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SYSTEMATIC REVIEW

Efficacy of Dapagliflozin in the Treatment of Type 2 Diabetes Mellitus Complicated by Coronary Heart Disease: A Meta-Analysis

Wenchao Ma[1], Kun Wang[2], Leina Sun[1], Fangcheng Su[1,*]

[1]Department of Emergency, Weifang People's Hospital, Weifang, Shandong, China
[2]Department of Respiratory and Critical Care Medicine, Weifang People's Hospital, Weifang, Shandong, China
*Correspondence: doctor7998@sina.com (Fangcheng Su)

Abstract

Aims/Background Dapagliflozin is a sodium-glucose cotransporter inhibitor that functions to lower blood sugar by promoting glucose excretion. We conducted a meta-analysis to assess the therapeutic efficacy of dapagliflozin in patients with type 2 diabetes mellitus complicated by coronary heart disease. The objective of this analysis is to provide additional clarity on dapagliflozin's effectiveness in this specific patient population.

Methods A systematic review of the literature was performed by searching China National Knowledge Infrastructure (CNKI), Wanfang, Wip Chinese Science, Technology Journals, China Biomedicine, Pubmed, Web of Science, and Cochrane Library. Related literature regarding the effectiveness of dapagliflozin, published since the inception of databases until October 2023, was searched and selected. Subsequent to the screening process, the Jadad scale was used to assess the quality of the gathered literature. The NoteExpress3.2 software (Beijing Aegean Music Technology Co., Ltd., Beijing, China) was utilized to manage the literature. Statistical analysis was conducted using RevMan5.4.1 software (The Cochrane Collaboration, London, UK). The *p*-value of the Q test determined the heterogeneity of the studies, guiding the choice between fixed or random effect models for establishing the combined effect. Forest plots were used to visualize dapagliflozin's efficacy in treating patients with type 2 diabetes mellitus and coronary heart disease. A funnel plot was plotted to assess potential publication bias.

Results Twenty-three studies were eligible for inclusion in this meta-analysis. The results revealed that dapagliflozin has better clinical efficacy (odds ratio [OR] = 3.88, 95% confidence interval [CI] 2.59 to 5.82), left ventricular ejection fraction (LVEF) (OR = 5.43, 95% CI 4.02 to 6.84). The values of left ventricular end-diastolic diameter (LVEDD) and N-terminal pro-brain natriuretic peptide (NT-proBNP) were lower in the experimental group (OR: –4.03 and –84.65, 95% CI –5.08 to –2.98 and –127.05 to –42.25, respectively). In addition, further analysis showed that the experimental group experienced a lower incidence of adverse reactions (OR = 0.30, 95% CI 0.16 to 0.57).

Conclusion Dapagliflozin is more effective in controlling type 2 diabetes mellitus complicated by coronary heart disease.

Key words: dapagliflozin; type 2 diabetes mellitus; coronary heart disease; meta-analysis

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Introduction

Cardiovascular disease poses a significant risk to individuals with type 2 diabetes (Li, 2020; Liu et al, 2021). Moreover, approximately 25% of individuals with

diabetes develop complications related to heart failure. Furthermore, diabetic patients with coronary heart disease exhibit poorer treatment outcomes and prognosis compared to those without diabetes.

Dapagliflozin is a sodium-glucose cotransporter 2 (SGLT2) inhibitor for diabetes treatment, whose primary function is to obstruct the reabsorption of glucose in the proximal glomerular tubule, leading to increased urinary glucose excretion and a decreased blood glucose level (Guo and Sun, 2023; Kong, 2017). Dapagliflozin is reportedly a remarkably safe and tolerable medication for its users. Besides reducing the risk of hypoglycemia, it also mitigates the likelihood of hypotension, slows down the progression of heart failure and kidney disease, enhances glomerular filtration, and diminishes urinary protein excretion (Mosenzon et al, 2019). Dapagliflozin has been demonstrated to favourably improve heart function without eliciting many adverse effects in patients with type 2 diabetes mellitus (Cao et al, 2021; Xiao et al, 2021; Zhao, 2022). Nonetheless, since these studies employed rather small-size samples, the findings concerning the effectiveness and safety of dapagliflozin, as well as the incidence of associated adverse reactions, remain contentious, necessitating further extensive clinical investigations for confirmation.

To address the limitations in the previous studies, we conducted a meta-analysis to assess the therapeutic efficacy of dapagliflozin in patients with type 2 diabetes mellitus complicated by coronary heart disease. The objective of this analysis is to provide additional clarity on dapagliflozin's effectiveness in this specific patient population.

