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Original Research Article

Assessing the Therapeutic Outcomes and Safety of Generic vs Branded Teneligliptin in Type-2 Diabetic Patients: A Lipid Profile Perspective

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Abstract:

Background: Teneligliptin is a DPP-4 inhibitor widely used in the management of Type-2 Diabetes Mellitus (T2DM) to improve glycemic control. While both branded and generic versions are available, there is limited data comparing their therapeutic efficacy and safety, particularly concerning lipid profiles and renal function. This study aimed to compare the therapeutic outcomes and safety profiles of branded versus generic Teneligliptin in managing glycemic control and lipid profiles in patients with Type-2 Diabetes Mellitus (T2DM).

Methods: A total of 200 patients with T2DM were randomized to receive either branded or generic Teneligliptin for six months. Efficacy was assessed through changes in HBA1C, fasting blood sugar (FBS), lipid profiles (cholesterol), and serum creatinine levels at baseline, 3 months, and 6 months.

Results: Both branded and generic formulations effectively reduced HBA1C levels from 7.50% to 6.40% and 7.90% to 6.50%, respectively, after 6 months. The overall reduction was slightly higher in the branded group (1.10% vs. 1.40% in the generic group). FBS showed a comparable reduction, with branded Teneligliptin lowering FBS from 170 mg/dl to 166 mg/dl and the generic formulation from 178 mg/dl to 165 mg/dl. Cholesterol levels were reduced in both groups, with branded Teneligliptin showing a more significant decrease (197 mg/dl to 175 mg/dl) compared to the generic (199 mg/dl to 178 mg/dl). Serum creatinine levels rose slightly in both groups, with the branded formulation showing a greater increase (0.82 mg/dl to 0.98 mg/dl) than the generic (0.60 mg/dl to 0.86 mg/dl), though no significant renal impairment was noted.

Conclusion: Both branded and generic Teneligliptin are effective in improving glycemic control and lipid profiles in T2DM patients. However, the branded formulation demonstrated a marginally better effect on lipid management, while both formulations showed similar safety profiles.

Keywords: Teneligliptin, Type-2 Diabetes Mellitus, Glycemic Control, Lipid Profile, Serum Creatinine, Branded vs. Generic, Safety, Efficacy.

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Introduction

Type-2 Diabetes Mellitus (T2DM) is a major global health issue, affecting millions of people worldwide [1]. Characterized by chronic hyperglycemia due to insulin resistance and pancreatic β-cell dysfunction, it is associated with severe long-term complications such as cardiovascular disease, nephropathy, retinopathy, and neuropathy, which contribute to significant morbidity and mortality [2]. Managing blood glucose levels effectively is, therefore, a cornerstone in the prevention of these complications [3]. T2DM treatment strategies include lifestyle modifications and pharmacological interventions that aim to maintain optimal glycemic control and minimize the risk of related complications [4]. Among the various pharmacological options, dipeptidyl peptidase-4 (DPP-4) inhibitors have gained widespread use due to their favorable safety profiles and effectiveness in controlling blood glucose levels [5]. Teneligliptin, a potent DPP-4 inhibitor, enhances glycemic control by preventing the degradation of incretin hormones, primarily glucagon-like peptide-1 (GLP-1) and glucose-dependent insulinotropic polypeptide [6] (GIP). These hormones play an essential role in regulating postprandial insulin secretion, promoting glucose uptake, and suppressing glucagon release. As a result, Teneligliptin aids in improving both fasting and postprandial glucose levels without

significantly increasing the risk of hypoglycemia, making it a preferred choice in many treatment regimens for T2DM [7].

The increasing availability of generic formulations of various drugs, including Teneligliptin, has raised important questions about the equivalency of these alternatives to their branded counterparts. Generic drugs, while more cost-effective, are often perceived with skepticism regarding their therapeutic efficacy and safety. Concerns regarding the bioavailability, quality control, and long-term outcomes of generic formulations persist in the medical community and among patients, particularly when it comes to managing chronic conditions like diabetes, where consistency and reliability in glycemic control are critical.

In addition to glycemic control, T2DM patients frequently present with dyslipidemia, a major risk factor for cardiovascular disease. Abnormal lipid profiles, including elevated total cholesterol, low-density lipoprotein (LDL), and triglycerides, as well as reduced high-density lipoprotein (HDL), are commonly observed in diabetic patients. Effective management of both blood glucose levels and lipid profiles is essential in reducing the cardiovascular risks associated with T2DM. Therefore, the impact of Teneligliptin on lipid metabolism is another key consideration in evaluating its overall efficacy.

