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Original Research Article

Assessment of Effect of Teneligliptin Vs Metformin on Glycemic Control in Patients with Type 2 Diabetes Mellitus at a Tertiary Centre in Bihar

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Abstract

Background: Diabetes mellitus (DM) is one of the very oldest diseases and was mentioned three thousand years ago in Egyptian literature.

Aim and objectives: The present study assessed effect of teneligliptin vs metformin on glycemic control in patients with type 2 diabetes mellitus.

Materials & Methods : The mean age of patients was 48.06±10.25 (Mean±SD) years and out of these 52.87% were males and 47.14% were females.70 type II DM patients of both genders were divided into two groups. Group I patients received 500 mg metformin monotherapy and group II patients received 20 mg teneligliptin monotherapy. Parameters such as changes from baseline FPG and 2h-PPG values at 12 weeks were evaluated.

Results: Group I had 25 males and 10 females and group II had 12 males and 23 females. The mean BMI (Kg/m^2) was 27.6 and 26.1, FBG (mg/dl) was 168.3 and 163.5, PPBG (mg/dl) was 240.2 and 242.5, HbA1c (%) was 7.8 and 7.9, LDL- C (mg/dl) was 132.5 and 145.1, HDL (mg/dl) was 41.7 and 44.3 and triglyceride (mg/dl) level was 187.2 and 195.4 in group I and group II respectively. The difference was non- significant ($P> 0.05$). There was significant decrease in HbA1c, FBG, PPBG in all groups ($P< 0.05$).

Conclusion: We observed that Teneligliptin, aDPP4 inhibitor reduced HbA1C, FBG and PPBG significantly as compared with monotherapy of metformin in treatment of type II diabetes mellitus.

Keywords: Diabetes Mellitus, Teneligliptin, Metformin, Glycemic Control.

Introduction

Diabetes is one of the most challenging health problemsof the 21st century. It is estimated that by 2040, some 642 million people, or one adult in 10,will have diabetes. This equates to almost 10 million

new cases per year. As per the International Diabetes Federation (IDF) 2015report, India is harbouring 69.2 million diabetes patients, second only to China (109.6 million). If the current trendscontinue, by 2040 India will have about 123.5 million patients with diabetes [1]. Diabetes mellitus (DM) is a globally expanding endocrine disorder, growing at a frightening rate both in developing and developed countries. There are two major types of diabetes mellitus these are type I, type II and one minor type called Gestational diabetes and maturity onset diabetes mellitus (MODY) [2]. The main cause of type I or Juvenile diabetes is due to autoimmune insulitis, where the insulin producing beta cells in the pancreas are destructed by the body's defence system. As a result, the body is unable to produce sufficient insulin that needs. Hence type I diabetes requires exogenous insulin therapy to survive [3]. Metformin has been found to be useful in the prevention of development of diabetes, it lowers fasting plasma insulin concentrations, total and low- density lipoprotein cholesterol, and free fatty acids [4]. Many patients with T2DM remain inadequately managed, which results in progressively declining glycemic control. Oral antidiabetic drugs (OADs) present multiple drawbacks such as treatment-limiting adverse effects, including hypoglycemia, gastrointestinal (GI) disorders, edema, and weight gain [5].

Teneligliptin is a novel DPP-4 inhibitor, having a unique chemical structure. Metformin mainly decreases FPG, while DPP-4 mainly inhibits PPG. Therefore, DPP-4 inhibitors could be more efficient in Indian patients consuming a traditional Indian diet [6,7,8].

Aim and objectives: The present study assessed effect of teneligliptinvs metformin on glycemic control in patients with type 2 diabetes mellitus.

Methods & Materials

The present prospective study was done under guidance of treating physicians and guide to examine the efficacy and safety of teneligliptin as initial therapy in treatment of 70 patients of both genders with newly-diagnosed type II DM as the subject of this study attending in the Outdoor patient, Department of Medicine, in collaboration with Department of pharmacology, Jannayak Karpoori Thakur Medical College & Hospital, Madhepura, Bihar (India) and Department of Pharmacology, Sri krishna Medical College & Hospital, Muzaffarpur, Bihar (India). The period of study was from July 2020 and September 2022. The ethical clearance of the study protocol was reviewed by the Institutional Ethical Committee of the institution and permitted by it. All patients gave their written consent for participation in the study. Data such as name, age, etc. was recorded.

