Indian Journal of Pharmacy and Pharmacology 2021;8(3):205–207

Content available at: https://www.ipinnovative.com/open-access-journals

Indian Journal of Pharmacy and Pharmacology

Journal homepage: https://www.ijpp.org.in/

Original Research Article

Retrospective, observational study on usage of evogliptin in T2DM patients: A real-World experience in Indian patients

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ARTICLE INFO

Article history:
Received 01-07-2021
Accepted 08-07-2021
Available online 04-09-2021

Keywords:
PPG
FBG
DPP-4
T2DM

ABSTRACT

Aim: This study aimed to assess effectiveness and safety of Evogliptin 5 mg in patients with T2DM who were prescribed Evogliptin alone or with other oral hypoglycemic agents in real world scenario.
Materials and Methods: Overall 20 patients who received Evogliptin as routine clinical practice in management of T2DM were analyzed retrospectively from single center. Data collected from past medical records. Primary endpoint was mean changes in HbA1c from baseline to weeks 24 and secondary endpoints were Change in HbA1c from baseline to weeks 12 Change from baseline in FPG & PPG at weeks 12 & 24.
Results: Significant reduction in HbA1c at the end of 12 and 24 weeks of Evogliptin therapy was - 0.9% and -1.45% respectively from the baseline of HbA1c 8.6% (p value <0.001).
At the end of 12 and 24 weeks of addition of Evogliptin, significant reduction in FBG were seen i.e -49.5 mg/dl and -90.7mg/dl respectively from base line of 182 mg/dl and reduction in PPG was -79.4mg/dl and -116.6mg/dl respectively from base line 277 mg/dl (p value <0.001).
Conclusion: Evogliptin was found to be effective when added to the patients who were uncontrolled on dual / triple oral anti-diabetic medications and even in treatment naïve patient. It effectively showed reduction in HbA1c, FBG and PPG and the end of 12 and 24 weeks when added to existing anti-diabetic medications & well tolerated in type 2 diabetes Indian patients.
Limitations: Small sample size and retrospective study

1. Introduction

Dipeptidyl peptidase (DPP)-4 inhibitors inhibit the activity of the enzyme responsible for the initial rapid degradation of the incretin hormones, thereby enhancing their antihyperglycemic effects. The first DPP-4 inhibitor to be approved for treatment of type 2 diabetes was Sitagliptin in 2006 and there are now various other gliptins are available in various countries like Vildagliptin, Teneligliptin, linagliptin and Evogliptin etc.

As a class, DPP-4 inhibitors have been approved for use as monotherapy (for patients in whom metformin is not indicated or not tolerated) and as add-on combination therapy (dual and triple therapy with metformin, sulphonylureas, thiazolidinediones, insulin) if treatment goals are not met with metformin alone. Their efficacy, as monotherapy and in combination with other agents, has now been demonstrated in numerous clinical trials, where they typically result in reductions in HbA1c of 0.6–1.0% (dependent on baseline levels, with reductions of up to ~2% being seen in subjects with elevated HbA1c concentrations).

Evogliptin, a novel potent and selective DPP-4I, demonstrated its safety & efficacy in both preclinical and clinical studies.[1–4]

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https://doi.org/10.18231/j.ijpp.2021.035

Evogliptin was available in India, for management of type 2 diabetes mellitus (T2DM), since its approval in August 2018. It is also available in South Korea (October 2015), Azerbaijan, Russia (June 2019), Bolivia (NDA approved) - For treatment of type-2 diabetes mellitus as an adjunct to diet and exercise to improve glycemic control, when used as a mono therapy or in combination with Metformin. Evogliptin is dosed at 5 mg once daily, Owing to its long half-life of 33 h. Jaeseong et al have demonstrated that evogliptin does not require dose titration in renal impairment. In a randomized, active-controlled trial conducted in Korean and Indian patients with uncontrolled type 2 diabetes on metformin, the efficacy of evogliptin was similar to that of Sitagliptin. [1–4]

Objective: study aimed to assess effectiveness and safety of Evogliptin 5 mg in patients with T2DM who were prescribed Evogliptin alone or with other oral hypoglycemic agents in real world scenario in Indian patients.