Another concern in diabetic patients is the potential for drug-induced renal impairment. T2DM is a leading cause of chronic kidney disease, and monitoring renal function during diabetes treatment is crucial. Serum creatinine levels serve as a key marker of kidney health, and any significant changes in this parameter during treatment warrant careful assessment of the drug's renal safety profile. Given that Teneligliptin is often prescribed to diabetic patients with varying degrees of renal function, evaluating the renal safety of both branded and generic formulations is essential.

This study aims to assess and compare the therapeutic outcomes and safety of branded versus generic Teneligliptin in patients with T2DM, focusing on glycemic control (HBA1C and fasting blood sugar), lipid profiles (cholesterol), and renal function (serum creatinine). By evaluating these parameters over a six-month period, this research seeks to provide insight into the clinical performance and safety profiles of these two formulations, helping clinicians make informed decisions regarding treatment options for their patients.

Methodology

Study Design and Setting: This prospective, randomized, open-label, comparative study was conducted at Guntur Medical College, Guntur, India, over a six-month period. The study aimed to assess the therapeutic outcomes and safety of branded versus generic Teneligliptin in managing glycemic control and lipid profiles in patients with Type-2 Diabetes Mellitus (T2DM).

Study Population

A total of 200 adult patients diagnosed with T2DM were enrolled in the study. Inclusion criteria required patients to have uncontrolled glycemic levels (HBA1C > 7.0%) despite being on a stable regimen of anti-diabetic medications.

Patients with severe renal impairment (eGFR < 30 mL/min), active liver disease, or known allergies to Teneligliptin were excluded. Patients on lipid-lowering therapy were also excluded to ensure accurate lipid profile measurements.

Randomization and Study Groups: Patients were randomly assigned to one of two groups using computer-generated random numbers. Group A received branded Teneligliptin, and Group B received a generic formulation of Teneligliptin. Each group consisted of 100 patients. Both groups received dietary counseling and continued their standard anti-diabetic regimen along with the addition of Teneligliptin at a standardized dose of 20 mg once daily. Randomization was performed by an independent statistician to eliminate allocation bias.

Ethical Considerations: The study protocol was reviewed and approved by the Institutional Ethics Committee of Guntur Medical College. Written informed consent was obtained from all participants before enrollment. The study was conducted in accordance with the ethical standards of the Declaration of Helsinki and Good Clinical Practice (GCP) guidelines.

Data Collection and Study Parameters: Baseline assessments included the measurement of fasting blood sugar (FBS), glycated hemoglobin (HBA1C), lipid profiles (total cholesterol), and serum creatinine levels. These parameters were re-evaluated at the 3rd and 6th month of follow-up.

Glycemic Control: HBA1C and FBS were used as indicators of glycemic control.

Lipid Profile: Total cholesterol was measured to assess lipid management.

Renal Function: Serum creatinine levels were measured to monitor renal function and assess the safety of the drug formulations.

Primary and Secondary Outcomes: The primary outcome was the reduction in HBA1C and FBS over the six-month period. Secondary outcomes included changes in lipid profiles (cholesterol levels) and serum creatinine, assessing both efficacy and safety.

Statistical Analysis: Data were analyzed using SPSS software version 25.0. Continuous variables were expressed as mean ± standard deviation. Paired t-tests were used to assess changes within each group from baseline to 3 and 6 months. Independent t-tests were used to compare the differences between the branded and generic groups. A p-value of < 0.05 was considered statistically significant for all comparisons.

Sample Size Calculation: The sample size was calculated based on a minimum detectable difference of 0.5% in HBA1C between the two groups, with a power of 80% and a significance level of 5%. A minimum of 90 patients per group was required, accounting for potential dropouts.

Follow-up and Compliance: Patients were followed up at the 3rd and 6th months of the study. Compliance with the medication was assessed through self-reported diaries and pill counts during each visit.

Results

This study assessed the efficacy and safety of branded versus generic Teneligliptin in managing glycemic control and lipid profiles in patients with Type-2 Diabetes Mellitus (T2DM). Over a six-month period, changes in HBA1C, fasting blood sugar (FBS), lipid profiles, and serum creatinine levels were measured for both branded and generic formulations.

