



Original Research Article

Retrospective, observational study to see the effect of evogliptin on continuous glucose monitoring (CGM) in T2DM Indian patients: A real-world experience

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ARTICLE INFO

Article history:

Received 22-09-2021

Accepted 29-09-2021

Available online 05-01-2022

Keywords:

Real world study

Evogliptin

Retrospective

CGM

Time in target

Add on therapy

ABSTRACT

Aim: This study aimed to assess effectiveness of Evogliptin 5 mg through continues glucose monitoring (CGM) in patients with T2DM in retrospective observational real world settings.

Materials and Methods: Overall 6 patients who received Evogliptin as routine clinical practice in management of T2DM were analyzed retrospectively from single center. Data collected from past medical records. FreeStyle Librepro 1.0.6 was used for CGM. CGM was done 15 days prior to adding Evogliptin and repeated immediately after that for next 15 days. Mean BG level, Percentage time in target range (80-140mg/dl), Percentage time above target and Percentage time below target were assessed prior and after adding Evogliptin in existing treatment regimen.

Results: Significant reduction in Mean blood glucose level seen after adding Evogliptin in existing treatment regimen from 215 mg/dl to 138 mg/dl (-77 mg/dl P=0.006). Significant improvement seen in Percentage time in target range (80-140mg/dl) from 17% to 44% (27% P value 0.007) and in Percentage time above target from 81% to 43% (- 38%, P valve 0.003). 13.5 % of the patients seen below target.

Conclusion: Evogliptin was found to be effective when added to the patients who were uncontrolled on other oral anti-diabetic medications. It effectively showed improvement in continues glucose monitoring (CGM) parameters like Mean blood glucose, more number of patients were in Time in Target range i.e (80-140mg/dl) after adding Evogliptin to existing anti-diabetic medications & well tolerated.

Limitations: Small sample size and retrospective study

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1. Introduction

The prime treatment goal for patients with diabetes is to avert the onset and progression of diabetic complications. To prevent cardiovascular events, patients should maintain optimal long-term glycemic control and avoid hypoglycemia.¹ High variability in blood glucose (BG) control in chronic glycemic control is linked with a high risk of hypoglycemia related hospitalization. BG fluctuations stimulate oxidative stress and have been associated with arteriosclerosis. Continuous glucose

monitoring (CGM) is useful for explaining BG variability in diabetes patients by analyzing the amplitude and timing of glucose fluctuations. DPP-4 inhibition improves endogenous in cretin action, and stimulates glucose dependent insulin secretion and optimal glucagon secretion. Thus, DPP-4 inhibitor like Evogliptin can improve hyperglycemia, without causing hypoglycemia in patients with diabetes.¹

In August 2018, Evogliptin was introduced in India, for management of type 2 diabetes mellitus (T2DM). It is also available in South Korea (October 2015), Russia (June 2019) Azerbaijan, Bolivia (NDA approved) — For treatment of type-2 diabetes mellitus as an adjunct to

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diet and exercise to improve glycemic control, when used as a mono therapy or in combination with Metformin with dosage of 5mg Once a day. No dose adjustment is required in mild to moderate hepatic insufficiency or renal insufficiency. Evogliptin causes a persistent inhibition of more than 80% of the enzyme activity, by interacting with the S2-extensive subsite of the dipeptidyl-peptidase-4 (DPP4) enzyme's active site. Clinical trials from different parts of the world (Korea, India, UK and Brazil) have reported good glycemic efficacy and safety of Evogliptin in T2DM.²⁻⁵

1.1. Objective

Very limited studies available to demonstrate effect of Evogliptin on continues glucose monitoring. This study aimed to assess effectiveness of Evogliptin 5 mg through continues glucose monitoring (CGM) in patients with T2DM in retrospective observational real world settings.

2. Materials and Methods

Overall 6 patients who received Evogliptin as routine clinical practice in management of T2DM were analyzed retrospectively from single center. Data collected from past medical records. Free Style Librepro 1.0.6 was used for CGM. CGM was done 15 days prior to adding Evogliptin and repeated immediately after that for next 15 days. Mean BG level, Percentage time in target range (80-140mg/dl), Percentage time above target and Percentage time below target were assessed prior and after adding Evogliptin in existing treatment regimen.

3. Result

3.1. Primary end point analysis

Significant reduction in Mean blood glucose level seen after adding Evogliptin in existing treatment regimen from 215 mg/dl to 138 mg/dl (-77 mg/dl P=0.006). Significant improvement seen in Percentage time in target range (80-140mg/dl) from 17% to 44% (27% P value 0.007) and in Percentage time above target from 81% to 43% (- 38%, P valve 0.003). 13.5 % of the patients seen below target.

