Clinical Update

The dyspepsia dilemma

Talley NJ, Vakil N, Ballard ED II, Fennerty MB. Absence of benefit of eradicating *Helicobacter pylori* in patients with nonulcer dyspepsia. *N Engl J Med* 1999;341(15):1106-11.

Background

Dyspepsia is one of the most frequent presenting complaints in primary care practice. More than 50% of affected patients do not have an ulcer, but as many as 30% may have *Helicobacter pylori* infection, indisputably the main cause of peptic ulcer. Various expert groups have issued recommendations, largely on the basis of consensus (i.e., no direct evidence), for and against therapy to eradicate *H. pylori*.

Question

Should patients with dyspepsia and positive test results for *H. pylori* be treated for eradication of the bacterium?

Design

A randomized controlled trial involving 170 patients with nonulcer dyspepsia (confirmed by endoscopy) and *H. pylori* infection were randomly assigned to receive triple therapy for eradication of the bacterium (omeprazole 20 mg, amoxicillin 1000 mg and clarithromycin 500 mg, twice daily for 14 days); 167 control subjects with the same condition were given identical-appearing placebos. Successful treatment was defined as the absence of symptoms or only mild pain or discomfort. The study was undertaken at multiple centres in the United States.

Results

At 12 months 46% of the subjects in the treatment group and 50% of those in the placebo group reported either no discomfort or no more than mild pain or discomfort in the upper abdomen during the 7 days preceding the assessment. The mean rate of antacid use was similar in both groups at 12 months. Urea breath test results 4–6 weeks after termination of active treatment indicated that 90% of the patients in the treatment group had negative results for *H. pylori*, as compared with 2% of those in the placebo group. In a subset of patients with chronic gastritis diagnosed during their entry gastroscopy, 86% of those in the treatment group no longer had the problem, as compared with 8% of those receiving placebos. When endoscopy was performed after 12 months, duodenal ulcer was found in 2% of the treated patients and 4% of the control subjects ($p = 0.22$).

Commentary

This was a carefully conducted, randomized, double-blind, placebo-controlled clinical trial. The primary outcome measure (symptom relief) is relevant. The authors also documented the presence of peptic ulcer at the final visit, did pill counts of antacid use and collected a variety of other measures of patient well-being that are not reported here. The study was multicentred; although the precise number of centres was not stated, each centre enrolled 6 patients on average. It is unclear whether patients in this study were similar to those seen in a primary care practice.

Implications for practice

Patients with moderate pain or discomfort in the upper abdomen (dyspepsia) who do not present with warning signs of more serious disease (age less than 50 or signs of blood loss) may have *H. pylori* infection. This study shows that the eradication of *H. pylori* does not convey a health benefit. The implication is that patients presenting with moderate upper abdominal discomfort but without warning signs do not require testing for *H. pylori* infection and should be managed with conventional therapy. A recent meta-analysis supports this recommendation.[1] — *John Hoey*, CMAJ

Reference

1. Danesh J, Pounder RE. Eradication of *Helicobacter pylori* and non-ulcer dyspepsia. *Lancet* 2000;355:766-7.

Breast cancer and distant metastatic disease

Braun S, Pantel K, Müller P, Janni W, Hepp F, Kentenich CRM et al. Cytokeratin-positive cells in the bone marrow and survival of patients with stage I, II, or III breast cancer. *N Engl J Med* 2000;342(8):525-33.

Background

Many women with breast cancer that appears localized to the breast or to the breast and regional lymph nodes are believed to have undetectable distant metastases at the time of initial staging. Because of this, current recommendations are that systemic chemotherapy be given to all women with regional node involvement and to those with no node involvement but a primary lesion greater than 1 or 2 cm in diameter. However, the improvement in outcome with chemotherapy is slight. In women