

Lansoprazole was not effective in young dyspeptic patients without *Helicobacter pylori*

Leung WK, Wu JC, Chan FK, et al. Initial treatment with lansoprazole in young dyspeptic patients with negative urea breath test result: a randomized controlled trial with 12-month follow-up. *Am J Gastroenterol*. 2007;102:1483-8.

Clinical impact ratings: GIM/FP/GP ★★★★★☆ Gastroenterology ★★★★★☆

QUESTION

Is lansoprazole effective in reducing dyspepsia and enhancing quality of life in young dyspeptic patients without *Helicobacter pylori*?

METHODS

Design: Randomized placebo-controlled trial.

Allocation: Concealed.*

Blinding: Blinded (patients, data collectors, {health care providers}†, and outcome assessors).*

Follow-up period: 12 months.

Setting: Outpatient clinic of a hospital in Hong Kong, China.

Patients: 157 uninvestigated patients 18 to 45 years of age (mean age 31 y, 78% women) with pain or discomfort in the upper abdomen persisting for ≥ 12 weeks. Exclusion criteria included symptoms indicative of gastroesophageal reflux disease (GERD) or the irritable bowel syndrome; alarming symptoms, such as unintentional weight loss, gastrointestinal bleeding, repeated vomiting, or anemia; use of nonsteroidal antiinflammatory drugs; family history of gastric cancer; history of peptic ulcer disease or gastric surgery; and prior *H. pylori* eradication.

Intervention: Lansoprazole, 30 mg daily, for 12 weeks ($n = 78$) or placebo ($n = 79$).

Outcomes: Primary outcome was treatment failure at 12 weeks. Treatment failure was defined as worsening of symptoms of > 2 points from baseline on a 7-point Likert scale. Secondary outcomes included health-related quality of life (HRQL), as measured by the physical and mental health summary scores of the SF-36, and need for endoscopy. The study had 80% power to detect a smaller failure rate in the lansoprazole group than in the placebo group.

Patient follow-up: 80% completed the study (100% in the intention-to-treat analysis).

MAIN RESULTS

At 12 weeks, the groups did not differ for treatment failure, resolution of symptoms

(Table), or HRQL ($P > 0.05$ for physical or mental health summary scores at all time points). At week 52, groups did not differ for proportion of patients who needed endoscopy (Table).

CONCLUSION

Lansoprazole did not reduce dyspepsia or enhance quality of life in young dyspeptic patients without *Helicobacter pylori*.

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*See Glossary.

†Information provided by author.

Lansoprazole vs placebo for young dyspeptic patients without *Helicobacter pylori*†

Outcomes	Lansoprazole	Placebo	RRI (95% CI)	NNH
Treatment failure at 12 wk	33%	30%	9.7% (–30 to 73)	Not significant
Need for endoscopy at 52 wk	29%	22%	37% (–20 to 136)	Not significant
RBR				
Complete resolution at 12 wk	13%	16%	22% (–64 to 63)	Not significant

†Abbreviations defined in Glossary. RRI, RBR, NNH, and CI calculated from data in article.

COMMENTARY

In patients with uninvestigated dyspepsia and no alarm features, there is consensus that noninvasive testing for *H. pylori* and empirical treatment of all infected cases is a rational and safe strategy, largely eliminating peptic ulcer disease (1). Identification of patients with *H. pylori*-negative dyspepsia is, however, common when this strategy is applied, and current guidelines recommend an empirical trial of acid suppression therapy (1, 2). The results of Leung and colleagues challenge the dogma that acid suppression is superior to placebo in patients with *H. pylori*-negative dyspepsia.

Importantly, the population studied was from China and was young and otherwise healthy; if upper endoscopy had been performed, almost all patients would presumably have had functional (nonulcer) dyspepsia. Patients who had treatment failure and those who were dissatisfied with study medication were offered upper endoscopy; of 40 patients so investigated, only 3 had any abnormalities. This suggests that performing endoscopy when empirical therapy initially fails is not useful unless new alarm features manifest.

Western countries have reported higher rates of endoscopic abnormalities in uninvestigated dyspepsia—in particular, reflux esophagitis—and nonerosive reflux disease may be more prevalent (3). This implies that results from the East do not necessarily apply to the West, and vice versa. In North America, high rates of unrecognized GERD probably

account for the response to acid suppression therapy (1, 2). Epigastric pain or nausea with little or no heartburn can be the presenting symptom of GERD. If a patient presents with heartburn, GERD is likely and proton pump inhibitors will be useful (1, 2).

Treatment of *H. pylori*-negative dyspepsia not associated with reflux remains challenging. Not all such patients need drugs. Leung and colleagues showed that the treatment failure rate was relatively low in both groups at 12 weeks. Limited prokinetic options are available, and their efficacy has been questioned (1, 2). Antacids, sucralfate, and bismuth do not work (2). The value of other drugs (e.g., antidepressants) has not been established (1).

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References

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