4. Discussion

Numerous studies have shown that increased glycaemic variability assessed by CGM was linked with diabetic complications, such as diabetic retinopathy, cardiovascular complications and mortality. Incretin-based DPP-4 inhibitors are associated with a low risk of hypoglycaemia and can improve β -cell function with a no effect on body weight

A previous study reported that DPP-4 inhibitors were associated with fewer fluctuations in blood glucose levels in both hypoglycaemic and hyperglycaemic status in a

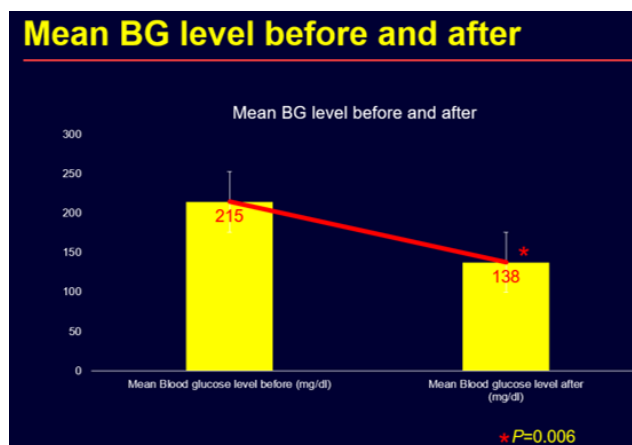


Fig. 1: Mean blood glucose (BG) level before and after

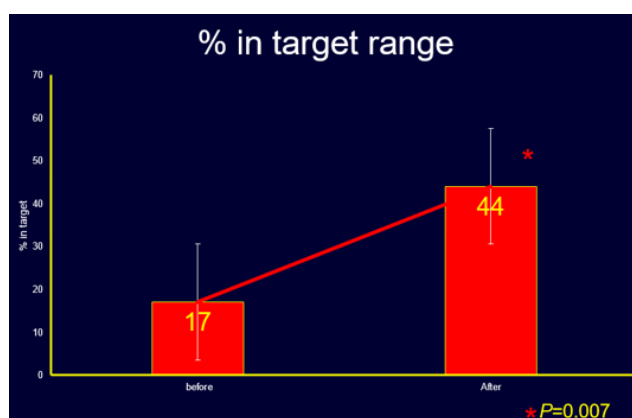


Fig. 2: Change in percentage in target range before and after adding evogliptin

glucose-dependent manner.

A 24-week randomized, double-blind, non-inferiority, EVOLUTION INDIA study showed significant change in HbA1c from base line after adding Evogliptin 5mg in Indian patients. It effectively improved glycemic control and was well tolerated in type 2 diabetes patients inadequately controlled by metformin.⁶

Study conducted by kim et al. showed Evogliptin treatment also resulted in improved glycaemic variability with increased glucose target ranges and decreased time in hypoglycaemia and hyperglycaemia investigated by the CGM system. Evogliptin was well tolerated during clinical trial duration of 24 weeks. HbA1c was decreased by 0.85% at week 12 and by 0.94% at week 24. Treatment with Evogliptin resulted in significantly reduced peak daily glucose levels, area under the curve for 2 hours after each meal, and the percentage of time spent in hyperglycaemia, representing its potent effect in controlling postprandial hyperglycaemia. Evogliptin group had no documented symptomatic hypoglycaemia during the 24-week study

period. These data support the safety and tolerability of Evogliptin.⁷ Our study also demonstrated improvement in continuous glucose monitoring (CGM) parameters like Mean blood glucose, more number of patients were in Time in Target range i.e (80-140mg/dl) after adding Evogliptin to existing anti-diabetic medications & well tolerated. Though smaller sample size and retrospective study are the limitations.

5. Conclusion

Evogliptin was found to be effective when added to the patients who were uncontrolled on other oral anti-diabetic medications. It effectively showed improvement in continuous glucose monitoring (CGM) parameters like Mean blood glucose, more number of patients were in Time in Target range i.e (80-140mg/dl) after adding Evogliptin to existing anti-diabetic medications & well tolerated.

6. Limitations

Small sample size, retrospective, observational, single centre study.

7. Source of Funding

None.

8. Conflict of Interest

Declaration of Competing Interest Dr. Abhijit Trailokya and Dr. Amol Aiwale 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, Erande S, Aiwale A. Retrospective, observational study to see the effect of evogliptin on continuous glucose monitoring (CGM) in T2DM Indian patients: A real-world experience. *Indian J Pharm Pharmacol* 2021;8(4):267-269.