Efficacy and Safety of Danuglipron and Orforglipron in the Treatment of Type 2 Diabetes: A Meta-Analysis Postprint

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Abstract

Background: Currently, multiple glucagon-like peptide-1 receptor agonists (GLP-1RAs) are used for the treatment of type 2 diabetes mellitus (T2DM); however, most are administered via subcutaneous injection, which reduces patient compliance. Danuglipron and Orforglipron are novel oral small-molecule GLP-1RAs that may become potent options among antihyperglycemic agents in the future.

Objective: To systematically evaluate the efficacy and safety of Danuglipron and Orforglipron in the treatment of type 2 diabetes.

Methods: A computerized search of PubMed, Embase, the Cochrane Library, Web of Science, Chinese Biomedical Literature Database, CNKI, Wanfang Database, and VIP Database was conducted to retrieve randomized controlled trials (RCTs) comparing the efficacy and safety of Danuglipron or Orforglipron (experimental group) versus placebo (control group) for T2DM, with the search period spanning from database inception to May 2024. Literature was screened according to predefined inclusion and exclusion criteria, and the quality of selected studies was assessed. Meta-analysis was performed using RevMan 5.4 software.

Results: Six studies were included. The analysis demonstrated that, in terms of efficacy, compared with the placebo group, the Danuglipron/Orforglipron group exhibited reductions in glycated hemoglobin (HbA1c) levels (MD=-1.04, 95%CI=-1.36~-0.73, P<0.00001), reductions in fasting plasma glucose (FPG) levels (MD=-1.88, 95%CI=-2.53~-1.23, P<0.01), and increases in fasting plasma insulin (FPI) levels (MD=4.68, 95%CI=2.42~6.95, P<0.0001). However, no statistically significant difference was observed in body weight reduction between the two groups (MD=-4.00, 95%CI=-10.14~2.15, P=0.20). Regarding safety, compared with the placebo group, the Danuglipron/Orforglipron

group showed increased incidences of nausea (OR=7.85, 95%CI=4.25~14.50, P<0.01), vomiting (OR=9.45, 95%CI=4.19~21.31, P<0.01), diarrhea (OR=1.96, 95%CI=1.13~3.39, P=0.02), decreased appetite (OR=4.56, 95%CI=1.75~11.91, P<0.01), dyspepsia (OR=3.35, 95%CI=1.54~7.32, P<0.01), belching (OR=4.79, 95%CI=1.13~20.23, P=0.03), constipation (OR=3.45, 95%CI=1.24~9.56, P=0.02), and total gastrointestinal adverse events (OR=5.37, 95%CI=3.32~8.69, P<0.01). No statistically significant differences were found in the incidences of abdominal distension (OR=2.67, 95%CI=0.72~9.86, P=0.14) or headache (OR=0.73, 95%CI=0.37~1.42, P=0.35).

Conclusion: The oral GLP-1RAs Danuglipron and Orforglipron can effectively reduce HbA1c and FPG levels and increase FPI levels, while also increasing the incidences of nausea, vomiting, diarrhea, decreased appetite, dyspepsia, belching, constipation, and total gastrointestinal adverse events, but have no effect on the incidences of abdominal distension or headache.

Full Text

Efficacy and Safety of Danuglipron and Orforglipron in the Treatment of Type 2 Diabetes Mellitus: A Meta-Analysis

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Abstract

Background: Currently, several glucagon-like peptide-1 receptor agonists (GLP-1RAs) are used for the treatment of type 2 diabetes mellitus (T2DM), but most require subcutaneous injection, which reduces patient compliance. Danuglipron and Orforglipron are novel oral small-molecule GLP-1RAs that may become strong contenders among hypoglycemic agents in the future.

Objective: To systematically evaluate the efficacy and safety of Danuglipron and Orforglipron in the treatment of T2DM.

Methods: A computerized search was conducted in PubMed, Embase, the Cochrane Library, Web of Science, SinoMed, CNKI, Wanfang, and VIP databases to collect randomized controlled trials (RCTs) comparing the efficacy and safety of Danuglipron or Orforglipron (experimental group) versus placebo (control group) for T2DM, from database inception to May 2024. Literature was screened according to predefined inclusion and exclusion criteria, and the quality of selected studies was assessed. Data were analyzed using RevMan 5.4 software.

