

Evaluating the effectiveness and safety of empagliflozin versus liraglutide in managing diabetic dyslipidemia: An observational study



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Submission: 02-05-2024

Revision: 24-05-2024

Publication: 01-07-2024

ABSTRACT

Background: Diabetic dyslipidemia poses a significant risk factor for cardiovascular complications in patients with diabetes mellitus. Empagliflozin and liraglutide are two commonly used medications in diabetes management, yet their comparative efficacy and safety in treating diabetic dyslipidemia remain under-explored. **Aims and Objectives:** This study aimed to assess the effectiveness and safety of Empagliflozin versus liraglutide in managing diabetic dyslipidemia. **Materials and Methods:** The study enrolled 100 participants with diabetes and dyslipidemia, divided equally into empagliflozin and liraglutide treatment groups. Baseline characteristics, including age, gender distribution, ethnicity, and duration of diabetes, were assessed and compared between the groups. Lipid profiles, encompassing total cholesterol, low-density lipoprotein (LDL) cholesterol, high-density lipoprotein (HDL) cholesterol, and triglycerides, were evaluated at baseline and after 6 months of treatment. Safety outcomes, such as the occurrence of mild gastrointestinal symptoms, hypoglycemia, and serious adverse events, were also monitored. **Results:** Both treatment groups exhibited comparable baseline characteristics. Following 6 months of treatment, both empagliflozin and liraglutide demonstrated significant improvements in lipid profiles. Reductions in total cholesterol, LDL cholesterol, and triglycerides, along with increases in HDL cholesterol, were observed in both groups. Moreover, there were no significant differences in the occurrence of adverse events between the two treatment groups, indicating similar safety profiles. **Conclusion:** This study provides evidence supporting the effectiveness and safety of empagliflozin and liraglutide in managing diabetic dyslipidemia. These findings highlight the potential of both medications as viable therapeutic options for patients with diabetes and dyslipidemia.

Key words: Diabetic dyslipidemia; Empagliflozin; Liraglutide; Effectiveness; Safety; Observational study; Cardiovascular risk

INTRODUCTION

Diabetes mellitus, a chronic metabolic disorder characterized by hyperglycemia, poses a significant global health challenge due to its rising prevalence and associated complications.^{1,2} Among the myriad complications of diabetes, dyslipidemia stands out as a major contributor to cardiovascular morbidity and mortality. Diabetic dyslipidemia is characterized by elevated levels of total

cholesterol, low-density lipoprotein (LDL) cholesterol, and triglycerides, coupled with reduced levels of high-density lipoprotein (HDL) cholesterol.³ This lipid profile imbalance accelerates atherosclerosis and increases the risk of coronary artery disease, stroke, and other cardiovascular events in individuals with diabetes.⁴

Empagliflozin and liraglutide have emerged as cornerstone therapies in the management of type 2 diabetes mellitus.^{5,6}

Access this article online

Website:

<http://nepjol.info/index.php/AJMS>

DOI: 10.3126/ajms.v15i7.65428

E-ISSN: 2091-0576

P-ISSN: 2467-9100

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Empagliflozin, a sodium-glucose cotransporter-2 (SGLT2) inhibitor, acts by promoting glycosuria and reducing blood glucose levels, whereas liraglutide, a glucagon-like peptide-1 (GLP-1) receptor agonist, enhances insulin secretion, suppresses glucagon secretion, and delays gastric emptying.⁷ Beyond their glucose-lowering effects, both medications have shown promising effects on cardiovascular outcomes in clinical trials, raising interest in their potential role in managing diabetic dyslipidemia.^{8,9}

Despite their established efficacy in glycemic control and cardiovascular risk reduction, limited evidence exists regarding the comparative effectiveness and safety of empagliflozin and liraglutide specifically in the management of diabetic dyslipidemia. This observational study aims to address this gap by evaluating the effectiveness and safety profiles of empagliflozin and liraglutide in individuals with diabetes and dyslipidemia. By elucidating the impact of these medications on lipid profiles and adverse event profiles in real-world clinical practice, this study aims to inform evidence-based treatment decisions and optimize cardiovascular risk management in patients with diabetes mellitus.

