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EVALUATION OF GLYCEMIC OUTCOMES AND RENAL SAFETY OF TENEGLIPTIN VERSUS LINAGLIPTIN AS AN ADD-ON THERAPY TO STANDARD DUAL THERAPY IN PATIENTS WITH TYPE-2 DIABETES MELLITUS AND RENAL IMPAIRMENT: A PROSPECTIVE OBSERVATIONAL STUDY

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ABSTRACT:

Type 2 Diabetes Mellitus (T2DM) is a chronic disease that can lead to kidney damage.

Many patients do not achieve proper blood sugar control with metformin and glimepiride alone.

So, a third drug like a DPP-4 inhibitor is often added to improve treatment outcomes.

Teneligliptin and linagliptin are commonly used options that are generally safe for kidney patients.

Both drugs helped in lowering blood sugar levels and improving kidney function.

However, linagliptin showed better results in reducing HbA1c and improving kidney markers.

Overall, linagliptin may be a more effective and safer choice for T2DM patients with kidney problems.

KEY WORDS:

Type 2 Diabetes Mellitus, Teneligliptin, Linagliptin, Add-on Therapy, Glycaemic Control, Renal Safety, DPP-4 Inhibitors

INTRODUCTION:

TYPE 2 DIABETES MELLITUS

Type 2 Diabetes Mellitus (T2DM) is a chronic, progressive metabolic disorder characterized by persistent hyper-glycaemia resulting from insulin resistance and impaired insulin secretion [1,2]. It is the most common form of diabetes, accounting for the majority of cases worldwide, and has emerged as a major public health concern due to its rapidly increasing prevalence. Lifestyle factors such as physical inactivity, unhealthy dietary habits, obesity, and genetic predisposition play a significant role in its development [3,4,5].

RENAL IMPAIRMENT IN TYPE 2 DIABETES MELLITUS

Renal impairment is one of the most common and clinically significant complications associated with Type 2 Diabetes Mellitus (T2DM). It primarily manifests as diabetic nephropathy, a progressive kidney disorder characterized by structural and functional changes in the renal system. Persistent hyper-glycemia leads to damage of the glomerular capillaries, resulting in increased glomerular permeability, albuminuria, and gradual decline in renal function over time [6].

LINAGLIPTIN

Linagliptin is an oral antidiabetic agent belonging to the class of dipeptidyl peptidase-4 (DPP- 4) inhibitors, widely used in the management of Type 2 Diabetes Mellitus. It exerts its pharmacological action by inhibiting the DPP-4 enzyme, thereby increasing the levels of incretin hormones such as glucagon-like peptide-1 (GLP-1) and glucose-dependent insulinotropic polypeptide (GIP). These hormones enhance glucose-dependent insulin secretion and suppress glucagon release, leading to improved glycemic control without causing significant hypoglycemia [7,8].

TENELIGLIPTIN

Teneligliptin is another DPP-4 inhibitor used in the management of Type 2 Diabetes Mellitus, particularly in Asian populations. It enhances incretin hormone activity by inhibiting the DPP- 4 enzyme, thereby promoting glucose-dependent insulin secretion and reducing glucagon levels. This mechanism results in effective reduction of blood glucose levels with a low risk of hypoglycemia [9-15].

RATIONALE FOR ADD-ON THERAPY TO METFORMIN AND GLIMEPIRIDE

The management of Type 2 Diabetes Mellitus follows a stepwise approach, beginning with lifestyle modifications and first-line pharmacotherapy using Metformin. Metformin acts by improving insulin sensitivity and reducing hepatic glucose production, making it the cornerstone of diabetes management. When glycemic targets are not achieved with Metformin alone, a second agent such as a sulfonylurea is added to enhance insulin secretion.

Addition of DPP-4 inhibitors to standard dual therapy provides better glycemic control by targeting postprandial glucose levels and improving overall glucose homeostasis. Importantly, in patients with renal impairment, drug selection becomes more critical, as many antidiabetic agents require dose adjustments or are contraindicated. Linagliptin, with its non-renal route of elimination, offers a distinct advantage in such patients, whereas Teneligliptin provides an alternative option with effective glycemic control.

Evaluating the comparative efficacy and renal safety of Teneligliptin and Linagliptin as add-on therapy to Metformin and Glimepiride is clinically relevant. This approach helps in identifying the most suitable

therapeutic option for patients with Type 2 Diabetes Mellitus and renal impairment, ensuring optimal glycemic control while minimizing potential risks.

METHODOLOGY:

Study Design:

A prospective observational study was conducted to evaluate and compare the glycaemic outcomes and renal safety of Teneligliptin versus Linagliptin as add-on therapy to standard dual therapy in patients with Type 2 Diabetes Mellitus and renal impairment.

Study Site:

The study was carried out in the Department of General Medicine of a Lalitha Super Specialty Hospital- a tertiary care teaching hospital.

Study Duration:

The study was conducted over a period of six months from September 2025 to March 2026.

Study Population:

Patients diagnosed with Type 2 Diabetes Mellitus with renal impairment and receiving treatment in the study site were included in the study.

