



Research article

Teneligliptin versus vildagliptin in Indian patients with type 2 diabetes inadequately controlled with metformin

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India is heading towards being the diabetes capital of the world indicating that every fifth diabetic in the world is an Indian. The aim to prevent and control diabetic complications can be achieved with a target of glycated haemoglobin (HbA1c) less than 7.0%. There is an urgent need for a cost-effective and safer therapeutic approach for the management of type 2 diabetes. The primary objective was to compare the reduction in fasting plasma glucose (FPG), 2-hour postprandial plasma glucose (2-h PPG), and HbA1c, in Group-1 and Group-2 at 6, 12, 18 and, 24 weeks with baseline values of two groups. This was a 24-week, randomized, open-label study. Patients with type 2 diabetes who were inadequately controlled on Metformin (850mg, twice a day) were randomized into two groups, Group-1 (Metformin 850mg, twice daily added with Vildagliptin 50mg, twice daily) and Group 2 (Metformin 850mg, twice daily added with Teneligliptin 20mg, once a day). Reductions in fasting plasma glucose, 2 hours postprandial plasma and HbA1c in the vildagliptin group (Group1) were comparable with the teneligliptin group (Group2). Patients in both groups showed similar tolerability with lesser episodes of hypoglycaemia and, are weight neutral. Teneligliptin is non inferior to vildagliptin in controlling glycaemic parameters and shows similar tolerability.

Keywords: Metformin, Teneligliptin, Vildagliptin, Diabetes mellitus type 2, HbA1c, DPP-4 inhibitors.

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INTRODUCTION

Diabetes is a complex, chronic illness requiring continuous medical care with multifactorial risk-reduction strategies beyond glycaemic control [1]. Type 2 diabetes mellitus (T2DM) mostly results from the interaction among genetic, environmental and, other risk factors but certain drugs (e.g., glucocorticoids, β -adrenergic agonist, thiazides and, statins, etc.) may also precipitate diabetes. [2,3] The factors contributing to hyperglycaemia comprise reduced insulin secretion, decreased glucose utilization, and increased glucose production [4].

In 2017, it was estimated that 451 million adults worldwide had diabetes, equivalent to around 1 adult in 11 living with the condition [5], and approximately 90% of these patients have type 2 diabetes [6]. India is marching towards being the capital for diabetes in the world indicating that every fifth person with diabetes in the world is an Indian. The contribution of India towards the global burden can be estimated with the recent data which states that approximately 73 million people were diagnosed with type 2 diabetes in the year 2017 [7].

Management of diabetes aims to improve quality of life and reduce diabetes-related symptoms and complications. The treatment goal is usually individualized based on patient preferences and disease factors [8]. The aim to prevent and control diabetic complications can be achieved with a target of glycated haemoglobin (HbA1c) less than 7.0% [9]. There is an urgent need for a cost-effective and safer therapeutic approach for the management of type 2 diabetes [10].

The major classes of oral antidiabetic medications include biguanides, sulfonylureas, meglitinide, thiazolidinediones, dipeptidyl peptidase4 (DPP-4) inhibitors, sodium-glucose cotransporter inhibitors, and α -glucosidase inhibitors [1].

Metformin is the first-line anti-hyperglycaemic for the management of Type 2 diabetes in the absence of contraindications [11]. The combination of metformin with an agent from another class with a different mechanism of action may help to preserve β -cell function and maintain a long-term glycaemic efficacy [12]. Sulfonylureas, the next therapeutic approach is associated with weight gain, hypoglycaemia and may also lose efficacy as a result of

beta-cell failure [13]. Thiazolidinedione, which can be added to the therapy, may lead to edema and an increase in body weight [14]. Insulin therapy is not only costly but is not preferred due to poor patient compliance [15].

Gliptins or dipeptidyl peptidase-4 (DPP-4) inhibitors are a relatively new class of orally administered glucose-lowering agents for Type 2 diabetes. Gliptins inhibit the degradation of glucagon-like peptide-1, promote insulin secretion and, suppress glucagon secretion [16]. Compared to the other oral hypoglycaemic agents, gliptins possess several clinical advantages like a negligible risk of hypoglycaemia and weight neutrality [17].

Vildagliptin has been an effective and well-tolerated DPP-4 inhibitor that improves glycaemic control [18,19]. Clinical studies found that vildagliptin in combination with metformin resulted in better glycaemic control than high-dose metformin alone [20].

Teneligliptin is a DPP-4 inhibitor approved for the management of type 2 diabetes in some countries, namely, Japan (2012), South Korea (2014), and India (2015) [21,22,23]. Teneligliptin, 20mg/day as monotherapy and combination therapy in type 2 diabetes was shown to be effective in reducing HbA1c and fasting plasma glucose levels without any significant adverse events [24,25]. Teneligliptin has a longer half-life and is administered once daily as compared to vildagliptin, which is administered twice daily [25].

