Effectiveness of the Chinese herbal formula TongXieYaoFang for irritable bowel syndrome: a systematic review

CRD summary
The review assessed the Chinese herbal medicine TongXieYaoFang for irritable bowel syndrome. The authors concluded that TongXieYaoFang together with other Chinese medicinal herbs has the potential to improve symptoms of irritable bowel syndrome more than conventional medicines. It is highly likely that the evidence reviewed was biased towards results in favour of TongXieYaoFang.

Authors' objectives
To evaluate the effectiveness of TongXieYaoFang (TXYF) with or without additional Chinese herbal medicines for the management of irritable bowel syndrome (IBS).

Searching
MEDLINE, EMBASE, the Cochrane Controlled Trials Register and the Cochrane Complementary Medicine Field Trials Register were searched up to December 2004. CBM-disc (1978 to 1988) and the Chinese Journals Full-text Database (1994 to 2004) were also searched. The search terms were reported. Study design filters were not used and the search was not restricted by language.

Study selection
Study designs of evaluations included in the review
Randomised and quasi-randomised trials were eligible for inclusion. None of the included studies provided enough information to ascertain if they were truly randomised.

Specific interventions included in the review
Studies using any form of TXYF, including decoction or tablet, or TXYF with the addition of other Chinese medicinal herbs (TXYF-A), were eligible for inclusion. Most of the included studies compared TXYF-A with conventional drugs. The herbal additions differed between studies. One three-arm trial compared TXYF and TXYF-A with a conventional drug. In one trial TXYF-A was given together with a conventional drug. Decoctions prepared from crude herbs were used in all the studies, and the duration of treatment ranged from 10 days to 8 weeks. The conventional drugs included oryzandum, dioctahedral smectite, cisapride, loperamide, diphenoxylatum, pinaverium bromide and nifedipinum.

Participants included in the review
Studies in patients with IBS diagnosed according to Rome I, Rome II, Manning or the Chinese National Chronic Diarrhoea Association criteria were eligible for inclusion. No details of the participants in the included studies were reported in the review.

Outcomes assessed in the review
The inclusion criteria appeared to be change in clinical measures such as abdominal pain, diarrhoea, constipation and abdominal distention. The outcome measured in the included studies was symptoms. In most studies authors defined the criteria for improvement in symptoms, while two studies used published criteria (see Other Publications of Related Interest). The symptoms were measured either immediately after treatment (near-term effectiveness), or at 3 months (short-term effectiveness) or at least 6 months (long-term effectiveness) after completion of treatment.

How were decisions on the relevance of primary studies made?
One reviewer selected potentially eligible items from the search results and two reviewers independently assessed the retrieved studies.
Assessment of study quality
Four criteria were used to assess study quality: the method of randomisation, allocation concealment, blinding, and withdrawals and drop-outs. The studies were thereby grouped as having a low, moderate or high risk of bias. The authors did not state how the validity assessment was performed.

Data extraction
Two reviewers extracted the data independently. The clinical outcome data that appeared to have been extracted were the numbers of participants who experienced a disappearance or significant improvement in symptoms in the treatment and control groups, and the total number of participants in each group. This was described in the analysis as the total rate of recovery and improvement.

Methods of synthesis
How were the studies combined?
The studies were combined in a meta-analysis using a random-effects model. Pooled estimates of the relative risk (RR) for recovery and improvement were calculated along with 95% confidence intervals (CIs). The studies were grouped according to whether they assessed near-term, short-term or long-term effectiveness. Pooled estimates of effect were calculated within each subgroup and overall. A funnel plot was used to assess the possibility of publication bias.

How were differences between studies investigated?
A statistical test for heterogeneity was applied in the meta-analyses. The authors considered differences in the intervention, control and outcome measures to justify their decision to pool the data.

Results of the review
Twelve studies including 1,125 participants were included in the review.

All of the included studies had a high risk of bias. It was uncertain if the studies were in fact randomised trials. The funnel plot suggested the presence of publication bias in the review in favour of studies with positive effects.

A meta-analysis of 4 studies reporting near-term effectiveness showed a statistically significant beneficial effect of TXYF-A on the rate of recovery and improvement compared with the control interventions (RR 1.34, 95% CI: 1.16, 1.54). The statistical test for heterogeneity was not significant. The pooled analysis of 2 studies reporting short-term effectiveness gave similar results (RR 1.39, 95% CI: 1.17, 1.64). In the subgroup of 6 studies that reported long-term effectiveness, the overall effect was again similar (RR 1.34, 95% CI: 1.12, 1.61) but with statistically significant heterogeneity. When all 12 studies were pooled the RR was 1.35 (95% CI: 1.21, 1.50).

None of the studies reported side-effects.

Authors' conclusions
There is evidence to suggest a potential usefulness of TXYF-A to improve the clinical symptoms of IBS. The validity of the conclusion is weakened by the poor quality of the evidence.

CRD commentary
The review addressed a clear question and stated the inclusion criteria. The search was thorough and the authors made some attempt to reduce selection bias. All of the included studies were published in Chinese journals. Appropriate criteria were used to assess the potential for bias in the included studies, and steps were taken to minimise errors in data extraction. Some aspects of the characteristics of the included studies, in particular the participants and outcome measures, were not well described. The reporting of the data extraction and analysis methods was poor. The authors pooled the data despite the obvious clinical differences between the trials. A less partial conclusion would be more appropriate given the uncertainty around study design, outcome assessment and quality in the included studies, and the likelihood of publication bias in favour of studies with positive effects.
Implications of the review for practice and research
Practice: The authors did not state any implications for practice.

Research: The authors stated that well-designed double-blind placebo-controlled randomised trials are needed to confirm the effectiveness of TXYF and TXYF-A for IBS.

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Bibliographic details

Other publications of related interest

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Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.