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Original Article

Teneligliptin as an Adjuvant Therapy in Type 2 Diabetic Management: A Prospective Observational Study

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ABSTRACT

Background: Diabetes Mellitus (DM) is a metabolic disorder with hyperglycemia. Management of diabetes is a global health challenge. The goal of this research was designed to prospectively analyze the safety of Teneligliptin, as a supplement therapy in the management of Type 2 DM in south Indian population. **Materials and Methods:** 302 subjects with diabetes who received teneligliptin (20 mg, oral dose) for a minimum of two months were varied with teneligliptin received for six months. The baseline data before initiating the teneligliptin treatment has also been assessed in the study and any changes in each study parameter were analyzed after two and six months of teneligliptin therapy, respectively. Efficacy was measured for all the patients after supplemental therapy on teneligliptin and was achieved by calculating FPG, BSPP for two, four, six months and HbA_{1c} value at the sixth month from the baseline value. **Results:** The results show that there is a statistically significant FPG, BSPP and HbA_{1c} values compared to that of the baseline value. It is evident that safety was achieved by supplemental therapy on teneligliptin at the dose of 20 mg. In this study, add-on therapy of teneligliptin with other 3 or 4 oral antidiabetic drugs has been used to control the glucose level. **Conclusion:** However, there are no hypoglycemic episodes found in our study and hence, it is concluded that teneligliptin achieved good blood glucose control and is well tolerated.

Keywords: Teneligliptin, Type-2 diabetic, Dipeptidyl peptidase-4 inhibitors, Adjuvant therapy, Prospective observational study.

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INTRODUCTION

Diabetes is a metabolic process and endocrine condition characterized by high blood glucose levels.[1] Diabetes affects roughly 422 million individuals globally, the majority of whom live in low- and middle-income countries and diabetes is directly responsible for 1.5 million fatalities per year, according to the WHO. Diabetes is significantly increasing in both the number of cases and the prevalence over the last few years. Type I diabetes is caused by the damage of pancreatic beta cells resulting in a lack of production of insulin and eventually causing insulin dependency from external sources. Type II diabetes; on the other hand, is characterized by condition of insulin action in the body and a lack of insulin discharge by the pancreas.

Treatment for Type II diabetes usually starts with an Oral Antidiabetic Drug (OAD), such as Metformin, which lowers blood glucose levels by blocking hepatic glucose synthesis and enhancing insulin sensitivity in the liver and skeletal muscles. Amongst the diverse key mechanism and drugs available for controlling diabetes, the Dipeptidyl Peptidase-4 (DPP-4) inhibitors are a new class of oral hypoglycemic drugs and are available for the treatment of Type II diabetes since 2006. Augmentation of a DPP-4 enzyme inhibitor with metformin has been proven to be useful due to increase in GLP-1levels[2] Also, these inhibitors bind to the catalytic site of DPP-4 and per se do not have any glucose-lowering activity; their efficacy is mediated through substrates such as the incretin hormone. It is worth noting that DPP-4 Inhibitors (DPP-4Is) have an excellent safety profile, tolerance and glycemic control in the majority of Type II diabetes patients.[3,4]

However, monotherapy alone cannot achieve the glycemic control in long term, indicating the need for combination therapy. For persons with these disorders, the American Diabetes Association suggests combined treatment with a Glucagon-Like Peptide-1 receptor agonist (GLP-1 RA) or a Sodium-Glucose Transport Protein 2 (SGLT-2) inhibitor. Incretins are GLP-1 RAs. Incretins stimulate the secretion of insulin from the pancreas and inhibit the secretion of glucagon after a meal. The amount of glucose secreted by the liver is reduced as a result. GLP-1 incretins are

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hormones that assist regulation of the secretion of insulin, while DPP-4 is an enzyme that destroys them.[5]

