Original Article

ISSN (O): 2663-8290; ISSN (P): 2663-8282

To evaluate the Efficacy of Teneligliptin as an add-on Therapy in type 2 Diabetes Mellitus (T2DM) Patients with Inadequate Glycemic Control with a Stable dose of Metformin 1 to 2g and Glimipride 1 to 6mg Per Day

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Abstract

Background: To evaluate the effectiveness of Teneligliptin as an add-on therapy in type 2 diabetes mellitus (T2DM) patients inadequately controlled with a stable dose of Metformin and Glimipride. **Subjects and Methods:** Pateints with type II DM on Metformin 1-2gm per day and Glimipride 1-4mg per day were prescribed with TENELIGLIPTIN 20mg tablet once daily. The patients Were followed up in OPD every month till 3 months. At the end of 3 months, Blood Pressure, Body weight CBC,KFT,LFT, Lipid Profile, Fasting Blood sugar, 2 hours Post parandial Blood sugar and HbA1c was assessed. The difference in all the mentioned parameters was used to determine the effectiveness of TENELIGLIPTIN. **Result:** There were more males as compared to females. Mean age among the study subjects was 59.08±12.17 years Family history of diabetes was revealed in 34.17% of the subjects.48.33% of the subjects had diabetes since 5-10 years. Hypertension and cardiovascular disease was revealed in 14.17% and 6.67% of the subjects respectively. After intervention, mean weight among study subjects reduced to 71.97 from 72.61. After intervention; HbA1c, FBS and PPBS reduced to 7.02±0.44, 131.70±6.17 and 204.95±9.39 Mean Triglyceride, HDL, LDL and VLDL among the study subjects was 151.76±6.19, 38.28±2.87, 108.11±6.43 and 39.32±3.12 among the study subjects. **Conclusion:** The present assessment shows patients with T2DM who were treated with teneligliptin had measurably large and clinical important reductions in HbA1c levels.

Keywords: Diabetes Mellitus, Metformin, Teneligliptin

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Received: 14 October 2021 **Revised: 21 November 2021** **Accepted: 02 December 2021** **Published: 31 December 2021**

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. By 2040, this number is expected to rise to six hundred forty-two million. There has been a fast ascent of diabetes in India, affecting more than 77 million Indians, as indicated by International Diabetes Federation (IDF) information from 2019.[1]

Sedentary way of life and undesirable dietary patterns are the major contributors to the expanding preponderance of T2DM6. Adequate glycemic control in T2DM is related with decrease of mortality and morbidity.[2] Practically 60% patients, who can't accomplish target HbA1c level of 6% to 7% encounter complications.[3,4]

It is imperative to recognize that due to associated obesity and inadequate lifestyle modifications, only metformin along with lifestyle management may not just be enough in initial management of patients.

Current practice suggests metformin monotherapy as first-line pharmacologic therapy, which ought to be intensified if the glycosylated hemoglobin(HbA1c) target isn't accomplished following 3 months.

Beta Cell dysfunction with antidiabetic prescriptions have provoked scientists toward theorize so as to long-term

utilization of these medications might be hurtful to the left over beta cells.[5]

While a few medications, for example, sulphonylureas be related with moderate beta-cell misfortune; gliptins further develop insulin secretion commencing the beta-cells of the pancreas in light of expanded blood glucose levels.[6]

Since the primary discovery of a specialist of this class in 2006, the utilization of DPP-4 inhibitors has expanded astoundingly. They are the most common drugs utilized as extra therapy to metformin or sulfonylureas, and their utilization as monotherapy specialists has continuously expanded in the course of recent years.[7]

Fasting plasma glucose (FPG) and postprandial plasma glucose (PPG) levels are controlled by DPP-4 inhibitors, which cause extended plasma groups of dynamic glucagon like peptide1. DPP-4 inhibitors have no weight-related side effects and pose no risk of hypoglycemia.[8–10]

Teneligliptin is a gliptin that is relatively new. It has really contributed to better in F.P.G levels in people with T2DM.

