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Efficacy and safety of Chinese herbal formulas plus Western medicine for functional dyspepsia: a systematic review and meta-analysis

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INTRODUCTION

Review question / Objective This systematic review and meta-analysis evaluates the efficacy and safety of the integration of traditional Chinese medicine (TCM) and Western medicine (WM) for functional dyspepsia (FD). The objective is to provide clinicians with an up-to-date, evidence-based reference for decision-making on the efficacy and safety of integrated therapeutic strategies in managing FD.Additionally, this review seeks to synthesise the currently fragmented evidence by systematically appraising the overall value of TCM–WM as a comprehensive therapeutic paradigm, moving beyond the assessment of individual therapies in isolation.

Condition being studied Functional dyspepsia (FD) is a prevalent functional gastrointestinal disorder characterised by epigastric pain, epigastric burning, postprandial fullness and early satiety, in the absence of identifiable organic, metabolic or systemic causes. The global prevalence of FD ranges from 7% to 15%, imposing a considerable burden on patients' quality of life and work productivity, as well as on healthcare systems worldwide.

METHODS

Participant or population Eligible participants were adult participants (≥18 years) diagnosed with functional dyspepsia according to Rome II, III or IV criteria. Studies were excluded if they included participants with severe concomitant diseases of the heart, lungs, brain or other major digestive disorders.

Intervention The experimental group received oral Chinese herbal medicine combined with conventional WM, with a treatment duration of at least 2 weeks. Conventional WM was defined as standard pharmacotherapies for functional dyspepsia, including PPIs (e.g. omeprazole), prokinetic agents (e.g. domperidone, mosapride)

and psychotropic agents (e.g. flupentixol–melitracen, venlafaxine), administered at approved therapeutic doses. The herbal preparations actually evaluated across the included trials comprised Shugan Jieyu capsule combined with WM, modified Xiangsha Liujunzi decoction combined with WM and modified Banxia Xiexin decoction combined with WM, and treatment duration in the included studies ranged from 3 to 8 weeks.

Comparator The control group received the same WM regimen as the experimental group, without any additional Chinese herbal medicine or placebo; placebo-controlled designs were not included because blinding in Chinese herbal medicine trials is practically infeasible.

Study designs to be included Only randomised controlled trials (RCTs) are included.

Eligibility criteria Studies were eligible if they met the following criteria: (1) RCTs; (2) adult participants (≥18 years) diagnosed with functional dyspepsia according to Rome II, III or IV criteria; (3) oral Chinese herbal medicine combined with conventional WM in the experimental group; (4) treatment duration of at least 2 weeks; and (5) reporting at least one of the following outcomes: overall clinical response rate, symptom scores, motilin levels, Hamilton Anxiety Scale (HAM-A) scores, recurrence rates or adverse reactions. Conventional WM was defined as standard pharmacotherapies for functional dyspepsia, including PPIs (e.g. omeprazole), prokinetic agents (e.g. domperidone, mosapride) and psychotropic agents (e.g. flupentixol–melitracen, venlafaxine), administered at approved therapeutic doses. The control group received the same WM regimen as the experimental group, without any additional Chinese herbal medicine or placebo, and placebo-controlled designs were not included because blinding in Chinese herbal medicine trials is practically infeasible.
Studies were excluded if they were non-RCTs; had incomplete data or unavailable full text; were duplicate publications; included participants with severe concomitant diseases of the heart, lungs, brain or other major digestive disorders; or had inconsistent treatment durations between the intervention and control groups.

Information sources A comprehensive literature search was performed in nine electronic databases from their inception to 30 November 2025. The English-language databases searched included PubMed, the Cochrane Library, Embase, Web of Science and the National Library of Medicine; the Chinese databases searched included the China National Knowledge Infrastructure, the Wanfang Database, the Chinese Biomedical Literature Database and the VIP Chinese Science and Technology Journal Database.