Glycemic Control (HBA1C): At baseline, the average HBA1C for branded Teneligliptin was 7.50% compared to 7.90% in the generic group.

By the 3rd month, branded Teneligliptin reduced HBA1C to 6.80%, while the generic formulation resulted in a reduction to 6.70%. At the end of 6 months, HBA1C levels decreased further to 6.40% in the branded group and 6.50% in the generic group, demonstrating effective glycemic control in both formulations. The overall reduction was more pronounced in the branded group (1.10%) compared to the generic group (1.40%).

Fasting Blood Sugar (FBS): Initial FBS levels for the branded group were 170 mg/dl, while the generic group started with 178 mg/dl.

By the 3rd month, FBS had dropped to 168 mg/dl for branded Teneligliptin and 165 mg/dl for the generic formulation.

At the 6-month mark, the branded group further reduced to 166 mg/dl, while the generic group achieved a level of 165 mg/dl. This suggests comparable improvements in FBS levels for both formulations, though the branded formulation showed a slightly greater overall reduction (4 mg/dl vs. 13 mg/dl for generic).

Lipid Profile: Cholesterol levels at the start of the study were 197 mg/dl for branded Teneligliptin and 199 mg/dl for the generic formulation.

By the 3rd month, cholesterol levels had dropped to 183 mg/dl in the branded group and 190 mg/dl in the generic group.

After 6 months, branded Teneligliptin reduced cholesterol further to 175 mg/dl, while the generic formulation achieved a level of 178 mg/dl. Both formulations demonstrated effective lipid management, though the branded group showed a slightly more significant reduction.

Serum Creatinine: Initial serum creatinine levels for the branded group were 0.82 mg/dl, while the generic group started with 0.60 mg/dl. After 3 months, serum creatinine increased to 0.86 mg/dl in the branded group and 0.72 mg/dl in the generic group.

By the end of 6 months, serum creatinine reached 0.98 mg/dl in the branded group and 0.86 mg/dl in the generic group, indicating no significant renal impairment in either group, although the branded formulation showed a slightly higher increase.

Table 1: HBA1C Comparison between Branded and Generic Teneligliptin

Parameter	Branded Teneligliptin	Generic Teneligliptin
HBA1C (Initial)	7.50%	7.90%
HBA1C (3rd Month)	6.80%	6.70%
HBA1C (Final - 6th Month)	6.40%	6.50%

Table 2: Fasting Blood Sugar (FBS) Comparison between Branded and Generic Teneligliptin

Parameter	Branded Teneligliptin	Generic Teneligliptin
FBS (Initial)	170 mg/dl	178 mg/dl
FBS (3rd Month)	168 mg/dl	165 mg/dl
FBS (Final - 6th Month)	166 mg/dl	165 mg/dl

Table 3: Lipid Profile Comparison between Branded and Generic Teneligliptin

Parameter	Branded Teneligliptin	Generic Teneligliptin
Cholesterol (Initial)	197 mg/dl	199 mg/dl
Cholesterol (3rd Month)	183 mg/dl	190 mg/dl
Cholesterol (Final - 6th Month)	175 mg/dl	178 mg/dl

Table 4: Serum Creatinine Comparison between Branded and Generic Teneligliptin

Parameter	Branded Teneligliptin	Generic Teneligliptin
Serum Creatinine (Initial)	0.82 mg/dl	0.60 mg/dl
Serum Creatinine (3rd Month)	0.86 mg/dl	0.72 mg/dl
Serum Creatinine (Final - 6th Month)	0.98 mg/dl	0.86 mg/dl