Third generation group of DPP-4Is such as teneligliptin is used in the management of type 2 diabetes. It is a class 3 drugs that interact with S1, S2 and S2E extensive sub-sites.[6] Teneligliptin is the most widely used gliptin in the world, offering pharmacokinetic and pharmacodynamic benefits as well as greater cost-effectiveness when compared to other gliptins.[7] When compared to other DPP-4Is, teneligliptin provides an effective second-line medication for the management of type 2 Diabetes Mellitus at a lower average price of INR 39 per day. [8] Hyperglycemia has a huge economic impact on individuals, society, the health sector, employers, as well as the nation in lost productivity; T2DM has a direct and strong financial effect on the lives of people in poor-income settings. Many studies evaluate its efficacy and safety in Indian population. But the current study includes improvement in population size for more significant result and the efficacy was assessed every two months for FPG, BSPP value and initial and end of the study with HbA_{1c} value.With this framework, the present study was designed to prospectively analyze the safety and performance of teneligliptin, a DPP-4I as supplement therapy in the management of T2DM in diabetic patients.

MATERIALS AND METHODS

A prospective observational, non-randomised research was carried out in population with T2DM, who were not restricted by triple-drug treatment viz. Metformin, Sulphonylureas, pioglitazone, or alpha-glucosidase inhibitors and further supplemented with a DPP-4I; Teneligliptin (20 mg, oral dose) as a fourth drug. The study was carried out with prior permission from the Institutional Ethics Committee (Approval ID DCC/IEC/026/2021). Before starting the study, consent was obtained from the patients. All the patients are regular visitors of diabetic study center at Erode, Tamilnadu, India. The timeline and the data collection were done from March 2021 to February 2022 on the basis of the inclusion and exclusion criterion. All population with regular follow-up records of three or more months. Patients with poor glycemic control despite of 3 Oral Antidiabetic Drugs (OADs) (metformin, sulphonylureas, pioglitazone, or alpha-glucosidase inhibitors) medication. Low glycemic control was defined as fasting blood sugar FBS ≥130 mg/dL, postprandial PPG≥ 180 mg/dL, or Glycated Hemoglobin >7.0. DPP-4 inhibitor-treat patients (Teneligliptin) were included in our study. History of pancreatitis, pregnant and lactating women is excluded from this study.

Study Procedure

This is non-randomized research; the populations were selected only based on satisfying the inclusion criteria as described above. The data were collected from the patients *viz.* general information like age, gender, body weight, duration of being diabetic and BMI and specific information like Fasting Blood Sugar (FBS), two- hour's post-prandial blood sugar (2 hr PPBS), Glycated hemoglobin, at baseline (Initial values) and two, four- and six-months post-treatment. Efficacy was achieved at 8 weeks and was examined with those at baseline levels via statistical tool (Karl Pearson coefficient method). Baseline data before initiating the teneligliptin treatment has been assessed and any changes in each study parameter after two, four and six months of teneligliptin therapy were analyzed. Data were statistically analyzed using SPSS (version 22.0). Karl Pearson coefficient method was carried out for this study.

RESULTS

A total of 302 populations were incorporated in the data investigation and an observational study was conducted to determine the effectiveness. Table 1 represents the baseline characteristics information collected from these patients, Table 2 shows the group of patients and their treatment profile followed by Table 3 showed the efficacy of the treatment regimen.

From this baseline characteristic Table 1, the males were more prevalent than female patients. Most of the populations were in the age groups of 40-69. Out of the 302 patients, 141 patients had 1-5 years of duration of diabetic history and the least number 3 patients had 26-30 duration of diabetes. In our study 128 subjects were having normal weight, 102 subjects were overweight, 53 subjects were obese and 14 subjects were underweighted. 142 co-morbidities were found among the 302 patients. Out of the 302 patients, 158 had >9% of HbA_{1c} value, 95 patients had 7.6-9% of HbA_{1c} value, 35 patients had 6.5-7.5% of HbA_{1c} value and 14 patients had <6.5 % of HbA_{1c} value. From this study, 148 patients had ≤200 of FBS value and 124 patients had ≥200 of FBS value. Out of 302 patients, 45 patients had ≤200 of PPBS value and 257 patients had ≥200 of PPBS value.