Results: Six studies were included. The analysis showed that compared with the placebo group, the Danuglipron/Orforglipron group demonstrated significant reductions in glycated hemoglobin (HbA1c) levels (MD=-1.04, 95%CI=-1.36~-0.73, P<0.00001) and fasting plasma glucose (FPG) levels (MD=-1.88, 95%CI=-2.53~-1.23, P<0.01), as well as an increase in fasting plasma insulin (FPI) levels (MD=4.68, 95%CI=2.42~6.95, P<0.0001). However, there was no statistically significant difference in weight reduction between the two groups (MD=-4.00, 95%CI=-10.14~2.15, P=0.20). Regarding safety, the Danuglipron/Orforglipron group exhibited higher incidences of nausea (OR=7.85, 95%CI=4.25~14.50, P<0.01), vomiting (OR=9.45, 95%CI=4.19~21.31, P<0.01), diarrhea (OR=1.96, 95%CI=1.13~3.39, P=0.02), decreased appetite (OR=4.56, 95%CI=1.75~11.91, P<0.01), dyspepsia (OR=3.35, 95%CI=1.54~7.32, P<0.01), belching (OR=4.79, 95%CI=1.13~20.23, P=0.03), constipation (OR=3.45, 95%CI=1.24~9.56, P=0.02), and overall gastrointestinal adverse reactions (OR=5.37, 95%CI=3.32~8.69, P<0.01). No statistically significant differences were observed in the incidence of bloating (OR=2.67, 95%CI=0.72~9.86, P=0.14) or headache (OR=0.73, 95%CI=0.37~1.42, P=0.35).

Conclusion: Oral GLP-1RAs Danuglipron and Orforglipron can effectively reduce HbA1c and FPG levels while increasing FPI levels, but they also increase the incidence of nausea, vomiting, diarrhea, decreased appetite, dyspepsia, belching, constipation, and overall gastrointestinal adverse reactions. They have no significant effect on the incidence of bloating or headache.

Keywords: Diabetes mellitus, type 2; Danuglipron; Orforglipron; Evidence-based medicine; Efficacy; Safety; Treatment outcome

Introduction

Glucagon-like peptide-1 receptor agonists (GLP-1RAs) provide a new therapeutic pathway for type 2 diabetes mellitus (T2DM) by activating the glucagon-like peptide-1 receptor (GLP-1R), which stimulates insulin secretion in a glucose-dependent manner and suppresses glucagon secretion, thereby lowering blood glucose levels. Currently, multiple GLP-1RAs have been approved for T2DM treatment, including liraglutide and semaglutide, which demonstrate excellent glycemic efficacy and additionally reduce body weight and blood pressure. However, their subcutaneous injection route reduces patient compliance. In contrast, patients generally prefer and are more likely to adhere to oral regimens. At present, semaglutide is the only oral GLP-1RA approved by the FDA for T2DM treatment, but its administration requires taking the medication at least 30 minutes before the first food, beverage, or other oral medications of the day, with water intake limited to approximately 120 mL, and avoiding food or beverages for at least 30 minutes after dosing to ensure adequate absorption and efficacy. These restrictive intake conditions may reduce patient compliance,

making the search for oral GLP-1RAs with simpler administration requirements an important therapeutic goal.

Danuglipron and Orforglipron are both small-molecule oral formulations of GLP-1RAs currently under development for T2DM treatment. Danuglipron is recommended for twice-daily oral administration, while Orforglipron is recommended for once-daily dosing. Because Orforglipron exhibits stronger effects on cyclic adenosine monophosphate (cAMP) signaling than on β-arrestin recruitment, its risk of receptor desensitization is lower than that of other GLP-1RAs. This meta-analysis examines the efficacy and safety of Danuglipron and Orforglipron in T2DM treatment to provide evidence for their clinical application.

Methods

1.1 Search Strategy

We conducted a computerized search of PubMed, Embase, the Cochrane Library, Web of Science, SinoMed, CNKI, Wanfang, and VIP databases. Chinese search terms included "糖尿病, 2 型" (diabetes mellitus, type 2), "Danuglipron," "Orforglipron," and "随机对照试验" (randomized controlled trial). English search terms included "Diabetes Mellitus, Type 2," "non insulin dependent diabetes mellitus," "Danuglipron," "Orforglipron," and "randomized controlled trial." The search timeframe spanned from database inception to May 2024.