2. Materials and Methods

Single centric, retrospective, observational, real world study. Overall 20 patients who received Evogliptin as routine clinical practice in management of T2DM were analyzed retrospectively from single center. Data collected from past medical records in retrospective manner. Primary endpoint was mean changes in HbA1c from baseline to weeks 24 and secondary endpoints were Change in HbA1c from baseline to weeks 12 Change from baseline in FPG & PPG at weeks 12 & 24.

3. Results

Overall 20 patients suffering from T2DM and who received Evogliptin as routine clinical practice where analyzed retrospectively.

Table 1: Demographic parameters

Age (years)	Mean± SD = 56.6 ± 10.54
Gender	Male: 9 (45%); Female: 11 (55%)
Weight (kg)	Mean ± SD = 74.6 ±14.86
Height (cm)	Mean ± SD = 165.5 ± 8.02
BMI (kg/m^2)	Mean ± SD = 27.7 ± 4.51
T2DM since (Yrs)	Mean ± SD = 8.35 ± 4.23

(In this study most of the patients had comorbid conditions like hypertension, ischemic heart disease, dyslipidemia and obesity)

3.1. Primary end point analysis

Significant reduction in HbA1c at the end of 12 and 24 weeks of Evogliptin therapy was — 0.9% and -1.45% respectively from the baseline of HbA1c 8.6% (p value <0.001).

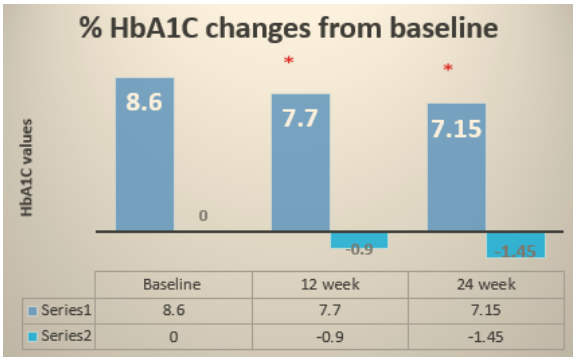

Fig. 1: % HbA1C changes from baseline

3.2. Change in FBG & PPG

At the end of 12 and 24 weeks of addition of Evogliptin, significant reduction in FBG were seen i.e -49.5 mg/dl and -90.7mg/dl respectively from base line of 182 mg/dl and reduction in PPG was -79.4mg/dl and -116.6mg/dl respectively from base line 277 mg/dl (p value <0.001).

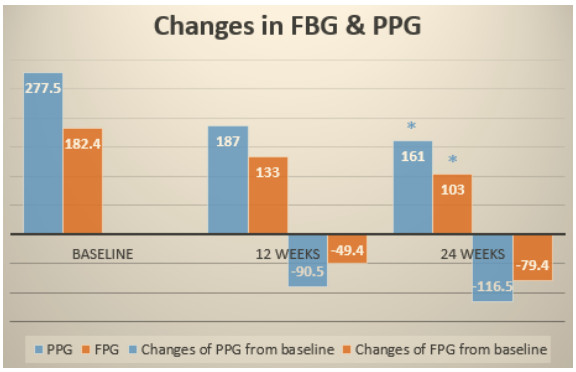

Fig. 2: Changes in FBG & PPG

In this retrospective study 90% of patients were already on dual oral anti-diabetic medications like Metformin + Glimepiride / Gliclazide & Metformin + canagliflozin. 5 % patients were on triple combination of Metformin + Gliclazide + Voglibose and remaining 5% were treatment naïve.

In this study most of the patients had comorbid conditions like hypertension, ischemic heart disease, dyslipidemia and obesity. Mean duration of T2DM was 8.35 years.