Inclusion criteria

- Type 2 diabetes mellitus patients aged ≥18 to ≤70 years inclusive of either sex
- Patient with inadequate glycaemic control, HbA1c >7% to ≤8.5% with diet and exercise therapy alone and treatment.
- Patient with ability to understand and provide written informed consent form

Exclusion criteria

- Patients with type 1 diabetes, secondary diabetes, acute complications of diabetes,
- Pregnant or lactating women,
- Patients with hypertensive emergencies, unstable coronary heart disease, acute myocardial infarction, advanced kidney or liver failure, and cerebral stroke, severe infection etc.
- Patients receiving treatment with systemic corticosteroids.

Patients were randomized into two groups. Group I patients received oral dosage

form, 500 mg tablet orally OD, metformin monotherapy and group II patients taken orally once daily before breakfast every morning 20 mg tablets teneligliptin monotherapy.

Parameters such as changes from baseline FBG and 2h-PPBG values at 12 weeks were assessed in both groups.

Data thus obtained were subjected to statistical analysis through Microsoft Excel 16 and Statistical package for social sciences (SPSS, Version 22). P value ≤ 0.05 was considered significant.

Results

The mean age of patients was 48.06±10.25 (Mean±SD) years and out of these 52.87% (37/70) were males and 47.14% (33/70) were females.

Table 1: Distribution of patients

Groups	Group I	Group II
Drug	500 mg metformin	20 mg teneligliptin
M:F	25:10	12:23

Table I shows that group I had 25 males and 10 females and group II had 12 males and 23 females.

Table 2: Comparison of parameters in both groups

Parameters In (Mean ± SD)	Group I (Metformin monotherapy)	Group II (Teneligliptin monotherapy)	P value
BMI (Kg/m2)	27.6±3.1	26.1±2.6	0.41
FBG (mg/dl)	168.3±17.9	163.5±20.8	0.54
PPBG (mg/dl)	240.2±36.7	242.5±48.9	0.81
HbA1c (%)	7.80±0.50	7.9±0.61	0.85
LDL- C (mg/dl)	132.5±38.6	145.1±46.4	0.92
HDL(mg/dl)	41.7±5.6	44.3±6.8	0.72
Triglyceride (mg/dl)	187.2±34.8	195.4±32.6	0.91

Table II, graph I shows that mean± SD of BMI (Kg/m2) was 27.6±3.1 and 26.1±2.6, FBG (mg/dl) was 168.3±17.9 and 163.5±20.8, PPBG (mg/dl) was 240.2±36.7 and 242.5±48.9, HbA1c (%) was 7.80±0.50and 7.9±0.61, LDL- C (mg/dl) was 132.5±38.6 and 145.1±46.4, HDL (mg/dl) was 41.7±5.6 and 44.3±6.8 and triglyceride (mg/dl) level was 187.2±34.8 and 195.4±32.6 in group I and group II respectively. The difference was non- significant (P> 0.05).

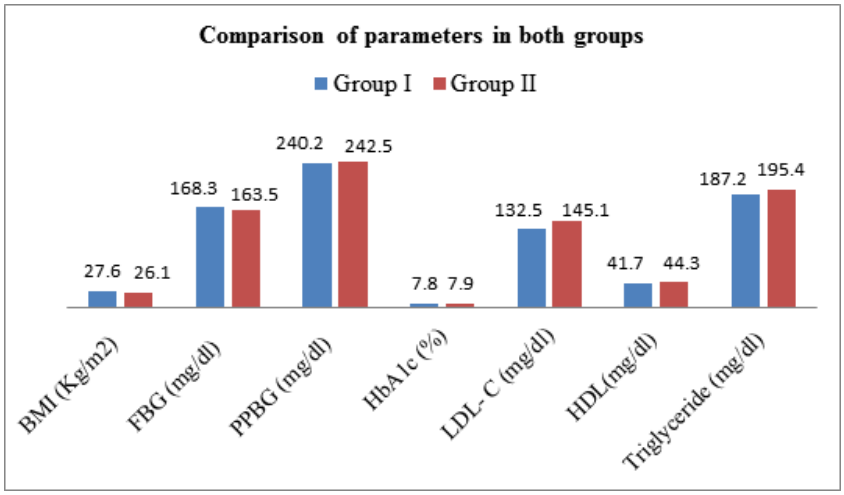

Figure 1: Comparison of parameters in both groups

Table 3: Changes in glycemic parameters in both groups

Parameters	Groups	Mean difference	P value
HbA1c (%)	Group I	-0.50	0.05
	Group II	-0.61	0.03
FBG (mg/dl)	Group I	-17.9	0.02
	Group II	-20.8	0.01
PPBG (mg/dl)	Group I	-36.7	0.03
	Group II	-48.9	0.04

Table III shows that there was significant decrease in HbA1c, FBG, PPBG in all groups (P< 0.05).

