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The Clinical Effectiveness of Traditional Chinese Medicine in Treating Diabetes-Related Pruritus: A systematic review and meta-analysis

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ADMINISTRATIVE INFORMATION

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 18 July 2025 and was last updated on 18 July 2025.

INTRODUCTION

Review question / Objective To conduct a systematic review and meta-analysis evaluating the efficacy and safety of traditional Chinese medicine (TCM) or integrated TCM–Western therapy for diabetic pruritus, providing evidence-based references for clinical application.

Condition being studied Diabetes mellitus is a metabolic disease caused by defects in insulin secretion or action. Clinically, it is primarily characterized by hyperglycemia and is often accompanied by various chronic complications. The global prevalence of diabetes continues to rise and has become a major public health issue that significantly threatens human health and socioeconomic development. Pruritus is one of the common cutaneous complications in diabetes. It is characterized by a high incidence, prolonged course, and frequent recurrences, which not only affect patients' quality of life but also increase the difficulty of treatment. The pathogenesis of

diabetic pruritus is not yet fully understood in modern medicine. Factors such as hyperglycemia or unstable blood glucose levels, peripheral circulation disorders, and neurological dysfunction or nerve damage in diabetic patients can all lead to skin itching. From the perspective of Western medicine, studies have found that the sugar content in the skin tissue of diabetic patients increases with rising blood glucose levels, which leads to a reduction in the water content of the stratum corneum, causing dry skin and itching. Moreover, elevated blood glucose levels can alter the osmotic pressure of plasma and interstitial fluid, exciting the nerve endings and causing a sensation of itching. Other research has also shown that autonomic nerve dysfunction, especially damage to the sympathetic nerve function, can lead to abnormal sweating, which in turn causes itching. Additionally, damage to the sensory C-fibers caused by diabetic peripheral neuropathy may also directly lead to itching. In traditional Chinese medicine (TCM), there is no specific disease name for "diabetic pruritus." TCM surgery classifies it under the category of "wind

pruritus.” The condition is primarily caused by pathogenic factors such as wind, dampness, heat, parasites, and blood deficiency, which stimulate the skin surface and lead to abnormal changes in local qi, blood, and body fluids, resulting in subjective symptoms such as itching, burning, and dryness. Diabetes (referred to as “xiao ke” in TCM) is mainly characterized by yin deficiency with dry heat and deficiency of both qi and yin. Over time, the body's resistance decreases, making it more susceptible to external pathogenic factors, leading to wind pruritus. As the ancients said, “Excess dampness leads to itching.” On the basis of yin deficiency in diabetes, long-term illness can invade the collaterals, forming stasis syndrome, manifested as systemic collateral blood stasis, that is, microvascular complications, and secondary nerve damage, resulting in skin itching and even limb numbness and pain. Diabetic pruritus mainly includes the following syndromes: wind-heat stagnation syndrome, blood-heat generating wind syndrome, yin deficiency with blood dryness syndrome, damp-heat in the lower jiao syndrome, and blood stasis obstruction syndrome.

Currently, conventional treatments for diabetic pruritus include blood glucose control, topical glucocorticoid ointments, and antihistamines. However, the treatment outcomes are often not satisfactory. Western medicine has many side effects and strong irritation on skin itching symptoms, especially when corticosteroids are used for a long time, which can easily lead to increased skin sensitivity, atrophy, and telangiectasia. Against this backdrop, the application of TCM in the treatment of diabetic pruritus has become increasingly prevalent in recent years. According to TCM theory, diabetic pruritus commonly falls under the categories of “Xiaoke” (consumptive thirst), “Feng sao yang” (wind-induced pruritus), or “damp-heat accumulating in the skin,” with key pathogenesis typically involving yin deficiency with internal heat, blood stasis and toxin obstruction, deficiency of qi and blood, where ‘qi’ refers to the vital energy or life force within the body that sustains physiological functions and ‘blood’ pertains to the nourishing and material foundation, and invasion of wind pathogens.

METHODS

Participant or population Study participants met the diagnostic criteria for diabetes (as defined by WHO, ADA, etc.) and had concomitant pruritus (pruritus etiologically related to diabetes or accompanied by diabetic eczema, dry skin, etc.). There were no restrictions on age or sex.

Intervention The intervention group involved TCM treatment (e.g., oral Chinese herbal medicine, topical herbal washes, acupuncture, steaming therapy, or combined herbal and Western medication) or integrated TCM and Western medicine.

