

# To Compare Effectiveness and Safety of Tenziglipitin vs Glimepiride in Patients with Type 2 Diabetes Mellitus

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## Abstract

**Background:** To determine the efficacy of Tenziglipitin [DPP-4 inhibitor] vs Glimepiride [sulfonylurea] in patients with type 2 diabetes mellitus. **Materials and Methods:** Patients with inadequate glycemic control with maximum tolerable dose of metformin were randomly divided into 2 groups (Group A & Group B). Group A was started on Tenziglipitin and Group B on Glimepiride. The patients were assessed for weight, fasting plasma glucose (FPG), post prandial glucose (PPG), HbA1c and Lipid Profile. The patients were followed up in OPD for 3 months. The difference in all the mentioned parameters were used to determine the efficacy of Tenziglipitin V/S Glimepiride. **Result:** There were more males as compared to females. Most of the subjects in both the groups were having age >50 years. Mean age in group A and B was  $58.72 \pm 12.78$  and  $59.31 \pm 13.06$  years individually. Family history of diabetes was discovered in 38.69% and 45.61% of the subjects in group A and B individually. The duration of diabetes was 42.11% and 47.37% of the subjects in group A and B since 5-10 years. Hypertension and cardiovascular disease were found in 14.04%, 5.26% and 19.30%, 3.51% of the subjects in group A and B. Lipid profile viz. Cholesterol, HDL, LDL and VLDL was similar among both the groups as  $p > 0.05$ . **Conclusion:** In the current research, Glimepiride as well as Tenziglipitin were very much endured when added to Metformin. Patients on Metformin+Tenziglipitin displayed better command in control of glycemic profile as well as lipid profile. Thus, Tenziglipitin is the better choice as an add-on medication to Metformin in type 2 diabetes patients.

**Keywords:** Tenziglipitin, Glimepiride, Type 2 Diabetes Mellitus

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## Introduction

Diabetes is a common disease that has spread to epidemic proportions in many countries. Diabetes affects people worldwide and is one of the top causes of death. Type 2 diabetes mellitus (T2DM), which accounts for 90% of all diabetes cases, is caused by insulin resistance and insulin insufficiency. Sedentary way of life and undesirable dietary patterns are the major contributors to the expanding preponderance of T2DM.<sup>[1]</sup> The choice of an orally delivered antidiabetic pharmaceutical medicine is dependent on the patient's medical state as well as the drug's pharmacological properties and side effects. Metformin monotherapy is recommended as a first-line pharmacologic treatment,<sup>[2]</sup> which is intensified if the glycosylated haemoglobin (HbA1c) goal is not met after 3 months,<sup>[3]</sup> according to current practise guidelines. If blood sugar control isn't always achieved, we add a second

medicine, such as glimepiride, a second-generation sulfonylurea that is inexpensive, effective, and widely available. DPP-4 works by stimulating glucagon like peptide-1 (GLP-1) in the bloodstream by inhibiting DPP-4, which boosts glucose-based insulin production while inhibiting glucagon release, resulting in lower glucose levels and a lower risk of hypoglycemia.

Tenziglipitin was made available in India for the first time in May 2015, and it costs a  $1/3^{rd}$  of the price of other DPP-4. In short amount of time (8 to 9 months), tenziglipitin has become the most commonly approved DPP-4 in India.<sup>[4]</sup> There has been no specific study in India to assess the efficacy of Tenziglipitin [DPP-4inhibitor] vs Glimepiride [sulfonylurea] in patients with T2DM. Many clinicians are combining sulfonylurea or a dipeptidylpeptidase (DPP-4) inhibitor with metformin as the first-line of treatment for T2DM.

Metformin-Glimepiride and Metformin-Teneligliptin were chosen for the study because Metformin-Glimepiride is the most extensively used, whilst Teneligliptin is a novel medicine with longer half-life, dual route of removal, and lower cost than other DPPs. As a result, in people with type 2 diabetes, this study assessed the efficacy of Teneligliptin [DPP-4 inhibitor] vs. Glimepiride [Sulfonylurea].

**Materials and Methods**

**Study Population**

- The study was conducted in 114 patients (minimum sample size after accounting for patients lost to follow up) fulfilling inclusion and exclusion criteria & presenting in department of General Medicine at Teerthanker Mahaveer medical college and Research Centre, Moradabad, Uttar Pradesh, India.

**Inclusion Criteria**

- The patients who are diagnosed with type II diabetes, uncontrolled with maximum tolerable dose of Metformin for atleast 1 month.

Poor Glycemic Control will be defined as.<sup>[5]</sup>

Preprandial capillary plasma glucose	>130 mg/dL
Peak postprandial capillary plasma glucose	>180 mg/Dl
HbA1c	7%-9%

- Patients with HbA1c between 7 and 9.

**Exclusion Criteria**

- Pregnant and lactating women.
- Patients with pancreatic complications.
- Patients taking Insulin
- Patients with Intestinal Obstruction.
- Patient with Creatinine clearance less than 30 ml/min.