Sample Size:

A total of 200 patients were included in the study and divided into two groups: Group A: Patients receiving Teneligliptin-20 mg as add-on therapy (n = 100)

Group B: Patients receiving Linagliptin-5 mg as add-on therapy (n = 100)

Inclusion Criteria:

- Patients aged 18 years and above
- Patients diagnosed with Type 2 Diabetes Mellitus
- Patients with renal impairment (reduced eGFR and/or elevated serum creatinine)
- Patients inadequately controlled on standard dual therapy (Metformin and Glimepiride)
- Patients receiving Teneligliptin or Linagliptin as add-on therapy
- Patients willing to provide informed consent

Exclusion Criteria:

- Patients with Type 1 Diabetes Mellitus
- Pregnant and lactating women
- Patients with severe hepatic impairment
- Patients on insulin therapy
- Patients with incomplete clinical data
- Patients not willing to participate in the study

Study Procedure:

- Eligible patients were identified based on inclusion and exclusion criteria. After obtaining
- informed consent, baseline data including demographic details, clinical history, and laboratory parameters were recorded using a structured Case Report Form (CRF). Patients were categorized into two groups based on the add-on therapy prescribed (Teneligliptin or Linagliptin). Baseline glycaemic

parameters (fasting blood glucose and HbA1c) and renal parameters (serum creatinine and eGFR) were recorded.

- Follow-up data were collected after 3 months of therapy to assess changes in these parameters.

Data Collection Method:

- Data were collected using a structured Case Report Form which included patient demographics,
- medical history, treatment details, laboratory parameters, and safety outcomes such as adverse drug reactions and hypoglycaemia.

Study Variable

a) Primary Variables:

- Fasting Blood Glucose (FBS) Glycated Haemoglobin (HbA1c)

b) Secondary Variables:

- Serum Creatinine
- Estimated Glomerular Filtration Rate (eGFR)

Safety Variables:

Adverse Drug Reactions (ADRs) Hypoglycaemic episodes

Statistical Analysis:

Data were entered and analysed using statistical software. Continuous variables were expressed as mean ± standard deviation (SD), and categorical variables were expressed as frequency and percentage.

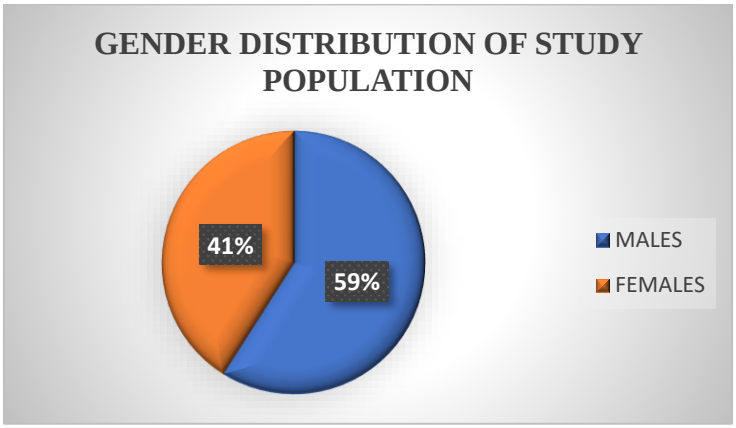
Paired Student's t-test was used to compare baseline and follow-up values within each group, while unpaired Student's t-test was used to compare differences between the two groups. Chi-square test was applied for categorical variables. A p-value of less than 0.05 was considered statistically significant.

RESULT:

Table 1: Distribution of Patients Based on Gender

Gender	Teneligliptin (n=100)	Linagliptin (n=100)	Total	%
Male	58	60	118	59
Female	42	40	82	41
Total	100	100	200	100

Figure 1: Gender Distribution of Study Population



The gender distribution of the study population is presented in Table 1. Out of the total 200 patients included in the study, 118 (59%) were males and 82 (41%) were females. In the Teneligliptin group, 58 patients (58%) were male and 42 patients (42%) were female, whereas in the Linagliptin group, 60 patients (60%) were male and 40 patients (40%) were female.

Furthermore, the distribution of gender between the two treatment groups was comparable, suggesting that there was no significant difference in baseline demographic characteristics. This homogeneity between groups ensures that gender does not act as a confounding factor in influencing the outcomes of the study.

Overall, the balanced distribution of male and female patients in both groups supports the reliability of the comparative analysis carried out in the present study.

Statistical Test Used: Chi-Square Test (χ^2)

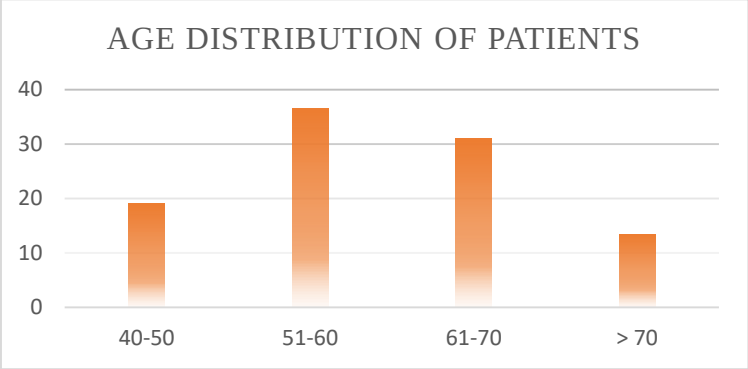
Interpretation:

The distribution of gender between Teneligliptin and Linagliptin groups was comparable, and no statistically significant difference was observed ($p > 0.05$).