Prior to entering in the research, roughly 8.6% of patients had received DDP-4Is as monotherapy, while the remaining patients had received DPP-4Is as an add-on therapy with one or more antidiabetic drugs. The most frequently administered antidiabetic drugs along with adjuvant therapy DPP-4 inhibitor were Metformin and Glimepride (43.7%), followed, in decreasing order of use, by Metformin (11.3%), Teneligliptin+Glimepride (4%) and Teneligliptin+Glimepride+Voglibose (6.3%) and so on as listed in Table 2.

The comparison of changes in mean FBS, mean PPBS and mean HbA_{1c} between the patient groups treated with teneligliptin and other antidiabetic drugs were represented in Tables 4-6.

The Tables 4-6 depicts the efficacy of the treatment regimens (Groups I-VII) in 302 patients. Data from the mean value of the first, second and third reviews are compared with the baseline (i.e., standard value). There was a statistically significant fall in

Table 1: Demographic information on the study population.

Demographic Data	No. of patients, n (%)
Total no. of patients	302 (100)
Sex	
Male	169 (55.9)
Female	133 (44.1)
Age in years	
20-29	04(1.32)
30-39	26 (8.60)
40-49	83 (27.48)
50-59	98 (32.45)
60-69	64 (21.19)
70-79	24 (7.95)
80-89	03 (0.99)
Duration of DM in years	
1-5	141 (46.69)
6-10	94 (31.13)
11-15	28 (9.27)
16-20	24 (7.95)
21-25	04 (1.32)
26-30	03 (0.99)
Newly identified DM	08 (2.65)
Body Mass Index (BMI)	
Normal wt	128 (42.38)
Under wt	14 (4.64)
Over wt	102 (33.77)
Obese	53 (17.55)
Co-morbidities	
Hypertension	56(18.54)
Dyslipidemia	61(20.2)
CAD	16(5.3)
COPD	01(0.33)
Asthma	02(0.66)
Anaemia	03(0.99)
Hypothyroidism	02(0.66)
Stable Angina	01(0.33)
Hemoglobin A1c (HbA1c)	
<6.5%	14 (4.65)
6.5-7.5%	35 (11.59)
7.6-9%	95 (31.46)
>9%	158(52.32)
Baseline fasting blood sugar level (FBS) (mg/dL)	
≤ 200	178 (58.94)
≥ 200	124 (41.06)
Baseline post prandial blood sugar level (PPBS) (mg/dL)	
≤ 200	45 (14.90)
≥ 200	257 (85.1)

the levels of FBS, PPBS and Hb1Ac in all the groups. Moreover, it is important to note that all the groups had teneligliptin as one of the drugs. However, the correlation analysis revealed that all the treatment regimens had a positive correlation in terms of efficacy, as evidenced by the FBS analysis (Table 4).

FBS

The histogram shows that there is an apparent decrease in the Fasting Blood Sugar (Glucose) in all the treatment regimens when compared to the baseline group. Group I (Teneligliptin monotherapy) and Group II (Teneligliptin+Metformin) showed the constant maintenance of the blood glucose levels, whereas Groups III, IV and VII marginally lowered the FBS. However, Group II, V and VI caused an increase in FBS during the second review (Figure 1).

PPBS

PPBS analysis showed the teneligliptin monotherapy (Group 1), Group III and IV showed appreciably better performance than that of the remaining groups in terms of maintaining the PPBS (Figure 1).

Glycosylated Hemoglobin (HbA_{1c})

All the treatment regimens caused a reasonable decrease in Hb1Ac levels when compared to the baseline (Figure 1).

DISCUSSION

Despite a high prevalence of T2DM, diabetes management in India remains poor. Obesity, lack of lifestyle changes and the burden of treatment expenditures are undoubtedly key contributors to India's inadequate diabetes management. In the present study, males may be more affected than females due to changes in social habits and lifestyle. Most of the patients affected were in the age group 40-69. Similarly, the study conducted by Rizvi Jet.al, suggested that the majority of the diabetic patients were in the age groups of 41-60 years.[9] This was because aging disrupts the carbohydrate metabolism due to a decrease in insulin secretion in response to a glucose load, as well as increasing insulin resistance in peripheral tissues and insulin sensitivity diminishes with age and fat.[10]

A total of 302 populations were incorporated in the data examination to assess the study's efficacy. The American Association of Clinical Endocrinologists (AACEs) and the International Diabetes Federation (IDF), propose that an HbA_{1c}

Table 3: Efficacy of treatment regimen.