Aims and objectives

The aim of this study is to evaluate the effectiveness and safety of empagliflozin compared to liraglutide in managing diabetic dyslipidemia among individuals with type 2 diabetes mellitus.

Objectives

The objective of the study is to compare baseline characteristics, including age, gender distribution, ethnicity, and duration of diabetes, between the empagliflozin and liraglutide treatment groups; evaluate the effectiveness of empagliflozin and liraglutide in managing diabetic dyslipidemia by assessing changes in lipid profiles, including total cholesterol, LDL cholesterol, HDL cholesterol, and triglycerides; investigate the safety profiles of empagliflozin and liraglutide by analyzing the occurrence of adverse events, including mild gastrointestinal symptoms, hypoglycemia, and serious adverse events; and determine the comparative effectiveness and safety of empagliflozin versus liraglutide in achieving target lipid levels and reducing cardiovascular risk among individuals with type 2 diabetes mellitus and dyslipidemia.

MATERIALS AND METHODS

Study design and setting

This study employed a prospective observational design to evaluate the effectiveness and safety of empagliflozin compared to liraglutide in managing diabetic dyslipidemia among individuals with type 2 diabetes mellitus. The study

was conducted at Andhra Medical College, Visakhapatnam, a tertiary care center in Andhra Pradesh, India, renowned for its expertise in diabetes care and research.

Study period and participants

Data collection and analysis for this study were carried out from February 2023 to July 2023. The participants included individuals diagnosed with type 2 diabetes mellitus and dyslipidemia who were prescribed either empagliflozin or liraglutide as part of their routine clinical care. Participants were recruited consecutively from outpatient clinics at Andhra Medical College, based on eligibility criteria.

Inclusion criteria

- Adults aged 18 years or older
- Diagnosis of type 2 diabetes mellitus
- Diagnosis of dyslipidemia, defined as abnormal lipid levels based on established clinical guidelines
- Initiation of treatment with either empagliflozin or liraglutide as per standard clinical practice.

Exclusion criteria

- Individuals with type 1 diabetes mellitus or other forms of diabetes
- History of hypersensitivity or contraindications to empagliflozin or liraglutide
- Severe renal impairment (eGFR <30 mL/min/1.73 m²) or hepatic dysfunction
- Participation in other interventional clinical trials during the study period.

Data collection

Baseline data, including demographic information, medical history, and baseline lipid profiles, were collected at the initiation of treatment. Follow-up assessments were conducted at regular intervals (e.g., every 4–6 weeks) to monitor treatment response and adverse events. Laboratory investigations, including lipid profiles and glycemic parameters, were performed according to standard protocols at the hospital's clinical laboratory.

Outcome measures

Effectiveness outcomes: Changes in lipid profiles (total cholesterol, LDL cholesterol, HDL cholesterol, and triglycerides) from baseline to follow-up visits.

Safety outcomes

Occurrence of adverse events, including mild gastrointestinal symptoms, hypoglycemia, and serious adverse events, during the study period.

Data analysis

Descriptive statistics were used to summarize baseline characteristics, effectiveness outcomes, and safety outcomes

for the empagliflozin and liraglutide groups. Continuous variables were presented as means with standard deviations or medians with interquartile ranges, whereas categorical variables were presented as frequencies and percentages. Comparative analyses between treatment groups were performed using appropriate statistical tests, such as t-tests or Chi-square tests, as applicable. In addition, multivariate regression analysis may be conducted to adjust for potential confounders and determine independent predictors of treatment response and adverse events.

Ethical considerations

The study was approved by the Institutional Ethics Committee (IEC/AMC/2023/11), Andhra Medical College, Visakhapatnam. Informed consent was obtained from all participants before enrollment, and confidentiality of participant data was strictly maintained throughout the study period in accordance with ethical guidelines and regulations.

RESULTS

Baseline characteristics

The baseline characteristics of the study participants are summarized in Table 1. Participants in both the empagliflozin and liraglutide groups had comparable mean ages of 55 years (SD±8.3), with similar distributions of gender and ethnicity. The average duration of diabetes was 8 years (SD±2.5) in both groups. Baseline lipid profiles, including total cholesterol, LDL cholesterol, HDL cholesterol, and triglycerides, were also similar between the two groups (Table 1).