Methods

Material Sources and Retrieval Strategies

The databases utilized in this study include China National Knowledge Infrastructure (CNKI), Wanfang Database, WeiPu Chinese Journal Database (VIP), PubMed, and Cochane Library, among others. The search period spanned from the inception date of each database up until October 2023. The Chinese search terms employed were "Daglejing", "type 2 diabetes", and "coronary heart disease". These keywords were combined using the logical operator "AND", and the search was expanded through the inclusion of keyword synonyms. Meanwhile, "dapagliflozin", "type 2 diabetes", and "coronary heart disease" were used as English search terms. For keywords in English, the search was conducted using: Dapagliflozin [Mesh] or Type 2 Diabetes [Mesh] or coronary heart disease. Subject terms and free terms were also included in the literature search.

Criteria for Inclusion and Exclusion of Documents

The criteria defined for including the suitable studies are as follows:

(1) Subjects were required to meet the 1979 diagnostic criteria for coronary heart disease established by the World Health Organization, as well as the 2012 diagnostic criteria for type 2 diabetes set by the International Diabetes Federation. Furthermore, they had to willingly participate in the study and be in a good state of consciousness.

(2) The experimental group received routine treatment in combination with dapagliflozin, while the control group received conventional therapy along with either nitrates (nitroglycerin, isosorbide mononitrate, isosorbide dinitrate) or placebo.

(3) The primary outcome measure was the clinical effectiveness of the treatment, which was categorized as significantly effective, effective, or ineffective, based on electrocardiographic examination and improvement or disappearance of symptoms such as chest pain, chest tightness, and palpitation. The secondary outcome measures included cardiac ultrasound indicators like left ventricular ejection fraction (LVEF), left ventricular end-diastolic diameter (LVEDD), and N-terminal pro-brain natriuretic peptide (NT-proBNP).

Further inclusion and exclusion criteria for this analysis are as follows:

(1) any duplicate or irrelevant studies were excluded;

(2) only randomized controlled trials were included;

(3) studies with unclear, incomplete, or incorrect data descriptions were not considered;

(4) only studies with full-text availability were included;

(5) literature not written in either Chinese or English was excluded.

Literature Screening and Data Extraction

Two researchers conducted a thorough review of the gathered literature. Data were extracted based on a pre-established literature feature table, which included information such as the first author, publication date, research design, sample size and so on. This manuscript was prepared in accordance with the PRISMA guidelines (see **Supplementary material**).

Document Quality Evaluation

Two researchers independently rated the quality of evidence according to the assessment of the literature using the Jadad scale, which assigns a total score of 5. Criteria for evaluation include randomization, blinding, handling of withdrawal and loss of follow-up. Any literature scoring below 3 points was considered to be of low quality.

Statistical Analysis

Data extracted from the articles were processed in an Excel spreadsheet, and the NoteExpress3.2 software (Beijing Aegean Music Technology Co., Ltd., Beijing, China) was utilized for literature management, Excel 2003 software (Microsoft Corporation, Redmond, WA, USA) was used in data collection and extraction. For the meta-analysis, we employed Revman5.4.1 software (The Cochrane Collaboration, London, UK). The Q test was employed to assess the heterogeneity of the extracted data, which was evaluated using the I^2 value. A p-value of greater than 0.10 or an I^2 value of lower than or equal to 50% indicates low heterogeneity, which suggests the feasibility of using a fixed-effect model (FEM). Conversely, if $I^2 \geq 50\%$ and $p < 0.1$, the source of heterogeneity needs to be further determined, and after excluding the obvious clinical heteroplasmic impact, the random-effects model (REM) can be used for analysis. The data in this paper are expressed as odds ratio (OR) with its

Table 1. Basic characteristics and quality evaluation table of documents.