Main outcome(s) The primary outcome was the overall response rate, defined as the sum of cured, markedly improved and improved cases based on the TCM syndrome scoring criteria; it was analysed as a dichotomous outcome and reported as an odds ratio with 95% CI at the end of treatment. Secondary outcomes included (1) symptom scores, with symptom severity including abdominal pain, heartburn and early satiety graded on a 0–3 scale (0 = none, 1 = mild, 2 = moderate, 3 = severe) and the total symptom score calculated as the sum of individual symptom scores; (2) plasma motilin levels, measured via enzyme-linked immunosorbent assay (ELISA) and reported in picograms per millilitre (pg/mL); (3) HAM-A scores; (4) recurrence rates during follow-up (one study reported a 3-month follow-up, 3 studies reported a 6-month follow-up and the remaining studies did not specify follow-up duration); and (5) adverse reactions, including types and severity grading when reported in the original studies.

Quality assessment / Risk of bias analysis Literature quality was assessed using the Cochrane risk-of-bias 2.0 (RoB 2.0) tool across five domains: randomisation process, deviations from intended interventions, missing outcome data, measurement of the outcome and selection of the reported result. The overall risk of bias for each study was classified as Grade A (low risk, all domains rated as low risk), Grade B (some concerns, one or more domains raised some concerns but no high-risk domain, overall findings considered credible) or Grade C (high risk, at least one domain rated as high risk, substantially reducing confidence in the results).

Strategy of data synthesis Full-text review and data extraction were independently conducted by two reviewers using a standardised form based on the Cochrane Handbook, which was piloted beforehand, capturing study characteristics, participant demographics, intervention and control details, treatment duration, follow-up, outcome data (effect sizes with 95% confidence intervals) and risk-of-bias assessment elements. Meta-analysis was performed using RevMan (version 5.4.1; Cochrane Collaboration, London, UK). For dichotomous data, odds ratios (ORs) with 95% CIs were calculated; for continuous data, mean differences (MDs) with 95% CIs were used. Heterogeneity was assessed using the I^2 statistic,

with a fixed-effect model applied when $I^2 < 50\%$ and a random-effects model when $I^2 \geq 50\%$. Where meta-analysis is not appropriate, findings will be summarised narratively. Publication bias was evaluated using funnel plots and, when at least 10 studies were available for a given outcome, Egger's test was additionally applied to provide a more objective statistical assessment; for outcomes with fewer than 10 studies, funnel plot inspection was supplemented by qualitative interpretation of the symmetry, and the limited power of formal statistical tests was acknowledged. A significance level of alpha = 0.05 was set for all analyses.

Subgroup analysis Subgroup analyses were planned by type of Chinese herbal formula when at least two studies were available for a specific intervention, to explore potential differences in treatment effects across commonly used herbal preparations. Accordingly, subgroup analyses of the overall response rate were conducted for Shugan Jieyu capsule combined with WM (three studies), modified Xiangsha Liujunzi decoction combined with WM (three studies) and modified Banxia Xiexin decoction combined with WM (two studies); for the abdominal pain symptom score, subgroup analysis was performed using 'Course of treatment' as the grouping variable, and the results showed statistically significant heterogeneity among subgroups ($P < 0.001$), indicating that 'Course of treatment' was a source of heterogeneity. Nevertheless, the subgroup analyses were based on only two or three studies, substantially reducing statistical power and robustness; therefore, these results should be considered hypothesis-generating rather than definitive, and well-powered comparative effectiveness trials are needed to confirm the relative efficacy of specific formulas.

Sensitivity analysis Sensitivity analyses were conducted by sequentially excluding individual studies to assess the robustness of the pooled estimates. For the overall response rate, sequential exclusion of individual studies did not substantially alter the pooled estimate, and the same applied to the three formula-specific subgroups, where no individual study disproportionately influenced the pooled estimate. For the total symptom score, sequential exclusion of individual studies did not eliminate heterogeneity (I^2 remained > 50%), but the pooled effect remained statistically significant ($P < 0.001$), confirming the robustness of the finding; the same pattern was observed for the abdominal pain symptom score. For heartburn and early satiety, sensitivity analysis revealed that excluding the study by Wen reduced heterogeneity to $I^2 = 63\%$ and $I^2 = 79\%$ respectively, although the pooled effects remained significant; for motilin levels, excluding the study by Wang reduced heterogeneity to $I^2 = 64\%$, with the pooled effect remaining significant, supporting the stability of the result.

Country(ies) involved China.

Keywords Integrated traditional Chinese and Western medicine; Functional dyspepsia; safety; Treatment principles;Meta-analysis.

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