Table 2: Age Distribution of Study Population

Age Group (years)	Teneligliptin	Linagliptin	Total	%
40–50	20	18	38	19
51–60	35	38	73	36.5
61–70	30	32	62	31
>70	15	12	27	13.5
Total	100	100	200	100

Figure 2: Age Distribution of Patients



The age-wise distribution of patients included in the study is presented in Table 2. Among the total 200 patients, the majority belonged to the age group of 51–60 years, accounting for 73 patients (36.5%), followed by 61–70 years with 62 patients (31%). Patients in the age group of 40–50 years constituted 38 (19%), while those aged above 70 years were 27 (13.5%).

In the Teneligliptin group, 35 patients were in the age group of 51–60 years, followed by 30 patients in the 61–70 years category. Similarly, in the Linagliptin group, the majority of patients were also in the 51–60 years age group (38 patients), followed by 32 patients in the 61–70 years category.

The findings indicate that Type 2 Diabetes Mellitus with renal impairment was more prevalent among middle-aged and elderly individuals, particularly in the 5th and 6th decades of life. This trend is consistent with the progressive nature of the disease, where the risk increases with advancing age due to prolonged exposure to metabolic risk factors and declining physiological function.

Moreover, the age distribution between the two treatment groups was comparable, suggesting that both groups were demographically similar at baseline. This ensures that age-related bias did not influence the comparative outcomes of the study.

Statistical Test Used: Chi-Square Test (χ^2)

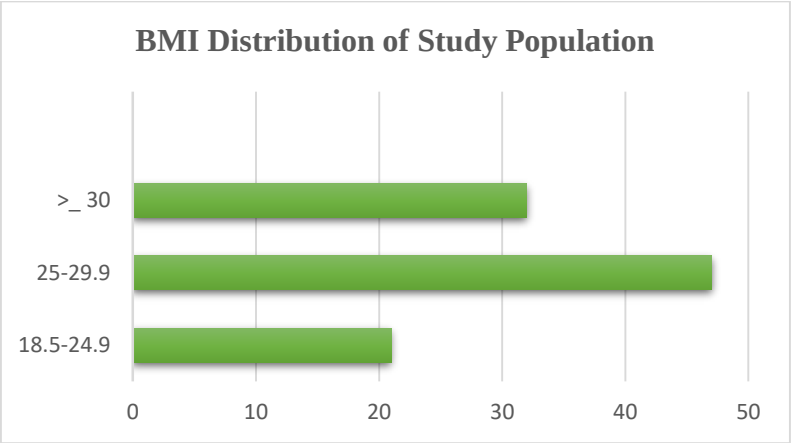
Interpretation:

Most patients were in the age group **51–60 years**, followed by 61–70 years. No significant difference in age distribution between groups ($p > 0.05$).

Table 3: Distribution of Patients Based on Body Mass Index (BMI)

BMI Category	Teneligliptin	Linagliptin	Total	%
Normal (18.5–24.9)	22	20	42	21
Overweight (25–29.9)	46	48	94	47
Obese (≥30)	32	32	64	32
Total	100	100	200	100

Figure 3: BMI Distribution of Study Population



The distribution of patients based on Body Mass Index (BMI) is presented in Table 3. Among the total 200 patients, the majority were categorized as overweight, accounting for 94 patients (47%), followed by obese individuals with 64 patients (32%), while 42 patients (21%) had a normal BMI. This indicates that a significant proportion of the study population had increased body weight, which is a well-established risk factor for the development and progression of Type 2 Diabetes Mellitus.

In the Teneligliptin group, 46% of patients were overweight, 32% were obese, and 22% had normal BMI. Similarly, in the Linagliptin group, 48% of patients were overweight, 32% were obese, and 20% had normal BMI. The distribution pattern was almost similar in both groups, indicating that there was no major difference in BMI characteristics between the treatment groups at baseline.

The higher prevalence of overweight and obesity observed in the study population highlights the strong association between increased body mass and insulin resistance. Excess adipose tissue, particularly visceral fat, contributes to metabolic disturbances, including impaired glucose utilization and increased insulin resistance, thereby playing a key role in the pathogenesis of Type 2 Diabetes Mellitus.

The comparable distribution of BMI categories between the Teneligliptin and Linagliptin groups suggests that both groups were well matched in terms of baseline anthropometric characteristics. This minimizes the potential confounding effect of BMI on treatment outcomes and strengthens the validity of the comparative analysis performed in the study.