First author	Number of cases (experimental group/control group)	Age (experimental group/control group)	Treatment scheme	Follow-up duration	Outcome index	JADAD score
(Zhao, 2022)	20/20	67.0 ± 2.3/66.5 ± 2.2	Experimental group: dapagliflozin; Control group: routine treatment	/	Blood glucose index, clinical effect	4
(Cao et al, 2021)	40/40	65 ± 10/65 ± 11	Experimental group: dapagliflozin; Control group: metformin	/	FBG, hs-CRP, HbAlC, CK-MB, Myo, cTnI, NT-proBNP, D-dimer, incidence of adverse events	3
(Xiao et al, 2021)	30/30	69.70 ± 8.30/68.10 ± 9.90	Experimental group: dapagliflozin; Control group: routine treatment	24 weeks	Blood pressure, blood glucose, blood lipids, vascular endothelial function, occurrence of adverse events	4
(Zeng et al, 2021a)	38/38	55.12 ± 2.30/54.76 ± 2.57	Experimental group: dapagliflozin; Control group: metformin	/	Clinical efficacy, fasting blood glucose, Hcy, CRP	4
(Zeng et al, 2021b)	31/31	63.62 ± 1.62/63.61 ± 1.65	Experimental group: dapagliflozin; Control group, metformin	3 courses of treatment	Indicators of inflammation, blood lipids and cardiac function	3
(Du, 2021)	104/104	69.43 ± 5.87/68.97 ± 6.14	Experimental group: dapagliflozin; Control group: routine treatment, such as metformin	/	Blood glucose, blood pressure, blood lipids, clinical efficacy	3
(Tohoti and Qadir, 2022)	40/40	68.72 ± 4.91/68.78 ± 4.87	Experimental group: dapagliflozin; Control group: routine treatment, such as metformin	/	Blood glucose, blood lipids, clinical efficacy	3
(Fan and Zhu, 2022)	40/40	68.72 ± 4.91/68.78 ± 4.87	Experimental group: dapagliflozin; Control group: routine treatment, such as metformin	/	Blood glucose, blood lipids, clinical efficacy	4
(Guan, 2021)	40/37	60.93 ± 7.13/61.62 ± 7.48	Experimental group: dapagliflozin; Control group: routine treatment	/	Blood glucose, blood lipids, cardiac ultrasound indexes, etc.	4

Table 1. Continued.

First author	Number of cases (experimental group/control group)	Age (experimental group/control group)	Treatment scheme	Follow-up duration	Outcome index	JADAD score
(Huang, 2021)	80/80	70.56 ± 1.23/70.56 ± 1.23	Experimental group: dapagliflozin; Control group: routine treatment	/	Clinical efficacy, blood glucose	4
(Lai, 2023)	30/30	60.5 ± 6.8/60.7 ± 6.7	Experimental group: dapagliflozin; Control group: routine treatment	/	Blood glucose, cardiac function, left ventricular remodelling index	4
(Li, 2023)	59/59	63.21 ± 10.02/61.05 ± 9.57	Experimental group: dagrezin; Control group: routine treatment	/	Myocardial enzymes, blood cells, BNP, occurrence of adverse events	3
(Liang and Lin, 2022)	30/30	61.82 ± 5.47/61.799 ± 5.42	Experimental group: dapagliflozin; Control group: acarbose	/	Clinical efficacy, blood glucose, inflammatory indicators, occurrence of adverse events	4
(Lu, 2021)	50/48	63 ± 8/64 ± 8	Experimental group: dapagliflozin; Control group: viglitine	Within 6 months	Cardiac metabolic index and occurrence of adverse events	3
(Luo, 2022)	45/45	65.11 ± 3.98/65.23 ± 3.45	Experimental group: dapagliflozin; Control group: metformin	/	Blood glucose, myocardial injury marker, inflammation index	3
(Lin and Zheng, 2022)	30/30	64.69 ± 6.81/63.25 ± 6.84	Experimental group: dapagliflozin; Control group: metformin	/	Blood glucose, cardiac function index, serological index	3
(Sun and Sun, 2023)	50/50	64.52 ± 2.61/63.10 ± 3.69	Experimental group: dapagliflozin; Control group: metformin	/	Blood glucose, cardiac function index, and adverse cardiovascular events	4
(Sun, 2021)	51/51	42.64 ± 2.63/42.13 ± 2.09	Experimental group: dapagliflozin; Control group: oral non-SGLT2 therapy	Within 24 weeks	Blood pressure, blood glucose, endothelial function, and incidence of adverse events	3
(Wang, 2022b)	50/50	51.26 ± 5.39/52.15 ± 4.31	Experimental group: dapagliflozin; Control group: veglitine	/	Clinical efficacy, blood glucose, blood lipids, serum content	3
(Wang et al, 2022a)	84/84	68.37 ± 5.37/69.21 ± 5.46	Experiment group: dagulitazine; Control group: veglitine	/	Clinical efficacy, blood glucose, cardiac function, incidence of adverse reactions	3

Table 1. Continued.