Discussion

T2DM induces microvascular and macrovascular complications, which place a huge burden on patients, caregivers, and health care systems [9,10]. American Diabetes Association (ADA) has recommended that initial treatment with metformin as monotherapy after inadequate life style modification, followed by sulfonylurea, thiazolidinedione, dipeptidyl peptidase-4 (DPP-4) inhibitor, sodium-glucose cotransporter 2 inhibitor (SGLT2-i), glucagon-like peptide 1 (GLP-1) receptor agonist and insulin alone or in combination [11,12]. The present study assessed effect of teneligliptin vs metformin on glycemic control in patients with type 2 diabetes mellitus.

We found that group I had 25 males and 10 females and group II had 12 males and 23 females. Suryawanshi et al [13] reported a significant −0.55% glycated hemoglobin (HbA1c) reduction in teneligliptin arm compared to control. While a significant reduction in 2 hours postprandial glucose (PPG) (−25.8 mg/dl) versus placebo was observed, an insignificant reduction in fasting plasma glucose (FPG) was seen (−8.8 mg/dl) in teneligliptin 20 mg arm. Similarly, higher percentage of patient achieved the target HbA1c of <7% in teneligliptin arm (43.4% vs. 27.3%) compared to the control and "overall" the drug was well tolerated.

We found that mean± SD of BMI (Kg/m2) was 27.6±3.1 and 26.1±2.6, FBG (mg/dl) was 168.3±17.9 and 163.5±20.8, PPBG (mg/dl) was 240.2±36.7 and 242.5±48.9, HbA1c (%) was 7.80±0.50and 7.9±0.61, LDL- C (mg/dl) was 132.5±38.6 and 145.1±46.4, HDL (mg/dl) was 41.7±5.6 and 44.3±6.8 and triglyceride (mg/dl) level was 187.2±34.8 and 195.4±32.6 in group I and group II respectively.

Eto et al. [14] found in their study that teneligliptin 10 mg has been shown to reduce 2-hour PPG after each meal (breakfast, lunch, and dinner) by -50.7, -34.8, and -37.5 mg/dl, respectively, against placebo in drug-naive T2DM patients. Similarly, teneligliptin 20 mg also reduced 2-hour PPG after each meal by -38.1, -28.6, and -36.1 mg/dL, respectively, against placebo at breakfast, lunch, and dinner.

We found that there was a significant decrease in HbA1c, FBG, and PPBG in all groups ($P \leq 0.05$). Kutoh et al. [15], in a 3-month study of 31 drug-naive Japanese T2DM patients, evaluated teneligliptin 20 mg daily as monotherapy. This study found a significant reduction in HbA1c (from 10.34 ±2.06 to 8.38 ±2.23%) and fasting blood glucose (from 211.3 ±68.4 to 167.3 ±70.2 mg/dL) from the baseline. Furthermore, homeostasis model assessment B (HOMAB) levels increased significantly, whereas high HOMAR levels decreased significantly. However, a significant increase in uric acid was also observed [16].

limitation of the study: The limitation of the study is the small sample size.

Conclusion

Diabetes is a complex, chronic illness requiring continuous medical care with multifactorial risk reduction strategies beyond glycemic control. We observed that teneligliptin and a DPP4 inhibitor reduced HbA1C, FBG, and 2-hour PPBG significantly as compared with monotherapy of metformin in the treatment of type II diabetes mellitus. There is a significant elevation of serum HDL-cholesterol compared to metformin. There is a deficiency in the reduction of these serum triglyceride levels. So, teneligliptin improves the serum lipid profile, which is very important in T2DM patients with dyslipidemia. Teneligliptin is generally well tolerated because it has a lower incidence of hypoglycemia with proper dose titration and a weight neutral effect.

