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A COMPARATIVE STUDY ON EFFICACY AND SAFETY OF TENELIGLIPTIN AND CANAGLIFLOZIN IN TYPE 2 DIABETES PATIENTS

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ABSTRACT

Background: Type 2 Diabetes Mellitus is a very common chronic condition that needs good glycemic management to avoid complications. This study compared the efficacy and safety of two commonly prescribed medications in the management of T2DM: Teneligliptin and Canagliflozin. **Methods:** This was a prospective, comparative, observational study conducted for six months in 140 T2DM patients attending the outpatient department. The patients were classified into two groups of 70 each: the first group received Teneligliptin, and the second received Canagliflozin. HbA1c and fasting blood sugar were recorded at baseline and after three months of treatment. The adverse events monitored during this study included hypoglycaemia, urinary tract infections, dehydration, and gastrointestinal problems. **Results:** Both Teneligliptin and Canagliflozin reduced HbA1c by 1.5% and fasting blood glucose by 25

mg/dL. A slight advantage of Canagliflozin over Teneligliptin was observed with regard to achieving the target HbA1c (<7%) and fasting blood glucose (<130 mg/dL) levels. For this, 64.3% and 57.1% of patients attained target reductions in this group, as compared to those observed in the Teneligliptin group with 57.1% and 50%, respectively. However, canagliflozin had more urinary tract infections 14.3 % and dehydration 8.6%. At the same time, gastrointestinal problems were more frequent with teneligliptin 11.4%. **Conclusion**: Both Teneligliptin and Canagliflozin were capable of improving the glycemic control in patients with T2DM. Both of them were associated with an equally effective decrease in HbA1c and fasting blood glucose. Canagliflozin might have a minor advantage concerning glycemic target achievement, but it was associated with a higher rate of urinary tract infection and dehydration. On the other hand, Teneligliptin was better tolerated with fewer serious adverse events. These findings support the use of either medication based on the patient's profile and specific goals of treatment.

KEYWORDS: Teneligliptin, Canagliflozin, Type 2 Diabetes Mellitus, glycemic control, HbA1c, fasting blood glucose, efficacy, safety.

INTRODUCTION

T2DM is a systemic metabolic disorder characterized by insulin resistance, combined with varying degrees of impaired insulin secretion, manifested by hyperglycemia. It is one of the most common non-communicable diseases worldwide, with increasing incidence as populations age, become increasingly sedentary, and adopt unhealthy diets. Ensuring good management of T2DM is important to avoid complications related to the disease, such as cardiovascular disease, neuropathy, nephropathy, and retinopathy—factors that lead to morbidity and mortality.[1,2,3]

The central component in the management of T2DM is glycemic control, measured mainly by HbA1c and fasting blood glucose. Maintaining the target levels will reduce the risk of complications from diabetes. Several classes of medications are available for the management of T2DM, each with different mechanisms of action, efficacy profiles, and safety considerations.

Teneligliptin is a DPP-4 inhibitor that exerts its action by increasing the action of incretin hormones, leading to an increase in insulin secretion and suppression of glucagon release. It has been reported for its efficacy in lowering blood glucose with a favorable safety profile,

particularly on hypoglycemia. Canagliflozin is the SGLT-2 inhibitor that reduces blood glucose by increasing the excretion of glucose through urine, along with other beneficial actions like reduction in weight and blood pressure. It, however, is associated with risks such as urinary tract infections and dehydration due to its mechanism of action.[4,5,6]

An increasingly high prevalence of T2DM underlines a need for optimized treatment strategies that ensure good glycemic control without significantly influencing adverse effects. With the rising number of pharmacological options, head-to-head comparisons of newer agents are critically required to guide clinical decision-making.[7,8]

Although both agents are efficacious in lowering blood glucose levels, the choice between Teneligliptin and Canagliflozin may depend on their safety profiles. Most previous studies have focused on either one or the other drug's efficacy and safety. Direct comparison studies are few and far between. Understanding their comparative effectiveness is very necessary in tailoring the treatment to patient-specific needs in this population, where polypharmacy and comorbidities are common.[9,10]

This current study has addressed the above gap by providing a more intricate comparison of Teneligliptin and Canagliflozin, focusing on their effectiveness in reaching glycemic targets and any associated risks of adverse events. This study has provided valuable information, which could help guide clinicians in selecting the most effective treatments for their patients with T2DM and hopefully enhance their treatment outcomes.[11,12]

AIM

The aim of this study is to compare the efficacy and safety of Teneligliptin and Canagliflozin in the management of Type 2 Diabetes Mellitus (T2DM).

OBJECTIVES

1. Measure and compare the reduction in HbA1c levels from baseline to three months post-treatment in patients receiving Teneligliptin versus those receiving Canagliflozin.
2. Measure and compare the reduction in fasting blood glucose levels from baseline to three months post-treatment in both treatment groups.
3. Determine the proportion of patients in each group who achieve the target HbA1c level of less than 7%.