First author	Number of cases (experimental group/control group)	Age (experimental group/control group)	Treatment scheme	Follow-up duration	Outcome index	JADAD score
(Yang and Zhang, 2022)	40/40	69.2 ± 2.5/69.1 ± 2.4	Experimental group: dapagliflozin; Control group: routine treatment	/	Blood glucose, metabolic indicators, total effective rate, blood lipids, incidence of cardiovascular events during treatment	3
(Yuan and Wang, 2023)	50/50	42.85 ± 8.17/62.58 ± 4.56	Experimental group: dapagliflozin; Control group: routine treatment	/	Inflammation index, cardiac function, blood glucose, incidence of adverse events	3
(Zhang et al, 2023)	51/51	68.4 ± 4.1/57.2 ± 5.5	Experimental group: dagulitazine; Control group: viglitine	/	VEGF, ET-1, NO, blood glucose, LVEF	4

Abbreviations: FBG, fasting blood glucose; hs-CRP, high sensitivity C-reaction protein; HbAlC, Hemoglobin A1c; CK-MB, creatine kinase-MB; cTnI, Cardiac troponin I; NT-proBNP, N-terminal pro-brain natriuretic peptide; SGLT2, sodium-glucose cotransporter 2; VEGF, vascular endothelial growth factor; ET-1, endothelin-1; NO, nitrogen monoxide; LVEF, left ventricular ejection fraction.

95% confidence interval (CI), and the results are illustrated using forest plots. To evaluate the robustness of the meta-analysis results, the Egger test was used to explore the source of heterogeneity, and publication bias was assessed using a funnel plot. A $p < 0.05$ (two-tailed) was considered statistically significant.

Results

Literature Retrieval

Literature was searched from China National Knowledge Infrastructure (CNKI), Wanfang Database, WeiPu Chinese Journal Database (VIP), PubMed, Cochane Library, among others. A total of 217 pieces of relevant literature were acquired from the database search. Subsequently, duplicate items obtained were eliminated. After examining the title, abstract, and full text, 23 articles were ultimately selected for inclusion (Cao et al, 2021; Du, 2021; Fan and Zhu, 2022; Guan, 2021; Huang, 2021; Lai, 2023; Li, 2023; Liang and Lin, 2022; Lin and Zheng, 2022; Lu, 2021; Luo, 2022; Tohoti and Qadir, 2022; Sun, 2021; Sun and Sun, 2023; Wang et al, 2022a; Wang, 2022b; Xiao et al, 2021; Yang and Zhang, 2022; Yuan and Wang, 2023; Zeng et al, 2021a; Zeng et al, 2021b; Zhang et al, 2023; Zhao, 2022). The process of literature screening and inclusion is illustrated in Fig. 1.

Baseline Characteristics and Quality Evaluation of Literature

Baseline information such as gender, age, disease progression, treatment strategy, outcome measures, and other relevant factors were collected. Each of the 24 articles included in this meta-analysis has a Jadad score ≥ 3, and the comprehensive descriptions of these articles are summarized in Table 1.

Meta-Analysis

Meta-Analysis of the Efficacy of Dapagliflozin

Eleven studies offer comparisons of therapeutic outcomes between the experimental group utilizing dapagliflozin and the control group using a standard treatment. There was no significant heterogeneity across these studies (Q test's $p > 0.10$). The meta-analysis adopted FEM to amalgamate the data from various literature sources. The experimental group demonstrated superior therapeutic efficacy of dapagliflozin (OR = 3.88, 95% CI 2.59 to 5.82, $p < 0.00001$) (Fig. 2).

Meta-Analysis of Cardiac Function-Related Indexes

Nine studies from the gathered literature present comparisons of the LVEF between the experimental and control groups. Significant heterogeneity was observed across these studies, as indicated by the Q test ($p < 0.10$). By employing the REM to synthesize the data from these studies, it was determined that the LVEF in the experimental group demonstrated a significant increase relative to the control group (OR = 5.43, 95% CI 4.02 to 6.84, $p < 0.00001$) (Fig. 3).

