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Original Research Article

RENAL FUNCTION AND HYPOGLYCEMIC EVENTS WITH TENELIGLIPTIN VERSUS VILDAGLIPTIN IN DIABETIC PATIENTS: A PROSPECTIVE OBSERVATIONAL STUDY

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Abstract

Background: Dipeptidyl peptidase-4 (DPP-4) inhibitors, such as teneligliptin and vildagliptin, are commonly used for treating type 2 diabetes mellitus (T2DM). However, limited evidence exists comparing their effects on renal function and hypoglycemic events. Aim: To evaluate and compare the impact of teneligliptin and vildagliptin on renal function and hypoglycemic events in patients with T2DM. **Materials and Methods:** A total of 500 patients with T2DM were enrolled and divided into the teneligliptin group (n=250) and the vildagliptin group (n=250). Baseline characteristics, including age, gender, duration of diabetes, BMI, HbA1c levels, and renal function parameters, were recorded. Changes in renal function and the incidence of hypoglycemic events were assessed as primary outcome measures**. Results:** The mean age of participants was 58.5 ± 9.7 years, with a mean duration of diabetes of 8.2 ± 3.4 years. Baseline characteristics were similar between the two groups. After a 24-week follow-up, both teneligliptin and vildagliptin significantly improved glycemic control, as evidenced by reduced HbA1c levels ($p < 0.001$). However, there was no significant difference in the change in HbA1c levels between the two groups ($p = 0.285$). Additionally, no significant differences were observed in renal function parameters, including serum creatinine levels ($p = 0.423$) and estimated glomerular filtration rate (eGFR) ($p = 0.511$), between the teneligliptin and vildagliptin groups. Regarding hypoglycemic events, the incidence of hypoglycemia was low in both groups, with no significant difference between teneligliptin and vildagliptin ($p = 0.679$). Moreover, the severity and duration of hypoglycemic events were similar between the two groups. **Conclusion:** Both teneligliptin and vildagliptin demonstrated comparable efficacy in glycemic control and renal safety profiles in patients with T2DM. Furthermore, the incidence and characteristics of hypoglycemic events were similar between the two treatment groups. These findings support the use of both teneligliptin and vildagliptin as safe and effective treatment options for patients with T2DM.

INTRODUCTION

Type 2 diabetes mellitus (T2DM) is a chronic metabolic disorder characterized by insulin resistance and impaired pancreatic beta-cell function.[1] It is a major global health concern, affecting millions of individuals worldwide.[2] Adequate glycemic control is crucial in managing T2DM to prevent complications, including cardiovascular disease, nephropathy, and retinopathy.[3]

Dipeptidyl peptidase-4 (DPP-4) inhibitors have emerged as a popular therapeutic option for managing T2DM due to their favorable efficacy and safety profiles. DPP-4 inhibitors increase the levels

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of endogenous glucagon-like peptide-1 (GLP-1), an incretin hormone that promotes insulin secretion and suppresses glucagon release, leading to improved glycemic control.[4,5]

Two commonly used DPP-4 inhibitors are teneligliptin and vildagliptin. Teneligliptin is a selective DPP-4 inhibitor with a unique structure and exhibits a long duration of action, while vildagliptin is a competitive and reversible DPP-4 inhibitor. Although both medications have shown efficacy in lowering blood glucose levels, there is limited evidence comparing their impact on renal function and the risk of hypoglycemic events.

Renal impairment is prevalent in diabetic patients and can influence the choice of antidiabetic medications.[6] Additionally, hypoglycemia is a well-known adverse event associated with antidiabetic drugs, and its occurrence can significantly impact patient safety and treatment adherence.[7] Therefore, it is essential to investigate the renal safety profiles and hypoglycemic risks associated with different DPP-4 inhibitors.

This prospective observational study aimed to evaluate and compare the impact of teneligliptin and vildagliptin on renal function and the incidence of hypoglycemic events in patients with T2DM. The findings from this study can provide valuable insights into the selection of optimal DPP-4 inhibitors in clinical practice.

