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Paper Title: Efficacy of GlucoReg in Improving Glycemic Control in Adults with Type 2 Diabetes Mellitus: A Randomized Controlled Trial

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Abstract

Background: Type 2 Diabetes Mellitus (T2DM) is a chronic condition that affects glucose metabolism. The need for innovative treatments to manage glycemic levels is critical for reducing the risk of diabetes-related complications.

Objective: To evaluate the efficacy and safety of GlucoReg, a new oral hypoglycemic agent, in improving glycemic control in adults with T2DM.

Methods: A 12-month, double-blind, placebo-controlled, randomized clinical trial was conducted. A total of 300 adults with poorly controlled T2DM (HbA1c 7.5-10%) were randomly assigned to receive either GlucoReg or a placebo. The primary outcome was the change in HbA1c levels from baseline to 12 months. Secondary outcomes included changes in fasting plasma glucose, lipid profile, body weight, and incidence of adverse events.

Results: The GlucoReg group showed a significant reduction in HbA1c (-1.5% ± 0.5) compared to the placebo group (-0.2% ± 0.3; P<0.001). Improvements in fasting plasma glucose, lipid profile, and body weight were also significantly better in the GlucoReg group. The incidence of adverse events was similar between the two groups.

Conclusion: GlucoReg is an effective and safe option for improving glycemic control in adults with T2DM.

Keywords: Type 2 Diabetes Mellitus, GlucoReg, glycemic control, randomized controlled trial.

Introduction

Type 2 Diabetes Mellitus (T2DM) represents a significant public health challenge globally, affecting millions of individuals and placing a substantial burden on healthcare systems. The pathophysiology of T2DM involves insulin resistance and an eventual decline in insulin production, necessitating the need for effective management strategies to control blood glucose levels and prevent complications. Current therapeutic options include lifestyle modifications, oral hypoglycemic agents, and insulin therapy. However, a considerable proportion of patients fail to achieve or maintain glycemic targets, underscoring the need for new therapeutic options.

GlucoReg, a novel dipeptidyl peptidase-4 (DPP-4) inhibitor, has emerged as a promising agent in managing T2DM. Preliminary studies have suggested that GlucoReg improves insulin secretion and sensitivity, thereby facilitating better glycemic control without the risk of weight gain or significant hypoglycemia. This randomized controlled trial was designed to evaluate the efficacy and safety of GlucoReg in adults with poorly controlled T2DM.

Methods

Study Design and Participants

We conducted a 12-month, multicenter, double-blind, placebo-controlled randomized trial between January 2023 and December 2023. Participants were eligible if they were aged 18-65 years, had a diagnosis of T2DM for at least one year, and had HbA1c levels of 7.5-10% despite receiving at least one oral hypoglycemic agent.

Interventions

Participants were randomly assigned in a 1:1 ratio to receive either GlucoReg (100 mg daily) or a matching placebo. Randomization was stratified by the site with the use of a computer-generated random-numbers table. All participants continued their usual care, including diet, exercise, and other medications for diabetes.

Outcomes

The primary outcome was the change in HbA1c levels from baseline to the study endpoint at 12 months. Secondary outcomes included changes in fasting plasma glucose (FPG), lipid profile (total cholesterol, LDL cholesterol, HDL cholesterol, and triglycerides), body weight, and the incidence of adverse events.

Statistical Analysis

We calculated that a sample size of 300 participants would provide 90% power to detect a 0.5% difference in HbA1c levels between groups, assuming a standard deviation of 1.0%, with a two-sided

alpha level of 0.05. Data were analyzed using the intention-to-treat principle. Continuous variables were compared using independent t-tests or Mann-Whitney U tests, and categorical variables were compared using chi-squared tests.

Results

Participant Characteristics

A total of 300 participants were randomized (150 to GlucoReg and 150 to placebo). The baseline characteristics were similar between groups. The mean age was 55 years, 52% were male, and the mean baseline HbA1c was 8.4%.

Efficacy Outcomes

At 12 months, the GlucoReg group exhibited a significant reduction in HbA1c levels compared to the placebo group (mean difference -1.3% [95% CI, -1.5 to -1.1]; P<0.001). Significant improvements were also observed in FPG, lipid profile, and body weight.

Safety Outcomes

The incidence of adverse events was similar between the GlucoReg and placebo groups. The most common adverse events in the GlucoReg group were mild gastrointestinal symptoms.

Discussion

This study demonstrates that GlucoReg is effective in significantly improving glycemic control among adults with T2DM, with a favorable safety profile. The reductions in HbA1c and improvements in FPG and lipid profiles with GlucoReg treatment are clinically meaningful and could potentially reduce the risk of diabetes-related complications. Our findings support the inclusion of GlucoReg as an option for the management of T2DM.

Conclusion

GlucoReg offers a new and effective treatment modality for improving glycemic control in adults with T2DM, demonstrating significant benefits in terms of HbA1c reduction, FPG, and