Statistical Test Used: Chi-Square Test (χ^2)

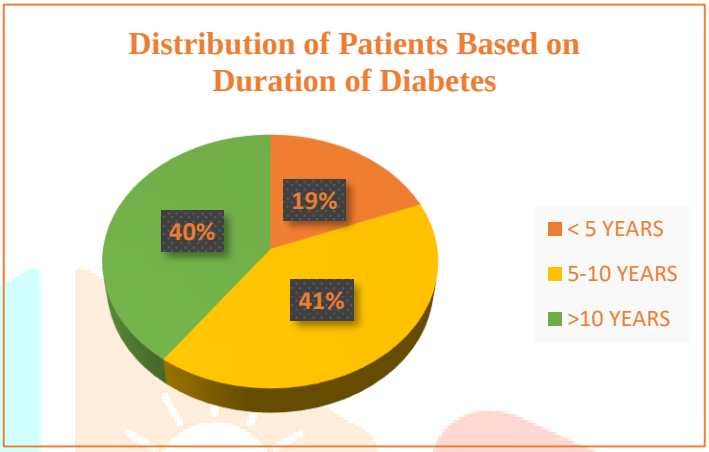
Interpretation

Since $\chi^2 = 0.136 < 5.99$, there is no statistically significant difference in BMI distribution between the two groups ($p > 0.05$). Most patients were in the overweight category.

Table 4: Distribution of Patients Based on Duration of Diabetes

Duration (years)	Teneligliptin	Linagliptin	Total	%
<5 years	18	20	38	19
5–10 years	42	40	82	41
>10 years	40	40	80	40
Total	100	100	200	100

Figure 4: Distribution of Patients Based on Duration of Diabetes



The distribution of patients based on duration of diabetes is presented in Table 4. Among the total 200 patients, the majority had a duration of diabetes between 5–10 years, accounting for 82 patients (41%), followed closely by those with a duration greater than 10 years, comprising 80 patients (40%). Patients with a duration of less than 5 years were 38 (19%).

In the Teneligliptin group, 42% of patients had a duration of diabetes between 5–10 years, followed by 40% with more than 10 years and 18% with less than 5 years. Similarly, in the Linagliptin group, 40% of patients had a duration between 5–10 years, 40% had more than 10 years, and 20% had less than 5 years.

The findings indicate that a large proportion of patients had long-standing diabetes, reflecting the progressive nature of the disease. With increasing duration, there is gradual decline in pancreatic β-cell function and worsening insulin resistance, which necessitates intensification of therapy, including the use of add-on medications.

The distribution of duration of diabetes was comparable between the two treatment groups, indicating that both groups were similar at baseline. This minimizes the influence of disease duration as a confounding factor and supports the validity of the comparative outcomes observed in the study.

Statistical Test Used: Chi-Square Test (χ^2)

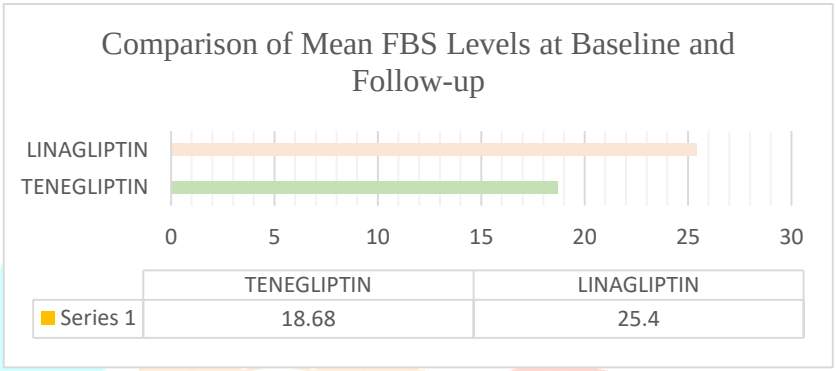
Interpretation:

Since $\chi^2 = 0.152 < 5.99$, there is no statistically significant difference in duration of diabetes between the two groups ($p > 0.05$). Most patients had diabetes duration between 5–10 years.

Table 5: Comparison of Fasting Blood Glucose (FBS) Levels at Baseline and Follow-up

Group	Baseline FBS (mg/dL)	Follow-up FBS (mg/dL)	% Reduction
Teneligliptin	182 ± 25	148 ± 18	18.68
Linagliptin	185 ± 27	138 ± 16	25.4

Figure 5: Comparison of Mean FBS Levels at Baseline and Follow-up



The comparison of fasting blood glucose (FBS) levels at baseline and follow-up is presented in Table 5. In the Teneligliptin group, the mean baseline FBS was 182 ± 25 mg/dL, which reduced to 148 ± 18 mg/dL after 3 months of add-on therapy, showing a percentage reduction of 18.68%. Similarly, in the Linagliptin group, the mean baseline FBS was 185 ± 27 mg/dL, which decreased to 138 ± 16 mg/dL at follow-up, corresponding to a higher percentage reduction of 25.4%.

The results indicate that both Teneligliptin and Linagliptin were effective in significantly reducing fasting blood glucose levels in patients who were inadequately controlled on standard dual therapy. The observed reduction in FBS in both groups reflects improved glycaemic control following the addition of DPP-4 inhibitors.

