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Sequential versus triple therapy for the first-line treatment of Helicobacter pylori: a multicentre, open-label, randomised trial.

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Abstract

BACKGROUND: Whether sequential treatment can replace triple therapy as the standard treatment for Helicobacter pylori infection is unknown. We compared the efficacy of sequential treatment for 10 days and 14 days with triple therapy for 14 days in first-line treatment.

METHODS: For this multicentre, open-label, randomised trial, we recruited patients (≥20 years of age) with H pylori infection from six centres in Taiwan. Using a computer-generated randomisation sequence, we randomly allocated patients (1:1:1; block sizes of six) to either sequential treatment (lansoprazole 30 mg and amoxicillin 1 g for the first 7 days, followed by lansoprazole 30 mg, clarithromycin 500 mg, and metronidazole 500 mg for another 7 days; with all drugs given twice daily) for either 10 days (S-10) or 14 days (S-14), of 14 days of triple therapy (T-14; lansoprazole 30 mg, amoxicillin 1 g, and clarithromycin 500 mg for 14 days; with all drugs given twice daily). Investigators were masked to treatment allocation. Our primary outcome was the eradication rate in first-line treatment by intention-to-treat (ITT) and per-protocol (PP) analyses. This trial is registered with ClinicalTrials.gov, number NCT01042184.

FINDINGS: Between Dec 28, 2009, and Sept 24, 2011, we enrolled 900 patients: 300 to each group. The eradication rate was 90.7% (95% CI 87.4-94.0; 272 of 300 patients) in the S-14 group, 87.0% (83.2-90.8; 261 of 300 patients) in the S-10 group, and 82.3% (78.0-86.6; 247 of 300 patients) in the T-14 group. Treatment efficacy was better in the S-14 group than it was in the T-14 group in both the ITT analysis (number needed to treat of 12.0 [95% CI 7.2-34.5]; p=0.003) and PP analyses (13.7 [8.3-40], p=0.003). We recorded no significant difference in the occurrence of adverse effects or in compliance between the three groups.

INTERPRETATION: Our findings lend support to the use of sequential treatment as the standard first-line treatment for H pylori infection.

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Defining the role of sequential therapy for H pylori infection. [Lancet. 2013] First-line eradication therapy for Helicobacter pylori: time for a change? [Gastroenterology. 2013]