Comparator The control group received conventional Western therapy (e.g., antihistamines, insulin, or oral hypoglycemic agents) or placebo; if the control group also received some adjunct therapy, the literature should explicitly state this. The primary outcomes included: efficacy rate (symptom improvement rate, marked effective rate, etc.), pruritus visual analog scale (VAS) score (or other scales), and incidence of adverse reactions.

Study designs to be included Published randomized controlled trials (RCTs). A small number of quasi-randomized controlled trials or clinical controlled trials with rigorous designs may also be considered, but they will be noted and subjected to sensitivity analysis in subsequent evaluations.

Eligibility criteria Inclusion criteria: Published randomized controlled trials (RCTs). A small number of quasi-randomized controlled trials or clinical controlled trials with rigorous designs may also be considered, but they will be noted and subjected to sensitivity analysis in subsequent evaluations. Study participants met the diagnostic criteria for diabetes (as defined by WHO, ADA, etc.) and had concomitant pruritus (pruritus etiologically related to diabetes or accompanied by diabetic eczema, dry skin, etc.). There were no restrictions on age or sex. The intervention group involved TCM treatment (e.g., oral Chinese herbal medicine, topical herbal washes, acupuncture, steaming therapy, or combined herbal and Western medication) or integrated TCM and Western medicine. The control group received conventional Western therapy (e.g., antihistamines, insulin, or oral hypoglycemic agents) or placebo; if the control group also received some adjunct therapy, the literature should explicitly state this. The primary outcomes included: efficacy rate (symptom improvement rate, marked effective rate, etc.), pruritus visual analog scale (VAS) score (or other scales), and incidence of adverse reactions. Exclusion criteria: Non-clinical research (e.g., animal experiments, in vitro studies), review articles or case reports, duplicate publications, studies with incomplete data or from which key information could not be extracted, populations other than diabetic patients or participants whose main symptom was not pruritus, and interventions not meeting TCM/TCM–Western combined criteria.

Information sources This study searched the following major Chinese and international databases from their inception to December 2024: CNKI, PubMed, Web of Science, and ScienceDirect. Additionally, the reference lists of the included articles were manually checked to identify any potentially missing studies. Search terms (in Chinese and English) included but were not limited to: “diabetes”, “pruritus”, “traditional Chinese medicine”, “Chinese herbal medicine”, “external treatment in TCM”, “diabetes”, “pruritus”, and “traditional Chinese medicine.” These were combined using Boolean operators (AND, OR, NOT) and appropriate subject headings (e.g., MeSH) to construct comprehensive search strategies.

Main outcome(s) A total of 1702 articles were retrieved from the four Chinese and international databases (ScienceDirect, PubMed, CNKI, Web of Science). After removing duplicates and studies obviously unrelated to the topic, 1657 studies remained for title and abstract screening. Of these, 1390 articles were excluded due to inconsistency with the intervention measures, study populations, or outcome indicators. The remaining 267 articles underwent full-text evaluation, and 254 studies were excluded (e.g., non-TCM interventions, incomplete data, or duplicate publications). Ultimately, 13 articles were included for this systematic review and meta-analysis. The primary outcomes included efficacy rate, incidence of adverse reactions, and pruritus severity (VAS score).

Clinical Efficacy Rate

A total of 11 studies provided data on clinical efficacy rate, with 487 participants in both the treatment and control groups. Using a random-effects model, the pooled results indicated that TCM interventions significantly improved clinical efficacy rates compared to the control groups (RR = 1.30, 95% CI: 1.17–1.45, $p < 0.001$), with moderate heterogeneity ($I^2 = 51.3\%$, $p = 0.0245$).

Pruritus Severity (VAS Score)

A total of 8 studies reported VAS scores for pruritus, including 320 participants each in the treatment and control groups. The pooled analysis (MD = -1.09, 95% CI: -2.20–0.03, $p \approx 0.06$) approached statistical significance, but the heterogeneity was very high ($I^2 = 92.8\%$, $p < 0.0001$).

Incidence of Adverse Reactions

Five studies reported incidence of adverse reactions [4, 19, 20, 22, 24], with 242 participants each in the treatment and control groups. A significantly lower incidence of adverse reactions in the TCM or integrated TCM–Western groups (RR

= 0.37, 95% CI: 0.19–0.73, $p = 0.0156$), with very low heterogeneity ($I^2 = 0.0\%$, $p = 0.7081$).

Quality assessment / Risk of bias analysis

Egger’s linear regression test was conducted for each of the three outcome indicators (clinical efficacy rate, VAS score, and incidence of adverse events) to quantitatively evaluate funnel plot symmetry and thus detect potential publication bias or small-study effects, as shown in Figures 8–10.

