

INPLASY

Efficacy and safety of dapagliflozin in the treatment of diabetic nephropathy : a systematic review and meta-analysis

INPLASY202450088

doi: 10.37766/inplasy2024.5.0088

Received: 18 May 2024

Published: 18 May 2024

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ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - Preliminary searches.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202450088

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 18 May 2024 and was last updated on 18 May 2024.

INTRODUCTION

Review question / Objective By inhibiting SGLT2, dapagliflozin reduces renal reabsorption of glucose, thereby increasing glucose excretion and reducing blood glucose levels. Dapagliflozin has a certain prospect in delaying the progression of diabetic nephropathy and improving renal outcomes. This study will conduct a systematic review and meta-analysis of dapagliflozin in the treatment of diabetic nephropathy, in order to provide evidence-based basis for dapagliflozin.

Condition being studied Diabetic nephropathy is a manifestation of diabetic microangiopathy and one of the main causes of renal failure in diabetic patients. The onset of diabetic nephropathy is insidious, and the early symptoms are not obvious. It often enters a period of massive proteinuria when the diagnosis is clear, and the condition is difficult to reverse when a large amount of proteinuria is present. The etiology and

pathogenesis of diabetic nephropathy are complex and have not yet been fully elucidated. Its pathogenesis mainly involves hemodynamic changes, advanced glycosylation products, activation of polyol metabolic pathways, increased protein kinase C activity, and activation of multiple cytokines. The long-term existence of these factors leads to various structural and functional changes in the kidney, such as glomerular basement membrane thickening, glomerular hypertrophy, mesangial matrix expansion, podocyte loss, etc., and then develops into glomerulosclerosis and tubulointerstitial fibrosis, and eventually leads to renal fibrosis and end-stage renal disease.

METHODS

Participant or population Participants who were definitely diagnosed with Diabetic nephropathy would be included, and there will be no limitation on sex, ages, and other factors.

Intervention The experimental group was treated with dapagliflozin, which can be a single treatment or combined with other hypoglycemic drugs.

Comparator The control group was treated with conventional hypoglycemic drugs (such as insulin, liraglutide, etc.).

Study designs to be included Randomized controlled trial.

Eligibility criteria The study time was 12 weeks, and the disease diagnosis criteria were in accordance with the ' Chinese standard '.

Information sources The following online databases will be comprehensively searched including: The Cochrane Library, PubMed, EMBASE, Web of Science Chinese Biomedical Literature Database, Chinese National Knowledge Infrastructure Database, the weipu Database and the Wanfang Database. All the literature retrieved is from the inception of the database to 16 May 2024. There are no language restrictions or regional restrictions. The subject words mainly include: diabetic nephropathy, diabetic nephrosis, Dapagliflozin, Diabetic Nephropathies.

Main outcome(s) Clinical efficacy, fasting blood glucose, 2h postprandial blood glucose, renal function, glycosylated hemoglobin, inflammatory factors, adverse reactions, etc.

Data management Two researchers respectively imported the retrieved literature into Endnote X9.0 software for management and screening. For the controversial literature, they the decision or leave it to the third researcher to decide.

Quality assessment / Risk of bias analysis The quality of the literature was evaluated using the Cochrane bias risk tool V.2.0. The two researchers independently evaluated the literature and cross-checked it, and the questionable part of the discussion was resolved or left to the third researcher to decide.

Strategy of data synthesis Meta-analysis was performed using Stata17.0 software. The odds ratio (OR) was used as the effect analysis statistic for the count data, and the mean difference (MD) or standardized mean difference (SMD) was used as the effect analysis statistic for the measurement data. The 95 % confidence interval (CI) was calculated for all effect quantities. The heterogeneity between the results of the included studies was analyzed by I² test (test level $\alpha = 0.1$), and the heterogeneity was quantitatively judged by

I². When $P \geq 0.10$ and $I^2 \leq 50\%$, the heterogeneity between studies was small, so the fixed effect model was used for analysis. When $P < 0.10$ and $I^2 > 50\%$, it suggested that the heterogeneity between studies was large, so the random effect model was used for analysis.

Subgroup analysis If there is significant heterogeneity between studies, subgroup analysis will be performed on patients of different ages and genders.

Sensitivity analysis Furthermore, if necessary, a sensitivity analysis will be performed.

Country(ies) involved China (Civil Aviation General Hospital).

Keywords diabetic nephropathy, diabetic nephrosis, Dapagliflozin, Diabetic Nephropathies, etc.

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