

ORIGINAL ARTICLE

*Comparative Study for Evaluation of Efficacy, Safety and Tolerability with add on Therapy of Tenueligliptin Versus other DPP4 Inhibitors in Type II Diabetes Mellitus*Pravin Sheshrao Sarkate¹, Kashmiri Lal¹ and Rakesh Kumar²¹Department of General Medicine, ²Department of Pharmacology¹SBS Civil Hospital, Jalandhar. ²Punjab Institute of Medical Sciences, Jalandhar, Punjab-144006, India.**Abstract:**

Background: Medical care of diabetes involves oral hypoglycemic medications and/or insulin and DPP4 inhibitors. However, the clinical data regarding the safety and effectiveness of DPP4 among Type II DM patients are still lacking. **Objectives:** To compare efficacy, safety and tolerability with add-on therapy of Tenueligliptin versus other DPP4 inhibitors in Type II diabetes mellitus patients. **Material and Methods:** A single-centre, cross-sectional analytical comparative observational study was conducted in a tertiary care hospital. Total 140 individuals were selected with the purposive sampling technique and were split into two groups. Group-1 included patients with T2DM who were using Metformin-Glimepiride-Tenueligliptin combination, while group-2 consisted of T2DM patients who were using Metformin-Glimepiride-Sitagliptin/Vildagliptin combination. HbA1c measurement, FBS and adverse drug reactions were compared in both the groups. Data were represented as "frequency, percentage distribution, mean \pm standard deviation, and median (range)" where appropriate when describing variables. **Results:** Level of HbA1c had improved among 62(88.6%) patients taking tenueligliptin as an add-on therapy which was significantly higher than the patients taking others DPP4 inhibitors 49(70%). A total of 68(97.1%) patients in group-1 while 58(82.9%) in group-2 had a level of FBS <126mg/dl. Patients using tenueligliptin as an add-on therapy reported fewer adverse reactions 58(82.9%), which was less than those patients who were using other DPP4 inhibitors 63(90%). **Conclusion:** Tenueligliptin when combined with metformin and glimepiride reduces HbA1c and FBS level more efficiently with minor side effects as compared to other DPP4 inhibitors thus improving the glycemic indices in T2DM patients.

Keywords: Tenueligliptin, Vildagliptin, Sitagliptin, Type II Diabetes Mellitus, Oral hypoglycemic, DPP4

Inhibitors.

Introduction:

Diabetes mellitus (DM) is a metabolic disorder, due to insulin insufficiency, insulin incompetence, or both. Diabetes mellitus is multifactorial in origin; non-modifiable risk factors include age, family history, sex, and ethnicity, whereas, improvement can be achieved with modifiable risk factors like physical activity, obesity, sedentary lifestyle.^[1] Type II diabetes is a chronic disease that affects the beta cells of the pancreas, resulting in diminished cell activity, leading to increased blood glucose levels. It is often accompanied by peripheral tissues having an increased sensitivity to insulin, such as the liver and muscles. As the World Health Organization projects, the global population continues to grow, the diabetes prevalence is expected to exceed 425 million by 2025; of these, 90% are believed to have Type II diabetes mellitus (T2DM). T2DM is becoming prevalent around the globe, with South Asia being one of the most affected regions.^[2] Diagnostic criteria for DM include the presence of classical symptoms (kidney disorder, extreme thirst and unexplained weight reduction) as well as a fasting blood glucose concentration that is more than 126mg/dl, or a 2-hour postprandial glucose level that is more than 200mg/dl. HbA1c targets levels <7% define good control of DM.^[3] Treatment of DM involves diet and physical activity along with blood glucose-lowering drugs and modification/management of the known risk factors. Glycated hemoglobin (HbA1c) level less than 7% is not sufficient for judging the effect of DM treatments. Factors, which are called patient-reported outcomes, are just as important (PROs).^[4] Other than insulin supplementation, current therapies are often insufficient to accomplish glycemic control and may result in undesired side effects such as obesity and hypoglycemia. Most guidelines recommended Metformin as first-line therapy for T2DM. Insulin resistance and pancreatic β -cell dysfunction are the main pathophysiological features

