



Efficacy and safety of Gegen Qinlian decoction for normalizing hyperglycemia in diabetic patients: A systematic review and meta-analysis of randomized clinical trials



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ABSTRACT

Objectives: A systematic review and meta-analysis was conducted to evaluate the efficacy and safety of Gegen Qinlian decoction (GQD) for normalizing hyperglycemia in T2DM patients by pooling all available RCTs.

Methods: All relevant RCTs were searched using the keywords: “GQD”, “T2DM”, “hyperglycemia” and “insulin” from the electronic databases including PubMed, EMBASE, Cochrane Library, Korean databases, Chinese medical databases, and Indian scientific database. Each RCT included the control (metformin) and experimental (GQD + metformin) groups. The outcome measures were the assessments of changes in the severity of diabetic symptoms such as “markedly effective” and “effective” (fasting plasma glucose levels: < 7 and 7–9, respectively; 2 h postprandial glucose levels: < 8.3 and 8.3–10.5 mmol/L, respectively) after 8 weeks of treatment in each RCT.

Results: There were 186 articles selected from the initial searches and 181 irrelevant and duplicate articles were removed. Finally, 5 relevant RCTs involving 499 patients were included in this review. The meta-analysis showed the odds ratio of favorable GQD effect on the marked effectiveness of glycemia (n = 499, OR: 2.34, 95% CI: 1.63–3.37, P < 0. In a subgroup analysis by GQD composition, 4 RCTs with original GQD composition also showed the odds ratio of the original GQD effect on the marked effectiveness of glycemia (n = 339, OR: 2.58; 95% CI = 1.65–4.02, P < 0.0001) in comparison to the control group. All five studies used an appropriate method for randomization of the subjects but some of them included allocation concealment and blinding of patients and practitioners. There was no significant publication bias in the meta-analysis.

Conclusion: The GQD and metformin had a synergistic effect on glycemic control in comparison to metformin alone as a T2DM therapy. More rigorous and larger studies are needed to confirm the therapeutic efficacy of GQD for hyperglycemia due to the moderate to high risk of bias in the 5 RCTs.

1. Background

The number of individuals diagnosed with type 2 diabetes has grown approximately 9% worldwide, especially in low- and middle-income countries.¹ This number is estimated to increase to 642 million people by 2040. Type 2 diabetes is the fifth leading cause of mortality in the 21st century.² When type 2 diabetes develops, people can achieve normoglycaemia by several treatments such as insulin therapy, pharmacotherapy, and dietary adjustments. The improvement of blood glucose control leads to substantial reduction in diabetes-related complications, especially microvascular disease outcomes including damage to the eyes, kidneys and nerves.³ Eventually, diabetic patients can

develop cardiovascular disease and kidney failure.^{3,4} Therefore, treatment strategies for type 2 diabetes aim to achieve optimal glycaemic control to minimize long-term micro- and macro-vascular complications.

Type 2 diabetes manifests when insulin secretion is unable to compensate for insulin resistance. Unlike Caucasians, Asians easily experience the failure of β -cell function when insulin resistance increases. This is related to the reduced β -cell mass in Asians.¹ Thus, impaired β -cell function is a major risk factor for the development of type 2 diabetes in East Asians. Treatments for Asians with type 2 diabetes should not only enhance insulin sensitivity but also potentiate β -cell function and mass. Patients in the early stages of diabetes undergo

Abbreviations: GQD, Gegen Qinlian decoction; T2DM, type 2 diabetes; RCTs, randomized clinical trials; AMPK, AMP-activated protein kinase; DPP-4, dipeptidyl peptidase-4; TCM, traditional Chinese medicines; OR, odds ratio; CI, confidence intervals; FPG, fasting plasma glucose; PG, 2 h plasma glucose levels

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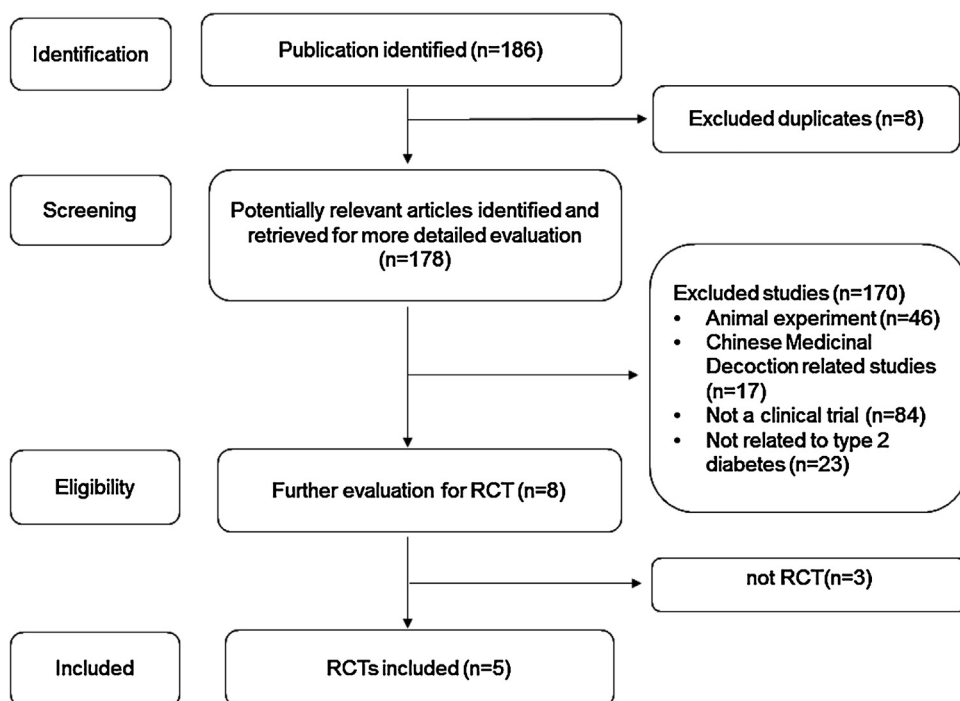