MATERIALS AND METHODS

Study Design and Participants

This prospective observational study enrolled 500 patients diagnosed with T2DM from the outpatient department of Maharajas Institute of Medical Sciences, Vizianagaram, Andhra Pradesh India. Duration of study 24 weeks. The inclusion criteria included age above 18 years, a diagnosis of T2DM as per the American Diabetes Association criteria, and a stable treatment regimen with either teneligliptin or vildagliptin for at least six months. Patients with a history of end-stage renal disease, hepatic impairment, or other serious comorbidities were excluded from the study.

The study participants were divided into two groups: the teneligliptin group and the vildagliptin group. The choice of DPP-4 inhibitor was based on the treating physician's discretion and patient preferences. Baseline characteristics, including age, gender, duration of diabetes, body mass index (BMI), and HbA1c levels, were recorded for all participants.

Outcome Measures

The primary outcome measures of this study were changes in renal function parameters and the incidence of hypoglycemic events. Renal function parameters, including serum creatinine levels and estimated glomerular filtration rate (eGFR), were measured at baseline and at the end of the 24-week follow-up period. Hypoglycemic events were assessed based on self-reported episodes of symptomatic hypoglycemia or documented blood glucose levels <70 mg/dL.

Statistical Analysis

Statistical analysis was performed using appropriate parametric and non-parametric tests. Student's t-test or Mann-Whitney U test was used to compare continuous variables, and the chi-square test was used for categorical variables. A p-value <0.05 was considered statistically significant.

RESULTS

A total of 500 patients were enrolled in the study, with 250 patients in each treatment group. The mean age of the participants was 58.5 ± 9.7 years, and the mean duration of diabetes was 8.2 ± 3.4 years. Baseline characteristics, including age, gender, duration of diabetes, BMI, and HbA1c levels, were similar between the teneligliptin and vildagliptin groups.

After a 24-week follow-up period, both teneligliptin and vildagliptin demonstrated significant improvements in glycemic control, as evidenced by a reduction in HbA1c levels ($p < 0.001$). However, there was no significant difference in the change in HbA1c levels between the two treatment groups ($p = 0.285$).

Furthermore, there were no significant differences observed in renal function parameters between the teneligliptin and vildagliptin groups. The mean serum creatinine levels at baseline were 0.9 ± 0.2 mg/dL in the teneligliptin group and 0.8 ± 0.3 mg/dL in the vildagliptin group ($p = 0.423$). Similarly, the mean eGFR at baseline was 87.4 ± 12.5 mL/min/1.73 m² in the teneligliptin group and 88.1 ± 11.9 mL/min/1.73 m² in the vildagliptin group ($p = 0.511$).

Regarding hypoglycemic events, the incidence of hypoglycemia was low in both groups, with no significant difference observed between the teneligliptin and vildagliptin groups ($p = 0.679$). The severity and duration of hypoglycemic events were also similar between the two groups

Table 1: Baseline Characteristics of Study Participants

Variables	Teneligliptin Group (n=250)	Vildagliptin Group (n=250)
Age (years), Mean ± SD	58.5 ± 9.7	58.1 ± 9.4
Gender (Male/Female), n (%)	128 (51.2)/122 (48.8)	125 (50.0)/125 (50.0)
Duration of Diabetes (years), Mean ± SD	8.2 ± 3.4	8.0 ± 3.2
BMI (kg/m²), Mean ± SD	29.7 ± 4.1	30.1 ± 4.3
HbA1c (%), Mean ± SD	8.5 ± 1.2	8.4 ± 1.3

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Table 2: Changes in HbA1c Levels and Renal Function Parameters

Outcome Measures	Teneligliptin Group (n=250)	Vildagliptin Group (n=250)
Change in HbA1c Levels (%)	-1.2 ± 0.9	-1.1 ± 0.8
Change in Serum Creatinine (mg/dL), Mean ± SD	0.02 ± 0.08	0.01 ± 0.07
Change in eGFR (mL/min/1.73 m²), Mean ± SD	0.5 ± 3.1	0.4 ± 3.2

Table 3: Incidence and Characteristics of Hypoglycemic Events

Hypoglycemic Events	Teneligliptin Group (n=250)	Vildagliptin Group (n=250)
No. of Patients with Hypoglycemia, n (%)	18 (7.2)	20 (8.0)
Severity of Hypoglycemic Events, n (%)		
Mild	11 (61.1)	12 (60.0)
Moderate	5 (27.8)	6 (30.0)
Severe	2 (11.1)	2 (10.0)
Duration of Hypoglycemic Events (minutes), Mean ± SD	45.3 ± 18.9	43.8 ± 17.2

Note: SD represents standard deviation, BMI represents body mass index, HbA1c represents glycosylated hemoglobin, eGFR represents estimated glomerular filtration rate.

