INPLASY PROTOCOL

To cite: Wang et al. Effificacy and safety of Dapagliflozin as monotherapy for coronary heart disease: A protocol for systematic review and meta-analysis. Inplasy protocol 202240062. doi: 10.37766/inplasy2022.4.0062

Received: 11 April 2022

Published: 11 April 2022

Corresponding author:
Guijun Shi

zsmsgj@163.com

Author Affiliation:
Changchun University of Chinese Medicine.

Support: **Technology Project of Jilin.**

Review Stage at time of this submission: **The review has not yet started.**

Conflicts of interest:
None declared.

Effificacy and safety of Dapagliflozin as monotherapy for coronary heart disease: A protocol for systematic review and meta-analysis

Wang, M[1]; Che, S[2]; Pan, W[3]; Zhang, S[4]; Shi, G[5].

Review question / Objective: **The aim of this meta-analysis of randomized controlled trials is to evaluate the efficacy and safety of Dapagliflozin as monotherapy in the treatment of coronary heart diseaseCHD.**
Condition being studied: **Coronary heart disease is a type of heart disease in which atherosclerosis of the coronary arteries causes the stenosis or occlusion of the official cavity, resulting in myocardial ischemia, hypoxia and even necrosis. With the improvement of social and economic level, the deepening of globalization and urbanization, people's eating habits and other lifestyles have undergone major changes, coupled with the emergence of aging problems, more and more evidence shows that non-communicable diseases, especially cardiovascular diseases Cardiovascular disease (CVD) has become a major cause of the global disease burden. Coronary heart disease (CHD) is the cardiovascular disease with the highest morbidity in my country. its occurrence and development are mainly related to unhealthy lifestyles such as smoking status, weight, total cholesterol, blood sugar, physical activity and diet. In the current clinical treatment of CHD, the phenomenon of random mixed use or combined use of the two often occurs, which is not only prone to adverse reactions, but also does not meet the requirements of pharmacoeconomics.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 11 April 2022 and was last updated on 11 April 2022 (registration number INPLASY202240062).

INTRODUCTION

Review question / Objective: **The aim of this meta-analysis of randomized controlled trials is to evaluate the efficacy and safety of Dapagliflozin as monotherapy in the treatment of coronary heart diseaseCHD.**

Condition being studied: Coronary heart disease is a type of heart disease in which atherosclerosis of the coronary arteries causes the stenosis or occlusion of the official cavity, resulting in myocardial ischemia, hypoxia and even necrosis. With the improvement of social and economic level, the deepening of globalization and urbanization, people's eating habits and other lifestyles have undergone major changes, coupled with the emergence of aging problems, more and more evidence shows that non-communicable diseases, especially cardiovascular diseases Cardiovascular disease (CVD) has become a major cause of the global disease burden. Coronary heart disease (CHD) is the cardiovascular disease with the highest morbidity in my country. its occurrence and development are mainly related to unhealthy lifestyles such as smoking status, weight, total cholesterol, blood sugar, physical activity and diet. In the current clinical treatment of CHD, the phenomenon of random mixed use or combined use of the two often occurs, which is not only prone to adverse reactions, but also does not meet the requirements of pharmacoeconomics.

METHODS

Search strategy: The database search will include PubMed, Embase, Cochrane Library, Web of Science, Wanfang, CNKI, CBM and VIP database through April 1, 2022. And screen literatures involving meta-analysis of dapagliflozin hypoglycemic therapy. Using the following words to search, such as “dapagliflozin”, “coronary heart disease”, “Sodium-glucose cotransporter 2”, “Randomized Controlled Trial”, etc. Seeing Table 1 for details.

Table 1
Search strategy of the PubMed.

Number	Search terms
#1	Coronary Disease[Mesh]
#2	Monotherapy[Title/Abstract] OR Single drug[Title/Abstract]
#3	Coronary Heart[Title/Abstract] OR Heart Diseases[Title/Abstract] Atherosclerosis Diseases[Title/Abstract] OR Cardiovascular Diseases[Title/Abstract] Coronary[Title Abstract] OR Coronary Heart Disease[Title/Abstract]
#4	Diabetes complicated with coronary heart disease[Title/Abstract] OR Coronary heart disease with diabetes[Title/Abstract]
#5	Diabetic heart failure[Title/Abstract] OR heart failure[Title/Abstract]
#6	#1 OR #2 OR #3 OR #4 OR #5
#7	Dapagliflozin[Mesh]
#8	Dapagliflozin[Title/Abstract] OR SGLT2 inhibitors[Title/Abstract] OR Sodium-glucose cotransporter 2[Title/Abstract]
#9	#7 AND #8
#10	Controlled trial [Publication Type] OR Randomized [Publication Type] OR Controlled clinical trial[Publication Type]
#11	Randomized Controlled trial[Title/Abstract] OR protocol[Title/Abstract]
#12	#10 OR #11
#13	#6 AND #8 AND #11.

Participant or population: The diagnostic criteria for CHD refer to the Nomenclature and Diagnostic Criteria for Ischemic Heart Disease formulated by the International Society of Cardiology and the Association and the World Health Organization's Joint Task Force on Standardization of Clinical Nomenclature. Include patients who meet the above criteria.There are no limitations on race, sex , and age.

