Noninvasive *Helicobacter pylori* testing was as effective as endoscopy for managing dyspepsia


**QUESTION:** In patients with upper gastrointestinal symptoms presenting for investigation of dyspepsia, is treatment based on a urea breath test for *Helicobacter pylori* alone as effective as endoscopy and urea breath testing?

**Design**
Randomised [allocation concealed†‡,†‡ unblinded,* controlled trial with 1 year of follow up.

**Setting**
A gastroenterology clinic in Glasgow, UK.

**Patients**
708 patients (mean age 37 y, 53% men) who were referred by their general practitioners for investigation of upper gastrointestinal symptoms. Exclusion criteria were age >55 years, nonsteroidal anti-inflammatory drugs, or sinister symptoms. Follow up was 83%.

**Intervention**
Patients were allocated to endoscopy plus the noninvasive

\[ \text{C}\text{-area breath test} \]

or the breath test alone

\[ \text{H pylori} \]

for determination of *H pylori* status. Patients were informed of their status after the test, and patients with positive results were prescribed a 7 day course of *H pylori* eradication treatment with omeprazole, 20 mg twice daily; clarithromycin, 250 mg 3 times daily; and amoxicillin, 500 mg (or metronidazole, 400 mg) 3 times daily.

**Main outcome measures**
Change from baseline on the Glasgow Dyspepsia Severity Score (GDSS). Secondary outcomes were use of medical resources, patient assessment of the procedures, and safety.

**Main results**
Analysis was by intention to treat. At 1 year, the mean change from baseline on the GDSS was similar between groups (p=0.69) (table). The study had 90% power to detect a difference in mean change on the GDSS of 1.03 and 1.41 between the groups that were positive and negative for *H pylori*, respectively. The mean reduction in GDSS was 46% in the endoscopy group and 45% in the breath test alone group. Groups did not differ for resolution of dyspepsia (14% v 11%, p=0.25). More patients who received the breath test alone were referred for further endoscopy than were those who received the breath test and endoscopy (8.2% v 1.7%, p<0.001). Groups did not differ for further nonendoscopic investigations.

**Conclusion**
In patients with upper gastrointestinal symptoms presenting for investigation of dyspepsia, a urea breath test for *Helicobacter pylori* was as effective as endoscopy plus breath test for managing dyspepsia.

*See glossary.
†Information provided by author.
‡CI defined in glossary.
Helicobacter pylori eradication improved dyspepsia symptoms


**QUESTION:** In patients with dyspepsia and a positive test result for Helicobacter pylori, is an H pylori eradication strategy more effective than placebo for improving dyspepsia symptoms?

**Design**
Randomised (allocation concealed*†, blinded (clinicians, patients, data collectors, outcome assessors, data analysts, and manuscript writers!)), placebo controlled trial with 1 year of follow up.

**Setting**
36 family practices in Canada.

**Patients**
294 patients (mean age 49 y, 50% men) who were ≥ 18 years of age and had uninvestigated symptoms of dyspepsia for ≥ 3 months. Dyspepsia was defined as a complex of epigastric pain including heartburn, acid regurgitation, excessive burping or belching, increased abdominal bloating, nausea, abnormal or slow digestion, or early satiety. All patients had to have positive test results for H pylori on the Helisal rapid blood test and the 13C-urea breath test. Exclusion criteria included gastrosophageal reflux disease, upper gastrointestinal investigation in the previous 6 months or ≥ 2 times in the past 10 years, eradication therapy for H pylori in the past 6 months, previous gastric surgery, ulcer disease or endoscopic oesophagitis, and irritable bowel syndrome. Follow up was 87%.

**Intervention**
Patients were allocated to omeprazole, 20 mg; metronidazole, 250 mg (eradication) (n = 145) or omeprazole, 20 mg, and placebo metronidazole and placebo clari-thromycin (placebo) (n = 149) twice daily for 7 days.

**Main outcome measures**
Global overall severity (GOS) of dyspepsia symptoms assessed with a 7 point scale (1 = no problem, 7 = very severe problems). Treatment success was a score of 1 or 2. Secondary outcomes were proportion of asymptomatic patients and treatment success according to H pylori status.

**Main results**
Analysis was by intention to treat, and an analysis with all evaluable patients was also done (n = 267). Patients in the eradication group had greater treatment response than did those in the placebo group (table). More patients in the eradication group were completely asymptomatic (table). Treatment was more successful in patients in whom H pylori was eradicated than in those it was not (54% vs 39%, p = 0.02). Eradication treatment reduced societal costs, but the difference was not statistically significant (Cdn $53, 95% CI – 86 to 180).

**Conclusion**
In patients with dyspepsia and a positive test result for Helicobacter pylori, an H pylori eradication strategy was more effective than placebo for improving dyspepsia symptoms.

*See glossary.
†Information provided by author.

**H pylori eradication v placebo for uninvestigated dyspepsia at 1 year**

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Eradication</th>
<th>Placebo</th>
<th>RBI (95% CI)</th>
<th>NNT (CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment success</td>
<td>50%</td>
<td>36%</td>
<td>37% (5 to 80)</td>
<td>7 (4 to 63)</td>
</tr>
<tr>
<td>Completely asymptomatic</td>
<td>28%</td>
<td>15%</td>
<td>92% (21 to 205)</td>
<td>8 (5 to 24)</td>
</tr>
</tbody>
</table>

†Abbreviations defined in glossary; RBI, NNT, and CI calculated from data in article.

**COMMENTARY**
Further, patients with nonulcer dyspepsia may also benefit from H pylori eradication. A Cochrane review of 9 placebo controlled trials of H pylori eradication treatment in patients without peptic ulcers or oesophagitis at endoscopy found a number needed to treat of 15.5

The CADET-Hp trial does not show conclusively that H pylori test and treat is more cost effective in primary care than omeprazole alone, because it was only done in H pylori-positive patients. The cost effectiveness of this strategy needs to be tested by randomising patients with dyspepsia, both positive and negative for H pylori, before noninvasive testing for H pylori, to determine the effect of the management strategy on the whole group. It does, however, lend more support to the eradication of H pylori in all patients known to be infected.

Brendan Delaney, MD, FRCP, MRCPG
University of Birmingham
Birmingham, UK