1.2 Inclusion and Exclusion Criteria

Inclusion criteria: (1) Study type: randomized controlled trials (RCTs). (2) Study population: patients with T2DM, with no restrictions on gender, age, nationality, or race, who met the diagnostic criteria for diabetes at the time of the study. (3) Intervention: the experimental group received Danuglipron or Orforglipron treatment, while the control group received placebo or other hypoglycemic drugs, with no restrictions on dosage or treatment duration. (4) Outcome measures: (i) fasting plasma glucose (FPG); (ii) glycated hemoglobin (HbA1c); (iii) body weight; (iv) fasting plasma insulin (FPI); (v) adverse reactions such as gastrointestinal adverse events and headache.

Exclusion criteria: (1) Studies with incomplete data; (2) Case reports, reviews, conference abstracts, meta-analyses, and animal studies; (3) Studies with obvious errors in the original literature or duplicate publications.

1.3 Literature Screening and Data Extraction

Two researchers independently screened the titles, abstracts, and full texts of the retrieved literature, excluded studies according to the inclusion and exclusion criteria, and then cross-checked their selections. Disagreements were resolved through discussion or consultation with a third researcher. After finalizing the included studies, data were extracted, including baseline FPG and HbA1c levels, disease duration, treatment duration, and outcome measures.

1.4 Literature Bias Risk Assessment

The Cochrane Handbook 5.1.0 risk of bias assessment tool for RCTs was used to evaluate bias risk across seven domains: random sequence generation, allocation concealment, implementation bias, measurement bias, follow-up bias, reporting bias, and other sources of bias.

1.5 Statistical Methods

Statistical analysis was performed using RevMan 5.4 software. For continuous variables, mean difference (MD) was used as the effect size, while for dichotomous variables, odds ratio (OR) was used, with corresponding 95% confidence intervals (CI) provided. Heterogeneity among included studies was assessed using the ^{2} test combined with the I^2 statistic. A fixed-effects model was used for meta-analysis if I^2<50%; otherwise, a random-effects model was employed.

Results

2.1 Literature Search Results

The initial search yielded 78 Chinese and English articles. After removing 47 duplicate articles, 31 remained. Following abstract and full-text review, we excluded trial registration records, conference abstracts, reviews, meta-analyses, and studies with non-type 2 diabetic subjects, ultimately including 6 published RCTs. Four studies used Danuglipron as the experimental intervention, while the other two used Orforglipron. The literature screening process is shown in [Figure 1: see original paper], and the baseline characteristics of included studies are presented in .

2.2 Quality Assessment of Included Studies

Among the 6 included RCTs, 3 described the randomization method, while the remaining 3 only mentioned "randomization"without specific details. All studies employed double-blinding, and only 1 study reported using allocation concealment. The risk of selective reporting and other sources of bias was unclear across all 6 studies.

2.3 Outcome Measures

2.3.1 Efficacy Outcomes (1) Change in HbA1c levels: Four studies reported changes in HbA1c levels before and after Danuglipron or Orforglipron treatment compared with placebo. Significant statistical heterogeneity existed among studies (P=0.04, I^2=63%), and a random-effects model was used to pool effect sizes. Results showed that HbA1c levels were lower in the Danuglipron/Orforglipron group than in the placebo group (MD=-1.04, 95%CI=-1.36~-0.73, P<0.01), as shown in [Figure 2: see original paper].

(2) Change in FPG levels: Four studies reported changes in FPG levels before and after Danuglipron or Orforglipron treatment compared with placebo. Significant statistical heterogeneity was observed among studies (P=0.04, I^2=65%), and a random-effects model was used. Results demonstrated that FPG levels were lower in the Danuglipron/Orforglipron group than in the placebo group (MD=-1.88, 95%CI=-2.53~-1.23, P<0.01), as shown in [Figure 3: see original paper].

(3) Change in body weight: Four studies reported changes in body weight before and after Danuglipron or Orforglipron treatment compared with placebo. Significant statistical heterogeneity existed among studies (P<0.01, I^2=98%), and a random-effects model was applied. Results indicated no statistically significant difference in weight reduction between the Danuglipron/Orforglipron group and the placebo group (MD=-4.00, 95%CI=-10.14~2.15, P=0.20), as shown in [Figure 4: see original paper].