of T2DM. Combination therapies are often required to target both these defects.^[5] In the last few years, a class of drugs called Dipeptide Peptidase 4 inhibitor (DPP4 inhibitors), which is a relatively new treatment option for diabetes, is currently recommended as monotherapy or second-line therapy by numerous diabetes and endocrine-organization guidelines, including the American Diabetes Association (ADA) and American Association of Clinical Endocrinology (AACE) 2016. DPP4 inhibitors slow down the release of glucagon-like peptide-1 (GLP-1) from the intestine; as a result, there is an increase in the amount of circulating GLP-1 in the bloodstream. DPP4 inhibitors, which are different from sulfonylureas, and insulin, are non-uniformly distributed throughout the body and hence not influenced by body weight. These DPP4 inhibitors particularly inhibit the DPP4 enzyme, which breaks down two key incretin hormones: gastric inhibitory polypeptide and GLP-1.^[6] DPP4 inhibitors are a rapidly expanding group of hypoglycemic drugs and include sitagliptin, vildagliptin, saxagliptin, and teneligliptin.^[7] It is interesting to note that though there are many DPP4 inhibitors with differing mechanisms of action and pharmacokinetics, they are very comparable with regards to their ant hyperglycemic activities and little likelihood of any unwanted side effects (weight neutral and free of the hypoglycemic side effects). They have low risk of gastrointestinal (GI) side effects, few drug interactions, fewer adverse events (AEs) and considered cardiosafe compared to metformin and sulfonylureas (SUs) in geriatric patients.^[8] However, the clinical data regarding the safety and effectiveness of DPP4 (especially teneligliptin) among Type II DM patients are still lacking. Given the potential of the teneligliptin in the logical management of DM and the lack of enough literature on this subject, it is very important to study its safety and efficacy in comparison to the existing add-on therapy regimes with the DPP4 inhibitors. This study aims to compare the efficacy, safety and tolerability with add-on therapy of Teneligliptin versus other DPP4 inhibitors in Type II diabetes mellitus patients.

Material and Methods:

This single-center, cross-sectional, analytical comparative observational study was undertaken from January 2020 to January 2021, at the Outpatient Department of General Medicine, SBLS Civil Hospital, Jalandhar to evaluate the efficacy, safety and tolerability of add-on therapy of Teneligliptin versus other DPP4 inhibitors in Type II diabetes mellitus patients. Only those patients were selected who were having a combination of two ant diabetic medications

(Metformin 1000mg/day and Glimepiride 2mg/day with add-on Teneligliptin or other DPP4 inhibitors (sitagliptin/vildagliptin) for at least for 03 months' duration. To use a purposive sampling strategy, a non-probability sampling approach was used. Patients with T2DM were screened, and those who satisfied the selection criteria were recruited in the research. Patients with Type I diabetes were excluded. The study was approved by the Ethics Committee of PIMS Hospital, Jalandhar by vide no: PIMS/IEC/19/31. To detect a difference of 0.5 standard deviations between the means of the HbA1c% of the study groups (Teneligliptin vs others), it was calculated that a total of 140 patients in the research were necessary to have a power of 80 percent and type-I error of 5%. In all, 140 patients were divided into two groups of 70 each. Group-1 entails patients with T2DM who were using Metformin-Glimepiride-Teneligliptin combination, while group-2 consisted of T2DM patients who were using Metformin-Glimepiride-Sitagliptin/Vildagliptin combination. To examine the effectiveness, HbA1c measurement was evaluated in all patients. FBS was assessed for the threshold limit of 126mg/dl. The HbA1c proportion of patients who will be below 7% is a good metric for the quality of management of the glycemic state. To examine tolerability and safety, the researchers looked at the number of ADRs that each group of participants experienced and compared the numbers. Data were represented as "frequency, percentage distribution, mean \pm standard deviation, and median (range)" where appropriate when describing variables. Using the SPSS statistical program version 21, the information was examined. The use of the Chi-square test was appropriate to ascertain if categorical data could be processed. Parametric data was examined using a t-test employing continuous variables.

Results:

Demographic information of the subjects is presented in Table 1 and socio demographic variable are comparable in both the groups. The mean age of 140 patients was 51.57 ± 10.46 . 37(26.4%) have past history out of which 1(0.7%) had Coronary artery disease, 31(22.1%) had hypertension and 5(3.6%) had both. 05(3.6%) were smokers, out of which 04 smoke 10 cigarettes per day and 01 smoked 06 cigarettes per day. 43(30.7%) were alcoholic, out of which 36(83.72%) consume 60ml per day and 07(16.28%) consume 90ml per day. 27(19.3%) had a family history of diabetes in both parents. 42(30%) had no brothers and 26(18.6%) have no sisters while 98(70%) have brothers and 114(81.4%) have sisters. These 98 patients having a total of 138 brothers and out of which 110 (79.71%) were non-diabetics and 28

(20.29%) were having Type II Diabetic Mellitus. These 114 patients having a total of 232 sisters and out of which 186 (80.17%) were non-diabetics sisters and 46(19.83%) were Type II Diabetic Mellitus. The level of HbA1c had improved among 62(88.6%) patients taking teneligliptin as an add-on therapy (group-1) which was significantly higher than the patients taking other DPP4 inhibitors.