Fig. 1. Flow chart of study selection.

pharmacotherapy and diet therapy instead of using insulin injections.⁵ Pharmacotherapy for type 2 diabetes includes several classes of oral antidiabetic drugs such as biguanides, sulfonylureas, thiazolidinediones, and meglitinides.⁵ Metformin is often prescribed to early-stage type 2 diabetic patients in combination with other pharmacotherapies.⁶ Metformin improves hyperglycaemia mainly by suppressing hepatic gluconeogenesis and improving hepatic insulin signalling.^{6,7} In addition, metformin has been reported to activate AMP-activated protein kinase (AMPK), although its mechanism remains controversial.⁷ Thus, metformin may not be sufficient to normalize serum glucose levels, especially in patients with a lower insulin secretion capacity. Asians require therapeutic agents that potentiate glucose-stimulated insulin secretion without exhausting the β -cell mass.⁴ Sulfonylurea has been used with metformin to increase insulin secretion, but sulfonylurea had some adverse effects. Recently, glucagon like peptide-1 agonists and dipeptidyl peptidase-4 (DPP-4) inhibitors have been used in combination with metformin. Alternative medicines are another approach to optimize blood glucose control and reduce diabetic complications.

Gegen Qinlian decoction (GQD) is a traditional Chinese medicine well-known for treating symptoms of infectious diseases such as chills, diarrhoea and infection.⁸ Recently, it was reported that GQD was effective for treating type 2 diabetes mellitus.⁹ GQD is a water extracts of mainly 4 herbs comprised of Lobed Kudzuvine Root (*Puerariae Lobatae* Radix; Gegen; *Pueraria lobata* (Willd.) Ohwi (*Fabaceae*); Baical Skullcap Root (*Scutellariae* Radix; Huangqin; *Scutellaria baicalensis* Georgi); Golden Thread (*Coptidis* Rhizoma; Huanglian; *Coptis chinensis*); and Liquorice root (*Glycyrrhizae* Radix et Rhizoma Praeparata cum Melle; Zhigancao; *Glycyrrhiza uralensis*).¹⁰ Modified GQD includes other herbs into the original formulation comprising these 4 herbs. Each herb in GQD (Lobed Kudzuvine root, Baical Skullcap root, Golden Thread and Liquorice root) has been reported to have anti-diabetic activity.^{9,11–13} Thus, GQD has been examined for synergistic activity in treating diabetes. Both the original and modified GQD formulations have recently been reported to be a clinically effective treatment for type 2 diabetes.^{9,14} Therefore, it is important to conduct a systematic review of the anti-diabetic activities of GQD.

The objective of the current review was to systemically evaluate all randomized clinical trials using original or modified GQD to treat diabetic symptoms and to elucidate the efficacy of GQD for alleviating

diabetic symptoms. To the best of our knowledge, this is the first systematic review and meta-analysis of randomized clinical trials (RCTs) on the efficacy of GQD for diabetic symptoms.

2. Methods

2.1. Data sources and selection criteria

The following electronic databases were searched for articles written in English, Korean or Chinese: the English databases EMBASE, PUBMED, Springer, Elsevier, and Cochrane Library; the Korean databases DBpia, the Research Information Service System (RISS) and the Korean Information Service System (KISS); the Chinese databases Wanfang, the China National Knowledge Infrastructure (CNKI), and VIP information-Chinese Scientific journal database (CSJD-VIP) and the Indian databases Indian Medical Journals and the Indian Journals. Dissertations were also included. The search was performed with the following keywords of the Medical Sub Headings (MeSH) terminology: “Gegen Qinlian tang”, “Gegen Qinlian decoction”, “Lobed Kudzuvine root”, “*Puerariae Lobatae* radix”, “*Pueraria Lobata* (Willd.) Ohwi”, “*Scutellariae* radix”, “*Scutellaria baicalensis* Georgi”, “Golden Thread”, “*Coptidis* Rhizoma”, “*Coptis chinensis*”, “Liquorice root”, “*Glycyrrhizae* Radix et Rhizoma Praeparata cum Melle”, “*Glycyrrhiza uralensis*”, “randomized”, “controlled trial”, and “clinical trial”. All randomized clinical trials that studied the effects of GQD on diabetic symptoms were included from all available databases from available years; for example, all PubMed articles published between 1966 and August 2016.

2.2. Manuscript evaluation and selection

Two independent reviewers (ML and SC) searched the papers to select appropriate RCTs. Papers irrelevant to the themes of this review were ruled out based on the titles and abstracts. Potentially relevant articles were retrieved in full text and validated for inclusion in this systematic review. A third reviewer (SP) independently validated the selected papers.

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