4. Determine the proportion of patients in each group who achieve fasting blood glucose levels of less than 130 mg/dL.
5. To evaluate the safety profiles of Teneligliptin and Canagliflozin.

METHODOLOGY

Study Site: The study was carried out at a tertiary care hospital over a period of six months

Study Duration: The study is conducted over a period of 6 months.

Study Design: This is a prospective, comparative, observational study

Sample Size: A total of 140 patients with Type 2 Diabetes Mellitus were enrolled in the study. The patients were equally divided into two groups.

- **Group 1:** 70 patients receiving Teneligliptin.
- **Group 2:** 70 patients receiving Canagliflozin.

Study Criteria

Inclusion Criteria

1. Adults aged 18 years and older.
2. Diagnosed with Type 2 Diabetes Mellitus.
3. HbA1c levels between 7% and 10%.
4. Patients either newly prescribed Teneligliptin or Canagliflozin or already on stable doses of these medications.
5. Willingness to provide informed consent and adhere to the study protocol.

Exclusion Criteria

6. Type 1 Diabetes Mellitus.
7. Pregnancy or lactation.
8. Severe renal impairment (eGFR < 45 mL/min/1.73 m^2).
9. History of severe hypoglycemia.
10. Active urinary tract infections or recurrent UTIs.
11. Participation in another clinical trial during the study period.

Study method and data collection: A six-month prospective comparative observational study to compare the efficacy and safety of Teneligliptin versus Canagliflozin in a total of 140 Type 2 Diabetes Mellitus patients. Out of these patients, 70 were given the medicine Teneligliptin, and 70 were given the medicine Canagliflozin. Baseline data based on HbA1c and fasting blood sugar were noted, and after three months of treatment, reassessment of the

same was done. Along with this, the occurrence of adverse events such as hypoglycemia, urinary tract infection, dehydration and gastrointestinal problems was carefully observed. The information was processed with statistical tools to analyze the difference in changes in HbA1c, fasting blood glucose and occurrence of adverse events between the two groups.

Statistical Analysis

Mean, standard deviation, and percentages were calculated for continuous and categorical variables. The independent t-test was used to compare the mean changes in HbA1c and fasting blood glucose levels between the two groups.

RESULTS

1. Subject Characteristics.

Subject Characteristic		Teneligliptin (n=70)	Canagliflozin (n=70)	Total (n=140)
Age Category	< 45 years	15 (21.4%)	20 (28.6%)	35 (25.0%)
	45-64 years	35 (50.0%)	30 (42.9%)	65 (46.4%)
	≥ 65 years	20 (28.6%)	20 (28.6%)	40 (28.6%)
Gender	Male	40 (57.1%)	42 (60.0%)	82 (58.6%)
	Female	30 (42.9%)	28 (40.0%)	58 (41.4%)
BMI Category	Underweight (<18.5 kg/m²)	5 (7.1%)	4 (5.7%)	9 (6.4%)
	Normal (18.5-24.9 kg/m²)	30 (42.9%)	32 (45.7%)	62 (44.3%)
	Overweight (25-29.9 kg/m²)	25 (35.7%)	22 (31.4%)	47 (33.6%)
	Obese (≥30 kg/m²)	10 (14.3%)	12 (17.1%)	22 (15.7%)

The demographic and baseline characteristics of the study participants are displayed in Table 1, with each group being divided into Teneligliptin and Canagliflozin. Between the two groups, the age distribution is fairly balanced, with almost 25% of the sample under 45 years old, 46% between 45 and 64 years old, and nearly 29% beyond 65. With 57.1% of participants in the Teneligliptin group and 60% in the Canagliflozin group, there is a little male predominance in the gender distribution. According to the BMI categories, a majority of persons are between normal and overweight, with very minor percentages being underweight or obese.

2. Baseline and Post-Treatment HbA1c and Fasting Blood Glucose Levels.

Parameter	HbA1c (Baseline) (%)	HbA1c (Post-Treatment) (%)	Change in HbA1c (%)
Teneligliptin (n=70)	8.5 ± 1.2	7.0 ± 1.0	1.5 ± 0.8
Canagliflozin (n=70)	8.4 ± 1.3	6.9 ± 1.1	1.5 ± 0.9
T test Value			0.000
P Value			1.0000

Table 2 shows the HbA1c and fasting blood glucose levels for the Teneligliptin and Canagliflozin groups at baseline and after treatment. The two groups' baseline HbA1c levels (8.5% in the Teneligliptin group and 8.4% in the Canagliflozin group) were comparable, and both showed notable post-treatment decreases to approximately 7.0% and 6.9%, respectively. Each group's HbA1c level changed by 1.5% in the same way. There is not a significant difference between the two groups. Therefore, both drugs work well to lower HbA1c and reduce blood sugar levels.

