Omeprazole was better than cisapride or placebo for controlling heartburn at 4 and 8 weeks

Hatlebakk JG, Hyggen A, Madsen PH, et al., on behalf of the Norwegian Heartburn Study Group. **Heartburn treatment in primary care: randomised, double blind study for 8 weeks.** BMJ. 1999 Aug 28;319:550-3.

Question

In patients with heartburn, are omeprazole and cisapride effective for controlling symptoms?

Design

8-week randomized (allocation concealed*), blinded (patients and outcome assessors),* controlled trial.

Setting

65 primary care practices in liaison with endoscopy units and pharmacies in Norway.

Patients

{484}† patients who were 18 to 80 years of age (median age 47 y in the cisapride group, 49 y in the omeprazole group, 50 y in the placebo group; 52% men) and had had heartburn for ≥ 3 d/wk for ≥ 3 months during a 14-day run-in period. Exclusion criteria were grade 2 or 3 esophagitis; Barrett esophagus; peptic ulcer disease; gallstone disease; esophagogastric surgery; use of prokinetic, antisecretory, or antibiotic medication in the 2 weeks before endoscopy; substance abuse; need for an interpreter; or other diseases that might affect symptom assessment. Follow-up was {96%}† at 4 weeks and 90% at 8 weeks; all patients except 1 were included in the analysis.

Intervention

Patients were allocated to omeprazole, one 20-mg capsule daily (n = 161); cisapride, two 10-mg tablets twice daily (n = 163); or placebo (n = 159). Calcium carbonate antacid tablets were given for use when heartburn occurred.

Main outcome measures

Adequate control of heartburn (defined as ≤ 1 d with no more than mild heartburn in the previous 7 d). Adverse events were also assessed.

Main results

Omeprazole led to greater control of heartburn than did placebo or cisapride at 4 (P < 0.001) and 8 weeks (P < 0.001) (Table). Patients who received cisapride reported more adverse events after 4 weeks than did those who received omeprazole (P = 0.024) or placebo (P = 0.004).

Conclusion

In patients with heartburn, omeprazole was more effective than cisapride or placebo for achieving adequate control.

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*See Glossary.

†Additional information supplied by the BMJ Web site (http://www.bmj.com).

Omeprazole (Ome), cisapride (Cis), and placebo for heartburn‡

Outcomes	Ome	Cis	Placebo	RBI (95% CI)	NNT (CI)
Adequate heartburn control at 4 wk	71%	—	18%	288% (179 to 451)	2 (2 to 3)
	71%	22%	—	221% (139 to 338)	3 (2 to 3)
	—	22%	18%	21% (–21 to 87)	Not significant
Adequate heartburn control at 8 wk	76%	—	30%	151% (97 to 226)	3 (2 to 3)
	76%	40%	—	90% (55 to 136)	3 (3 to 4)
	—	40%	30%	32% (–2 to 79)	Not significant

‡Abbreviations defined in Glossary; RBI, NNT, and CI calculated from data in article.

Commentary

The study by Hatlebakk and colleagues provides evidence of estimable quality. It includes all of the elements necessary for a therapeutic trial, and the final result is an impressive vindication of the benefits of omeprazole for heartburn without complications. This does not mean, however, that all patients with heartburn should now be treated with omeprazole.

The patients in this trial may not be typical patients with heartburn. 50% had heartburn every day, and 75% reported that heartburn interfered with daily activities. They may be more typical of primary care patients because 51% had grade 1 esophagitis only and the rest had none, although this and other studies suggest that endoscopic findings may not correlate closely with symptoms (1).

The scope for nondrug measures was not tested. These measures should remain a first-line strategy primarily because, if effective, the benefits are likely to be sustained. The benefits of omeprazole in this trial have only been shown to last for the 8 weeks of drug therapy. Longer-term treatment may be needed to sustain benefit, and omeprazole may prove expensive if it has to be taken for a long period. Antacids or H_2-blockers may be adequate for some patients. Other proton-pump inhibitors may be less expensive and equally effective. An intermittent regimen might also be effective (2). The appropriate use of such inhibitors is not as simple a matter as this study might imply.

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References

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