Parameter	Gp-I	Gp-II	Gp-III	Gp-IV	Gp-V	Gp-VI	Gp- VII
Mean FBS Value (milligram/deci litre)							
Base line	183.62	211.82	241.42	196.67	191.37	204.17	208.82
1st Review	161.19	159.71	193.83	167.98	162.95	177.4	197.22
2nd Review	159.04	177.71	176	163.42	185.79	188.5	189.73
3rd Review	155.96	152.62	169.17	152.49	176.63	174.23	179.10
Mean PPBS Value (mg/dL)							
Base line	304.12	303.79	305.79	306.92	251.79	314.07	314.55
1st Review	247	256.74	274.75	273.34	224	276.37	259.49
2nd Review	234.65	266.29	261.83	255.6	257.26	261.27	259.26
3 rd Review	238.54	277.41	231.5	257.43	233.53	279.37	273.12
Mean HbA_{1c} Value (%)							
Baseline	9.01	9.34	9.6	9.3	8.97	10.16	9.4
1st Review	7.95	8.39	7.94	7.71	8.05	8.42	7.59

Table 2: Group of patients and their treatment profile.

Groups	Treatment Profile	No. of respondents	Percentage (%)
I	Teneligliptin monotherapy	26	8.6
II	Teneliglipin+Metformin	34	11.3
III	Teneligliptin+Glimepride	12	4.0
IV	Teneligliptin+Metformin+Glimepride	132	43.7
V	Teneligliptin+Glimepride+Voglibose	19	6.3
VI	Teneligliptin+Metformin+Glimepride+Pioglitazone	30	9.9
VII	Teneligliptin+Metformi+Glimepride+Insulin	49	16.2
Total		302	

Table 4: Analysis of FBS based on period among the various groups.

Parameters	n	Mean	S.D.	Base line (FBS)		1st Review	2nd Review	3rd Review
Base line (FBS)	7	205.4129	18.70511	R	-	0.674	0.283	0.190
				Sig.	-	0.097	0.539	0.683
1st Review (FBS)	7	174.3257	15.65172	R	0.674	-	0.456	0.617
				Sig.	0.097	-	0.303	0.140
2nd Review (FBS)	7	177.1700	12.10955	R	0.283	0.456	-	0.829*
				Sig.	0.539	0.303	-	0.021
3rd Review (FBS)	7	165.7429	11.72086	R	0.190	0.617	0.829*	-
				Sig.	0.683	0.140	0.021	-

Values are presented as the mean±SD. Karl Pearson coefficient showed a *correlation is significant at the 0.05 level.

≤6.5% is the suitable target for population with T2DM and decreases the threat for micro vascular events. The AACE, NICE and ADA guidelines suggest including a DPP-4I as a supplement therapy to Metformin as a second-line treatment, in cases where there is a substantial risk of low blood sugar or if a sulfonylurea is contraindicated or poorly tolerated. Gliptin provides an antidiabetic effect along with weight neutral effect and maintains low blood sugar levels. Comparatively, gliptin is more overpriced than the other agents.[11]

The study results show that adjuvant therapy of antidiabetic drug with teneligliptin is well tolerated in diabetic patients and resulted a remarkable lowering in glycated hemoglobin volume when compared to the baseline. In the study, the guidelines for Indian Council for Medical Research were implemented by judicious use of medication as the prescribing pattern was followed. Metformin