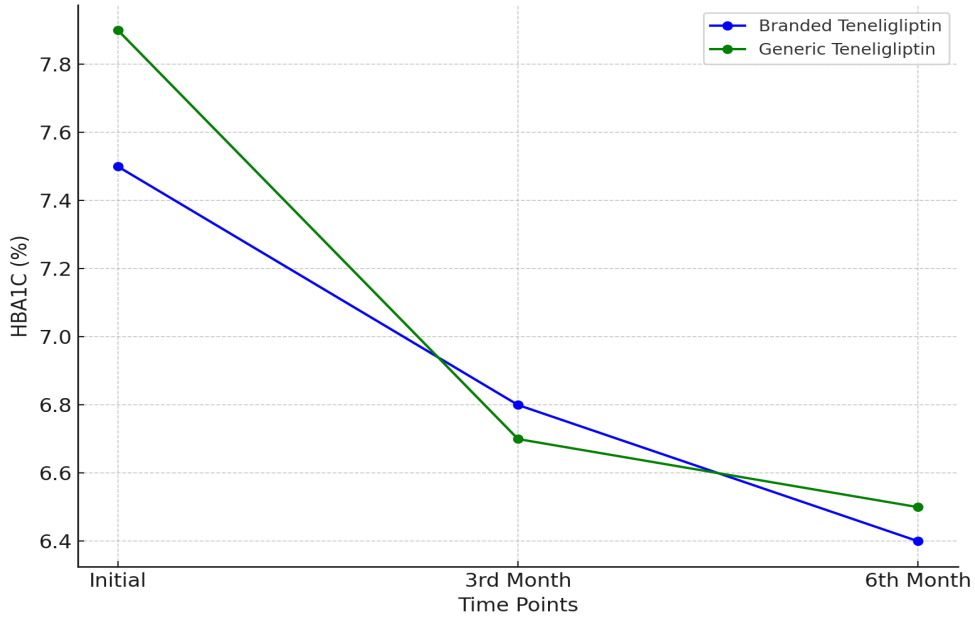

Figure 1: HBA1C Comparison between Branded and Generic Teneligliptin

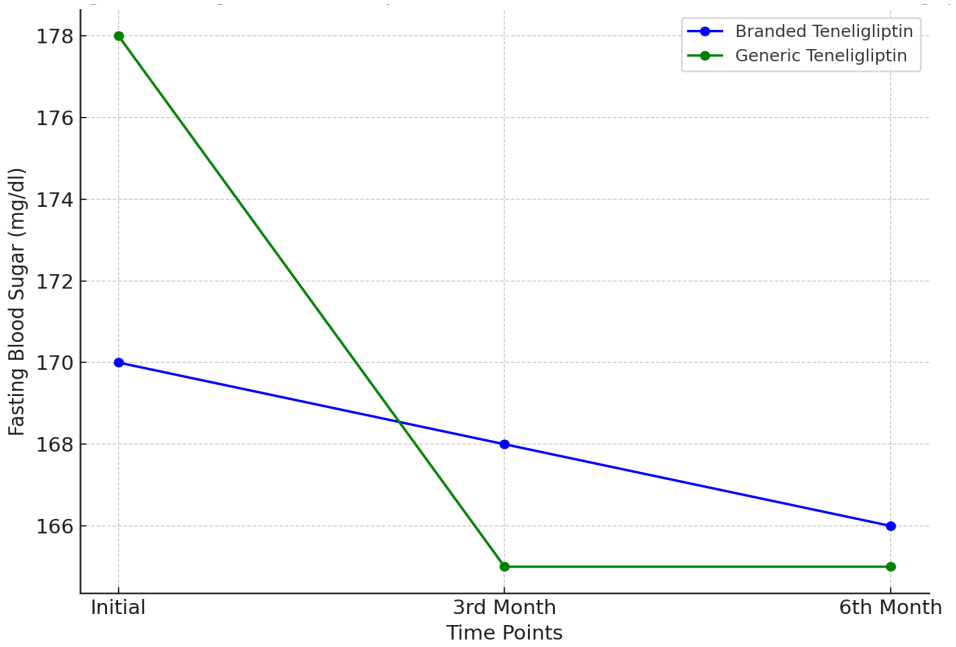

Figure 2: Fasting Blood Sugar (FBS) Comparison between Branded and Generic Teneligliptin