Three studies compared the left ventricular end-diastolic diameter (LVEDD), an important metric for assessing cardiac function, between the experimental group and the control group. No significant heterogeneity was found between the three studies ($p > 0.10$ according to the Q-test). To integrate the literature data, FEM was

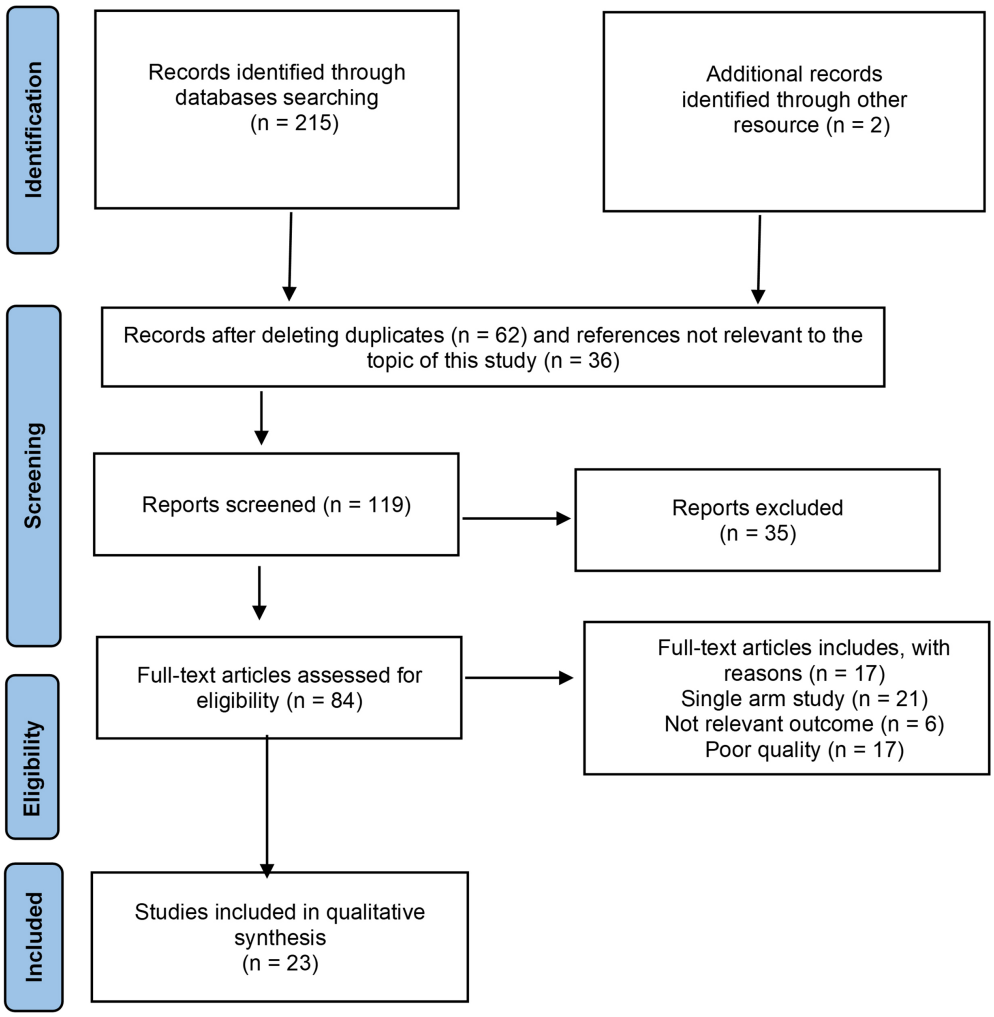

Fig. 1. Flowchart depicting the process of literature screening and inclusion.

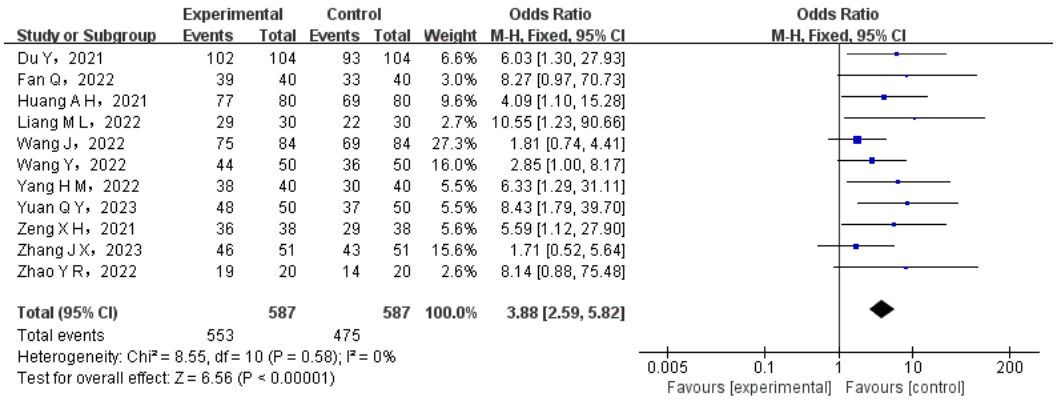

Fig. 2. Comparison of clinical efficacy between the experimental and control groups. A fixed-effect model was used to amalgamate the data from various literature sources. The experimental group demonstrated superior therapeutic efficacy of dapagliflozin. CI, confidence interval.

employed. Our analysis revealed a statistically significant difference in LVEDD between the two groups, with the experimental group displaying a smaller LVEDD (OR = –4.03, 95% CI –5.08 to –2.98), $p < 0.00001$ (Fig. 4).