Table 1: Comparison of sociodemographic variables among type II diabetes mellitus patients in both groups

Socio-demographic Variables	N=140	Group-1 (n=70)	Group-2 (n=70)	P value
Age Mean±SD)	51.57±1.046 Min. 30; Max. 80	52.63±1.138	50.51±9.41	t=1.197, df=138 P=0.233
SexN(%)	Male: 78(55.7%) Female: 62 (44.3%)	Male: 41(58.6%) Female: 29 (41.4%)	Male: 37(52.9%) Female: 33 (47.1%)	$X^2=0.463$, df=1 P=0.496
Rural/Urban N(%)	Rural: 39 (27.9%) Urban: 101 (72.1%)	Rural: 28 (40%) Urban: 42(60%)	Rural: 11(15.7%) Urban: 59 (84.3%)	$X^2=10.272$, df=1 P=0.001
Past History N(%)	Yes: 37 (26.4%) No: 103 (73.6%)	Yes: 25 (35.7%) No: 45 (64.3%)	Yes: 12 (17.1%) No: 58 (82.9%)	$X^2=6.208$, df=1 P=0.013
Family history N(%)	Yes: 27 (19.3%) No: 113 (80.7%)	Yes: 18 (25.7%) No: 52 (74.3%)	Yes: 9 (12.9%) No: 61 (87.1%)	$X^2=3.71$, df=1 P=0.054
Smokers N(%)	Yes: 5(3.6%) No: 135 (96.4%)	Yes: 3(4.3%) No: 67 (95.7%)	Yes: 2 (2.9%) No: 68 (97.1%)	$X^2=0.207$, df=1 P=0.649
Alcoholic N(%)	Yes: 43 (30.7%) No: 97 (69.3%)	Yes: 23 (32.9%) No: 47 (67.1%)	Yes: 20 (28.6%) No: 50 (71.4%)	$X^2=0.302$, df=1 P=0.583

Only 49(70%) patients had shown improved HbA1c levels in group-2. (Table 2)A total of 68(97.1%) patients in group-1 had a level of FBS<126mg/dl while in group-2 patients 58(82.9%) had a level of FBS<126mg/dl. (Table 3)

Table 2: Comparison of the level of HbA1c in selected groups

Groups		HbA1c		Total
		Improved (6-7%)	Moderate (7-8%)	
Group 1	Count	62	8	70
	% within Group	88.6%	11.4%	100.0%
	% within HbA1c	55.9%	27.6%	50.0%
Group 2	Count	49	21	70
	% within Group	70.0%	30.0%	100.0%
	% within HbA1c	44.1%	72.4%	50.0%
Total	Count	111	29	140
	% within Group	79.3%	20.7%	100.0%
	% within HbA1c	100.0%	100.0%	100.0%

($X^2=7.35^*$, df=1) *significant at p<0.05

Table 3: Comparison of the level of FBS in selected groups

Groups		FBS level		Total
		FBS<126 mg/dl	FBS >126 mg/dl	
Group 1	Count	68	2	70
	% within Group	97.1%	2.9%	100.0%
	% within HbA1c	54.0%	14.3%	50.0%
Group 2	Count	58	12	70
	% within Group	82.9%	17.1%	100.0%
	% within HbA1c	46.0%	85.7%	50.0%
Total	Count	126	14	140
	% within Group	90.0%	10.0%	100.0%
	% within HbA1c	100.0%	100.0%	100.0%

$X^2=7.94^*$, df=1) *significant at p<0.05

Patients using teneligliptin as an add-on therapy reported fewer adverse reactions 58(82.9%), which was less than those patients who were using other DPP4 inhibitors 63(90%). Twelve participants in group-1 and seven participants in group-2 did not record any instances of ADR.

