defined by persistently high blood sugar levels brought on by deficiencies in insulin secretion, insulin action, or both.1 Glucose intolerance and persistently high blood sugar are the results of inadequate insulin.2 The most severe clinical manifestations of diabetes include ketoacidosis and non-ketotic hyperosmolar condition, which can result in coma and death, as well as polydipsia, polyphagia, polyuria, blurred vision, and weight loss.3

TYPES OF DIABETES MELLITUS:

Type 1 Diabetes mellitus:

Insulin insufficiency and the ensuing hyperglycemia are the hallmarks of type 1 diabetes, a chronic autoimmune illness.4 Insulin dependent diabetes is another name for type 1 diabetes. This mostly affects children and young people; it usually manifests suddenly and could be fatal.5

Type 2 Diabetes mellitus:

Type 2 diabetes mellitus is a long-term metabolic illness whose prevalence has been gradually rising

globally.6 T2DM patients have an increased risk of microvascular consequences (retinopathy, nephropathy, and neuropathy) as well as macrovascular issues (cardiovascular comorbidities) because to hyperglycemia and certain elements of the insulin resistance (metabolic) syndrome.7

Gestational Diabetes mellitus:

A major pregnancy problem known as gestational diabetes mellitus (GDM) occurs when women who have never been diagnosed with diabetes before have persistent hyperglycemia during pregnancy. Usually, the cause of severe hyperglycemia is a history of chronic insulin resistance combined with decreased glucose tolerance brought on by pancreatic β -cell malfunction..8

EPIDEMOLOGY

In many regions of the world, the prevalence of diabetes is rising as a result of rapid economic development and urbanization..9 More than 590 million people with type 2 diabetes are expected to be diagnosed by 2035. Despite regional variations in T2DM incidence and prevalence, T2D is nevertheless regarded as a worldwide illness..10 The main causes of the global T2DM epidemic are obesity and overweight, sedentary lifestyles, and rising consumption of diets heavy in processed and red meat, refined carbohydrates, and beverages sweetened with sugar.11 An higher risk of several major health issues is present in those with diabetes. Blood glucose levels that are regularly too high can cause major health problems that impact the heart, blood vessels, kidneys, eyes, nerves, and teeth. Diabetes is a major cause of heart disease, blindness, renal failure, and lower limb amputation in practically all high-income countries.12 Individuals over 65 years of age have experienced the highest rate of rise in the total prevalence of diagnosed diabetes throughout time.13

TYPE 2 DIABETES MELLITUS



Roughly 90% of all occurrences of diabetes are type 2 diabetes mellitus, also known as non-insulin dependent diabetes, which is caused by the body's inefficient use of insulin.12 In T2DM, the response to insulin is diminished, and this is defined as insulin resistance. During this state, insulin is ineffective and is initially countered by an increase in insulin production to maintain glucose homeostasis, but over time, insulin production decreases, resulting in T2DM.14 The most well-known indicators of an increased risk of diabetes are high blood sugar levels during fasting, high blood sugar levels during the first and second hours following an oral glucose tolerance test, obesity, and signs of impaired insulin function.15 **SIGNS AND SYMPTOMS:**

The common signs and symptoms of diabetes include:

- More frequent urination than normal
- Extreme thirst, hunger pangs even after eating,
- Fatigue
- Having visual impairment
- Having recurrent infections or slowly healing wounds and lesions
- Loss of weight
- Feeling tingly, painful, or numb in the hands or feet.16

RISK FACTORS:

Genetic, environmental, and metabolic factors are intertwined and play a role in the onset of type 2 diabetes, 17 Commonly observed risk factors in diagnosed cases of diabetes mellitus include advancing age, family history of diabetes, sedentary lifestyle, and central obesity. Hence, there is a necessity for lifestyle modifications and increased awareness about these risk factors to gain control over diabetes.18 A diet low in fiber and high in glycemic index has been linked to a higher risk of diabetes, and certain types of dietary fats may impact insulin resistance and diabetes risk differently.19

PATHOPHYSIOLOGY OF TYPE 2 DIABTES MELLITUS:

The pathogenesis of type 2 diabetes mellitus is characterized by peripheral insulin resistance, inadequate regulation of the livers glucose production, and a decrease in β -cell function that eventually leads to β -cell failure.20

A few serious, occasionally fatal effects of uncontrolled hyperglycaemia include damage to the kidneys, heart, nerves, eyes, and peripheral vascular system.21

1. Insulin Resistance:

Insulin resistance and elevated blood glucose levels are caused by the desensitization of muscle to the insulin released by the pancreas to drive glucose absorption.22