Teneligliptin is currently marketed in India with limited available clinical studies and data comparing the efficacy and safety of the different DPP-4 inhibitors. Therefore, the present study was designed to assess the efficacy and safety of vildagliptin and teneligliptin as an add-on therapy to patients inadequately controlled on metformin alone.

METHOD

The present study was conducted in the Department of Pharmacology and Rajiv Gandhi Centre for Diabetes and Endocrinology, J.N. Medical College and Hospital, AMU Aligarh on the patients of Type 2 diabetes attending the Out Patient Department (OPD) from March 2016 to September 2017. This was a randomized, prospective, open-labelled and, parallel-group study. Eligible patients were randomized into two groups (Group-1 and Group 2) according to the table generated by random allocation software. The randomization was generated having 20 patients in each block.

Ethical clearance for the study protocol was obtained from the Institutional Ethics Committee (IEC) of J.N. Medical College and Hospital, AMU, Aligarh on 02.02.2016(D. No: 2249/FM). The study was also registered with the clinical trial registry of India (Ref No. ctri/2017/02/007766).

Type 2 diabetes patients with inadequate glycaemic control on Metformin (850mg twice daily) were added with Vildagliptin or Teneligliptin by treating physician selected for the study. Patients on

other oral anti-diabetic agents and significant systemic illness were excluded from the study.

Informed and written consent was obtained from all patients before enrolling them in the study.

Diagnosis of diabetes was made according to criteria for the diagnosis of diabetes mellitus of the American Diabetes Association (2017).

The patients were divided into two groups, Group-1 (Vildagliptin Group) and Group-2 (Teneligliptin Group).

Group-1

Vildagliptin (50mg, twice a day) was administered as add-on therapy to all the patients of who were already receiving Metformin 850mg twice a day.

Group-2

Teneligliptin (20mg, once a day) was administered as add-on therapy to all the patients of who were already receiving Metformin 850mg twice a day.

The patients of all groups were followed up at 6,12,18 and 24 weeks. They were also advised to consult the endocrinologist/treating physician/investigator for any queries or adverse events if occurring during the treatment period. All the patients were recommended to take a diabetic diet as advised by the registered dietician of the hospital.

FPG, 2 Hours PPG and HbA1c, Complete blood count, Renal Function Test (Blood urea, Serum creatinine), Urine - Routine/Microscopic, Liver Function Test, Lipid Profile, and, other investigations (If and when indicated) were done by the treating physician.

The efficacy of vildagliptin and teneligliptin was compared by measuring the FPG, 2 Hours PPG and HbA1c at 0 (baseline values), 6,12, 18 and, 24 weeks.

Safety assessment was done using Naranjo's Adverse Drug Reaction Probability Scale [26]. The severity of the reaction was assessed using Adverse Drug Reaction Severity Assessment Scale, Modified Hartwig and Siegel [27].

Statistical analysis

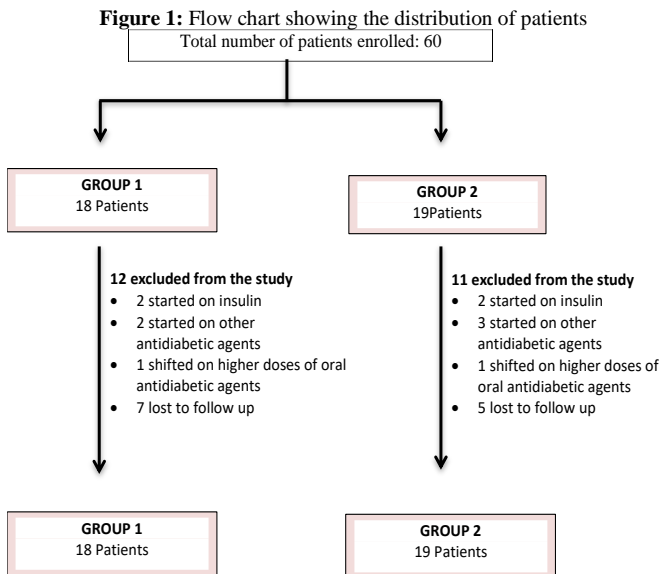
For descriptive statistics; frequency, percentage, mean \pm standard deviation, graphs, and pie charts were used to present the study results. Intra and inter-group analysis of the two groups was done using repeated measure ANOVA (RM-ANOVA). $P < 0.05$ was considered to be statistically significant. Statistical analysis was done using Statistical Package for Social Sciences (SPSS-23) software and charts were prepared using Microsoft Excel 2013.

RESULT AND DISCUSSION

A total of 60 patients were enrolled, 30 patients in each (Group-1and Group-2) and finally 18 patients of Group-1and 19 patients of Group-2 were analysed.