(4) Change in FPI levels: Two studies reported changes in FPI levels before and after Danuglipron or Orforglipron treatment compared with placebo. Minimal statistical heterogeneity was observed among studies (P=0.48, I^2=0%), and a fixed-effects model was used. Results showed that FPI levels were higher in the Danuglipron/Orforglipron group than in the placebo group (MD=4.68, 95%CI=2.42~6.95, P<0.01), as shown in [Figure 5: see original paper].

2.3.2 Safety Outcomes (1) Overall incidence of gastrointestinal adverse reactions: Four studies reported the overall incidence of gastrointestinal adverse reactions in the Danuglipron/Orforglipron group compared with the placebo group. Minimal statistical heterogeneity was observed (P=0.35, I^2=8%), and a fixed-effects model was used. Results showed that the overall incidence of gastrointestinal adverse reactions was higher in the Danuglipron/Orforglipron group than in the placebo group (OR=5.37, 95%CI=3.32~8.69, P<0.01).

(2) Incidence of nausea: All six studies reported the incidence of nausea in the Danuglipron/Orforglipron group compared with the placebo group. Minimal statistical heterogeneity existed (P=0.74, I^2=0%), and a fixed-effects model was applied. Results demonstrated that the incidence of nausea was higher in the Danuglipron/Orforglipron group (OR=7.85, 95%CI=4.25~14.50, P<0.01).

(3) Incidence of vomiting: All six studies reported the incidence of vomiting. Minimal statistical heterogeneity was observed (P=0.52, I^2=0%), and a fixed-effects model was used. Results showed that the incidence of vomiting was higher in the Danuglipron/Orforglipron group (OR=9.45, 95%CI=4.19~21.31, P<0.01).

(4) Incidence of diarrhea: All six studies reported the incidence of diarrhea. Minimal statistical heterogeneity existed (P=0.38, I^2=5%), and a fixed-effects model was applied. Results indicated that the incidence of diarrhea was higher in the Danuglipron/Orforglipron group (OR=1.96, 95%CI=1.13~3.39, P=0.02).

(5) Incidence of decreased appetite: Five studies reported the incidence of decreased appetite. Minimal statistical heterogeneity was observed (P=0.84, I^2=0%), and a fixed-effects model was used. Results showed that the incidence of decreased appetite was higher in the Danuglipron/Orforglipron group (OR=4.56, 95%CI=1.75~11.91, P<0.01).

(6) Incidence of dyspepsia: Five studies reported the incidence of dyspepsia. Minimal statistical heterogeneity existed (P=0.95, I^2=0%), and a fixed-effects model was applied. Results demonstrated that the incidence of dyspepsia was higher in the Danuglipron/Orforglipron group (OR=3.35, 95%CI=1.54~7.32, P<0.01).

(7) Incidence of belching: Four studies reported the incidence of belching. Minimal statistical heterogeneity was observed (P=0.79, I^2=0%), and a fixed-effects model was used. Results showed that the incidence of belching was higher in the Danuglipron/Orforglipron group (OR=4.79, 95%CI=1.13~20.23, P=0.03).

(8) Incidence of bloating: Four studies reported the incidence of bloating. Minimal statistical heterogeneity existed (P=0.88, I^2=0%), and a fixed-effects model was applied. Results indicated no statistically significant difference in bloating incidence between the Danuglipron/Orforglipron group and the placebo group (OR=2.67, 95%CI=0.72~9.86, P=0.14).

(9) Incidence of constipation: Three studies reported the incidence of constipation. Minimal statistical heterogeneity was observed (P=0.60, I^2=0%), and a fixed-effects model was used. Results showed that the incidence of constipation was higher in the Danuglipron/Orforglipron group (OR=3.45, 95%CI=1.24~9.56, P=0.02).

(10) Incidence of headache: Four studies reported the incidence of headache. Minimal statistical heterogeneity existed (P=0.91, I^2=0%), and a fixed-effects model was applied. Results indicated no statistically significant difference in headache incidence between the Danuglipron/Orforglipron group and the placebo group (OR=0.73, 95%CI=0.37~1.42, P=0.35).