In the present meta-analysis, we compared the levels of NT-proBNP, an indicator of cardiac function, using relevant data derived from five gathered studies. These included studies exhibited significant heterogeneity (Q test's $p < 0.10$). To consolidate the literature data, an REM was utilized. The findings revealed that the experimental group had significantly lower NT-proBNP levels, compared to the control group (OR = –84.65, 95% CI –127.05 to –42.25, $p < 0.0001$) (Fig. 5).

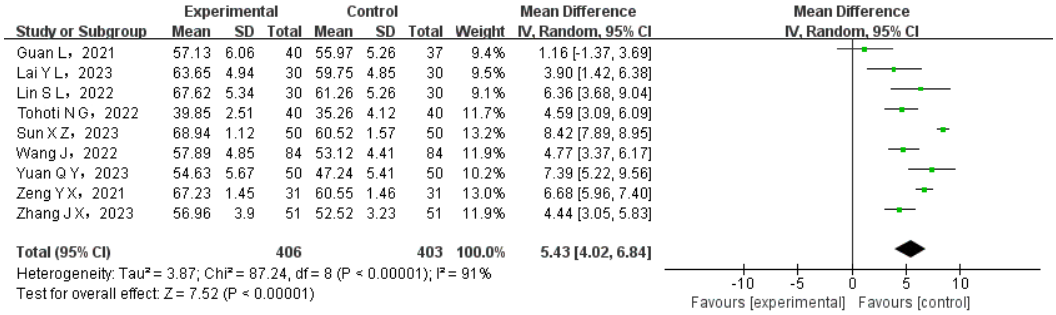

Fig. 3. Comparison of left ventricular ejection fraction (LVEF), a cardiac function-related index, between the experimental and control groups. A random-effects model was used to synthesize the data from the selected studies. Based on the analysis, the LVEF in the experimental group demonstrated a statistically significant increase, relative to the control group.

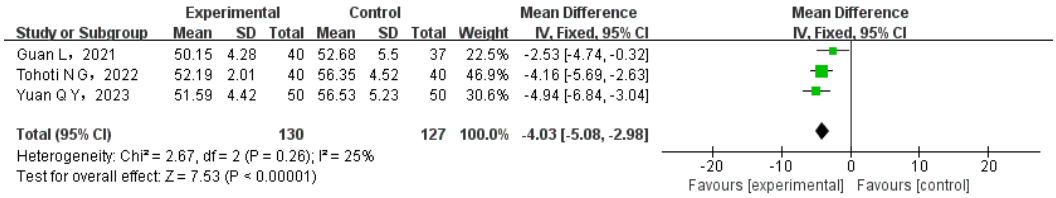

Fig. 4. Comparison of left ventricular end-diastolic diameter (LVEDD), a cardiac function-related index, between the experimental and control groups. A fixed-effect model was employed to integrate the literature data. The analysis revealed a statistically significant difference in LVEDD between the two groups, with the experimental group displaying a smaller LVEDD.

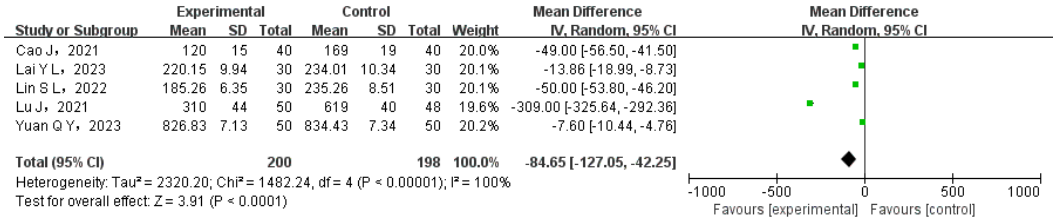

Fig. 5. Comparison of NT-proBNP, a cardiac function-related index, between the experimental and control groups. A random-effects model was utilized to consolidate the literature data. The analysis revealed that the experimental group had lower NT-proBNP levels.