2. Impaired Insulin Secretion:

Beta cells in the pancreas that generate insulin may eventually stop working properly. When blood glucose levels rise, they are unable to secrete enough insulin.23

3. Overproduction of Glucose by the Liver:

Unregulated Gluconeogenesis: Gluconeogenesis is the normal process by which the liver manufactures glucose. Even when fasting, high blood sugar levels are a result of the liver's frequent overproduction of glucose in type 2 diabetes.24

4. Dysfunction of Adipose Tissue:

Obesity-related dysfunction of adipose tissue leads to conditions that exacerbate inflammation, elevate cholesterol, and impair insulin resistance. Type 2 diabetes mellitus (T2DM) is influenced by several variables. 25

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6. Genetic Predisposition:



It is commonly known that both genetic and environmental variables can influence an individual's risk of developing type 2 diabetes, which runs in families. However, estimates of heritability in different studies have ranged from 25% to 80%.26

7. Environment and Lifestyle Factors:

Sedentary Lifestyle and Obesity: Insulin resistance and type 2 diabetes are largely influenced by excessive adiposity, especially abdominal fat, and a sedentary lifestyle.27



Figure 1: Pathogenesis of Type 2 Diabetes mellitus

DIAGNOSIS OF TYPE 2 DIABETES MELLITUS:

Diabetes can be diagnosed using plasma glucose criteria, including either the fasting plasma glucose (FPG) value or the 2-hour plasma glucose (2-h PG) value from a 75-g oral glucose tolerance test (OGTT), or by HbA1C criteria.28

Fasting blood sugar test:

A fasting blood sugar test is a test performed on the blood after eight to twelve hours, usually overnight, without food or drink. The typical blood sugar level after fasting is 5.6 mmol/L, or less than 100 mg/dL.

Random blood sugar test:

Blood collected at any point during the day, without consideration to when you last had food, is possible for a random blood sugar test. 70-140 mg/dL(3.9-7.8 mmol/L) is the usual range for a random blood sugar test

Hemoglobin A1C test:

The HbA1C test determines your average blood sugar level over the previous two or three months. The normal range for HbA1C is 4.56 to 5.56% this test can be done at any time of the day.

Oral Glucose Tolerance Test (OGTT) :

The oral glucose tolerance test requires consuming a flavored glucose solution followed by blood sugar level measurements before and after.29

MANAGEMENT OF TYPE 2 DIABETES MELLITUS:

A combination of medication and lifestyle modifications is used to treat type 2 diabetes

Lifestyle modifications:

The lifestyle choices of individuals, including their diet, weight management, physical activity, tobacco use and alcohol consumption, indicate that weight loss is the primary factor in preventing diabetes.

Weight loss:

Several successful methods for achieving weight loss include adhering to low-fat and low-calorie diets, consuming diets high in fiber and protein, and engaging in exercise.30

Exercise:

Many studies have highlighted the importance of physical activity (PA) for health, and recent evidence now points to the positive improvements associated with exercise in type 2 diabetes mellitus (T2DM).31

TREATEMENT:

Treatment for type 2 diabetes can be difficult due to the several therapeutic targets and patient variability, necessitating precise, individualized care. Diabetes can be easily treated with diet and exercise, which are essential components.32



The pharmacological therapy for type 2 diabetes include : Twelve classes of drugs are approved to treat T2D: biguanides (e.g., metformin), sulfonylureas, thiazolidinediones (TZDs), DPP4is, SGLT2is, GLP1RAs, insulins, α -glucosidase inhibitors, dopaminergic antagonists, bile acid sequestrants, meglitinides, and amylinomimetics.33

Biguanides:

Biguanides (mainly Metformin) are widely prescribed antihyperglycemic agents that suppress hepatic glucose production, increase peripheral glucose uptake, and moderately reduce LDL cholesterol and triglyceride levels. Glucose control with the aid of biguanides appears to decrease the risk of diabetes-related complications,.34

Sulfonylureas:

Sulfonylureas primarily increase insulin levels in the bloodstream, making them useful only when some pancreatic β - cells remain functional.35

Thiazolidinediones:

Thiazolidinediones enhance insulin sensitivity by promoting glucose utilization in adipose tissue and muscle. They also have a minor effect on reducing glucose production in the liver.36

SGLT-2 Inhibitors:

SGLT2 inhibitors could be beneficial for obese and hypertensive individuals due to their potential for weight loss and lowering blood pressure. Combining metformin with an SGLT2 inhibitor might be advantageous for patients with a high risk of hypoglycemia, as SGLT2 inhibitors pose a lower risk of hypoglycemia compared to insulin and sulfonylureas.37