However, when comparing the two groups, Linagliptin demonstrated a greater reduction in FBS levels compared to Teneligliptin. This suggests that Linagliptin may have superior efficacy in improving fasting glycaemic parameters. The enhanced effect of Linagliptin may be attributed to its sustained DPP-4 inhibition and favorable pharmacokinetic profile.

The reduction in fasting blood glucose is clinically important, as it contributes to overall glycaemic control and helps in reducing the risk of diabetes-related complications. Improved fasting glucose levels also reflect better basal insulin activity and reduced hepatic glucose production.

Overall, the findings of the present study indicate that while both drugs are effective as add-on therapy, Linagliptin provides a comparatively greater improvement in fasting blood glucose levels, supporting its potential advantage in patients with Type 2 Diabetes Mellitus and renal impairment.

Statistical Test:

Paired Student's t-test (within group)

Unpaired Student's t-test (between groups)

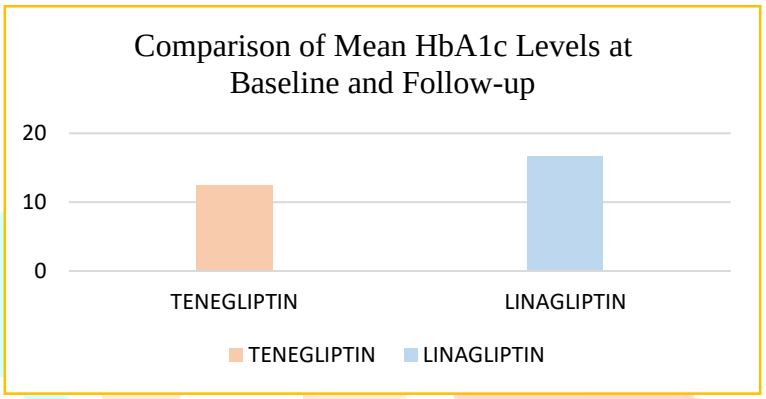
Interpretation:

Both Teneligliptin and Linagliptin significantly reduced fasting blood glucose levels. However, Linagliptin showed a greater reduction compared to Teneligliptin, which was statistically significant ($p < 0.05$).

Table 6: Comparison of Glycated Haemoglobin Levels at Baseline and Follow-up

Group	Baseline HbA1c (%)	Follow-up HbA1c (%)	% Reduction
Teneligliptin	8.9 ± 0.8	7.8 ± 0.6	12.35
Linagliptin	9.0 ± 0.9	7.5 ± 0.5	16.67

Figure 6: Comparison of Mean HbA1c Levels at Baseline and Follow-up



The comparison of glycated haemoglobin (HbA1c) levels at baseline and follow-up is presented in Table 6. In the Teneligliptin group, the mean baseline HbA1c was 8.9 ± 0.8%, which decreased to 7.8 ± 0.6% after 3 months of add-on therapy, showing a percentage reduction of 12.35%. In the Linagliptin group, the mean baseline HbA1c was 9.0 ± 0.9%, which reduced to 7.5 ± 0.5% at follow-up, corresponding to a higher percentage reduction of 16.67%.

The findings indicate that both Teneligliptin and Linagliptin were effective in significantly improving long-term glycaemic control, as evidenced by the reduction in HbA1c levels.

Statistical Test:

Paired Student's t-test (within group)

Unpaired Student's t-test (between groups)

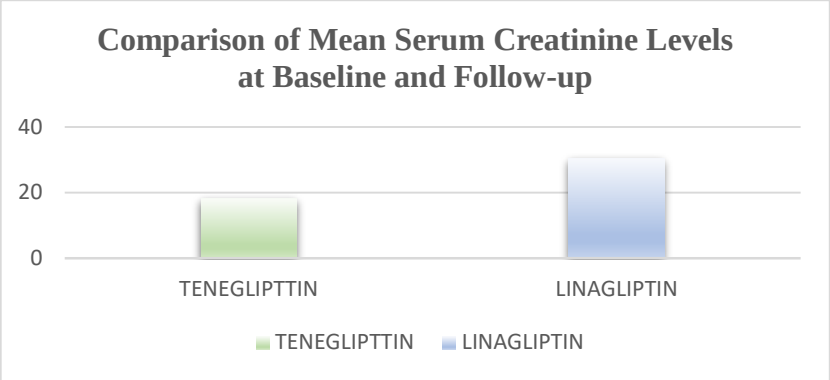
Final Interpretation:

Both Teneligliptin and Linagliptin significantly reduced HbA1c levels from baseline to follow-up. However, Linagliptin demonstrated a greater reduction compared to Teneligliptin, which was statistically significant ($p < 0.05$).