Teneligliptin is a peptidomimetic with one-of-a-kind design consisting of five continuous rings. Because of this one-of-a-kind design, teneligliptin binds to DPP-4's S2 extensive subsite, increasing its power and selectivity.

What's more, pleiotropic advantages of teneligliptin have been accounted for, remembering improvement for the endothelial capacity and lipid profile, which are significant variables in the management of metabolic diseases.

DPP4 Inhibitors are known to reduce HbA1c by 0.8 to 1 percent. But the cost of drugs which are being used is very high. Teneligliptin despite its lower cost may be able to replicate what other DPP4 Inhibitors do. No Study has been done in this part of the country where managing the cost of treatment is challenging for the patients. So Teneligliptin might be able to reduce the monetary burden on the pocket of the patient with the same efficacy as other DPP4 Inhibitors.

Aim of the Study

- To evaluate the effectiveness of Teneligliptin as an add-on therapy in type 2 diabetes mellitus (T2DM) patients inadequately controlled with a stable dose of Metformin and Glimipride

Objectives

- To assess the effect of Teneligliptin over a period of 3 months in patients with inadequate glycemic control after using Metformin and Glimipride on:

1. Fasting Blood Sugar
2. Post prandial Blood Sugar
3. HbA1c
4. Other Biochemical Parameters

Subjects and Methods

Sample Size

- The study will be done in minimum of 120 patients 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

- Patients who had poor glycemic control despite taking a stable dose of metformin 1-2gm amd Glimipride 1-4mg for atleast one month.

Inadequate Glycemic Control will be defined as [11]

Preprandial capillary plasma glucose	>130 mg/dL
Peak postprandial capillary plasma glucose	>180 mg/Dl
HBA1c	7%-9%

Exclusion Criteria

- Patients with Type I DM.
- Patients who are on Insulin.
- Patient prescribed any other Antidiabetic medication after adding Teneligliptin to Metformin and Glimipride.
- Patients in which the dose of Metformin or Glimipride has to be altered.
- Patients with Hypersensitivity to the drug.
- Patients who are known case of Pancreatitis.
- Patients with Intestinal Obstruction.

Result

Table 1: Gender distribution among the study subjects

Gender	N	%
Male	71	59.17
Female	49	40.83
Total	120	100

The present research done by General Medicine at TMMC & RC among 120 patients with poor glycemic control despite taking a stable dose of metformin 1-2gm amd Glimipride 1-6mg for atleast one month. They were prescribed with TENELIGLIPTIN 20mg tablet once daily. Overall there were

71 males and 49 females. Hence there was slightly more males as compared to females. [Table 1].

Most of the subjects in this study were having age >50 years. Mean age among the study subjects was 59.08±12.17 years respectively [Figure 1].

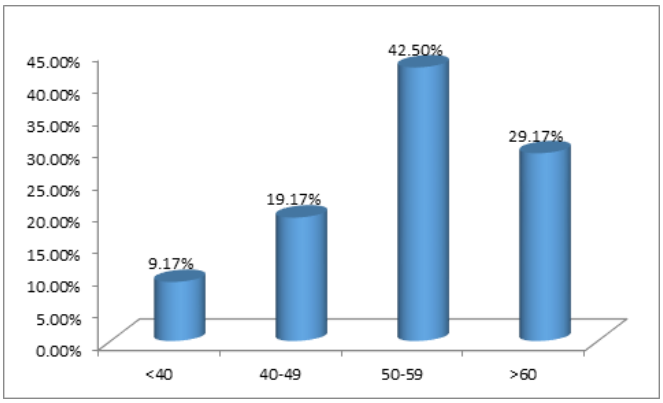

Figure 1: Age distribution among the study subjects

Family history of diabetes was revealed in 34.17% of the subjects as shown in [Figure 2].