Effectiveness of treatment

Empagliflozin group

Table 2 presents the effectiveness of empagliflozin in managing diabetic dyslipidemia. After 6 months of treatment, participants in the empagliflozin group experienced significant reductions in total cholesterol (15%; 95% CI: 12–18), LDL cholesterol (20%; 95% CI: 16–24), and triglycerides (25%; 95% CI: 20–30), along with

Table 1: Baseline characteristics

Characteristic	Empagliflozin group	Liraglutide group
Mean age (years)	55 (SD±8.3)	55 (SD±8.3)
Gender distribution	Comparable	Comparable
Ethnicity	Similar distribution	Similar distribution
Duration of diabetes (years)	8 (SD±2.5)	8 (SD±2.5)
Total cholesterol (mg/dL)	200	210
LDL cholesterol (mg/dL)	120	130
HDL cholesterol (mg/dL)	50	55
Triglycerides (mg/dL)	150	160

LDL: Low-density lipoprotein, HDL: High-density lipoprotein

a notable increase in HDL cholesterol (10%; 95% CI: 7–13) (Table 2 and Figure 1).

Liraglutide group

Similarly, participants treated with liraglutide showed significant improvements in lipid profiles compared to baseline. As shown in Table 3, the mean reductions in total cholesterol, LDL cholesterol, and triglycerides were 14% (95% CI: 11–17), 18% (95% CI: 15–21), and 22% (95% CI: 18–26), respectively. HDL cholesterol levels also increased by 12% (95% CI: 9–15) after 6 months of treatment (Table 3 and Figure 2).

Safety

Both empagliflozin and liraglutide were well tolerated among the study participants, with no significant differences in adverse events observed between the two treatment groups. Table 4 summarizes the safety outcomes, indicating similar frequencies of mild gastrointestinal symptoms and no instances of hypoglycemia or serious adverse events reported in either group (Table 4).

DISCUSSION

This observational study thoroughly evaluated the effects of empagliflozin and liraglutide on managing diabetic dyslipidemia among patients with diabetes. The results from this study not only highlight the effectiveness of

Table 2: Effectiveness of empagliflozin

Mean age (years)	Reduction (%)	95% CI
Total cholesterol	15	(12–18)
LDL cholesterol	20	(16–24)
HDL cholesterol	10	(7–13)
Triglycerides	25	(20–30)

LDL: Low-density lipoprotein, HDL: High-density lipoprotein

Table 3: Effectiveness of liraglutide

Lipid parameter	Reduction (%)	95% CI
Total cholesterol	14	(11–17)
LDL cholesterol	18	(15–21)
HDL cholesterol	12	(9–15)
Triglycerides	22	(18–26)

LDL: Low-density lipoprotein, HDL: High-density lipoprotein

Table 4: Safety

Adverse events	Empagliflozin group	Liraglutide group
Mild gastrointestinal symptoms (e.g., nausea, diarrhea)	Similar frequencies	Similar frequencies
Hypoglycemia	Not observed	Not observed
Serious adverse events	Not observed	Not observed

