INPLASY PROTOCOL

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Review Stage at time of this submission: Data extraction.

Conflicts of interest:
None declared.

Systematic evaluation and meta-analysis of the efficacy and tolerability of tegoprazan in an Asian population

Chen, YF[1]; Chen, Y[2]; Li, TX[3]; Cheng, YL[4]; Huang, ZW[5]; Cai, TY[6]; Bai, JJ[7]; Wu, ZM[8]; Liu, C[9]; Fu, WG[10].

Review question / Objective: P (Population): Diabetic patients and healthy subjects. I (Intervention): Different doses of dasiglucagon. C (Comparison): Placebo. O (Outcome) : The primary outcome was the median time to recovery of plasma glucose (PG) (first PG increase of ≥20 mg/dL from the baseline after treatment initiation). The number of occurrences in which PG initially increased by ≥20 mg/dL from the baseline within 10, 15, 20, and 30 minutes was one of the secondary outcomes. The median time to reach a PG level of ≥70 mg/dL was another secondary outcome. The aforementioned outcomes were established without the use of intravenous rescue glucose. S (Study design) : The data in this study were obtained from randomized controlled trials.

INTRODUCTION

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rescue glucose. S (Study design) : The data in this study were obtained from randomized controlled trials.

Rationale: PubMed, Cochrane Library, Embase, ClinicalTrials.gov, and other databases were searched, and a comprehensive collection of clinical randomized controlled trials comparing dasiglucagon to other glucagon or placebo for hypoglycemia efficacy and tolerability were meta-analyzed using Stata 15.0 software.

Condition being studied: In the treatment of patients with severe hypoglycemia, dasiglucagon offers a rapid and convenient onset of action, providing distinct advantages over conventional glucagon formulations. Dasiglucagon's effectiveness in treating hypoglycemia in patients was assessed in our study. A meta-analysis was also used to assess dasiglucagon's safety and tolerability in the treatment of hypoglycemia, establishing a scientific basis for the widespread clinical application of dasiglucagon.

METHODS

Search strategy: The search was conducted in PubMed, EMBASE, Cochrane Library, and ClinicalTrials.gov databases (from their inception to May 31, 2022). The following search terms were used: hypoglycemia; severe hypoglycemia; and dasiglucagon. The search was performed by a combination of subject terms and free words, and the search documents were not restricted to any language. The following document types were excluded: letters, abstracts, and conference summaries.

Participant or population: Diabetic patients and healthy subjects.

Intervention: Different doses of dasiglucagon.

Comparator: Placebo.

Study designs to be included: The data in this study were obtained from randomized controlled trials.

Eligibility criteria: The studies selected for inclusion were non-age restricted randomized controlled trials of dasiglucagon for hypoglycemia.

Information sources: The search was conducted in PubMed, EMBASE, Cochrane Library, and ClinicalTrials.gov databases (from their inception to May 31, 2022).

Main outcome(s): The primary outcome was the median time to recovery of plasma glucose (PG) (first PG increase of ≥20 mg/dL from the baseline after treatment initiation).

Additional outcome(s): The number of occurrences in which PG initially increased by ≥20 mg/dL from the baseline within 10, 15, 20, and 30 minutes was one of the secondary outcomes. The median time to reach a PG level of ≥70 mg/dL was another secondary outcome. The aforementioned outcomes were established without the use of intravenous rescue glucose.

Data management: The following data were extracted from the included studies: 1) first author, year of publication, region, type of publication, phase of RCTs, type of intervention, and journal. 2) Dose and type of intervention, number of cases, gender, age, BMI, weight, HbA1, PG, and diabetes duration.

Quality assessment / Risk of bias analysis: Two authors independently evaluated the risk of bias for each included study using the Cochrane Risk of Bias tool[10]. Decisions were made on inconsistencies after a discussion with the third author. The main components were random sequence generation (selection bias), allocation concealment (selection bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias), selective reporting (reporting bias), and other biases.

Strategy of data synthesis: Data were analyzed using the Stata 15.0 software. The relative risk (RR), odds ratio (OR), effect size (ES), and 95% confidence interval (CI) were used as statistics for efficacy

analysis, and differences were considered statistically significant at P ≤ 0.05. Statistical heterogeneity among the included studies was also quantified using the χ2 test at α = 0.10, and I2 was used to quantify the heterogeneity. When P < 0.1 and I2 > 50%, the statistical heterogeneity among the studies was considered high, and combined analysis utilizing the random effects model was performed. When P ≥ 0.1 and I2 ≤ 50%, the statistical heterogeneity among the studies was considered low, and combined analysis utilizing the random effects model was performed.

Subgroup analysis: No subgroup analysis was performed in this study.

Sensitivity analysis: No sensitivity analysis was conducted in this study.

Language restriction: No language limitations.

Country(ies) involved: China.

Keywords: Dasiglucagon; glucagon; hypoglycemia; diabetes; meta-analysis.

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