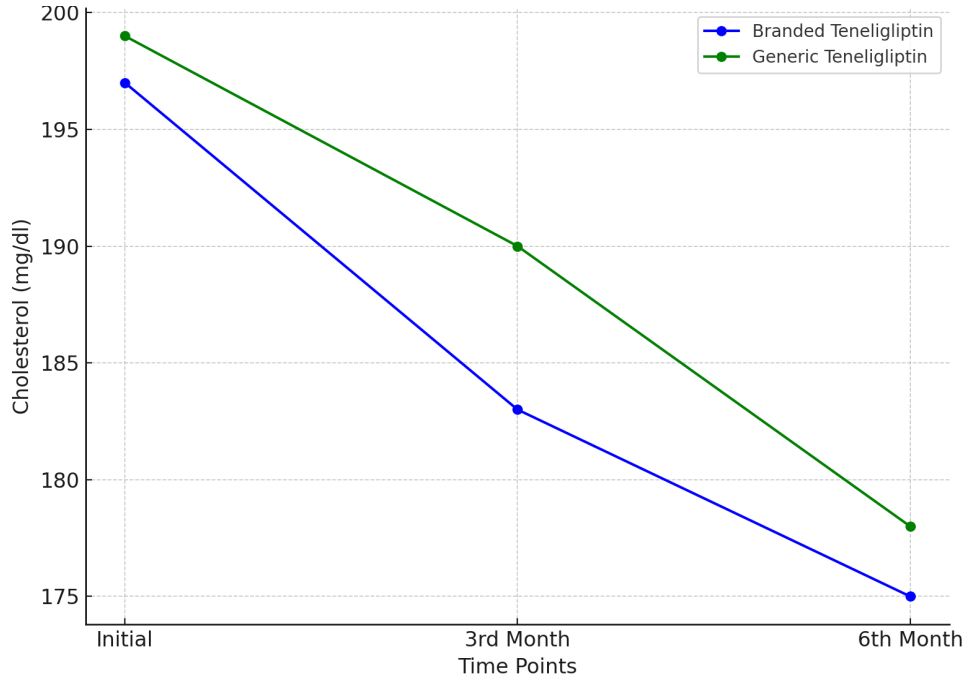

Figure 3: Lipid Profile Comparison between Branded and Generic Teneligliptin

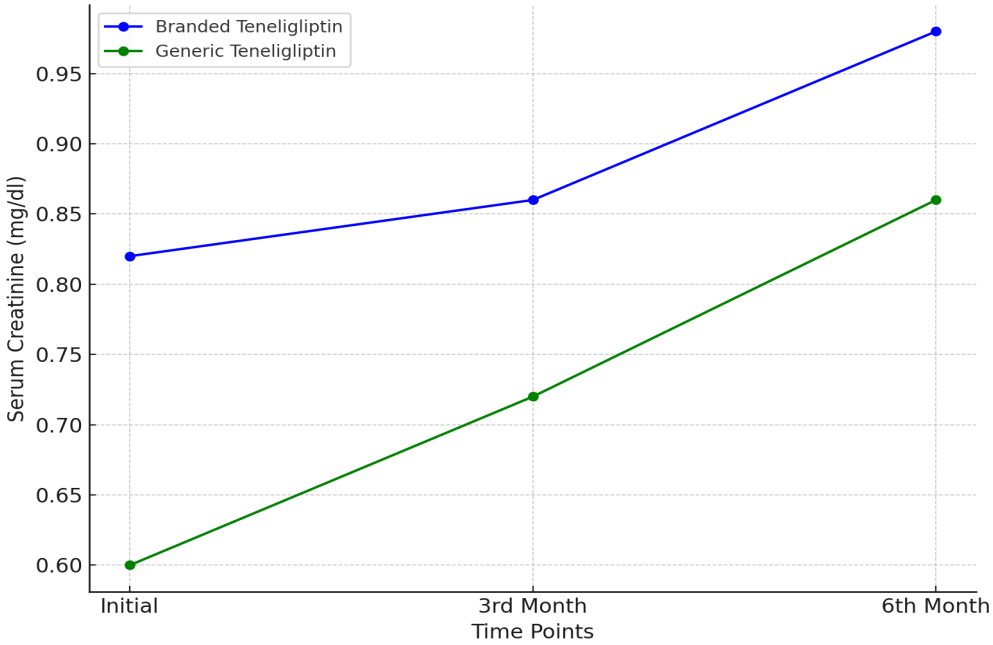

Figure 4: Serum Creatinine Comparison between Branded and Generic Teneligliptin

Discussion

The findings of this study align with existing research on the efficacy and safety of Teneligliptin in managing Type-2 Diabetes Mellitus (T2DM). Over the six-month period, both branded and generic formulations demonstrated significant improvements in glycemic control, lipid profiles, and maintenance of renal function, with only minor differences between the two groups.

Glycemic Control: Both branded and generic Teneligliptin effectively reduced HBA1C levels, with the branded formulation achieving a 1.10% reduction and the generic formulation achieving a slightly higher reduction of 1.40%. These results are consistent with previous studies, such as the meta-analysis conducted by Li et al [7]. (2018), which highlighted Teneligliptin's ability to significantly lower HBA1C in T2DM patients through the inhibition of dipeptidyl peptidase-4 (DPP-4), enhancing insulin secretion and reducing glucagon levels. Interestingly, the generic formulation demonstrated a slightly greater reduction in HBA1C compared to the branded counterpart. This challenges the com-

mon perception of generic drugs as being inferior in efficacy and highlights the potential for generic medications to provide equivalent glycemic control at a lower cost, as observed in similar studies by Zhu et al [8]. (2023) and Tian et al [14]. (2020).