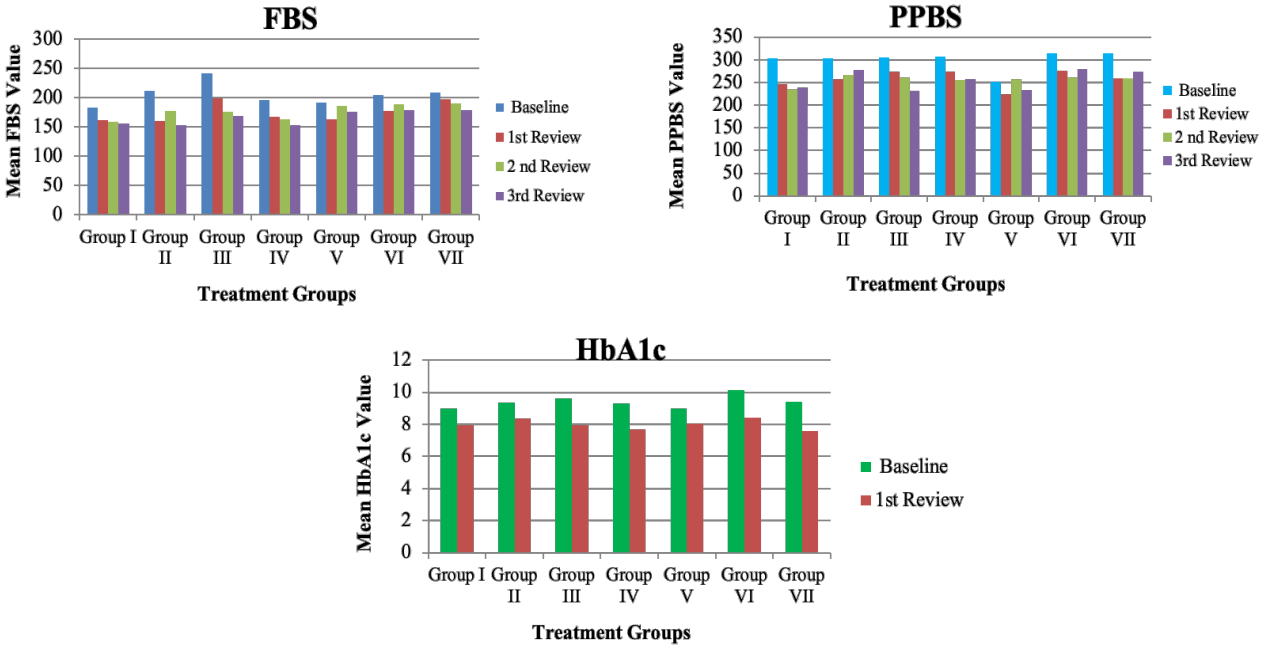

Figure 1: Efficacy of FBS, PPBS, HbA_{1c} among the diverse groups at different period.

Table 5: Analysis of PPBS based on period among the various groups.

Parameters	n	Mean	S.D.	Base line (PPBS)		1st Review	2nd Review	3rd Review
Base line (PPBS)	7	300.1471	21.78099	R	-	0.841*	0.031	0.554
				Sig.	-	0.018	0.947	0.197
1st Review (PPBS)	7	258.8129	18.83931	R	0.841*	-	0.318	0.415
				Sig.	0.018	-	0.488	0.355
2nd Review (PPBS)	7	256.5943	10.27433	R	0.031	0.318	-	0.459
				Sig.	0.947	0.488	-	0.300
3rd Review (PPBS)	7	255.8429	21.25054	R	0.554	0.415	0.459	-
				Sig.	0.197	0.355	0.300	-

Values are presented as the mean±SD. Karl Pearson coefficient showed a *correlation is significant at the 0.05 level.

Table 6: Analysis of HbA_{1c} based on period among the various groups.

Parameters	n	Mean	S.D.		Baseline (HbA_{1c})	1st Review (HbA_{1c})
Baseline (HbA_{1c})	7	9.3971	0.40169	R	-	0.412
				Sig.	-	0.359
1st Review (HbA_{1c})	7	8.0071	0.31330	R	0.412	-
				Sig.	0.359	-

has been the most preferred antidiabetic medicine in all diabetes categories. As a second-line medication after metformin, DPP-4inhibitor seems to rapidly catch up with sulfonylurea. Glimepiride was the most frequently prescribed medication in sulfonylureas along with teneligliptin. Most patients demand insulin therapy for their glycemic control which in turn increases the duration of diabetes. Glimepiride with metformin was a wildly used combination of medication.[12] Teneligliptin achieves good glycemic control as add on therapy of metformin and sulfonylurea and also teneligliptin has a desirable safety profile that can be used in geriatric patients and sick people with the mild renal disease without dose adjustment; they have such a weight- neutral effect and therefore do not cause hypoglycaemia on their own.