Adverse Reactions

A total of five studies reporting the incidence of adverse reactions during the post-treatment follow-up period in both the experimental and control groups were selected and analyzed. Statistical analysis revealed no significant heterogeneity among these studies ($p > 0.10$, as indicated by the Q test). To consolidate the literature data, a FEM was employed. A significantly lower incidence of adverse reactions was observed in the experimental group than in the control group (OR = 0.30, 95% CI 0.16 to 0.57, p =0.0002) (Fig. 6).

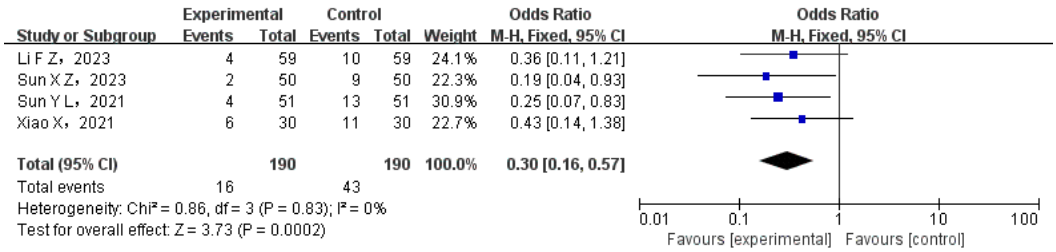

Fig. 6. Comparison of adverse reaction events between the experimental and control groups. A fixed-effect model was utilized to consolidate the literature data. The analysis showed that a lower proportion of adverse reaction events were observed in the experimental group, compared to the control group.

Sensitivity Analysis and Literature Bias Test

Upon excluding the irrelevant and/or inappropriate studies, this meta-analysis considered only the remaining literature regarding the efficacy of dapagliflozin in managing type 2 diabetes mellitus complicated by coronary heart disease. The sensitivity analysis reveals an OR (95% CI) of 4.66 (2.93 to 7.40), with a p-value of less than 0.0001, indicating the reliability of the study results. It should be noted that all outcome indicators examined in this analysis exhibited some biases. Notably, the funnel plot displays an asymmetrical pattern, suggesting the presence of publication bias (Fig. 7).

Discussion

A tremendous improvement in the standard of living has led to a noticeable shift in social lifestyle, which is the underlying factor of the increasing prevalence of diabetes. Generally, type 2 diabetic patients face the infliction of a range of complications. Among these, the cardio-cerebrovascular complication is a leading cause of death in individuals with type 2 diabetes (Zhang et al, 2018). Additionally, patients with type 2 diabetes mellitus who also have coronary heart disease often fall victim to severe coronary artery lesions that affect multiple vessels (Xu et al, 2013). Consequently, it is imperative to investigate the effectiveness of medications to manage type 2 diabetes mellitus complicated by coronary heart disease, so as to prevent disease progression.