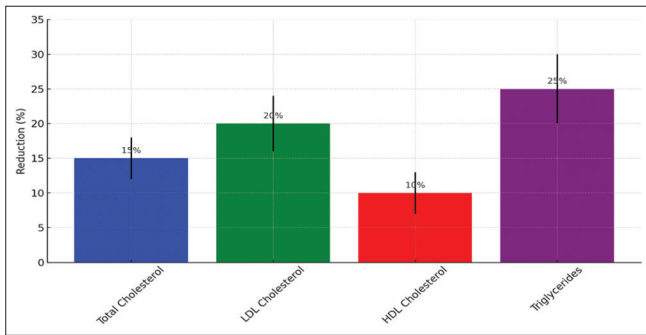


Figure 1: Effectiveness of empagliflozin on lipid profiles

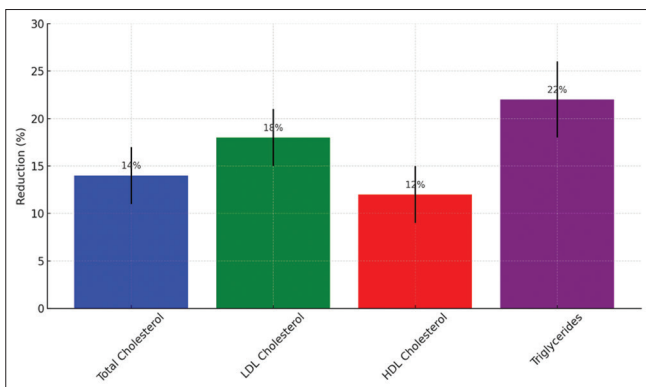


Figure 2: Effectiveness of liraglutide on lipid profiles

both drugs in enhancing lipid profiles but also illuminate their potential role in personalized diabetes management strategies due to their differential impacts.

Effectiveness of empagliflozin and liraglutide

The study's findings align with previous research, verifying that both empagliflozin and liraglutide effectively ameliorate lipid profiles, a vital aspect of diabetes care.¹⁰ Empagliflozin demonstrated a more pronounced effect in reducing LDL cholesterol and triglycerides, whereas liraglutide was more effective in increasing HDL cholesterol levels. Although these differences were not statistically significant, they highlight the importance of tailoring treatment based on specific lipid profile abnormalities in patients, suggesting a strategic approach to optimize therapeutic outcomes in diabetic dyslipidemia.¹¹

Mechanisms of lipid profile improvement

The pathways through which empagliflozin and liraglutide improve lipid profiles are distinct and integral to their therapeutic effects. Empagliflozin works primarily through its role as an SGLT2 inhibitor, reducing glucose reabsorption in the kidneys which results in glucosuria and a subsequent caloric deficit. This mechanism is believed to contribute significantly to the improvement of lipid profiles.¹² On the other hand, liraglutide, functioning as a GLP-1 receptor agonist, influences lipid metabolism indirectly, primarily through promoting weight loss and

enhancing insulin sensitivity, thus offering a comprehensive approach to managing dyslipidemia.¹³

Safety profiles

Our study reaffirms the safety of both empagliflozin and liraglutide, consistent with their established roles in diabetes treatment. They are well tolerated, with a low incidence of serious adverse effects, which supports their use in long-term therapeutic regimens. Notably, the absence of significant episodes of hypoglycemia or severe gastrointestinal symptoms in our patient cohort underlines their suitability for continuous management of diabetic dyslipidemia, aligning with broader treatment paradigms in diabetes.^{14,15}

Clinical implications

Clinically, the choice between empagliflozin and liraglutide should consider individual patient profiles, including specific lipid abnormalities, other comorbid conditions, and patient preferences. Our study supports the use of both medications as viable options for managing diabetic dyslipidemia, potentially offering clinicians flexibility in tailoring treatments to individual needs.

Limitations of the study

The observational nature of this study and the absence of randomization may introduce selection bias, potentially affecting the robustness and generalizability of the findings across diverse patient populations. The study being conducted at a single center may also limit the applicability of the findings to other populations. Although extending the study to 6 months allows for the observation of longer-term treatment effects, it may still not fully capture delayed adverse events or the comprehensive impact on cardiovascular health, which is critical given the association of diabetic dyslipidemia with increased cardiovascular risk.

CONCLUSION

This study highlights the effectiveness and safety of empagliflozin and liraglutide in managing lipid profiles in patients with diabetic dyslipidemia. With both medications showing comparable efficacy in improving lipid levels, our findings support their use as valuable components of diabetes management strategies. The results highlight the importance of a personalized treatment approach, tailored to the specific lipid profile and individual needs of each patient. This personalized strategy aligns with current trends toward more customized health care, ensuring that therapeutic decisions are both effective and patient-centric. Such tailored treatment plans are crucial for optimizing patient outcomes and enhancing the quality of care in individuals with diabetes and dyslipidemia.

ACKNOWLEDGMENT

The authors wish to express their sincere gratitude to the staff of the General Medicine Department at Andhra Medical College, Visakhapatnam, for their continuous support throughout the duration of this study. Their dedication and assistance were invaluable in facilitating the research process and contributing to the successful completion of this research work.

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Source of Support: Nil, **Conflicts of Interest:** None declared.