Table 7: Comparison of Serum Creatinine Levels at Baseline and Follow-up

Group	Baseline Creatinine (mg/dL)	Follow-up Creatinine (mg/dL)	% Reduction
Teneligliptin	2.2 ± 0.4	1.8 ± 0.3	18.18
Linagliptin	2.3 ± 0.5	1.6 ± 0.3	30.43

Figure 7: Comparison of Mean Serum Creatinine Levels at Baseline and Follow-up



The comparison of serum creatinine levels at baseline and follow-up is presented in Table 7. In the Teneligliptin group, the mean baseline serum creatinine was 2.2 ± 0.4 mg/dL, which decreased to 1.8 ± 0.3 mg/dL after 3 months of add-on therapy, showing a percentage reduction of 18.18%. In the Linagliptin group, the mean baseline serum creatinine was 2.3 ± 0.5 mg/dL, which reduced to 1.6 ± 0.3 mg/dL at follow-up, corresponding to a higher percentage reduction of 30.43%.

The results indicate that both Teneligliptin and Linagliptin contributed to improvement in renal function, as evidenced by the reduction in serum creatinine levels. This suggests that effective glycaemic control achieved through add-on therapy may have a beneficial impact on renal parameters.

When compared between the two groups, Linagliptin demonstrated a greater reduction in serum creatinine levels than Teneligliptin, indicating superior renal safety and efficacy. This finding may be attributed to the pharmacokinetic profile of Linagliptin, which is primarily eliminated through the hepatobiliary route and does not accumulate in patients with renal impairment.

The reduction in serum creatinine is clinically significant, as elevated creatinine levels are associated with declining kidney function. Improvement in this parameter reflects better renal clearance and stabilization of kidney function, which is particularly important in patients with diabetic nephropathy.

Overall, the findings suggest that while both drugs are effective in improving renal parameters, Linagliptin provides a comparatively greater benefit in reducing serum creatinine levels, supporting its preferential use in patients with Type 2 Diabetes Mellitus and renal impairment.

Statistical Test:

Paired Student’s t-test (within group)

Unpaired Student’s t-test (between groups)

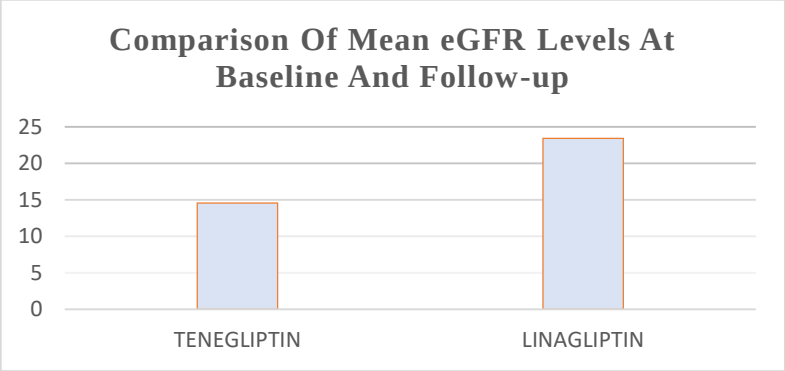
Final Interpretation:

Both Teneligliptin and Linagliptin improved renal function as evidenced by reduction in serum creatinine levels. However, Linagliptin demonstrated a greater reduction compared to Teneligliptin, which was statistically significant ($p < 0.05$).

Table 8: Comparison of Estimated Glomerular Filtration Rate (eGFR) at Baseline and Follow-up

Group	Baseline eGFR (mL/min/1.73m²)	Follow-up eGFR (mL/min/1.73m²)	% Increase
Teneligliptin	48 ± 8	55 ± 7	14.58
Linagliptin	47 ± 9	58 ± 6	23.4

Figure 8: Comparison of Mean eGFR Levels at Baseline and Follow-up



The comparison of estimated glomerular filtration rate (eGFR) at baseline and follow-up is presented in Table 8. In the Teneligliptin group, the mean baseline eGFR was 48 ± 8 mL/min/1.73m², which increased to 55 ± 7 mL/min/1.73m² after 3 months of add-on therapy, showing a percentage increase of 14.58%. In the Linagliptin group, the mean baseline eGFR was 47 ± 9 mL/min/1.73m², which improved to 58 ± 6 mL/min/1.73m² at follow-up, corresponding to a higher percentage increase of 23.4%.

The findings indicate that both Teneligliptin and Linagliptin contributed to improvement in renal function, as evidenced by the increase in eGFR levels. Since eGFR is a key indicator of kidney function, an increase reflects improved filtration capacity and better renal status.

On comparison between the two groups, Linagliptin demonstrated a greater increase in eGFR levels compared to Teneligliptin, suggesting superior renal protective effects. This may be attributed to its non-renal route of elimination, which reduces the burden on the kidneys and enhances its suitability in patients with renal impairment.

The improvement in eGFR is clinically significant, as declining eGFR is associated with progression of chronic kidney disease. Stabilization or improvement in eGFR indicates slowing of disease progression and better overall renal outcomes.

Overall, the results suggest that both drugs are effective in improving renal function; however, Linagliptin provides a comparatively greater benefit in increasing eGFR levels, supporting its preferential use in patients with Type 2 Diabetes Mellitus and renal impairment.

