INPLASY

INPLASY2023110120

doi: 10.37766/inplasy2023.11.0120

Received: 30 November 2023

Published: 30 November 2023

Effectiveness and safety of Huangqi-containing Chinese medicine for the treatment of diabetes: A systematic review and meta-analysis

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ADMINISTRATIVE INFORMATION

Support - No financial supports were received.

Review Stage at time of this submission - Formal screening of search results against eligibility criteria.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY2023110120

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 30 November 2023 and was last updated on 30 November 2023.

INTRODUCTION

Review question / Objective This study aims to comprehensively summarize the clinical evidence evaluating the effectiveness and safety of integrating Huangqi-containing Chinese medicines with western medicines for the treatment of T2DM by systematic review and meta-analyses. This study investigated whether integrated therapy of Chinese medicines and western medicines could provide a more effective and more safe treatment option for T2DM comparing to western medicines alone. Moreover, this study attempted to explore whether the add-on effects of Huangqi-containing Chinese medicines differed in heterogeneous patient subgroups, and whether it was especially more or less effective for a segment of the target population. This study aims to comprehensively summarize the clinical evidence evaluating the effectiveness and safety of integrating Huangqi-containing Chinese medicines with western medicines for the treatment of T2DM. This study investigated whether integrated therapy of Chinese medicines and western medicines could provide a more effective and more safe treatment option for T2DM comparing to western medicines alone. Moreover, this study attempted to explore whether the add-on effects of Huangqi-containing Chinese medicines differed in heterogeneous patientsubgroups.

Condition being studied Type 2 Diabetes mellitus (T2DM).

METHODS

Participant or population Patients diagnosed with T2DM; no restrictions were imposed on patients' clinical characteristic (e.g., patient age, gender, disease severity).

Intervention Tianqi jiangtang tablet (TQJT), Jinqi jiangtang tablet (JQJT), Shenqi jiangtang capsule (SQJT), Qiyao xiaoke capsule (QYXK) and Xiaoke pill (XKP).

Comparator Metformin, sulfonylureas, thiazolidinedione, insulin, Dipeptidyl peptidase 4 (DPP-4) inhibitors, sodium-glucose cotransporter-2 (SGLT2) inhibitors, a-glucosidase inhibitors, or Glucagon-like peptide-1 receptor agonists (GLP-1 RAs).

Study designs to be included Randomized controlled trials (RCTs).

Eligibility criteria The studies were included if they satisfied the following criteria: 1) randomized controlled trials (RCTs) comparing the effectiveness and safety of combining HQ-containing patented Chinese medicines with western medicines (WMs) to WMs monotherapy; 2) patients diagnosed with T2DM, no restrictions were imposed on patients' clinical characteristic (e.g., patient age, gender, disease severity); 3) RCTs investigated the five Huangqi-containing patented Chinese medicines that were recommended by the national T2DM treatment guidelines, including Tianqi jiangtang tablet (TQJT), Jinqi jiangtang tablet (JQJT), Shenqi jiangtang capsule (SQJT), Qiyao xiaoke capsule (QYXK) and Xiaoke pill (XKP); 4) combined western medicines were either metformin, sulfonylureas, thiazolidinedione, insulin, Dipeptidyl peptidase 4 (DPP-4) inhibitors, sodium-glucose cotransporter-2 (SGLT2) inhibitors, a-glucosidase inhibitors, or Glucagon-like peptide-1 receptor agonists (GLP-1 RAs).

Information sources Databases including three Chinese medical databases (i.e., China National Knowledge Infrastructure, WanFang and SinoMed) and three English medical databases (i.e., PubMed, Embase and Web of Science WoB) were searched from inception to 1st June.

Quality assessment / Risk of bias analysis The risk of bias for included studies was assessed with the Cochrane Risk of Bias Tool, which evaluates the risk of bias arouse from the random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting and other bias. The overall risk-of-bias judgement could be "low", "high" or "uncertain". The overall quality of evidence was assessed with the Grades of Recommendations Assessment, Development and Evaluation (GRADE) approach (5), which considered five criteria consisting of risk of bias, indirectness, inconsistency, imprecision, and publication bias. RCT was rated as high quality by default in baseline, then quality of evidence was downgraded by one level for serious concerns and by two levels for very serious concerns. Ultimately, the quality of evidence for each outcome was graded as "high", "moderate" or "low" or "very low".

Strategy of data synthesis Statistical analysis was conducted with meta package in R software (version 4.2.2, 2022-10-31). For dichotomous data, we presented combined results as odds ratio (OR) with 95% confidence intervals (CIs). For continuous data, we calculated the change for mean with the formular: mean "prior-treatment"– mean "post-treatment"; we calculated the change for SD with the formula: sqrt (SD2 "post-treatment"- SD2 "prior-treatment" + (2* coefficient r * SD "post-treatment" * SD "prior-treatment")). We presented combined results as standardized mean difference (SMD) for both post-treatment value and change value. $\chi 2$ and I2 quantitative tests were used to test the heterogeneity among the studies. When P50%, the significant heterogeneity was implied and random-effects model was applied for meta-analysis, and when P>0.10, I2<50%, a fixed-effect model was applied to aggregate the data.

Subgroup analysis Regarding the three primary outcomes, FPG, 2hPG and HbA1c, subgroup analyses were conducted to examine the impacts of follow-up duration, baseline value and disease subtypes on the synthesized results. Subgroup analysis was also implemented as an approach to explore the potential source of heterogeneity. The disease subtypes were categorized into the following subgroups: first diagnosed T2DM, patients with unsatisfactory responses to prior treatments, patients with insulin resistance, elderly patients, obesity patients, and patients with Qi and Yi deficiency.

Sensitivity analysis The sensitivity analysis was conducted by excluding individual studies successively and remerging the remaining studies.

Country(ies) involved China.

Keywords Chinese medicine; diabetes; systematic review; meta-analysis.

Contributions of each author

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