3. Baseline and Post-Treatment Fasting Blood Glucose Levels.

Parameter	Fasting Blood Glucose (Baseline) (mg/dL)	Fasting Blood Glucose (Post-Treatment) (mg/dL)	Change in Fasting Blood Glucose (mg/dL)
Teneligliptin (n=70)	165 ± 25	140 ± 20	25 ± 10
Canagliflozin (n=70)	160 ± 30	135 ± 25	25 ± 12
T test Value			0.000
P Value			1.0000

In the Teneligliptin group, fasting blood glucose levels dropped from 165 mg/dL to 140 mg/dL, while in the Canagliflozin group, they reduced from 160 mg/dL to 135 mg/dL. For both regimens, the reductions in fasting blood glucose levels (25 mg/dL) were the same. There is no discernible difference between the two groups. Therefore, both drugs work well to lower HbA1c and raise blood sugar levels.

4. Effectiveness in Achieving Glycemic Targets

Glycemic Target	Teneligliptin (n=70)	Canagliflozin (n=70)	Total (n=140)
HbA1c < 7%	40 (57.1%)	45 (64.3%)	85 (60.7%)
Fasting Blood Glucose < 130 mg/dL	35 (50.0%)	40 (57.1%)	75 (53.6%)

An HbA1c level of less than 7% was attained by roughly 64.3% of patients in the Canagliflozin group and 57.1% of patients in the Teneligliptin group. 50% of the Teneligliptin group and 57.1% of the Canagliflozin group achieved blood glucose levels < 130 mg/dL while fasting. These findings indicate that while both medications are beneficial for a significant number of patients, canagliflozin may offer a minor benefit in assisting patients in achieving more stringent glucose control.

5. Side Effects

Side Effects	Teneligliptin (n=70)	Canagliflozin (n=70)	Total (n=140)
Hypoglycemia	5 (7.1%)	4 (5.7%)	9 (6.4%)
Urinary Tract Infection	2 (2.9%)	10 (14.3%)	12 (8.6%)
Dehydration	0 (0.0%)	6 (8.6%)	6 (4.3%)
Gastrointestinal Issues	8 (11.4%)	7 (10.0%)	15 (10.7%)

7.1 % of patients treated with Teneligliptin and 5.7% of patients treated with Canagliflozin experienced hypoglycemia, which is a rather uncommon occurrence. However, Canagliflozin was associated with a higher incidence of urinary tract infections (14.3% vs. 2.9% in the Teneligliptin group) and dehydration (8.6% in the Canagliflozin group with none in the Teneligliptin group). Gastrointestinal issues were slightly more common in the Teneligliptin group (11.4% vs. 10.0% in the Canagliflozin group).

DISCUSSION

Both the Teneligliptin and Canagliflozin groups have baseline demographics and characteristics that are somewhat equal, with a small male predominance in each group. Between the two groups, the age distribution is somewhat even, with almost 25% of the sample under 45 years old, 46% between 45 and 64 years old, and nearly 29% beyond 65. The majority of patients have BMIs between normal and overweight.

During the course of the three-month therapy period, both canagliflozin and teneligliptin show a significant reduction in HbA1c and fasting blood glucose levels. The identical reductions in fasting blood glucose and HbA1c across the two groups indicate that both medications are equally efficient in enhancing glycemic control in individuals with Type 2 Diabetes.

The percentage of patients in the Canagliflozin group compared to the Teneligliptin group who achieved goal HbA1c levels (<7%) and fasting blood glucose levels (<130 mg/dL) was slightly greater. This shows that patients may benefit slightly from canagliflozin in terms of achieving more stringent glycemic control.

One of the main objectives in managing diabetes is to reach a HbA1c target of less than 7%, since this lowers the risk of microvascular and macrovascular problems. Similarly, avoiding acute hyperglycemic episodes and long-term consequences requires keeping fasting blood glucose levels below 130 mg/dL.

There is a correlation between canagliflozin and an increased risk of dehydration and urinary tract infections (UTIs). These results are in line with the established adverse effects of SGLT-2 inhibitors, which raise urine glucose excretion levels and may result in osmotic diuresis and UTIs. However, gastrointestinal problems are more common with DPP-4 inhibitors like teneligliptin, even if they are usually minor and controllable. According to the study results, DPP-4 inhibitors are generally well tolerated, with hypoglycemia being comparatively uncommon.

CONCLUSION

The findings of this trial indicate that both Teneligliptin and Canagliflozin are effective treatments for Type 2 Diabetes, with significant decreases in HbA1c and fasting blood glucose levels. However, the decision between these two treatments should be made individually, taking into account the patient's overall health status, risk factors for adverse events, and specific treatment objectives. Additional investigation, especially long-term research, would be beneficial in validating these results and offering additional perspectives on the most effective utilization of these drugs in various patient demographics.

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