Moxifloxacin-based triple therapy versus clarithromycin-based triple therapy for first-line treatment of Helicobacter pylori infection: a meta-analysis of randomized controlled trials

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CRD summary
This review concluded that moxifloxacin-based triple therapy was more effective and did not increase the incidence of overall side effects compared with clarithromycin-based triple therapy in the treatment of Helicobacter pylori infection. These conclusions are supported by the results presented, but should be interpreted with some degree of caution due to the possibility of publication bias and small number of generally poor quality trials.

Authors’ objectives
To review the efficacy and tolerance of moxifloxacin-based triple therapy and compare it with clarithromycin-based triple therapy for the treatment of Helicobacter pylori infection.

Searching
The Cochrane Library, PubMed, EMBASE, Science Citation Index Expanded, and Chinese Biomedical Literature Databases were searched to December 2008. Search terms were reported. References of retrieved studies were screened. No language restrictions were applied.

Study selection
Randomised controlled trials (RCTs) that compared moxifloxacin-based triple therapy (amoxicillin or nitroimidazoles plus proton pump inhibitor) with clarithromycin-based triple therapy in patients with Helicobacter pylori (H. pylori) infection were eligible for inclusion. Trials had to report confirmation of infection eradication at least four weeks after treatment completion based on urea breath testing, or gastric mucosal biopsy for histology, or culture.

Included trials were conducted in China, Croatia, Italy and Turkey. Triple therapy regimes included tinidazole, amoxicillin, lansoprazole, esomeprazole, metronidazole, omeprazole or ranitidine bismuth citrate in addition to moxifloxacin or clarithromycin. Most trials included H. pylori positive patients with non-ulcer dyspepsia; one study included H. pylori positive adults. Treatment duration was one week in all but one trial (which was two weeks). Most trials confirmed eradication using the urea breath test; one trial used histology. Eradication was assessed after four to eight weeks follow-up.

The authors did not state how many reviewers selected studies for inclusion.

Assessment of study quality
Two reviewers independently assessed trial quality using the Jadad criteria which assessed randomisation, blinding and description of withdrawals and drop-outs. Trials were assigned a score out of 5 points. Concealment of treatment allocation was also assessed. Disagreements were resolved through consensus.

Data extraction
Two reviewers independently extracted data on the number of patients in which infection eradication was confirmed, and the number of patients with side effects in the intervention and control groups. These data were combined with data on the number of participants in each group to estimate relative risks (RR). Data were extracted on an intention-to-treat basis.

Methods of synthesis
Summary relative risks and 95% confidence intervals (CIs) were estimated using the DerSimonian and Laird model, which the authors described as a fixed-effect model. Heterogeneity was assessed using the \( I^2 \) statistic.

Results of the review
Four trials were included in the review (n=772 patients). Randomisation and concealment of treatment allocation were
adequate in two trials; one of these was adequately blinded. Two trials reported withdrawals; there were no withdrawals in the other two trials.

Moxifloxacin-based triple therapy significantly improved eradication rates compared with clarithromycin-based triple therapy (RR 1.13, 95% CI 1.01 to 1.27; four RCTs). There was some evidence of heterogeneity ($I^2=53\%$, $p=0.10$). There was no difference in adverse events between the treatment groups ($p=0.28$; three RCTs), but there was substantial heterogeneity ($I^2=89\%$; $p<0.001$).

Sensitivity analysis was conducted by excluding one trial, which was considered to differ from the other trials because of the method used to confirm $H. pylori$ infection and the duration of treatment. After exclusion of this trial, the significant improvement in eradication rates in the moxifloxacin-based triple therapy remained (RR 1.20, 95% CI 1.11 to 1.29; three RCTs); adverse events were also significantly reduced in this group (RR 0.40, 95% CI 0.27 to 0.60; two RCTs). Heterogeneity was no longer apparent in these analyses ($I^2=0\%$).

**Authors' conclusions**

Moxifloxacin-based triple therapy was more effective and did not increase the incidence of overall side effects compared with clarithromycin-based triple therapy in the treatment of $Helicobacter pylori$ infection.

**CRD commentary**

The review addressed a focused question and inclusion criteria were clearly defined. The literature search was adequate for published studies, but specific attempts were not made to locate unpublished studies, so there was a possibility of publication bias; this was not assessed in the review as there were insufficient trials. Appropriate steps were taken to minimise bias and errors for data extraction and quality assessment, but it was unclear whether such steps were also taken when selecting studies for inclusion.

Trial quality was assessed using appropriate criteria and the results of this were clearly presented. Appropriate methods appeared to have been used to pool trials, but the authors described the model used as a fixed-effect model when it was a random-effects model. Therefore, it was unclear whether fixed-effect or random-effects meta-analysis was performed (i.e. whether their description of the method or model used was incorrect).

The authors conclusions are supported by the results presented, but should be interpreted with some degree of caution due to the possibility of publication bias and small number of generally poor quality trials.

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

**Practice:** The authors stated moxifloxacin-based triple therapy provides an effective alternative regimen to clarithromycin-based triple therapy.

**Research:** The authors stated that there is a need for a high quality RCT comparing moxifloxacin-based triple therapy with clarithromycin-based triple therapy in Americans and Africans with $Helicobacter pylori$ infection.

**Funding**

The authors stated that this review was not funded by a pharmaceutical company, but details of funding were not reported.

**Bibliographic details**


**PubMedID**

20009394
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.