**Result**

The present forthcoming review was led in branch of General Medicine at TMMC and RC among 114 patients with lacking glycemic control with maximum tolerable dose of metformin. The enrolled patients were randomly separated into 2 groups for example group A (Teneligliptin) and Group B (Glimepiride). In general there were 60 males and 54 females. Henceforth there was somewhat more males when contrasted

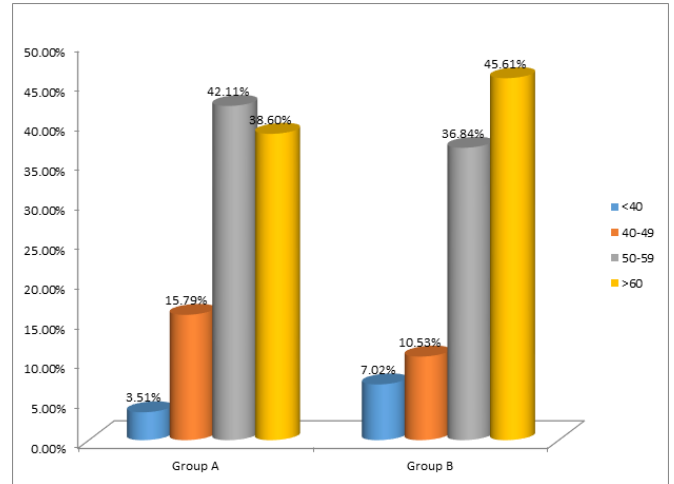


Figure 1: Age distribution among the study groups

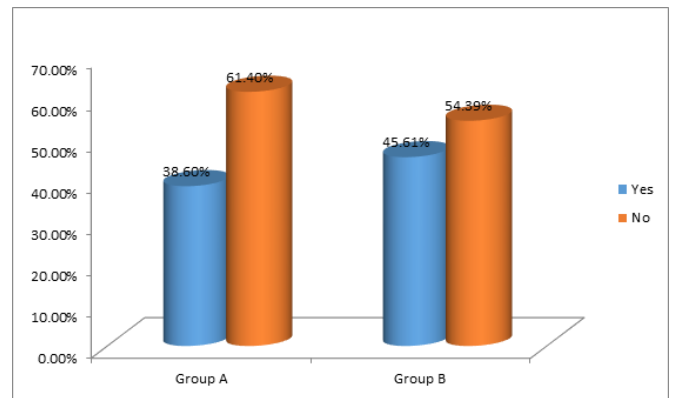


Figure 2: Family history among the study groups

with females. Sex circulation was similar among the groups [Table 1].

Most of the subjects in both the groups were having age >50 years. Mean age in group A and B was 58.72±12.78 and 59.31±13.06 years respectively [Table 2, Figure 1].

Family history of diabetes was revealed in 38.69% and 45.61% of the subjects in group A and B respectively with statistically insignificant difference (p>0.05) as shown in [Figure 2].

[Table 3] shows the duration of diabetes among the study groups. 42.11% and 47.37% of the subjects in group A and B respectively had diabetes since 5-10 years. Approximately 27% of the subjects had diabetes since >10 years. Duration of diabetes was comparable among both the study groups as p>0.05.

Mean baseline diabetic parameters viz. HbA1c, FBS and PPBS was comparable among both the groups as p>0.05 as shown in

**Table 1: Gender distribution among the study groups**

Gender	Group A: Metformin+ Teneligliptin (N=57)		Group B: Metformin+ Glimepiride (N=57)		Chi Square	p value
	N	%	N	%		
Male	31	54.39	29	50.88	0.47	0.76
Female	26	45.61	28	49.12		

**Table 2: Age distribution among the study groups**

Age Group (in years)	Group A: Metformin+ Teneligliptin (N=57)		Group B: Metformin+ Glimepiride (N=57)		Chi Square	p value
	N	%	N	%		
<40	2	3.51	4	7.02	1.17	0.41
40-49	9	15.79	6	10.53		
50-59	24	42.11	21	36.84		
>60	22	38.60	26	45.61		
Mean±SD	58.72±12.78		59.31±13.06			

**Table 3: Duration of diabetes among the study groups**

Duration (in years)	Group A: Metformin+ Teneligliptin (N=57)		Group B: Metformin+ Glimepiride (N=57)		Chi Square	p value
	N	%	N	%		
1-5	18	31.58	14	24.56	0.89	0.68
5-10	24	42.11	27	47.37		
>10	15	26.32	16	28.07		

**Table 4: Baseline comparison of diabetic parameters among the study groups**

Variables	Group A: Metformin+ Teneligliptin (N=57)		Group B: Metformin+ Glimepiride (N=57)		t test	p value
	Mean	SD	Mean	SD		
HbA1c	8.13	0.41	8.18	0.34	0.12	0.91
FBS	163.98	2.82	161.71	2.99	1.13	0.39
PPBS	264.80	11.57	251.06	13.28	1.24	0.32

**Table 5: Comparison of diabetic parameters among the study groups after the intervention**

Variables	Group A: Metformin+ Teneligliptin (N=57)		Group B: Metformin+ Glimepiride (N=57)		t test	p value
	Mean	SD	Mean	SD		
HbA1c	7.04	0.35	7.41	0.29	2.97	0.043*
FBS	122.21	4.90	134.49	5.03	3.41	0.032*
PPBS	187.69	10.14	189.33	9.72	1.80	0.39