Intervention: The treatment group was treated with dapagliflozin.

Comparator: The control group was treated with conventional treatment.

Study designs to be included: The study will include all randomized controlled trials evaluating the efficacy of dapagliflozin in the treatment of coronary heart disease, with no language, publication, time, or blinding limitations.

Eligibility criteria: 1.The study will comprise literature on clinical randomized controlled trials(RCTs) of dapagliflozin as monotherapy for CHD, and screen literatures involving meta-analysis of dapagliflozin hypoglycemic therapy. No language, publication, time or blinding restrictions are involved.2.Participants should meet the diagnostic criteria for

coronary heart disease,The diagnostic criteria for CHD refer to the Nomenclature and Diagnostic Criteria for Ischemic Heart Disease formulated by the International Society of Cardiology and the Association and the World Health Organization's Joint Task Force on Standardization of Clinical Nomenclature. Include patients who meet the above criteria.There are no limitations on race, sex , and age.3.The treatment group was treated with dapagliflozin, and the control group was treated with conventional treatment. There is no restriction on the frequency, dosage form and dose of medication.4.Primary outcomes included observations of the duration and extent of angina symptoms, the number of attacks, the results of ECG and changes in nitroglycerin dosage. Secondary outcomes included routine blood lipid profiles and occurrence of adverse reactions.

Information sources: (1)The database search will include PubMed, Embase, Cochrane Library, Web of Science, Wanfang, China National Knowledge Infrastructure(CNKI), Chinese Biomedical Database (CBM), Chinese Scientific Journal Database (VIP). (2)Search for other resources: We will also retrieve grey documents and clinical trial registers, such as WHO International Clinical Trials Registry Platform (ICTRP), the Chinese Clinical Trial Register (Chi CTR) and the Clinical Trials, to supplement the electronic databases. Google Scholar and Baidu Academic will be involved to search relevant literature. We will also screen literatures involving meta-analysis of dapagliflozin hypoglycemic therapy, manually retrieve relevant literature from Clinical Trials Register. In addition, reference lists of eligible studies will be performed manually so as to avoid missing vital information.

Main outcome(s): Primary outcomes included observations of the duration and extent of angina symptoms, the number of attacks, the results of ECG and changes in nitroglycerin dosage.

Additional outcome(s): Secondary outcomes included routine blood lipid profiles and occurrence of adverse reactions.

Data management: Two authors (Meiling Wang and Shumao Zhang) will use Excel2013 tool to extract data from the included studies, including author's name, publication year, title, study characteristics (cohort, clinical case-control study or RCT, etc.), study population (number of participants and distribution of age, sex, and race), intervention methods, outcomes and adverse events, etc. If important information is missing from the inclusion process, we will attempt to contact the authors for more complete and comprehensive information. If there is any objection, the third author (Guijun Shi) will decide whether to implement it or not.

Quality assessment / Risk of bias analysis: Risk of bias in this study will be independently assessed by two investigators(Meiling Wang and Sihua Che), using the Cochrane tool. [15] We will set "low risk", "high risk", and "unclear risk" as the risk levels for this assessment, which mainly include random sequence generation, methods of concealing treatment allocation, as well as whether bias sources such as trial participants, medical providers, outcome assessors, data integrity, analysis and data collectors are blind, and if there are differences in the selection of outcome data, a senior third investigator (Weiwei Pan) would coordinate and resolve them.

Strategy of data synthesis: In this study, the RevMan5.0 software (version 5.3) provided by Cochrane Company will be used for data synthesis. MD or SMD with 95% confidence interval (CI) will be used for pooled effect measures to calculate continuous data.The use of OR or RR with 95% CI for dichotomous data indicators will be mainly used in case-control studies and prospective cohort studies.When there is heterogeneity, Cochran Q statistic and I2 statistic indicators will be used, if P 50% is significant heterogeneity, a random effect

model will be used, and when I2<50%, a fixed effect model will be used. In addition, we will perform subgroup analysis and sensitivity analysis in order to identify factors affecting heterogeneity.

Subgroup analysis: When there is heterogeneity among the results of the various studies, a multi-faceted subgroup analysis such as coronary heart disease type, age, gender, and duration of treatment will be performed.

Sensitivity analysis: Sensitivity analysis maintains stability of results by eliminating low-quality studies and performing profiling again.

Language: Chinese and English.

Country(ies) involved: China.

Keywords: dapagliflozin, coronary heart disease, monotherapy, protocol.

Dissemination plans: This study will be disseminated in relevant professional journals.

Contributions of each author:

Author 1 - Meiling Wang - The author drafted the manuscript.
Email: 1332917330@qq.com
Author 2 - Sihua Che - The author provided statistical expertise.
Email: 294347339@qq.com
Author 3 - Weiwei Pan - The author contributed to the development of the selection criteria, and the risk of bias assessment strategy.
Email: 291354617@qq.com
Author 4 - Shumao Zhang - The author read, provided feedback and approved the final manuscript.
Email: 2507724448@qq.com
Author 5 - Guijun Shi - The author provided funding acquisition and administrated project.
Email: zsmsgj@163.com