The age of patients varies from 25 years to 75 years. The

mean BMI of patients in Group-1 and Group-2 was 27.87 ± 3.07 and 27.75 ± 3.75 kg/m² respectively.



EFFICACY OUTCOMES

Fasting plasma glucose (FPG)

The values at 0 weeks (baseline values) of FPG in Group-1

and Group-2 were comparable ($p > 0.05$). The reduction in mean values of FPG, when compared to baseline, was significant, at all the time points (at 6, 12, 18 and, 24 weeks) within the groups ($p < 0.001$). However, the values of FPG in Group-1 and Group-2 when compared at 0, 6, 12, 18 and, 24 weeks were found to be statistically insignificant ($p > 0.05$) [Table 1].

Values are expressed as Mean \pm SD; Intra-group comparison shows highly significant values ($p < 0.001$) at all-time points when compared to baseline value of respective group. Values were non-significant with $p > 0.05$ when inter-group comparison was made.

2 hours postprandial plasma glucose (2h ppg)

The values at 0 weeks (baseline) of 2-hour PPG in Group-1 and Group-2 were comparable ($p > 0.05$). The reduction in mean values of 2 hours PPG, when compared to baseline, was significant, at all time points (at 6, 12, 18 and, 24 weeks) within the groups ($p < 0.001$). However, the values of 2 hours PPG in Group-1 and Group-2 when compared at 0, 6, 12, 18 and, 24 weeks were found to be statistically insignificant ($p > 0.05$) [Table 2].

Table 1: Mean Fasting Plasma Glucose (FBG) Levels

Groups (n=37)	Baseline (mg/dL) Mean \pm SD	6 weeks (mg/dL) Mean \pm SD	12 weeks (mg/dL) Mean \pm SD	18 weeks (mg/dL) Mean \pm SD	24 weeks (mg/dL) Mean \pm SD	% Reduction	Intragroup comparison	Intergroup comparison
Group-1 (n=18)	141.16 \pm 29.01	130.38 \pm 19.92	113.33 \pm 25.61	113.61 \pm 19.00	97.50 \pm 23.18	30.97	$p < 0.001$	$p > 0.05$
Group-2 (n=19)	147.36 \pm 34.73	136.94 \pm 17.96	119.73 \pm 32.80	120.31 \pm 26.49	114.26 \pm 30.81	22.46	$p < 0.001$	$p > 0.05$

Table 2: Mean 2 hours Postprandial Plasma Glucose (2h PPG) Levels

Groups (n=37)	Baseline (mg/dL) Mean \pm SD	6 weeks (mg/dL) Mean \pm SD	12 weeks (mg/dL) Mean \pm SD	18 weeks (mg/dL) Mean \pm SD	24 weeks (mg/dL) Mean \pm SD	% Reduction	Intragroup comparison	Intergroup comparison
Group 1 (n=18)	228.16 \pm 59.15	205.16 \pm 39.59	184.94 \pm 53.36	185.94 \pm 32.95	171.16 \pm 24.81	24.98	$p < 0.001$	$p > 0.05$
Group-2 (n=19)	210.84 \pm 47.68	204.68 \pm 36.17	185.10 \pm 44.69	186.05 \pm 40.21	176.94 \pm 55.98	16.07	$p < 0.001$	$p > 0.05$

Values are expressed as Mean \pm SD; Intra-group comparison shows highly significant values ($p < 0.001$) at all-time points when compared to baseline value of respective group. Values were non-significant with $p > 0.05$ when inter-group comparison was made.

Glycosylated haemoglobin (HbA1c)

The values at 0 week (baseline) of HbA1c in Group-1 and Group-2 were statistically insignificant ($p > 0.05$). The reduction in mean values of glycosylated haemoglobin, when compared to baseline, was statistically significant, at both time points (12 and 24 weeks) within the groups ($p < 0.001$). However, the reduction in HbA1c in Group-1 and Group-2 at 12 and 24 weeks when compared with baseline values of two groups (Group-1 and Group 2) was found to be statistically insignificant ($p > 0.05$) [Table 3].

Table 3: Mean Glycosylated Haemoglobin (HbA1c)

Groups (n=37)	Baseline (%) Mean \pm SD	12 weeks (%) Mean \pm SD	24 weeks (%) Mean \pm SD	Percentage reduction at 24 weeks	Intragroup comparison	Intergroup comparison
Group 1 (n=18)	7.96 \pm 0.55	7.26 \pm 0.66	7.04 \pm 0.99	11.55	$p < 0.001$	$p > 0.05$
Group 2 (n=19)	8.29 \pm 0.92	7.65 \pm 0.91	6.87 \pm 0.95	17.12	$p < 0.001$	$p > 0.05$

Values are expressed as Mean \pm SD; Intra-group comparison shows highly significant values ($p < 0.001$) at all-time points when compared to baseline value of respective group. Values were non-significant with $p > 0.05$ when inter-group comparison was made.