\*: statistically significant

**Table 6: Baseline comparison of lipid profile among the study groups**

Variables	Group A: Metformin+ Teneligliptin (N=57)		Group B: Metformin+ Glimepiride (N=57)		t test	p value
	Mean	SD	Mean	SD		
Triglyceride	148.62	6.83	152.35	7.51	1.07	0.45
HDL	38.11	2.92	37.94	2.70	0.54	0.80
LDL	106.42	6.17	108.63	5.36	0.86	0.66
VLDL	39.16	2.59	39.97	3.30	0.52	0.77

**Table 7: Comparison of lipid profile among the study groups after the intervention**

Variables	Group A: Metformin+ Teneligliptin (N=57)		Group B: Metformin+ Glimepiride (N=57)		t test	p value
	Mean	SD	Mean	SD		
Triglyceride	144.66	6.67	150.53	7.14	1.89	0.13
HDL	40.38	2.75	39.97	2.61	0.63	0.72
LDL	102.30	5.83	101.98	5.49	0.48	0.79
VLDL	36.12	2.32	36.89	2.18	0.91	0.44

\*: statistically significant

[Table 4].

[Table 5] shows the comparison of diabetic parameters among the study groups after the intervention. Mean HbA1c, FBS and PPBS reduction was found both in group A and B after the intervention. However reduction was found more in group A w.r.t HbA1c and FBS as  $p < 0.05$ . PPBS was comparable in both the groups.

Mean baseline lipid profile viz. Triglyceride, HDL, LDL and VLDL was comparable among both the groups as  $p > 0.05$  as shown in [Table 6].

After intervention; improvement in HDL as well as VLDL while reduction in Triglyceride as well as LDL was found in both the groups and it was comparable as  $p > 0.05$  [Table 7].

## Discussion

In the current prospective trial, 114 patients with poor glycemic control in the department of General Medicine at TMMC & RC were assessed after being divided into 2 groups. There were more males as compared to females. Most of the subjects in both the groups were having age  $> 50$  years. Mean age in group A and B was  $58.72 \pm 12.78$  and  $59.31 \pm 13.06$  years individually. In their study, T. Nishanth et al,<sup>[6]</sup> found that Group A had a mean average age of 53.7 while Group B had a mean average age of 52.66. Family history of diabetes was uncovered in 38.69% and 45.61% of the subjects in group A and B individually with genuinely immaterial distinction ( $p > 0.05$ ). The duration of diabetes was 42.11% and 47.37% of the subjects in group A and B since 5-10 years. Hypertension

and cardiovascular disease were found in 14.04%, 5.26% and 19.30%, 3.51% of the subjects in group A and B separately with measurably unimportant contrast ( $p > 0.05$ ). HbA1c, FBS and PPBS was equivalent among both the groups as  $p > 0.05$ . Mean HbA1c, FBS and PPBS decrease was tracked down both in group A and B, anyway decrease was found more in group A w.r.t HbA1c and FBS as  $p < 0.05$ . PPBS was equivalent in both the groups. The mean FBS level in the Kim et al.<sup>[7]</sup> trial was 150.3 mg/dL, but HbA1c levels were comparable. Surprisingly, Gadge et al. discovered a critical drop in PPBS in their investigation. Only a few studies have shown that teneligliptin reduces PPBS.<sup>[8]</sup>

Lipid profile viz. Cholesterol, HDL, LDL and VLDL was similar among both the groups as  $p > 0.05$ . Later mediation; improvement in HDL just as VLDL while decrease in Triglyceride just as LDL was found in both the groups and it was similar as  $p > 0.05$ . T. Nishanth et al,<sup>[6]</sup> in their study comparably detailed that in both the groups there was a critical decrease in degrees of fatty oils level. There was more critical decrease in LDL in Group B than in Group A.

In their review, Nitika Hans found that in group 1, absolute cholesterol levels, fatty oil levels, HDL, and LDL were higher than in group 2.<sup>[9]</sup>

## Conclusion:

Metformin is a Biguanide medicine that is still used as treatment for T2DM because of its long-term safety profile and weight neutrality (helping patients lose weight).<sup>[10]</sup> Depending

on the clinical scenario, additional medications such as sulphonylureas, DPP-4 inhibitors, or other OHA's, as well as Insulin, may be considered if Metformin does not reduce HBA1c to desired level. Due to their efficacy safety & cost-effectiveness, sulphonylureas, particularly recent ones like Glimepiride are the most commonly used first add on to Metformin in Indian settings. DPP-4 are a well-known class of oral drugs that have a modest efficacy and a favourable overall safety profile. In the current research, Glimepiride as well as Teneiglipitin were very much endured when added to Metformin. In any case, patients on Metformin+Teneiglipitin displayed better command in excess of glycemic profile just as lipid profile. Thus, Teneiglipitin is the better choice as an add-on medication to Metformin in type 2 diabetes patients.

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