4. Discussion

While metformin will still be the preferred option for most patients, there is an increasing place for DPP-4 inhibitors to be used in monotherapy when metformin cannot be used. DPP-4 inhibitors are positioned as second-line agents in many therapeutic guidelines, including the American Diabetes Association (ADA)/ European Association for

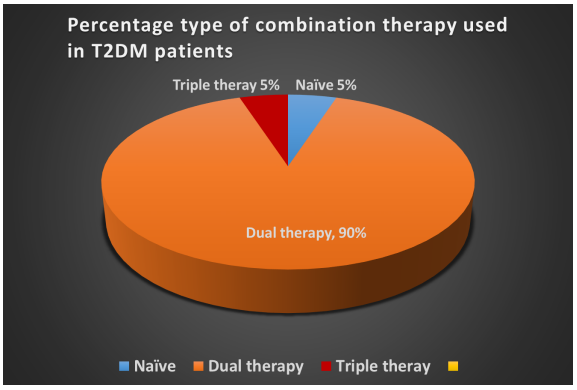

Fig. 3: Perventage type of combination therapy used in T2DM patients

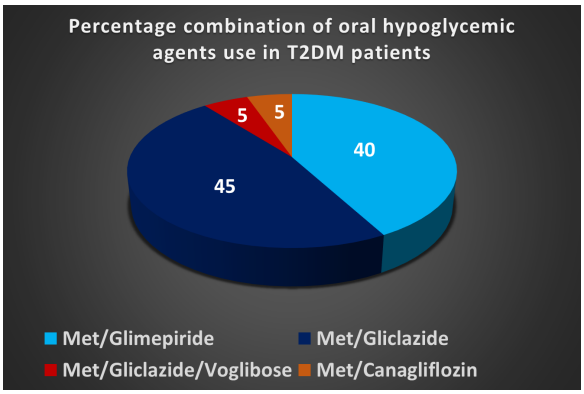

Fig. 4: Percentage combination of oral hypoglycemic agents use in T2DM

the Study of Diabetes (EASD) position statement and the American Association of Clinical Endocrinologists (AACE) and American College of Endocrinology (ACE) diabetes algorithms. They are commonly used in addition to ongoing metformin therapy if therapeutic targets are not attained. Fixed-dose combinations with metformin are now available with all of the individual inhibitors, giving the option of once daily use (when combined with the extended-release metformin formulation). The combination of metformin with a DPP-4 inhibitor has its merits because it effectively targets the underlying pathology of type 2 diabetes, with metformin improving insulin resistance and reducing hepatic glucose output, while the DPP-4 inhibitors address islet dysfunction via insulin-tropic and glucagonostatic effects mediated through GLP-1. The metformin/DPP-4 inhibitor combination gives rise to greater HbA1c lowering than when either agent is used alone without increasing the risk of hypoglycemia or weight gain.

Findings from this real world retrospective observational study demonstrated that Evogliptin improved glycemic control when given as an add-on treatment in Indian patients with type 2 diabetes not responding to optimal dose of other oral hypogycemiac agents like metformin.

Conclusion: Evogliptin was found to be effective when added to the patients who were uncontrolled on dual / triple oral anti-diabetic medications and even in treatment naïve patient. It effectively showed reduction in HbA1c, FBG and PPG and the end of 12 and 24 weeks when added to existing anti-diabetic medications & well tolerated in type 2 diabetes Indian patients.

5. Limitations

Small sample size, retrospective, observational, single center study

6. Source of Funding

None.

7. Conflict of Interest

Declaration of Competing Interest Dr. Abhijit Trailokya, Dr. Amol Aiwale and Dr. Roshan Pawar are the associated with Alkem Laboratories Limited, India. They help author in manuscript writing and publication. Authors declare no other competing interest.

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Cite this article: Trailokya A, Aiwale A, Pawar R, Erande S. Retrospective, observational study on usage of evogliptin in T2DM patients: A real-World experience in Indian patients. *Indian J Pharm Pharmacol* 2021;8(3):205-207.