Statistical Test:

Paired Student's t-test (within group)

Unpaired Student's t-test (between groups)

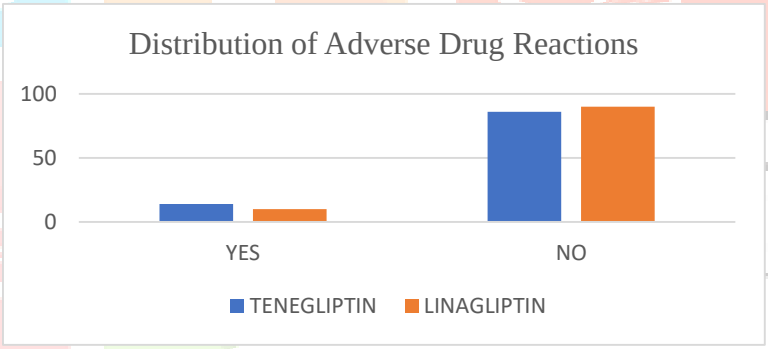
Final Interpretation:

Both Teneligliptin and Linagliptin significantly improved eGFR levels from baseline to follow-up, indicating improvement in renal function. However, Linagliptin showed a greater increase compared to Teneligliptin, which was statistically significant ($p < 0.05$).

Table 9: Comparison of Adverse Drug Reactions (ADR) between Teneligliptin and Linagliptin

ADR	Teneligliptin (n=100)	Linagliptin (n=100)	Total	%
Yes	14	10	24	12
No	86	90	176	88
Total	100	100	200	100

Figure 9: Distribution of Adverse Drug Reactions



The distribution of adverse drug reactions (ADRs) observed during the study period is presented in Table 9. Out of the total 200 patients, ADRs were reported in 24 patients (12%), while the remaining 176 patients (88%) did not experience any adverse events.

In the Teneligliptin group, 14 patients (14%) reported ADRs, whereas 86 patients (86%) did not report any adverse effects. In the Linagliptin group, ADRs were observed in 10 patients (10%), while 90 patients (90%) did not experience any ADRs.

The results indicate that both Teneligliptin and Linagliptin were generally well tolerated, with a low overall incidence of adverse drug reactions. Although the incidence of ADRs was slightly higher in the Teneligliptin group compared to the Linagliptin group, the difference was not statistically significant.

The low occurrence of ADRs in both groups highlights the favourable safety profile of DPP-4 inhibitors. These agents are known for their minimal risk of hypoglycaemia and good tolerability, especially when used as add-on therapy to existing antidiabetic regimens.

Overall, the findings suggest that both Teneligliptin and Linagliptin are safe treatment options, with Linagliptin showing a marginally better safety profile in terms of lower incidence of adverse drug reactions.

Statistical Test Used: Chi-Square Test (χ^2)

Interpretation:

The incidence of adverse drug reactions was slightly higher in the Teneligliptin group compared to the Linagliptin group; however, the difference was not statistically significant ($p > 0.05$). Both drugs were generally well tolerated.

DISCUSSION

The present prospective observational study was conducted to evaluate and compare the glycaemic outcomes and renal safety of Teneligliptin versus Linagliptin as add-on therapy to standard dual therapy (Metformin and Glimepiride) in patients with Type 2 Diabetes Mellitus and renal impairment. A total of 200 patients were included and followed for a period of 3 months to assess changes in glycaemic and renal parameters.

In the present study, the demographic characteristics such as age, gender distribution, and body mass index were comparable between both treatment groups, with no statistically significant differences observed ($p > 0.05$). The majority of patients belonged to the age group of 51–60 years, which is consistent with the known epidemiology of Type 2 Diabetes Mellitus. Similar findings were reported in studies by Sharma et al. and Gupta et al., where middle-aged individuals constituted the majority of the study population.

The duration of diabetes among the study population was predominantly between 5–10 years, indicating a chronic disease state requiring combination therapy. This finding is in accordance with previous studies which suggest that long-standing diabetes often necessitates intensification of therapy due to progressive β-cell dysfunction.

In terms of glycaemic control, both Teneligliptin and Linagliptin demonstrated significant reductions in fasting blood glucose (FBS) and HbA1c levels from baseline to follow-up ($p < 0.001$). However, Linagliptin showed a greater reduction compared to Teneligliptin. This finding is consistent with studies by Barnett et al. and McGill et al., which reported superior glycaemic control with Linagliptin in patients with renal impairment. The enhanced efficacy of Linagliptin may be attributed to its pharmacokinetic properties and sustained DPP-4 inhibition.

Regarding renal parameters, both groups showed improvement in serum creatinine and eGFR levels, indicating better renal function following add-on therapy. However, Linagliptin demonstrated a more pronounced improvement compared to Teneligliptin. This observation is supported by previous studies, which highlight that Linagliptin does not require dose adjustment in renal impairment due to its non-renal route of elimination, making it more suitable for such patients.