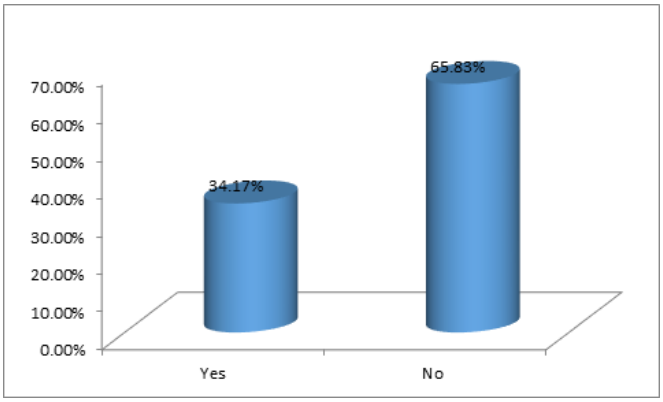

Figure 2: Family history among the study subjects

Table 2: Duration of diabetes among the study subjects

Duration	N	%
1-5	29	24.17
5-10	58	48.33
>10	33	27.50

[Table 2, Figure 3] shows the duration of diabetes among the study subjects. 48.33% of the subjects had diabetes since 5-10 years. Approximately 28% of the subjects had diabetes since >10 years.

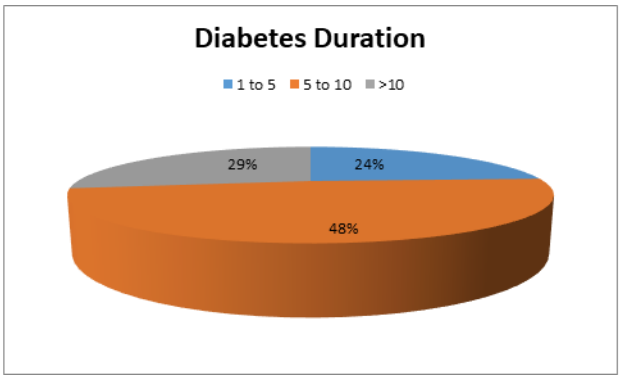

Figure 3: Duration of diabetes among the study subjects

Table 3: Co-morbidities among the study subjects

Co-morbidities	N	%
Hypertension	17	14.17
Cardiovascular Disease	8	6.67
Other	6	5.00

Hypertension and cardiovascular disease was revealed in 14.17% and 6.67% of the subjects respectively as shown in [Table 3, Figure 4].

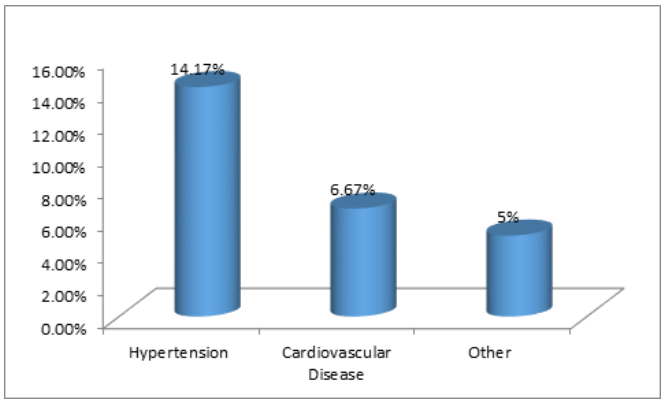

Figure 4: Co-morbidities among the study subjects

Table 4: Comparison of body weight before and after the intervention among the study subjects

Weight (kg)	Mean	SD
Before the Intervention	72.61	5.83
After the Intervention	71.97	4.58
t test	1.02	
p value	0.37	

[Table 4, Figure 5] shows the comparison of body weight before and after the intervention among the study subjects. Although there was reduction in body weight, but no significant was found when weight was compared before and after the intervention.