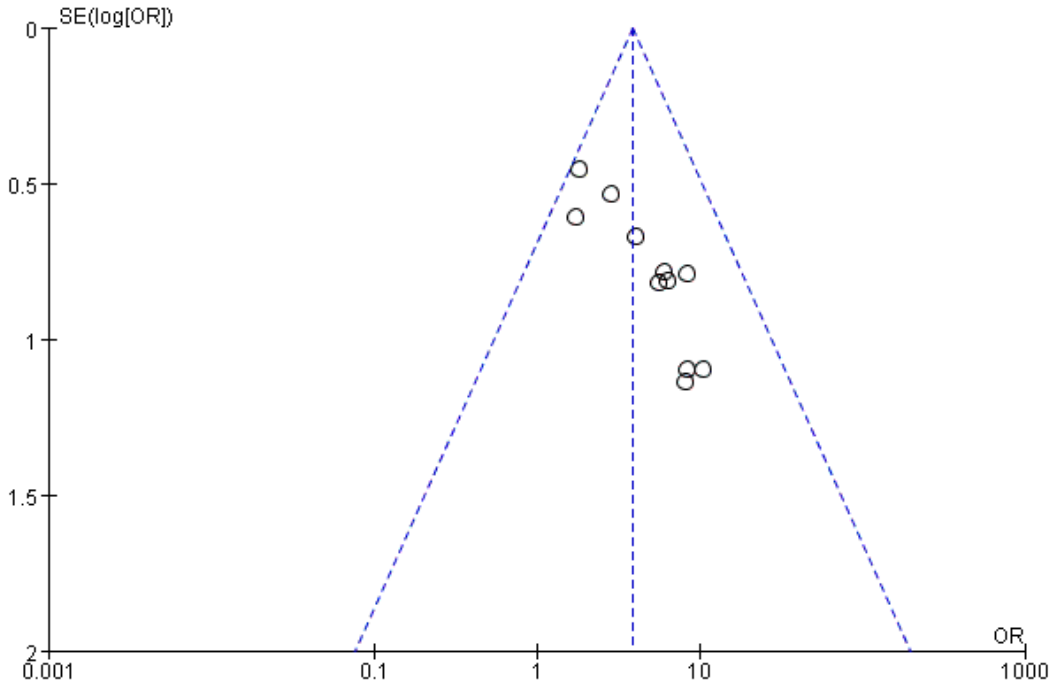

Fig. 7. Funnel plot of the clinical efficacy of dapagliflozin in managing type 2 diabetes mellitus complicated by coronary heart disease. The asymmetrical pattern in the plot indicated the presence of publication bias. SE, standard error; OR, odds ratio.

In this study, meta-analysis was used to quantitatively analyze the efficacy of dapagliflozin in the treatment of patients with type 2 diabetes mellitus complicated by coronary heart disease. According to clinical trials, the functions of dapagliflozin extend beyond lowering blood glucose and delaying renal disease progression. It has also been observed to effectively mitigate cardiovascular and cerebrovascular risks (Zinman et al, 2015), potentially through hyperosmotic diuresis. Dapagliflozin also boasts the potential to reduce blood pressure, alleviate cardiac burden, promote weight loss, and mitigate ventricular remodelling (Brown et al, 2017; Lytvyn et al, 2017). Notably, studies conducted by Sun and Sun (2023) and Wang et al (2022a) indicate that dapagliflozin outperforms other SGLT2 inhibitors in terms of cardiac function improvement.

The results showed that the utilization of dapagliflozin is associated with better therapeutic efficacy and higher LVEF, but lower LVEDD and NT-proBNP levels. In addition, the experimental group experienced a lower rate of adverse reaction events during the post-treatment follow-up period, consistent with the findings from Zhao (2022) and Cao et al (2021). Sensitivity analysis indicates that the results obtained in this meta-analysis regarding the clinical efficacy of dapagliflozin in managing type 2 diabetes mellitus complicated by coronary heart disease are reliable.

Several limitations of this study need to be highlighted. First, the findings of this meta-analysis could be biased as a result of the authors' tendency to exclusively publish positive outcomes. Thus, this accounts for the scarcity of literature focusing on the negative findings. A lack of literature on negative findings included in this meta-analysis is also a representation of selection bias. Apart from that, the

utilization of only Chinese and English databases for literature retrieval may introduce sampling bias, which may stem from the biased selection of literature from each database.

Conclusion

Compared to routine treatments, dapagliflozin is a safer option for treating type 2 diabetes mellitus complicated by coronary heart disease, showcasing enhanced therapeutic efficacy by improving cardiac function. Nevertheless, future investigations should focus on conducting multi-center case-control studies involving large, homogeneous samples.

Key Points

- Dapagliflozin is therapeutically more effective than routine treatment in managing type 2 diabetes mellitus complicated by coronary heart disease, and can significantly improve cardiac function.
- Compared to routine treatment, dapagliflozin offers a safer option for treating patients with type 2 diabetes mellitus complicated by coronary heart disease.
- For efficacy and safety purposes, it is recommended to apply dapagliflozin to manage type 2 diabetic patients with cardiac conditions.

Availability of Data and Materials

The datasets used and/or analyzed during the current study were available from the corresponding author on reasonable request.

Author Contributions

WCM designed the study. WCM, LNS, FCS and KW conducted the study. LNS and FCS collected and analyzed the data. WCM and KW participated in drafting the manuscript, and all authors contributed to critical revision of the manuscript for important intellectual content. All authors gave final approval of the version to be published. All authors participated fully in the work, took public responsibility for appropriate portions of the content, and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or completeness of any part of the work are appropriately investigated and resolved.

Ethics Approval and Consent to Participate

Not applicable.

Acknowledgement

Not applicable.

Funding

This research received no external funding.

Conflict of Interest

The authors declare no conflict of interest.

Supplementary Material

Supplementary material associated with this article can be found, in the online version, at https://www.magonlinelibrary.com/doi/suppl/10.12968/hmed.2024.0336.

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