Review: Proton-pump inhibitor therapy reduces symptoms in nonulcer dyspepsia better than placebo


Question

In patients with nonulcer dyspepsia (NUD), is proton-pump inhibitor (PPI) therapy better than placebo for reducing dyspepsia symptoms?

Methods

Data sources: Studies were identified by searching MEDLINE (1966 to September 2002), EMBASE/Excerpta Medica (1988 to September 2002), CINAHL (1982 to September 2002), Cochrane Controlled Trials Register (September 2002), and SIGLE; hand-searching general medical and major gastroenterology journals; and contacting pharmaceutical companies and experts in the field for unpublished studies.

Study selection and assessment: Studies in any language were selected if they were randomized controlled trials (RCTs) that compared PPI therapy with placebo, H2-receptor antagonists, prokinetic therapy, antacids, or mucosal protection agents (excluding Helicobacter pylori eradication therapy), and assessed symptoms of dyspepsia as an outcome in patients who fulfilled Rome or Working Party definitions and had negative findings at endoscopy (hiatal hernia, <5 gastrict erosions, or mild duodenitis was permitted).

Study quality was assessed for method of randomization, allocation concealment, and blinding of patients and investigators. Outcomes: Relief of dyspepsia symptoms and incremental cost-effectiveness of PPI therapy compared with over-the-counter (OTC) antacids from a health service perspective. Costs were in 2004 U.S. dollars with no discounting of costs or effects.

Main results

8 RCTs (n = 3293) met the selection criteria. PPIs evaluated were omeprazole (5 RCTs) and lansoprazole (3 RCTs). Adequate randomization was done in 6 RCTs, concealment in 3 RCTs, and blinding in 4 RCTs. More patients who received PPI therapy had relief of dyspepsia than did those who received placebo (Table). Groups did not differ for relief of dyspepsia in 2 RCTs that compared PPIs with H2-receptor antagonists (relative risk 0.93, 95% CI 0.84 to 1.02).

Outcome Number of trials (n) Weighted event rates RBI (95% CI) NNT (CI)

<table>
<thead>
<tr>
<th>Outcome</th>
<th>PPI Placebo</th>
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<tr>
<td>Dyspepsia symptom relief</td>
<td>8 (3293)</td>
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From a health services perspective, incremental cost-effectiveness ratios for PPI therapy compared with OTC antacids were $278/mo free from dyspepsia at managed care PPI prices ($90/mo) and $57/mo at OTC PPI prices ($20/mo). If consumers are willing to pay $94/mo for freedom from dyspepsia, a 95% probability exists that OTC PPI therapy is cost-effective.

Conclusions

In patients with nonulcer dyspepsia, proton-pump inhibitor (PPI) therapy is better than placebo for relieving dyspepsia. PPI therapy is cost-effective at over-the-counter prices.

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Commentary

Diagnosis of NUD requires a normal endoscopy result, but this is poorly handled in the literature. Before having endoscopy, many patients take acid-suppressive therapy, which can heal ulcers and erosions. Although clinical trials often exclude the use of such medication, patients take acid-suppressive therapy, which can heal ulcers and erosions. Although clinical trials often exclude the use of such medication, many patients or society to pay.

Given the lack of better alternatives, it is reasonable to give patients with NUD a 4- to 8-week trial of PPI therapy to document whether symptoms are acid-sensitive.

References