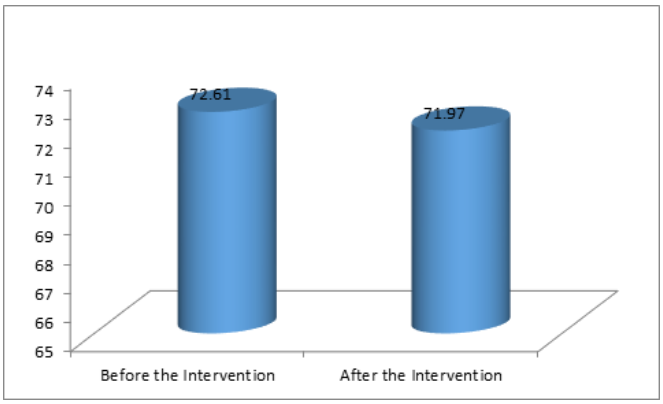

Figure 5: Comparison of body weight before and after the intervention among the study subjects

After intervention; significant improvement was found in all the diabetic parameters viz. HbA1c, FBS and PPBS when compared to baseline as p<0.05 [Table 6, Figure 6].

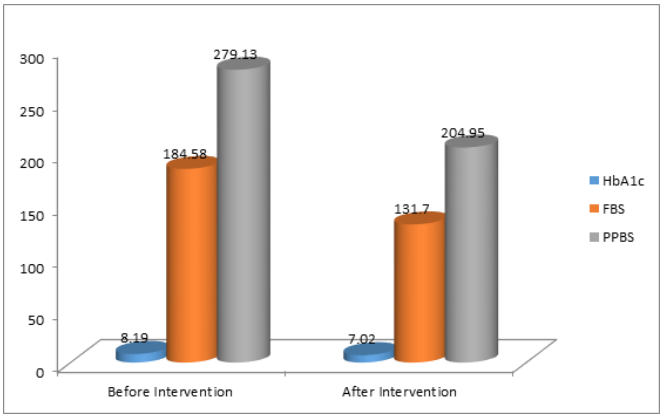

Figure 6: Comparison of diabetic parameters among the studysubjectsbefore and after the intervention

Statistically significant difference was found w.r.t. Triglyceride and HDL when compared before and after the intervention as p<0.05 as shown in [Table 7, Figure 8].

Discussion

The present assessment by unit of General Medicine at TMMC & RC among 120 patients with poor glycemic control despite

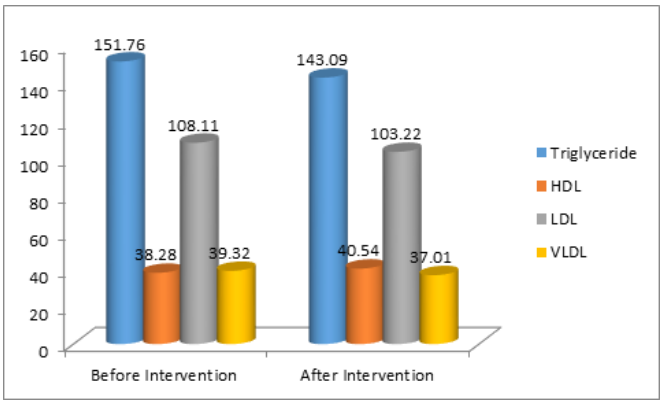

Figure 7: Comparison of biochemical parameters among the study subjects beforeandafter the intervention

