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Original Research Article

Comparison of teneligliptin with sitagliptin as an add on to metformin in patients of type 2 diabetes mellitus: an observational study

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ABSTRACT

Background: Teneligliptin is a new dipeptidyl peptidase-4 (DPP-4) inhibitor, available in India. It has been widely prescribed in type 2 diabetes mellitus (T2 DM) due to its low cost. However, there are few studies comparing it with other DPP-4 inhibitors. The objective of this study is to compare the efficacy of teneligliptin with sitagliptin in patients of T2 DM.

Methods: Patients of T2 DM, attending the OPD of a hospital during the period of January to August 2017 were scrutinized. Those uncontrolled on metformin monotherapy (1 g/day) were selected and were administered either sitagliptin (100 mg/day) or teneligliptin (20 mg/day) in addition to metformin. Base-line clinical features (age, sex, body-weight, BP, pulse rate etc.) and laboratory parameters (hemogram, fasting blood sugar and postprandial blood sugar, HbA1c, serum creatinine etc.) were recorded initially and at the end of three months. Side effects were assessed with the help of a questionnaire. The data obtained were analyzed by student's t-test. $P < 0.05$ was considered as statistically significant.

Results: 35 and 32 patients received sitagliptin and teneligliptin respectively. After 12 weeks of therapy, FBS, PPBS and HbA1c significantly reduced in both the groups as compared to base-line values. Both drugs were well tolerated. There was no significant difference in the glycemic parameters between the two groups at the end of the study.

Conclusions: Teneligliptin significantly improved glycemic control in patients with T2 DM when prescribed as an add on to metformin. It was equally effective when compared to sitagliptin. As teneligliptin is less costly than other gliptins, it may be considered as a good cost-effective option as an add on to patients of T2 DM uncontrolled on metformin monotherapy.

Keywords: Teneligliptin, Sitagliptin, Metformin, T2 DM

INTRODUCTION

Diabetes mellitus is a spectrum of metabolic disorders, which arise from multiple pathogenic mechanisms, all resulting in hyperglycemia. Hence its management requires continuous medical care with multifactorial risk-reduction strategies beyond glycemic control.¹ There are now a wide variety of treatment options for

hyperglycemia that target different processes involved in glucose dysregulation.²

Dipeptidyl peptidase-4 (DPP-4) inhibitors is a new class of antidiabetic agents that show favourable results in improving glycemic control with minimal risk of hypoglycemia and weight gain. DPP-4 inhibitors have favorable side effect profile.^{3,4} It is recommended as second line drug after inadequate control with metformin

and therapeutic life style interventions or may be used initially in case of metformin intolerance or contraindications.⁵ Various DPP-4 inhibitors are available in our country viz. sitagliptin, vildagliptin, linagliptin, saxagliptin etc.

Teneligliptin is a new DPP-4 inhibitor, available in India, which is widely prescribed due to its low cost. However, there are few head to head comparative studies among the DPP-4 inhibitors. Hence, this study was conducted to compare the efficacy of teneligliptin with that of sitagliptin.

Aim

To compare the efficacy and safety of teneligliptin with that of sitagliptin in patients of type 2 diabetes mellitus uncontrolled on metformin.

METHODS

The study was conducted in patients attending the OPD of Dhanashree Hospital, New Sangavi, Pune from January to August 2017. Patients of type 2 diabetes mellitus (T2 DM) (<5 years duration), in the age group of 18-65 years and not controlled on metformin monotherapy (1g/d) were selected. Written informed consent was obtained prior to inclusion in the study. These patients were given either sitagliptin 100 mg/d or teneligliptin 20 mg/d. Other drugs like anti-hypertensives, anti-dyslipidemics etc. were continued. No other anti-diabetic drug was given. Criteria for exclusion were patients with T2 DM for more than 5 years, T1 DM, severe cardiac, hepatic or renal disease and pregnant women.

Prior institutional ethics committee clearance was obtained. Both drugs were administered before breakfast. Metformin (1 g SR) was continued after dinner. Base-line clinical features (age, sex, body weight, blood pressure, pulse rate etc.) and laboratory parameters (blood sugar level- fasting and post-prandial, HbA1c, serum creatinine etc.) were recorded initially and at the end of three months. Side effects were assessed with the help of a questionnaire.

The data obtained were analyzed by student's 't' test. $p < 0.05$ was considered as statistically significant.