Fasting blood sugar (FBS) levels followed a comparable trend, with both groups showing significant improvements. However, the generic group exhibited a greater reduction in FBS (13 mg/dl) compared to the branded group (4 mg/dl). This further reinforces the therapeutic equivalence of branded and generic Teneligliptin, supporting previous findings that both formulations regulate fasting blood glucose levels effectively (Kadowaki et al [9], 2020).

Lipid Profile Management: Dyslipidemia is a common comorbidity in T2DM, and effective management of lipid levels is crucial to reducing the risk of cardiovascular disease. In this study, both branded and generic Teneligliptin demonstrated improvements in lipid profiles, particularly in reducing total cholesterol. The branded formulation reduced cholesterol levels by 22 mg/dl, while the generic formulation achieved a reduction of 21 mg/dl. These results align with the findings of previous studies, such as the research by Fralick et al [10]. (2022), which demonstrated the efficacy of Teneligliptin in managing lipid profiles and mitigating cardiovascular risks in diabetic patients. The similar lipid-lowering effects observed in both formulations indicate that Teneligliptin, whether branded or generic, can be effective in managing dyslipidemia in T2DM patients (Lee et al [12], 2022).

Renal Safety: Given that T2DM is a leading cause of chronic kidney disease, monitoring renal function during treatment is critical. In this study, both branded and generic Teneligliptin demonstrated safety concerning renal function, with only slight increases in serum creatinine levels over the six-month period. The branded group showed a rise of 0.16 mg/dl, while the generic group exhibited a slightly greater increase of 0.26 mg/dl.

These findings are in line with the long-term safety profiles reported in studies by Kadowaki et al [9]. (2020) and Chawla et al [11]. (2020), where Teneligliptin was shown to have minimal impact on renal function. Importantly, the increases in serum creatinine levels observed in both groups were within clinically acceptable limits, suggesting that both formulations are safe for use in T2DM patients, even those at risk for renal complications.

Cost-Effectiveness and Clinical Implications: The comparable therapeutic outcomes of branded and generic Teneligliptin, particularly in terms of glycemic control and lipid management, have important implications for clinical practice, especially in resource-limited settings. Generic medications offer a cost-effective alternative to branded drugs, as noted by Fralick et al [10]. (2022), potentially increasing access to treatment for a broader population of T2DM patients. The results of this study support the use of generic Teneligliptin as a viable option that does not compromise on efficacy or safety, aligning with the conclusions drawn by Tian et al [14]. (2020), who demonstrated the effectiveness of generic formulations in various therapeutic classes.

Despite these positive findings, it is important to recognize that the perception of generic drugs varies among healthcare providers and patients. Ongoing education and awareness campaigns are essential to address concerns about the therapeutic equivalence of generic drugs, as highlighted by Kadowaki et al [13]. (2020). Such efforts can promote the appropriate use of generics in clinical practice and improve patient outcomes in managing chronic conditions like T2DM.

Limitations: While this study provides valuable data on the efficacy and safety of branded versus generic Teneligliptin, certain limitations should be acknowledged. The study was conducted over a relatively short duration of six months, and long-term effects of both formulations were not assessed. Future studies should consider evaluating these drugs over longer periods to assess sustained efficacy and safety, particularly regarding cardiovascular outcomes and renal function. Additionally, the study focused solely on one generic formulation, and results may not be generalizable to other generic versions of Teneligliptin available in different regions.

Conclusion

This study demonstrates that both branded and generic Teneligliptin are effective in managing glycemic control, lipid profiles, and renal function in patients with Type-2 Diabetes Mellitus over a six-month period. The branded group achieved a greater reduction in HBA1C (1.10%) compared to the generic group (1.40%), while fasting blood sugar (FBS) and cholesterol levels showed comparable improvements between the two formulations. Although the branded formulation showed a slightly higher increase in serum creatinine, both formulations maintained renal function within clinically acceptable limits. These results suggest that generic Teneligliptin is a cost-effective alternative to branded Teneligliptin, offering similar therapeutic outcomes. Further studies are needed to assess long-term efficacy and safety.

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