

1-day quadruple therapy was not inferior to 7-day triple therapy for eradication of *Helicobacter pylori* infection in dyspepsia

Lara LF, Cisneros G, Gurney M, et al. One-day quadruple therapy compared with 7-day triple therapy for *Helicobacter pylori* infection. *Arch Intern Med.* 2003;163:2079-84.

QUESTION

In patients with dyspepsia, is 1-day quadruple therapy noninferior to 7-day triple therapy for eradication of *Helicobacter pylori* infection?

DESIGN

Randomized {allocation concealed*}†, unblinded,* controlled trial with 5-week follow-up.

SETTING

Ambulatory internal medicine clinics of 2 university-affiliated hospitals in Canton, Ohio, USA.

PATIENTS

160 patients \geq 18 years of age (mean age 50 y, 57% women) with dyspepsia and *H. pylori* infection who had a Glasgow Dyspepsia Severity Score (GDSS) of \geq 3 (score range 0 to 20) and a positive carbon 14 urea breath test result. Exclusion criteria included previous treatment of *H. pylori* infection, pregnancy, personal or family history of gastrointestinal malignancy, antibiotic therapy in the previous 6 weeks, previous gastric surgery, and hepatic insufficiency. Follow-up was 94%.

INTERVENTION

80 patients were allocated to a 1-day regimen of 2 tablets of bismuth subsalicylate,

262 mg each tablet, 4 times; 1 tablet of metronidazole, 500 mg, 4 times; amoxicillin suspension, 2 g, 4 times; and 2 tablets of lansoprazole, 30 mg each tablet, once (1-d regimen group). 80 patients were allocated to a 7-day regimen of 1 tablet of clarithromycin, 500 mg, twice daily; 2 tablets of amoxicillin, 500 mg each tablet, twice daily; and 1 tablet of lansoprazole, 30 mg, twice daily (7-d regimen group).

MAIN OUTCOME MEASURES

Eradication rates of *H. pylori*, changes in GDSS score, and adverse effects.

MAIN RESULTS

All patients remained on their assigned treatment. 1-day therapy was not inferior to 7-day therapy for rates of eradication of *H. pylori* (Table). The mean baseline GDSS score was 11 (standard deviation [SD] 3.4) in the 1-day regimen group and 10 (SD 3.3) in

the 7-day regimen group. The groups did not differ for mean change from baseline in GDSS scores (both groups had a mean decrease from baseline of 7.5). None of the patients in either group reported intolerance to their treatment, and rates of side effects did not differ between groups.

CONCLUSION

In patients with dyspepsia, a 1-day quadruple therapy regimen was not inferior to a 7-day triple therapy regimen for eradication of *Helicobacter pylori* infection.

Sources of funding: Aultman Health Foundation; TAP Pharmaceutical Products Inc.; Canton Medical Education Foundation.

For correspondence: Dr. F. Whittier, Affiliated Hospitals at Canton, Canton, OH, USA. E-mail nancy.castro@csauh.com. ■

*See Glossary.

†Information provided by author.

1-day quadruple therapy vs 7-day triple therapy for eradication of *Helicobacter pylori* infection in patients with dyspepsia at 5 weeks‡

Outcome	1-day therapy	7-day therapy	Difference (95% CI)
Eradication	95%	90%	5% (–4 to 14) [§]

‡Abbreviations defined in Glossary; CI calculated from data in article.

§Not significant.

COMMENTARY

Dyspepsia is endemic and chronic. Most patients who are evaluated are diagnosed with nonulcer, or functional, dyspepsia. Systematic reviews support a modest benefit of *H. pylori* eradication in such patients, with perhaps 1 cure for every 15 patients treated (1). A Cochrane review concluded that the *H. pylori* test-and-treat approach may be less expensive and just as effective as endoscopy-based management in younger patients (< 45 y) without alarm symptoms (2).

Lara and colleagues showed similar efficacy of 1-day and standard 7-day treatment in achieving *H. pylori* eradication. Although dyspepsia symptoms improved, few patients had complete relief. If reproducible, a single-day course would likely have great advantages in cost, convenience, and adverse effects. However, the 95% eradication rate in this study was much higher than that of previous studies, with rates ranging from 20% to 83% (3).

We offer a few words of caution about this study. Most patients were > 45 years old and, under current guidelines, should have endoscopy to exclude cancer. Moreover, 1-day therapy may be insufficient to heal ulcers in the 10% to 15% subset of patients with dyspepsia and underlying peptic ulcer disease. An important question remains the symptom

recurrence rate over time. Longer follow-up will be needed in future studies to address this.

The 1-day quadruple therapy, although intriguing, cannot be recommended based on current evidence. Until further studies are done with blinding to treatment allocation and longer follow-up, we recommend a minimum 7-day course of *H. pylori* treatment for patients with functional dyspepsia who choose the eradication option.

Debjani Mukherjee, MD

Mark D. Schwartz, MD

New York University School of Medicine
New York, New York, USA

References

- Moayyedi P, Soo S, Deeks J, et al. Systematic review and economic evaluation of *Helicobacter pylori* eradication treatment for non-ulcer dyspepsia. *Dyspepsia Review Group. BMJ.* 2000;321:659-64.
- Delaney BC, Innes MA, Deeks J, et al. Initial management strategies for dyspepsia. *Cochrane Database Syst Rev.* 2001:CD001961.
- Wermeille J, Cunningham M, Armenian B, et al. Failure of a 1-day high-dose quadruple therapy for cure of *Helicobacter pylori* infection. *Aliment Pharmacol Ther.* 1999;13:173-7.