Discussion

In recent years, GLP-1R has become an important therapeutic target for T2DM. Although injectable GLP-1RAs have proven effective in reducing blood glucose, their administration route limits patient compliance. Poor bioavailability of oral peptide drugs represents a major application barrier due to hydrolysis by digestive enzymes in the gastrointestinal tract and low permeability of intestinal epithelial cells. Current incretin therapies are limited to injectable formulations or oral peptide preparations containing absorption enhancers that require fasting before administration. Danuglipron and Orforglipron are non-peptide GLP-1RAs, which confer higher bioavailability and eliminate the need for water and food restrictions. Research indicates that renal impairment has no

clinically meaningful impact on the pharmacokinetics, safety, or tolerability of Danuglipron, suggesting that dose adjustment is unnecessary when treating T2DM patients with renal dysfunction. Therefore, Danuglipron and Orforglipron may become powerful options for hypoglycemic therapy in the future.

This meta-analysis included 6 RCTs of relatively high quality with reliable results, though certain limitations exist: (1) Both Danuglipron and Orforglipron remain in clinical trial phases, with some trials still ongoing, resulting in a small number of included studies. Larger clinical studies are needed to obtain more rigorous data. (2) Study subjects had different baseline characteristics, treatment durations varied, and drug dosages differed across experimental groups.

Regarding efficacy, compared with placebo, the Danuglipron/Orforglipron group effectively reduced HbA1c and FPG levels and increased FPI levels, but showed no significant difference in weight reduction. This may be related to the inclusion of certain dose groups in the pooled experimental arms that showed no weight difference compared with placebo, such as the Danuglipron 80 mg twice-daily HS regimen in a phase 2a study. Additionally, Danuglipron' s phase 2b trial results showed that only 80 mg or 120 mg doses produced weight reduction compared with placebo, while lower doses ($ $40 mg twice daily) showed no significant difference. Furthermore, some patients in both experimental and control groups continued metformin therapy before the study, which may have affected weight assessment.

In terms of safety, the Danuglipron/Orforglipron group exhibited higher adverse reaction rates than the placebo group, primarily including gastrointestinal adverse reactions such as nausea, vomiting, diarrhea, decreased appetite, dyspepsia, belching, and constipation, with no significant differences in bloating or headache incidence. Danuglipron' s gastrointestinal side effects may be target-related, and the carboxylic acid group in the drug may also influence these outcomes by affecting pharmacokinetic properties, dosing regimens, and directly exerting gastrointestinal stimulation. In Danuglipron-treated participants, gastrointestinal adverse events were associated with target doses (80-200 mg), while starting doses (5 mg vs. 10 mg) had no significant impact on nausea, vomiting, or diarrhea. In Orforglipron-treated participants, most gastrointestinal adverse events occurred during the first week of dosing (3 mg), suggesting that starting dose, as well as the frequency and magnitude of dose escalation, are associated with gastrointestinal adverse events.

The incidence of Danuglipron adverse reactions is dose-related. Although phase 1 trial results showed that Danuglipron' s gastrointestinal adverse event rates did not appear to increase in a dose-dependent manner, another phase 1 trial found that the lowest adverse event rates occurred in the low-dose 10 mg and 15 mg groups, while the high-dose 120 mg group reached 100% incidence, with gastrointestinal adverse event rates increasing with Danuglipron dosage. Moreover, Danuglipron' s phase 2 study also demonstrated that discontinuation rates and adverse event incidence increased correspondingly as target doses escalated from 80 mg twice daily to 200 mg twice daily. On the other hand, Danuglipron'

s efficacy is also dose-related. Compared with placebo, a larger proportion of Danuglipron-treated subjects achieved HbA1c below 7%, and this proportion generally increased with Danuglipron dose.

Orforglipron' s pharmacokinetic characteristics are dose-dependent, and most of its adverse reactions are also associated with dose escalation, being more pronounced in rapid dose-escalation groups. However, in Orforglipron's phase 1b trial, no obvious dose-dependent effect was observed, possibly due to limitations of small sample size and short steady-state exposure time.

In summary, Danuglipron and Orforglipron demonstrate favorable clinical efficacy in T2DM treatment, effectively reducing HbA1c and FPG levels. Their oral administration route offers promising clinical application prospects. Future research should include more studies to validate the efficacy of Danuglipron and Orforglipron and provide stronger evidence for their clinical application.

Author Contributions: MA Panpan was responsible for conceptualization and manuscript writing; WANG Sijing conducted literature retrieval and screening; YOU Na and DING Dafa revised the manuscript; LU Yibing was responsible for quality control and review.

Conflict of Interest: The authors declare no conflict of interest.

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Note: Figure translations are in progress. See original paper for figures.