Chinese herbal medicine modified xiaoyao san for functional dyspepsia: meta-analysis of randomized controlled trials

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CRD summary

This well-conducted review concluded that there was weak evidence that modified xiaoyao san appeared to be safe and more effective than prokinetic drugs for the treatment of functional dyspepsia, but further high-quality research was required to confirm this. Given the poor quality of the data and the risk of publication bias, the authors' cautious conclusions are likely to be reliable.

Authors' objectives

To assess the effectiveness of modified xiaoyao san for the treatment of functional dyspepsia.

Searching

MEDLINE (1989 to January 2009), CNKI (1994 to February 2009), Wanfang Data (1989 to February 2009), VIP database (1990 to February 2009), and the Cochrane Library (issue 1, 2009) were searched for full reports of studies published in English, Chinese, or Japanese. Search terms were reported and the reference lists of retrieved studies were checked for additional studies. Topic experts and manufacturers were contacted for unpublished data.

Study selection

Randomised controlled trials (RCTs) were eligible for inclusion if they compared modified xiaoyao san, as monotherapy or in combination with prokinetic agents, with prokinetic agents alone, in patients with functional dyspepsia. Only trials with treatments that lasted at least two weeks were included. Eligible trials had to report successful treatment using clearly defined criteria, which did not rely on the assessment of illness severity scores or intensity.

All of the included RCTs were carried out in China and written in Chinese. Half of them assessed modified xiaoyao san monotherapy and half assessed combination therapy, mainly with domperidone (10mg three times a day). The majority of included trials compared the intervention with domperidone (motilium; 10mg three times a day); other control groups included mosabilium (5mg three times a day), cisapride (10mg three times a day), omeprazole (20mg three times a day), and deanxit (1-2 tablets three times per day). Participants ranged in age from 16 to 72 years and all of the trials included mixed populations of men and women, but usually with more women than men. Treatment duration ranged from two weeks to two months, with the treatments in most of the trials lasting for four weeks.

At least two reviewers independently selected trials and discrepancies were resolved through discussion.

Assessment of study quality

Two reviewers independently assessed the validity of the trials using the Jadad scale. The criteria included randomisation, allocation concealment, blinding, and dropouts.

Data extraction

Two reviewers independently extracted the trial data and discrepancies were resolved through discussion or consultation with a third reviewer.

The number of responders per treatment arm were recorded. "Patients without symptoms", "patients with significant improvement of symptoms", "patients with excellent or good results", and similar expressions were considered to be responders or treatment success. Odds ratios with 95% confidence intervals were calculated for each trial.

Methods of synthesis

Trials were grouped according to intervention and the pooled odds ratio with 95% confidence interval was calculated

using a fixed-effect model. Statistical heterogeneity was calculated using χ^2 and I^2 tests. The risk of publication bias was assessed in a funnel plot.

Results of the review

Fourteen RCTs (1,310 patients) were included in the review. The sample size ranged from 48 to 209. All the trials were considered to be of poor quality. None of them reported allocation concealment, none reported whether there were any dropouts, and none were blinded.

There was a statistically significant reduction in symptoms associated with modified xiaoyao san in comparison with prokinetic drugs (OR 3.26, 95% CI 2.24 to 4.74; seven RCTs). Modified xiaoyao san plus prokinetic drugs appeared to be associated with a reduction in symptoms in comparison with prokinetic drugs alone (OR 4.32, 95% CI 2.64 to 7.08; seven RCTs). There was no evidence of significant heterogeneity and no serious adverse events were reported.

There were insufficient numbers of trials to produce a meaningful funnel plot to assess the risk of publication bias.

Authors' conclusions

There was weak evidence to suggest that modified xiaoyao san appeared to be safe and more effective than prokinetic drugs for the treatment of functional dyspepsia, but further research was required to confirm this.

CRD commentary

This review assessed a clear and well-defined research question. A number of relevant databases were searched for published studies and unpublished ones were sought from topic experts and manufacturers. Only full papers written in English, Chinese, or Japanese were included in the review, and the reviewers suggested that there was a risk of publication bias. The risk of reviewer error and bias was minimised by the involvement of multiple reviewers in the selection of trials, extraction of trial data, and assessment of trial quality. The quality of the trials was assessed, using appropriate criteria, but it was described as poor, suggesting that the data might not be reliable. Trials using different comparator groups were pooled together, but there was no evidence of significant statistical heterogeneity between them.

Despite the poor quality of the data and the risk of publication bias, the authors' cautious conclusions are likely to be reliable.

Implications of the review for practice and research

Practice: The authors did not state any implications for practice.

Research: The authors stated that further well-conducted controlled trials assessing outcomes including adverse events, were required to compare modified xiaoyao san with other drugs and placebo.

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