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*Aliment Pharmacol Ther.* 2012 Jan;35(1):56-65. doi: 10.1111/j.1365-2036.2011.04902.x. Epub 2011 Nov 8.

## Randomised clinical trial: a comparative study of 10-day sequential therapy with 7-day standard triple therapy for *Helicobacter pylori* infection in naïve patients.

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### Abstract

**BACKGROUND:** The eradication rates following standard triple therapy for *Helicobacter pylori* infection are declining worldwide. Recent studies have shown that sequential therapy for *H. pylori* infection yields high cure rates.

**AIM:** To compare the efficacy and tolerability of a sequential regimen as first-line treatment of *H. pylori* infection with a standard triple regimen.

**METHODS:** A total of 348 naïve *H. pylori*-infected patients from six hospitals in Korea were assigned randomly to standard triple or sequential therapy groups. Standard triple therapy consisted of 20 mg of rabeprazole, 1 g of amoxicillin and 500 mg of clarithromycin, twice daily for 7 days. Sequential therapy consisted of a 5-day dual therapy (20 mg of rabeprazole and 1 g of amoxicillin, twice daily) followed by a 5-day triple therapy (20 mg of rabeprazole, 500 mg of clarithromycin, and 500 mg of metronidazole, twice daily).

**RESULTS:** The intention-to-treat (ITT) and per-protocol (PP) eradication rates were 62.2% (95% CI 54.8-69.6%) and 76.0% (95% CI 68.5-83.5%) in the standard triple group, and 77.8% (95% CI 71.4-84.2%) and 87.9% (95% CI 82.3-93.5%) in the sequential group, respectively. The eradication rate was significantly higher in the sequential group compared with the standard triple group in both the ITT and PP populations ( $P = 0.002$  and  $P = 0.013$  respectively), whereas the incidence of adverse events was similar.

**CONCLUSIONS:** Ten-day sequential therapy is more effective and equally tolerated for eradication of *H. pylori* infection compared with standard triple therapy. Sequential therapy may have a role as first-line treatment for *H. pylori* infection.

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PMID:22066530[PubMed - indexed for MEDLINE]

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