Safety assessment

In Group-1 (Vildagliptin), four patients experienced adverse events and in Group-2 (Teneligliptin), five patients experienced adverse events. The most commonly observed adverse events were nausea and headache. Other adverse events observed were vomiting and change in bowel habits. No adverse events in patients of any group who have completed the study required discontinuation of therapy.

The adverse events were mild to moderate in severity in all of the cases. On Naranjo's ADR Probability Scale, the events were possible in 2 cases and probable in 2 cases in Group-1, while possible in 3 cases and probable in 2 cases in Group-2.

The guidelines for the treatment of type 2 diabetes mellitus, consensus statements established by the American Diabetes

Association and European Association of the Study of Diabetes, recommend the use of metformin as an initial treatment [8]. However, many patients cannot tolerate metformin in adequate amounts due to its gastrointestinal (GI) side effects such as nausea, vomiting, headache, diarrhoea, abdominal discomfort, loss of appetite, and metallic taste etc [28].

Gliptins, when administered to patients inadequately controlled with metformin cause a considerable improvement in HbA1c (0.50–0.75%) with twice the number of patients achieving an HbA1c of <7% compared to metformin alone [29]. The patients with HbA1c between 7–8% while on metformin therapy if added with gliptin to the already existing dose of metformin rather than increasing the dose of metformin, the HbA1c reduction is greater than up-titrating the dose of metformin [30].

Vildagliptin when added to metformin in patients with type 2 diabetes, the improvement in beta-cell function, post-meal insulin sensitivity with lowering the levels of HbA1c and fasting plasma glucose significantly has been seen [31].

In our study, vildagliptin (50mg, twice a day) and teneligliptin (20mg, once a day) were added in patients with type 2 diabetes inadequately controlled on stable doses of metformin (850 mg twice a day). We observed a change in mean HbA1c -0.92 % from the baseline in the vildagliptin group and -1.42% in the teneligliptin group (Table 3) at 24 weeks of the study period.

It has also been reported that vildagliptin as the add-on therapy with metformin may have a lower incidence of hypoglycaemia compared to the sulfonylurea group [32,33]. The observed adverse events in the current study were similar to previous studies with no episode of hypoglycaemia reported in either of the groups receiving vildagliptin or teneligliptin. The reduction in HbA1c, FPG, 2 hours PPG was greater in the group receiving teneligliptin. This may be explained by the structural advantage of teneligliptin, which binds to the S2 extensive subsites via an 'anchor lock domain', and this interaction may be related to the increased strength of inhibition, the residual time for binding to DPP-4, and the long duration of action in vivo [21].

Kutoh E et al. (2014) reported in the 12-week study, a significant change in HbA1c (-1.96%) and fasting blood glucose (-44mg/dL) after administration of teneligliptin [24]. We also observed that at 12-week, the change in HbA1c levels from baseline values in vildagliptin and teneligliptin were 0.70% and 0.64% respectively. The reduction in postprandial plasma glucose at 2 hours in vildagliptin was 43.22mg/dl and in teneligliptin group was 25.74mg/dl respectively. Kim MK et al. (2015) in the 16-week study where teneligliptin (20mg, once a day), as add on therapy to stable doses of metformin (>1000mg/day) improved HbA1c (-0.78%) and

Fasting plasma glucose (-22.42mg/dl) in Korean patients with type 2 diabetes [34].

Teneligliptin has a pharmacokinetic advantage of a longer half-life of 24.2 hours and causes more than 90% inhibition of the DPP-4 activity even after 24 hours, which favours once a day regimen for this drug [35].

In the present study, lipid profile, liver function tests (Serum bilirubin, aspartate aminotransferase (AST), Alkaline phosphatase (ALP) and renal function tests (blood urea, serum creatinine) showed no significant changes over 24 weeks in either group with 850 mg twice daily doses of metformin.

CONCLUSION

Teneligliptin and vildagliptin appear to effective and safe as add-on treatment for T2DM patients inadequately controlled on stable dose of metformin. Teneligliptin is non inferior to vildagliptin in controlling glycemic parameters (FPG, 2Hours PPG, and HbA1c).

DECLARATION

Source of funding

None

Conflict of interest

No conflict of interest exists.

Ethical Approval

Ethical clearance for the study was obtained from the Institutional Ethics Committee (IEC) of J.N. Medical College and Hospital, AMU, Aligarh on 02.02.2016(D. No: 2249/FM). The study was also registered with the clinical trial registry of India (Ref No. ctri/2017/02/007766).

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