taking a stable dose of metformin 1-2gm amd Glimipride 1-6mg for atleast one month. They were prescribed with TENELIGLIPTIN 20mg tablet once daily. The findings of the study are as follows: There were more males as compared to females. Most of the subjects in this study were having age >50 years. Mean age among the study subjects was 59.08±12.17 years respectively. Family history of diabetes was revealed in 34.17% of the subjects.48.33% of the subjects had diabetes since 5-10 years. Hypertension and cardiovascular disease was revealed in 14.17% and 6.67% of the subjects respectively. Before intervention, mean weight in kg among thestudy subjectswas 72.61±5.83. After intervention, mean kg among study subjects reduced to 71.97 from 72.61. Although there was reduction in body weight, but no significant was found when weight was compared before and after the intervention. According to Leena Varghese et al48, no change in BMI was observed which shows that it is weight neutral like other DPP4 inhibitors. A survey by Bohannon announced utilization of gliptins be related among no increment in weight subject with T2DM.[12] After intervention; HbA1c, FBS and PPBS reduced to 7.02 ±0.44, 131.70±6.17 and 204.95±9.39 among the study subjects. After intervention; significant improvement was found in all the diabetic parameters viz. HbA1c, FBS and PPBS when compared to baseline as p<0.05. Leena Varghese et al,[13] in their concentrate also showed that HbA1c Fasting Blood sugar and Post Prandial Blood sugar levels show a huge reduce in blood glucoselevels over a time of 90 days. Bae JC et al,[14] in their investigation comparably discovered that decrease in HbA1c was measurably huge in the teneligliptin gathering at week 16 contrasted and baseline. Mean Triglyceride, HDL, LDL and VLDL among the study subjects was 151.76±6.19, 38.28±2.87, 108.11±6.43 and 39.32±3.12 among the study subjects. According to Leena Varghese et al,[13] there was a decline in total cholesterol levels but no effect was found on LDL, HDL, Triglyceride values.

Table 5: Comparison of diabetic parameters among the study subjects before and after the intervention

Variables	Before Intervention		After Intervention		t test	p value
	Mean	SD	Mean	SD		
HbA1c	8.19	0.44	7.02	0.44	5.23	0.007*
FBS	184.58	5.08	131.70	6.17	14.42	<0.01*
PPBS	279.13	10.71	204.95	9.39	9.91	0.002*

*: statistically significant

Table 6: Comparison of biochemical parameters among the study subjects before andafter the intervention

Variables	Before Intervention		After Intervention		t test	p value
	Mean	SD	Mean	SD		
Triglyceride	151.76	6.19	143.09	5.85	3.14	0.042*
HDL	38.28	2.87	40.54	2.93	2.98	0.046*
LDL	108.11	6.43	103.22	6.43	2.71	0.07
VLDL	39.32	3.12	37.01	3.05	2/68	0.14

*: statistically significant

After intervention; improvement in HDL as well as VLDL while reduction in Triglyceride as well as LDL was reported among the study subjects. Statistically significant difference was found w.r.t. Triglyceride and HDL when compared before and after the intervention as $p<0.05$.

Conclusion

Lifestyle modifications are foundation for the control of Diabetes Mellitus and incorporate the solution of good Dietary Control, normal exercise and the management of stress. However, optimal control of glucose levels is not achieved sometimes which necessitates drug therapy. Because of the dynamic beta cell destruction nature of diabetes mellitus, monotherapy frequently causes lacking glycemic control which requires the use of various medications. The present assessment shows patients with T2DM who were treated with teneligliptin had measurably large and clinical important reductions in HbA1c levels. Treatment with teneligliptin sound tolerate. Teneligliptin medication for those with T2DM, it has been demonstrated to be effective. who are unable to control their diabetes with diet and exercise alone.

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How to cite this article: Gera A, Singh VK, Krishna H, Sharma A, Gupta S, Kumar SS. To evaluate the Efficacy of Teneligliptin as an add-on Therapy in type 2 Diabetes Mellitus (T2DM) Patients with Inadequate Glycemic Control with a Stable dose of Metformin 1 to 2g and Glimipride 1 to 6mg Per Day. Acad. J Med. 2021;4(2):61-66.

DOI: dx.doi.org/10.47008/ajm.2021.4.2.11

Source of Support: Nil, **Conflict of Interest:** None declared.