Efficacy Rate: The Egger test indicated $t = 3.53$ (df = 9, $p = 0.09$) and an intercept (bias estimate) of 3.7398 (SE = 0.8249). There was no significant evidence of publication bias.

Incidence of Adverse Reactions: The analysis showed $t = -1.25$ (df = 3, $p = 0.3005$), intercept = -1.2632 (SE = 1.0120), again suggesting no statistically significant publication bias ($p > 0.05$). However, given only 5 included studies, the power of the test might be insufficient to rule out any hidden bias completely.

VAS Score: The result ($t = -1.43$, df = 6, $p = 0.2019$; intercept = -2.6671, SE = 1.8617) also did not reach statistical significance. Similar to adverse reactions, the included VAS studies numbered fewer than 10, which might limit the power to detect potential bias.

Strategy of data synthesis Search terms (in Chinese and English) included but were not limited to: “diabetes”, “pruritus”, “traditional Chinese medicine”, “Chinese herbal medicine”, “external treatment in TCM”, “diabetes”, “pruritus”, and “traditional Chinese medicine.” These were combined using Boolean operators (AND, OR, NOT) and appropriate subject headings (e.g., MeSH) to construct comprehensive search strategies. The specific search strategy was as follows:

ScienceDirect: (diabetes OR diabetic) AND (pruritus OR itching) AND ("traditional Chinese medicine" OR TCM OR "Chinese herbal medicine")
Total retrieved: 1307 articles.

PubMed: ((diabetes[Title/Abstract] OR diabetic[Title/Abstract] OR "diabetes mellitus"[MeSH])) AND ((pruritus[Title/Abstract] OR itching[Title/Abstract] OR "pruritus"[MeSH])) AND (("traditional Chinese medicine"[Title/Abstract] OR TCM[Title/Abstract] OR "Chinese herbal medicine"[Title/Abstract] OR "medicine, Chinese Traditional"[MeSH])) Total retrieved: 6 articles.

CNKI (title and abstract search): 糖尿病 (diabetes) AND 瘙痒 (pruritus) AND (中医 OR 中药) Total retrieved: 386 articles.

Web of Science: TS = (diabetes) AND TS = (pruritus OR itching) AND TS = ("traditional

Chinese medicine" OR TCM OR "Chinese herbal medicine")

Total retrieved: 3 articles.

Literature Screening and Data Extraction

Preliminary screening: Two researchers independently reviewed the titles and abstracts of the retrieved articles, excluding studies clearly not meeting the inclusion criteria. Any articles presenting uncertainties or lacking sufficient information were retained for further review.

Full-text screening: The retained articles were assessed in full text according to the inclusion and exclusion criteria. Discrepancies were resolved through discussion or adjudication by a third researcher.

Data extraction: Two researchers used a standardized Excel spreadsheet to independently extract the following information: author, year of publication, sample size; intervention measures (TCM group) and control measures (Western medication group, etc.); treatment duration and follow-up time; primary outcome indicators (such as efficacy rate, adverse reaction rate, VAS score) and their detailed data (number of events/total cases, mean \pm standard deviation, etc.); and methodological characteristics (randomization method, blinding, allocation concealment, etc.).

When the two researchers had disagreements during the literature screening, data extraction, or quality assessment stages, they would first attempt to reach a consensus through discussion. If consensus could not be achieved, a third senior researcher would be consulted to arbitrate.

Subgroup analysis Data synthesis: For dichotomous data (e.g., efficacy rate, incidence of adverse reactions), risk ratio (RR) or odds ratio (OR) with 95% confidence intervals (CI) was used for pooled analysis. For continuous data (e.g., VAS scores), mean difference (MD) or standardized mean difference (SMD) with 95% CI was adopted. Heterogeneity assessment: Cochran's Q test and the I^2 statistic were used to assess heterogeneity across studies. An $I^2 > 50\%$ or $p < 0.10$ suggested significant heterogeneity. If marked heterogeneity was detected, a random-effects model (e.g., DerSimonian-Laird or REML) was preferred; otherwise, a fixed-effects model was used.

Sensitivity analysis Bias assessment: A funnel plot was used to visually assess publication bias. Egger's test (or Begg's test) was employed for quantitative analysis of funnel plot symmetry. A p -value < 0.05 was considered indicative of potential publication bias.

Software tools: R 4.4 (using packages meta and metafor) were used for data analysis and for generating forest and funnel plots. The choice of

software depended on practical considerations during this study.

Country(ies) involved China.

Keywords Traditional Chinese medicine; Pruritus; diabetic.

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