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References

1. International diabetes federation.IDF Diabetes Atlas.7th ed. Brussels, Belgium: International Diabetes Federation, 2015; Availableat: http://www. diabetesat las.org. Accessed 17 August,2017.
2. Scott LJ. Teneligliptin: a review in type 2 diabetes. Clin Drug Investig. 2015;35(11):765-72.
3. Wu W, Li Y, Chen X, Lin D, Xiang S, Shen F, Gu X. Effect of linagliptin on glycemic control in Chinese patients with newly-diagnosed, drug-Naïve type 2 diabetes mellitus: A randomized controlled trial. Medical science monitor: international medical J ExpClin Res. 2015; 21:2678.
4. Gallwitz B, Rosenstock J, Rauch T, Bhattacharya S, Patel S, von Eynatten M, et al. 2-year efficacy and safety of linagliptin compared with glimepiride in patients with type 2 diabetes inadequately controlled on metformin: a randomised, double-blind, non-inferiority trial. The Lancet. 2012 Aug 4;380(9840):475-83.
5. Kadowaki T, Kondo K. Efficacy, safety and dose-response relationship of teneligliptin, a dipeptidyl peptidase-4 inhibitor, in Japanese patients with type 2 diabetes mellitus. Diabetes Obes Metab 2013; 15:810-8.
6. Hauber AB, Mohamed AF, Johnson FR, Falvey H. Treatment preferences and medication adherence of people with Type 2 diabetes using oral

glucose lowering agents. Diabet Med. 2009; 26:416-24.
7. American Diabetes Association. Standards of medical care in diabetes-2016. Diabetes Care. 2016;39 (Suppl 1): S1-S106.
8. Garber AJ, Abrahamson MJ, Barzilay JI, Blonde L, Bloomgarden ZT, Bush MA, et al. Consensus statement by the American Association of Clinical endocrinologists and American College of Endocrinology on the comprehensive type 2 diabetes management algorithm-2016 executive summary. EndocrPract. 2016;22(1):84-113.
9. Otsuki H, Kosaka T, Nakamura K, Shimomura F, Kuwahara Y, Tsukamoto T. Safety and efficacy of teneligliptin: A novel DPP-4 inhibitor for hemodialysis patients with type 2 diabetes. Int Uro lN ephrol 2014;46:427-32.
10. Raghavan V, Lahiri A, Akul SK, Utpal U, Gupta CN, Sen S. Effect of teneligliptin vs metformin on glycemic control in Indian patients with newly-diagnosed, drug-naïve type 2 diabetes mellitus: A 12-week randomized comparative clinical study. Int J Adv Med. 2019; 6:481-8.
11. Li X, Huang X, Bai C, Qin D, Cao S, Mei Q, Ye Y, Wu J. Efficacy and safety of teneligliptin in patients with type 2 diabetes mellitus: A systematic review and meta-analysis of randomized controlled trials. Frontiers in Pharmacology. 2018 May 4; 9:449.
12. Ghosh S, Trivedi S, Sanyal D, Modi KD, Kharb S. Teneligliptin real-world efficacy assessment of type 2 diabetes mellitus patients in India (TREAT-INDIA study). Diabetes, Metabolic Syndrome Obesity: Targets Therapy. 2016; 9:347.
13. Suryawanshi S Y, Bhargava A, Agarwal P, Chamle V. Evaluation of safety and efficacy of teneligliptin in newly diagnosed Indian type 2 diabetes mellitus patients. 52nd Annual Congress of European Association of Study in Diabetes, Munich. 2016:753. PS067; Abstract number.
14. Eto T, Inoue S, Kadowaki T. Effects of once-daily teneligliptin on 24-h blood glucose control and safety in Japanese patients with type 2 diabetes mellitus: a 4-week, randomized, double-blind, placebo-controlled trial. Diabetes Obes Metab. 2012;14(11):1040-6.
15. Kutoh E, Hirate M, Ikeno Y. Teneligliptin as an initial therapy for newly diagnosed, drug naive subjects with type 2 diabetes. J Clin Med Res. 2014; 6:287-94.
16. V. A., Rajakumar S., & Rajagopal G. Possible steroidal effect of Boswellia serrata and homeostasis of Histidine – HDC- Histamine in Psoriasis. Journal of Medical Research and Health Sciences. 2022; 5(11): 2324–2328.