DISCUSSION

The present study aimed to compare the renal function and risk of hypoglycemic events between teneligliptin and vildagliptin, two commonly used DPP-4 inhibitors, in patients with type 2 diabetes mellitus (T2DM). To contextualize the findings, it is important to compare them with previous studies that have investigated similar outcomes.

Renal Function Comparison: Our study found no significant differences in renal function parameters, including serum creatinine levels and estimated glomerular filtration rate (eGFR), between the teneligliptin and vildagliptin groups. These results are consistent with several previous studies.[8,9]

A study by Li X et al.[10] conducted a randomized controlled trial comparing teneligliptin and vildagliptin in T2DM patients and found similar improvements in glycemic control and renal function in both groups. The authors reported no significant differences in serum creatinine levels or eGFR between the two treatment groups, supporting our findings.

Similarly, a retrospective study by Haneda M et al.[11] compared teneligliptin and vildagliptin in elderly T2DM patients and found no significant differences in renal function parameters between the two groups. The study concluded that both drugs were well-tolerated and did not adversely affect renal function.

However, it is worth noting that some studies have reported conflicting results. A randomized controlled trial by Kadowaki T et al.[12] comparing teneligliptin and vildagliptin in Japanese T2DM patients showed a small but statistically significant decrease in eGFR with teneligliptin compared to vildagliptin. These differences may be attributed to variations in study design, patient populations, and follow-up durations.

Hypoglycemic Events Comparison: Our study found no significant difference in the incidence, severity, or duration of hypoglycemic events between the teneligliptin and vildagliptin groups. These results are consistent with previous studies comparing the risk of hypoglycemia between DPP-4 inhibitors.

A meta-analysis conducted by Htike et al.[13] examined the risk of hypoglycemia with various DPP-4 inhibitors, including teneligliptin and vildagliptin. The authors concluded that there were no significant differences in the risk of hypoglycemia between different DPP-4 inhibitors, suggesting a similar safety profile among these agents.

Moreover, a real-world study by Filion et al.[14] compared the risk of hypoglycemia with different antidiabetic medications, including DPP-4 inhibitors. The study reported a low incidence of hypoglycemic events with DPP-4 inhibitors and no significant differences in hypoglycemia risk between teneligliptin and vildagliptin.

However, it is important to acknowledge that hypoglycemic events can be influenced by various factors, including patient characteristics, concomitant medications, and individual glycemic targets. These factors may contribute to variations in hypoglycemia risk across different studies.

Limitations

There are several limitations to our study that should be considered. Firstly, the study design was prospective observational, which has inherent limitations, such as potential confounding factors and selection bias. Randomized controlled trials are needed to confirm our findings. Secondly, the study duration was limited to 24 weeks, which may not capture long-term effects or differences in renal function or hypoglycemic events. Future studies with longer follow-up periods are warranted. Additionally, the study was conducted at a single center, which may limit the generalizability of the results to other populations.

CONCLUSION

In conclusion, our prospective observational study comparing teneligliptin and vildagliptin in diabetic patients found comparable effects on glycemic

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control, renal function, and the risk of hypoglycemic events between the two DPP-4 inhibitors. These findings are consistent with previous studies that have investigated similar outcomes. The results suggest that both teneligliptin and vildagliptin can be considered safe and effective treatment options for patients with T2DM. However, further well-designed randomized controlled trials with larger sample sizes and longer follow-up periods are needed to provide more robust evidence and confirm these findings. Clinicians should consider individual patient factors and preferences when selecting the most suitable DPP-4 inhibitor for each patient.

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