Managing Dyspepsia: Is the Test-and-Treat Strategy Effective in Primary Care?


Study Overview

Objective. To evaluate the “test-and-treat” strategy compared with immediate endoscopy for dyspepsia in primary care patients.

Design. Randomized controlled trial.

Setting and participants. Patients were recruited from 1 of 56 participating general practitioners within the Netherlands. Patients were considered eligible if they were diagnosed with dyspepsia and symptoms were severe enough to warrant either pharmacologic treatment or referral for upper endoscopy. Patients were excluded if: their symptoms were suggestive of gastroesophageal reflux disease (GERD); their symptoms were suggestive of serious underlying pathology; they had a previous documentation of peptic ulcer disease or GERD; they had undergone previous surgery of the upper alimentary tract; they had completed previous anti-Helicobacter pylori treatment; had used proton pump inhibitors or bismuth compounds within the month prior to enrollment; or had used either aspirin or nonsteroidal antiinflammatory medications 2 weeks prior to enrollment.

Intervention. Patients were randomized to either endoscopy or the test-and-treat strategy. Patients randomized to endoscopy underwent the procedure within 2 weeks of study inclusion. During endoscopy, 3 biopsy samples for H. pylori were obtained for culture and histologic examination. Patients diagnosed with peptic ulcer disease were treated with ranitidine hydrochloride, and patients with GERD were treated with lansoprazole for 3 months. Patients diagnosed with H. pylori were treated with 1 week of lansoprazole, amoxicillin, and either metronidazole or clarithromycin, depending on the organism’s culture and sensitivity. Patients with no evidence of H. pylori infection and normal endoscopy were treated with cisapride for 4 weeks. Patients randomized to the test-and-treat strategy underwent serologic testing for H. pylori through venous blood sampling. Patients with positive tests were treated with lansoprazole, amoxicillin, and clarithromycin. Patients with no evidence of H. pylori were treated with 4 weeks of cisapride.

Main outcome measures. Patients were followed for 12 months with outcome assessments obtained at baseline and at 12 months. Dyspepsia was defined as persistent or recurrent pain or discomfort centered in the upper abdomen. Outcome measures were based on patient surveys and included a dyspepsia severity questionnaire, quality of life assessment, and overall patient satisfaction. Secondary endpoints included number of primary care visits related to dyspepsia, total number of primary care visits, any additional dyspepsia diagnostic workup, specialist referrals, hospitalizations, and prescriptions of additional dyspepsia medications.

Main results. Of 281 consenting patients, 270 were eventually randomized. 141 patients were assigned to the test-and-treat strategy and 129 to the prompt endoscopy group. There were no significant differences in baseline characteristics between the groups. 46 (33%) patients allocated to the test-and-treat strategy were eventually referred for endoscopy. In both groups, the most common endoscopic diagnosis was GERD (test-and-treat group, 31%; prompt endoscopy group, 29%). All dyspepsia symptoms improved over the course of the study in both groups. There were no statistically significant differences in improvement levels between the groups. Similar to the dyspepsia symptom index, patient quality of life improved over the course of the study with no difference seen between the groups. Satisfaction scores also were similar between the groups with most patients (94%) noting satisfaction with their care. Patients randomized to the test-and-treat strategy had more dyspepsia-related medical visits compared with the prompt endoscopy group (3.06 versus 2.28; P = 0.005). Patients in the test-and-treat group were less likely to receive a proton pump inhibitor (29% versus 71%; P = 0.007) and more likely to receive a prokinetic agent (16% versus 12%) when compared with the prompt endoscopy group.

Conclusion. For patients who present to their primary care provider with complaints of dyspepsia, a strategy of test-and-treat was as effective as prompt upper endoscopy. About one third of patients in the test-and-treat strategy required endoscopy.
Commentary

Dyspepsia is a common patient complaint [1], and significant debate exists regarding the most appropriate therapy [2,3]. Multiple alternative strategies exist including routinely referring all patients for endoscopy; testing for *H. pylori* first followed by endoscopy for positive patients; testing patients for *H. pylori* and then treating those who are positive without endoscopy (test-and-treat strategy); or routine empiric treatment. While multiple decision-analytic models have been evaluated in order to determine the best approach, none have evaluated these strategies in a primary care setting [4,5]. Since dyspepsia is often diagnosed and managed entirely by primary care providers [6], the purpose of this randomized trial was to evaluate how these varying strategies may perform in a primary care setting.

In general, the test-and-treat strategy resulted in similar improvements in patients’ symptoms and quality of life when compared with a prompt endoscopy strategy. Only a minority of patients in the test-and-treat strategy eventually required endoscopy. While this study would support using a test-and-treat strategy for dyspepsia in primary care, there are several important study limitations which merit review. The most important is possible information bias. Many of the secondary outcomes were extracted by chart review, which was performed by the study’s author. No data were presented to determine the reliability of this process. Second, the primary care providers selected patients for inclusion in the study, which could have introduced a selection bias. Finally, on a practical level, most guidelines support an empirical strategy. Even though a test-and-treat strategy might have similar outcomes to a prompt endoscopy strategy, it is unclear how this strategy might perform against the more commonly employed empirical treatment strategy.

Applications for Clinical Practice

Routine upper endoscopy for primary care patients presenting with dyspepsia does not appear to offer any significant advantage over a more conservative test-and-treat strategy.

—Review by Harvey J. Murff, MD, MPH

References