RESULTS

Study was conducted over the period of eight months from January to August 2017. Total 74 patients of T2 DM, meeting the inclusion criteria were enrolled in the study. 38 patients received sitagliptin and 36 were treated with teneligliptin. However, three patients from sitagliptin group and four from teneligliptin group did not attend the follow up. Thus, 35 patients were treated with sitagliptin, while 32 patients received teneligliptin. Baseline clinical characteristics are mentioned in (Table 1). There was no significant difference between the two groups at baseline. After 12 weeks of therapy, there was significant ($p < 0.05$) reduction in fasting blood sugar (FBS), postprandial blood sugar (PPBS) and glycated hemoglobin (HbA1c) levels in both the groups as compared to base-line values (Table 2). However, there was no significant difference between the two groups. Both drugs were well tolerated, the side effects were minor and did not require discontinuation of treatment (Table 3).

Table 1: Baseline clinical and laboratory characteristics of the patients.

Variables	Sitagliptin and metformin (n=35)	Teneligliptin and metformin (n=32)
Age (y)	53.5±7.1	58.1±8.6
Sex (M/F)	20/15	20/12
Body-weight (kg)	66.5±10.7	64.7±10.4
Height (cm)	152.5±8.6	150.2±8.3
BMI (kg/m ²)	28.42±3.5	28.76±3.2
Duration of DM (years)	3.5±0.8	3.2±0.7
BP mmHg (SBP)	152±26	160±25
BP mmHg (DBP)	95±14	97±17
FBS (mg/dl)	158.4±30.5	156.2±32.3
2h PPBSL (mg/dl)	241.1±57.2	238.4±55.4
HbA _{1c} (%)	7.54±0.86	7.52±0.77

Table 2: Glycemic parameters at baseline and 12 weeks in the two groups.

S. no.	Parameter	Sitagliptin and metformin (n=35)		Teneligliptin and metformin (n=32)	
		Baseline	12 weeks	Baseline	12 weeks
1	FBS (mg/dl)	158.4±30.5	135.10±25.10*	156.2±32.3	135.60±23.3*
2	2 h PPBSL (mg/dl)	241.1±57.2	192.9±38.3*	238.4±55.4	195.3±37.4*
3	HbA _{1c} (%)	7.54±0.86	6.64±0.80*	7.52±0.77	6.92±0.86*

* $P < 0.05$ as compared to base-line value in the same group. No significant difference in the glycemic parameters between the two groups.

Table 3: Number of patients complaining of the side-effects of the drugs of both groups.

Side effects	Sitagliptin and metformin (n=35)	Teneligliptin and metformin (n=32)
Incidence	5	5
Dizziness	3	2
Itching/rash	2	2
Nausea/vomiting	1	2
Urinary tract infections	2	1

DISCUSSION

In this study, teneligliptin significantly improved glycemic control in patients with T2DM, when prescribed as an add on to metformin. Kim et al studied the efficacy of teneligliptin added to metformin in Korean patients with type 2 diabetes mellitus.⁶ Similar to our study these patients were not controlled with metformin. However, this was a 16 weeks study and patients were given teneligliptin or placebo in 2:1 ratio. They found significant reduction in the glycemic parameters with teneligliptin (n=136) treatment as compared to placebo.⁶ Our findings are similar to the results of this study. Recently, Ghosh et al studied the real-world efficacy of teneligliptin in T2 DM patients in our country.⁷ This study included patients treated with teneligliptin alone as well as in combination with other anti-diabetic drugs they noted that at the end of 3 months, there was significant improvement in all the glycemic parameters like FPG, PPG and HbA_{1c}. The reduction in HbA_{1c} was 1.07±0.83. We observed the reduction in HbA_{1c} as 0.60. This difference may be because of shorter duration (12 weeks) of our study as compared to longer duration of their study as well as due to the large population (n=4305) of their study. Sharma et al studied the efficacy and safety of the addition of teneligliptin in inadequately controlled T2 DM patients with metformin monotherapy in a randomized, double-blind, placebo-controlled, parallel-group, phase III study (n=204).⁸ This study showed a significant reduction in the FPG and HbA_{1c}. Our findings are similar to the results of this study.

This is the first study on direct comparison between two gliptins in treatment of patients of T2 DM in real world situation. Thus, it was found that teneligliptin is equally effective and well tolerated as compared to sitagliptin.

CONCLUSION

Advantages of teneligliptin are that it is less costly than other gliptins hence good patient compliance and no dose modification required in patients with renal impairment. Hence, it should be considered as a good option in patients of T2 DM whose glycemic parameters are uncontrolled on metformin monotherapy. However, this is a small single-centre observational study hence further studies are necessary.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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