Insulin resistance accelerates insulin secretion in the etiology of T2DM, resulting in β-cell functionality degradation. DPP-4 inhibitors were shown to exhibit great glycemic endurance, allowing them to minimize beta-cell death while keeping the beta-cell number and activity stable.[13] DPP-4 inhibitors have different structural heterogeneity and pharmacokinetic outline. The existing evidence suggests that DPP-4Is have similar glucose-lowering effectiveness in conjunction with other antidiabetic medications, similar weight-neutral effects and comparable safety and tolerability profiles. The recent study findings, depending on a prospective analysis, display that teneligliptin was efficient in a significant decline of glycemic parameter (such as FBS, PPBS and HbA_{1c}) as an adjuvant therapy for poorly controlled T2DM patients who were already on a diet and exercise regimen. The DPP-4Is have been used as a 4th drug in patients who had failed triple therapy, providing effective glucose control Vijay panikar *et al.*, concluded that a study on DPP-4Is, as a fourth drug, was found to be effective in obtaining good blood sugar control in T2DM patients within 8 weeks of initiation.[3] Saboo *et al.*, conducted a retrospective study on Type II DM patients treated with teneligliptin 20 or 40 mg once daily, as a single therapy or as a supplement treatment showing an appreciable glycemic control with no QTc prolongation, which is evident from their ECG report.[14]

Mohan *et al.*, teneligliptin provided a similar glycemic control as compared to sitagliptin and reduced the HbA_{1c}, FBG and PPBG values significantly within 12 weeks of treatment.[15] In Indian individuals with T2DM, both gliptins were shown to be safe and well-tolerated. According to Syngle *et al.*, teneligliptin improves not only glycemic control but also pseudomotor function, peripheral and autonomic neuropathy and vascular inflammation in type 2 diabetes.[16-19]

Panikar *et al.* concluded that the DPP-4Is is effective in achieving desired glycemic goals even when used as a fourth drug in patients.[3] Saboo *et al.*, in 2022, reported the addition of teneligliptin to the DM patients, whose blood glucose level is uncontrolled by Metformin monotherapy.[20-23] Their study report revealed there is a significant reduction in the glycemic variability and showed significant glycemic improvement.

CONCLUSION

This research demonstrated the effectiveness and safety of teneligliptin in individuals with poorly controlled T2DM. For six months, a substantial glucose-lowering impact was detected and sustained by the adjuvant therapy with DPP-4 inhibitors. As a fourth medicine, DPP-4Is were found to be effective in establishing glycemic control in type 2 diabetes patients within 8 weeks of starting. The large majority of diabetic treatment guidelines emphasize the fact that when three oral drugs fail to properly control blood glucose, gliptins should be started. In the current study, the adjuvant therapy of teneligliptin with other OADs was used to control the glucose levels from baseline to two- and six-month's duration. The study results showed there is no hypoglycemic episodes were found during this time period. Hence, teneligliptin achieved good glycemic control and is well tolerated.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

AUTHORS' CONTRIBUTIONS

MK framed the concept and collected the data of our research, PT drafted the manuscript, SP supervised, corrected the overall proof and verified.

ABBREVIATIONS

DM: Diabetes Mellitus; **TYPE2 DM:** Type 2 Diabetes Mellitus; **FBG:** Fasting Blood Glucose; **BSPP:** Blood Sugar Post Prandial; **HbA_{1c}:** Glycosylated Hemoglobin; **WHO:** World Health Organization; **OAD:** Oral Antidiabetic Drug; **DPP-4Is:** Dipeptidyl Peptidase-4 Inhibitors; **SGLT-2:** Sodium-Glucose Transport protein 2 inhibitor; **PPBS:** Post Prandial blood Sugar; **SPSS:** Statistical Package for the social sciences; **AACEs:** American Association of Clinical Endocrinologists; **IDF:** International Diabetes Federation; **NICe:** National Institute for Health and Care Excellence.

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