The safety profile of both drugs was comparable, with a low incidence of adverse drug reactions observed in both groups. Although slightly higher ADRs were noted in the Teneligliptin group, the difference was not statistically significant ($p > 0.05$). Both drugs were well tolerated, and no serious adverse events were reported. This finding aligns with existing literature indicating that DPP-4 inhibitors have a favorable safety profile with minimal risk of hypoglycaemia.

The results of the present study support the use of DPP-4 inhibitors as effective add-on therapy in patients inadequately controlled on standard dual therapy. The findings also suggest that while both Teneligliptin and Linagliptin are effective, Linagliptin may offer additional advantages in terms of both glycaemic control and renal safety, particularly in patients with renal impairment.

The findings of the present study can also be interpreted in the context of the pharmacological differences between Teneligliptin and Linagliptin. Although both belong to the same class of DPP-4 inhibitors and share a similar mechanism of action, their pharmacokinetic profiles differ significantly. Linagliptin is primarily eliminated via the biliary route, whereas Teneligliptin undergoes both renal and hepatic elimination. This difference becomes clinically important in patients with renal impairment, as accumulation of drugs eliminated through the kidneys may increase the risk of adverse effects. The better renal outcomes observed with Linagliptin in this study may be attributed to this unique elimination pathway.

Another important observation in the present study is the improvement in eGFR levels following add-on therapy. Traditionally, chronic kidney disease is considered progressive; however, effective glycaemic control can slow or even partially reverse early renal dysfunction. The improvement in renal parameters seen in both groups suggests that better glycaemic control plays a crucial role in preserving kidney function.

The greater reduction in HbA1c observed with Linagliptin may also be clinically significant, as even a 1% reduction in HbA1c is associated with a substantial decrease in the risk of diabetes-related complications. In the present study, Linagliptin achieved a higher reduction compared to Teneligliptin, indicating better long-term glycaemic control. This supports its potential role as a preferred add-on agent in patients requiring intensified therapy.

From a clinical practice perspective, the selection of add-on therapy depends on multiple factors including efficacy, safety, patient comorbidities, and ease of use. Both Teneligliptin and Linagliptin are administered once daily and have good tolerability, which enhances patient adherence. However, the absence of dose adjustment requirement for Linagliptin in renal impairment provides an added advantage, reducing the complexity of treatment and minimizing the risk of dosing errors.

The safety analysis in the present study showed a low incidence of adverse drug reactions in both groups, with no statistically significant difference. This finding is consistent with previous literature indicating that DPP-4 inhibitors are associated with minimal side effects and a low risk of hypoglycaemia, especially when compared to other classes such as sulfonylureas. The slightly higher incidence of ADRs in the Teneligliptin group may be related to its partial renal elimination, although this difference was not clinically significant.

The present study also highlights the importance of add-on therapy in patients who are inadequately controlled on standard dual therapy. As T2DM is a progressive disease, many patients eventually require combination therapy to achieve target glycaemic levels. The addition of DPP-4 inhibitors provides a rational approach by targeting incretin pathways without significantly increasing the risk of hypoglycaemia or weight gain.

Despite the strengths of the study, certain limitations should be considered. The study was conducted over a relatively short duration of 3 months, which may not fully capture long-term outcomes. Additionally, as an observational study, there may be potential confounding factors that were not controlled. Larger randomized controlled trials with longer follow-up periods are required to further validate these findings.

In conclusion, the present study reinforces the role of DPP-4 inhibitors as effective and safe add-on therapy in patients with Type 2 Diabetes Mellitus and renal impairment. While both Teneligliptin and Linagliptin demonstrated significant improvements in glycaemic and renal parameters, Linagliptin showed comparatively superior outcomes. These findings support its preferential use in patients with compromised renal function and contribute valuable real-world evidence to existing literature.

CONCLUSION

Present prospective observational study evaluated the comparative efficacy and renal safety of Teneligliptin and Linagliptin as add-on therapy to standard dual therapy (Metformin and Glimepiride) in patients with Type 2 Diabetes Mellitus and renal impairment.

Both drugs Teneligliptin and Linagliptin demonstrated significant improvement in glycemic parameters, including fasting blood glucose and HbA1c levels, indicating their effectiveness as add-on therapy in patients inadequately controlled on dual therapy. In addition to glycemic control, both drugs also showed improvement in renal parameters, as evidenced by reduction in serum creatinine and increase in eGFR levels.

Therefore, when compared between the two groups, Linagliptin exhibited a greater reduction in blood glucose levels and HbA1c, along with a more pronounced improvement in renal function parameters. This may be attributed to its unique non-renal route of elimination, making it more suitable for patients with renal impairment.

The safety profile of both drugs was comparable, with a low incidence of adverse drug reactions and no significant difference between the groups. Both medications were well tolerated and did not show major safety concerns during the study period.

Based on the findings of the present study, it can be concluded that while both Teneligliptin and Linagliptin are effective and safe as add-on therapy, Linagliptin may be considered a more favourable option in patients with Type 2 Diabetes Mellitus and renal impairment due to its superior efficacy and better renal safety profile. Thus, Linagliptin can be preferred as an add-on agent to standard dual therapy in this patient population for achieving optimal glycaemic control along with improved renal outcomes

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