Discussion:

This research aims to examine the efficacy, safety and tolerability for adding Teneligliptin as an add-on medication for type II diabetes mellitus patients to another DPP4 inhibitor. Sitagliptin and Vildagliptin were considered as others DPP4 inhibitors due to their same efficacy and numerically similar reported ADR. Mono or add-on treatment with gliptins is substantially superior to the other oral antidiabetic medications.^[9,10] The study conducted by Harris et al,^[11] shows that males were more likely to have type II diabetes than women is in line with the current study where the results show a higher predominance of T2DM in males patients. One of the key findings of the current research is that the highest proportion of the study population was those who were between the ages of 51 and 60. The study population had an average age of 51.4 years. Kishimoto's^[12] research demonstrates that type II diabetes is most prevalent in middle-aged persons, particularly after the age of 50. A previous study conducted by Singh H^[13] shows that the mean weight among type II DM patients was 70.4 ± 6.24 kg. In our study mean weight of all the selected patients was 73.56 ± 11.62 kg and the mean BMI score was 27.3. Hence, it can be said that overweight patients have more chances of developing type II DM. In our study patients taking Teneligliptin had a significant fall in HbA1c level than the patients taking other DPP4 inhibitors. This was similar to the previous studies^[7,14] which shows that when teneligliptin is administered along with metformin and glimepiride, its combination is more effective in terms of mean reduction of HbA1c than sitagliptin/vildagliptin add-on therapy, the structure of teneligliptin merely provides benefits, making it useful for diabetes treatments. Our findings suggest group-1 patients had a greater reduction in the level of FBS than group-2 patients. Similar results were reported by, Singh AK, Geng J, Dange SV.^[11,15,16] These reports concluded that patients using teneligliptin 20mg along with metformin 1gm have a significantly lower level of mean FBS than patients using other DPP4 inhibitors as add-on regimen. These findings show that when used in combination with metformin and glimepiride, teneligliptin is effective in managing glycemic control in people with T2DM. In contrast, Sharma SK and Agrawal P^[17,18] in their study concluded that teneligliptin was equally potent to any other available DPP4 inhibitor in terms of efficacy in maintaining HbA1c. In searching for further evidence, Dange SV^[16] reported that teneligliptin and sitagliptin do not exhibit any significant differences in glycemic indices when used as an add-on to metformin. However,

they concluded that the difference may be of limited clinical significance. When DPP4 inhibitors are used, there is no evidence of an increase in the occurrence of adverse effects,^[19] and the capability of minimizing the danger of medical complications might be advantageous.^[20] In this current study, patients using teneligliptin as an add-on therapy reported fewer adverse reactions than patients who were using other DPP4 inhibitors. This difference in the frequencies was statistically non-significant. Most of the studies^[10,21] have found that all DPP4 inhibitors did not differ significantly in terms of numerically reported ADRs. In both groups, patients reported no ADRs like diarrhoea, raised LFT, raised RFT, allergic reactions, and pallor. Mild ADRs were reported in group-1 patients like nasopharyngitis, abdominal pain, constipation, anorexia, headache, dyspepsia, and hypoglycemia. Maladkar M^[22] in his study observed that amongst people with T2DM who took part in clinical studies, teneligliptin (alone or in combination with other medicines) was usually well tolerated. However, Kadowaki T^[23] reported adverse events like hypoglycemia, GI irritation, headache, and nasopharyngitis in combination therapy of teneligliptin with metformin and glimepiride. Frequent ADRs reported in this group of patients were nausea 27(38.6%) and hypoglycemia 23(32.9%). Another research, done by Tang YZ,^[24] demonstrated that the vildagliptin drug's side effects include hypoglycemia and GI discomfort. In contrast, Hayati F^[25] concluded in their study that Sitagliptin is safe and well-tolerated with minimal reported ADRs. As with the research done by Mera J,^[26] we noticed a similar pattern with Vildagliptin and have discovered that it is a viable therapeutic and safe choice for people with T2DM. According to the research findings, it can be concluded that all ADRs recorded throughout the trial were quite mild. No instances of renal or hepatic toxicity were found. This research is a faithful replication of the one before it (Maladkar M, Langley AK, Ceriello A)^[22,27,28] shows no harmful effect of teneligliptin add-on therapy with metformin and glimepiride on renal or hepatic function. Hence, it can be said that teneligliptin and other DPP4 inhibitors were well-tolerated and safe for use. Many studies state that Teneligliptin,^[14,17,27] Sitagliptin,^[29] Vildagliptin^[26] and other DPP4 inhibitors^[30,31] appears to be well-tolerated when administered with metformin and glimepiride. Teneligliptin as a treatment regimen together with metformin and glimepiride had significantly more efficiency in improving glycemic control than other DPP4 inhibitors.

Conclusion:

Teneligliptin when combined with metformin and

glimepiride reduces HbA1c and FBS level more efficiently with minor side effects as compared to other DPP4 inhibitors thus improving the glycemic

indices in T2DM patients.

Sources of supports: Nil

Conflicts of Interest: Nil

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