α- glucosidase inhibitors:

Alpha-glucosidase inhibitors function as medications to reduce high blood sugar levels by slowing down the breakdown and absorption of complex carbohydrates during digestion. Their primary effect is to decrease the increase in blood glucose levels after meals in patients with noninsulin-dependent diabetes mellitus.38

Dipeptidyl peptidase -4 inhibitors:

DPP-4 inhibitors, as a group of diabetes medications, have gained global acceptance due to their convenient administration, mild impact on HbA1c levels, and minimal occurrence of severe adverse effects.39 The DPP-4 inhibitor was approved for managing diabetes. These medications block DPP-4, an enzyme that breaks down incretins, extending their activity. In humans, two main incretin hormones are known : GIP and GLP-1. GLP-1 aids in glucose control by boosting insulin secretion, promoting insulin production, reducing glucagon release, restraining appetite, and slowing digestion. In type 2 diabetes, GLP-1 secretion decreases, contributing to reduced incretin effect, where orally delivered glucose triggers a stronger insulin response than intravenous delivery. DPP-4 inhibitors prevent incretin breakdown, increasing active GLP-1 levels and lowering post-meal glucose levels and HbA1c without elevating hypoglycaemia risk.40 Following a meal, DPP-4 inhibitors boost active endogenous GLP-1 and GIP levels by two three times. This not only enhances insulin secretion in the presence of high blood sugar levels but also reduces the release of glucagon.41

METHODOLOGY

The protocol of the study was submitted to the Institutional Human Ethics Committee (IHEC, PSG) IMSR. The protocol was approved by the ethics committee with the proposal number 2023/Appr/Exp/294. The study was designed and conducted as prospective observational study. The study was conducted fo a period of one year. A total of 80 patients were selected based on the inclusion and exclusion criteria. The patients were divided into two groups i.e Group A (Patients who are receiving vildagliptin as an add on therapy) and Group B (Patients who are receiving teneligliptin as add on therapy). The patients were followed up to 3 months and compared whether there is a reduction in the biological parameters like HbA1c,



FBS, PPBS. Inclusion criteria consist of Patients who are diagnosed with type 2 diabetes mellitus and patients who are on add on therapy with DPP-4 inhibitors , Age > 18 years . Exclusion criteria consist of patients who are diagnosed with type 1 diabetes, pregnant women and lactating mother. The study was conducted for a period of one year . Informed consent was taken from the patients. Study was conducted in the General medicine department of PSG Hospitals, Coimbatore, Tamil Nadu ,India . Data ,were collected using the data collection form. All the statsistical analysis were carried out using SPSS version 20 . The groups are compared using the student t test (dependent t test) for within the groups and (independent t test) for between the groups.

RESULTS

GENDER WISE DISTRIBUTION

A total of 86 patients were recruited based on the inclusion and exclusion criteria out of which 6 patients were dropped out due to lost of follow up data. 80 patients were finally enrolled in the study, 40 patients were under group 1 (Vildagliptin) and the remaining 40 were under group 2 (Teneligliptin)

Table 1 - Gender based classification in Group 1 and Group 2				
Gender	No of patients in group 1(vildagliptin) (n=40)	Percentage	No of patients in group 2(Teneligliptin) (n=40)	Percentage
Male	12	30%	24	60%
Female	28	70%	16	40%

 Table 1 - Gender based classification in Group 1 and Group 2

DIABETIC PROFILE:

 Table 2 : Fasting Blood Sugar Levels within each group

Groups	Base (Mean ± SD) (mg/dl)	After 3 months (Mean± SD) (mg/dl)	Mean Difference	P value (Difference within Group)
Group1 (vildagliptin) (n=40)	155.47±43.77	130.37±31.29	25.1	0.006
Group2 (Teneligliptin) (n=40)	159.74±50.88	130.64±35.46	29.1	0.001

In both the groups Fasting Blood Sugar level within the groups was reduced after 3 months. The reduction was statistically significant (P vale <

0.05). But the Mean difference in FBS level was high in Group-2 when compared with Group-1



Figure 2: Mean difference in FBS

POST PRANDIAL BLOOD SUGAR LEVEL

Groups	Base line (Mean± SD) (mg/dl)	After 3 months (mean± SD) (mg/dl)	Mean Difference	P value (Difference within Group)
Group 1	227.03±61.60	196.55±22	30.48	0.017
Group 2	240.66±73.69	211.60±68.04	29.06	0.021

