A systematic review of treating Helicobacter pylori infection with traditional Chinese medicine

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CRD summary
This review concluded that there was insufficient evidence of the efficacy of traditional Chinese medicine in the treatment of Helicobacter pylori and although traditional Chinese medicine may be safer than triple therapy, it should not be recommended as monotherapy. Given the poor quality of the included studies, the authors' conclusions and recommendations for practice seem appropriate and reliable.

Authors' objectives
To evaluate the efficacy and safety of traditional Chinese medicine for the treatment of Helicobacter pylori (H. pylori).

Searching
MEDLINE, Cochrane Central Register of Controlled Trials (CENTRAL), Weipu and Wanfang databases were searched without language restrictions up to 2008; search terms were reported. Bibliographies of included trials and conference abstracts were searched.

Study selection
Randomised controlled trials (RCTs) that compared single herb, formulae or Chinese medicine products to treatments in patients with chronic or remnant gastritis, peptic ulcers or gastro-oesophageal reflux and diagnosed with H. pylori were eligible for inclusion. Both treatment and diagnosis of H. pylori had to be in accordance with the Consensus Report. Patients with bleeding ulcer or gastric cancer were excluded. Outcomes of interest were H. pylori eradication rates as defined by the Consensus Report and adverse events.

The Chinese medicines that were evaluated varied widely. Duration of treatment ranged from seven to 60 days. All comparators were triple therapies, with varying combinations of proton pump inhibitors, antacids and antibiotics; treatment duration was seven, 10 or 14 days. Where reported, participants' age ranged from 16 to 85 years and 48% to 79% were male.

Two independent reviewers screened studies for inclusion; disagreements were resolved by discussion or a third reviewer.

Assessment of study quality
Trial quality was assessed using the Jadad score; allocation concealment was also assessed. The number of authors who performed the quality assessment was not reported.

Data extraction
The numbers of patient in whom H. pylori was eradicated or who experienced an adverse event were extracted and relative risks (RR) with 95% confidence intervals (CI) calculated.

The number of authors who extracted data was not reported.

Methods of synthesis
Heterogeneity was assessed using the X² and I² statistics. Where I² was 0 a fixed-effect model was used, where I² was less than 50% a random-effects model was used; a pooled estimate was not calculated where I² was greater than 50%. As heterogeneity was more than 50%, average incidence rates were calculated and studies were combined in a narrative synthesis. Publication bias was assessed using a funnel plot.

Results of the review
Sixteen trials met the inclusion criteria (n=1,983, range 50 to 419). All trials scored either 1 or 2 on the Jadad scale; none reported allocation concealment or blinding. All were considered poor quality.

The average \textit{H. pylori} eradication rate (16 trials) was 72\% (95\% CI 36\% to 90\%) for traditional Chinese medicine and 78\% (95\% CI 44\% to 93\%) for triple-therapy controls. Relative risks across trials ranged from 0.43 (95\% CI 0.28 to 0.66) to 1.43 (95\% CI 1.01 to 2.03).

The average rates of adverse events (11 trials) were 2\% (21/903 patients) for traditional Chinese medicine and 29\% (204/697 patients) for triple-therapy controls. Twenty patients who received triple therapy withdrew from the trial due to adverse events.

The funnel plot indicated publication bias was present for the primary outcome.

**Authors' conclusions**
Available evidence was not convincing enough to show that traditional Chinese medicine had the same efficacy as triple-therapy in \textit{H. pylori} treatment, but traditional Chinese medicine may be safer.

**CRD commentary**
The authors addressed a clear research question with appropriate inclusion criteria. Several relevant sources were searched with no language restrictions; however, there were no specific attempts to identify unpublished studies and evidence of publication bias was observed. Study selection was conducted in duplicate; it was unclear whether similar methods to reduce error and bias were employed during data extraction and quality assessment. Study quality was assessed with appropriate criteria. All the included studies were open label and generally poor quality. The decision by the authors not to produce pooled relative risks seemed appropriate. Given the heterogeneity across the included studies, the value of the average incidence rates was uncertain. Given the poor quality of the included studies, the authors' conclusions and recommendations for practice seem appropriate and reliable.

**Implications of the review for practice and research**

**Practice:** The authors stated that traditional Chinese medicine should not be recommended as monotherapy for \textit{H. pylori} infection.

**Research:** The authors recommend clinical trials that assessed efficacy of traditional Chinese medicine should be performed to the requirements of evidence-based medicine. Problems with antibiotic resistance, high rates of adverse events and treatment cost should be considered.

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