 Table 3 : Post Prandial Blood Sugar levels within each Group

The Post Prandial Blood Sugar was reduced within the both groups. A statistically Significant difference was observed in both groups P value < 0.05 . But the mean difference in PPBS was high in Group 1 when compared to Group 2 $\,$



Figure 3: Mean difference in PPBS

HbA1C

Table 4 : HbA1c levels	within	each group	

Groups	Base line (Mean± SD) (%)	After 3 months (Mean ± SD) (%)	Mean Difference	P value (Difference within Group)
Group 1	8.40 ± 0.92	8.07±0.79	0.33	0.003
Group 2	8.40±0.86	8.05±0.68	0.35	< 0.001

The HbA1c was reduced in both groups. A value is <0.05. But the mean difference in HbA1c statistical significance was observed where the P in Group 2 is high when compared with Group 1



Figure 4: Mean difference in HbA1C



Sr. No	Comparison	P value
1.	Between Group 1 and Group 2	0.86

Table 5: Comparison of HbA1c levels between groups

DISCUSSION

DPP-4 inhibitors are the oral antidiabetic medications which are commonly used in the treatment of type 2 diabetes mellitus. Vildagliptin has been available for a longer period of time and is more widely studied, Teneligliptin is a newer agent in the class of DPP-4 inhibitors, that has shown comparable safety and efficacy profiles to vildagliptin. The present study aimed to assess the effectiveness and safety of Vildagliptin and Teneligliptin when added to the treatment regimen of patients with type-2 Diabetes mellitus who have inadequate glycaemic control. Both drugs showed positive outcomes such as reduction in Hba1c, FBS, PPBS it is due to the mechanism of action of DPP-4 inhibitors. They work by inhibiting the enzyme DPP-4, which in turn increase the levels of active incretin hormones such as GLP-1and GIP. These hormones play key roles in regulating blood sugar levels by stimulating insulin secretion, inhibiting glucagon secretion, and slowing gastric emptying. By enhancing the action of these incretin hormones, In this study the FBS, HbA1C reduction was higher in group 2 rather than in the group 1. The reduction of FBS in group 2 may be due to the drug potency, and medication adherence by the patients. And also a significant reduction in the HbA1c was also seen in group 2 which possibly may be due to the difference in the dosing regimen and frequency of administration of teneligliptin when compared with the vildagliptin. This was similar to a study conducted by Jameel Ahmad et al., 42 In accordance to this study PPBS was reduced highly in the group 1when compared to group 2 this may be due to the difference in the pharmacokinetics of the drug and timing of administration of the drug. The secondary

objective of this study was to assess the safety profile and tolerability of the both the drugs. Generally both the drugs were well tolerated . Hypoglycaemia was the adverse effect found in both the groups. Which may be due to the enhanced insulin secretion because DPP-4 inhibitors work by increasing the levels of incretin hormones, which stimulate insulin secretion from pancreatic beta cells. If the increase in insulin secretion is excessive or not balanced with glucose levels it can lead to hypoglycaemia . This results were comparable to a study conducted by Jameel Ahmad et al., 42

CONCLUSION

The outcome of this study which was conducted to assess the effectiveness of vildagliptin v/s teneligliptin as an add on therapy in type 2 diabetes mellitus patients showed that both Vildagliptin and Teneligliptin were effective as add-on therapies in reducing HbA1c levels in type 2 diabetes mellitus patients .A significant reductions in the glycaemic parameters, including fasting blood sugar (FBS) Post prandial blood sugar (PPBS), and HbA1c levels, were observed . In this study both the drugs exhibit favourable safety profiles, characterized by fewer incidence of hypoglycaemic episodes because DPP-4 inhibitors typically low risk have of hypoglycaemia. Moreover, making them suitable for a wide range of patients with diabetes. DPP-4 inhibitors like vildagliptin and teneligliptin, emerge as a safe and effective option for managing Type 2 diabetes mellitus. These results emphasize the potential of DPP-4 inhibitors as valuable therapeutic agent in the management of type 2 diabetes mellitus, offering both glycaemic control and improved safety outcomes. Both vildagliptin

and teneligliptin exhibit favourable effectiveness and safety characteristics, making them suitable to use as an adjuvant therapy with other oral hypoglycaemic agents in Type 2 diabetes mellitus patients.

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HOW TO CITE: Irine Thomas, Prudence A. Rodrigues,
Saravanan T., Effectiveness Of Vildagliptin Versus
Teneligliptin As An Add On Therapy In Type 2 Diabetes
Mellitus Patients, Int. J. of Pharm. Sci., 2024, Vol 2,
Issue 5, 582-592.
https://doi.org/10.5281/zenodo.11183698

