Primary-Care Physicians' Perceptions and Practices on the Management of GERD: Results of a National Survey

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BACKGROUND: Gastroesophageal reflux disease (GERD) is frequently managed by primary-care physicians (PCPs)

although little is known about their current practices and management patterns.

METHODS: We administered a questionnaire-based survey to PCPs attending sponsored educational

conferences on GERD. Questionnaires were completed anonymously before the conferences and asked about prescribing patterns, indications for surgical referral, and issues concerning Barrett's

esophagus and H. pylori infection.

RESULTS: A total of 1046 completed questionnaires (97% acceptance rate) were received. Most PCPs

prescribed a proton pump inhibitor (PPI) for GERD without prior authorization and without first using an H₂-receptor antagonist (H₂RA). Many gave an H₂RA with once-daily PPI treatment for patients with nocturnal heartburn. Most referrals for anti-reflux surgery were for inadequate response to medical treatment, although PCPs usually first sought gastroenterological consultation. There was a widespread acceptance of screening GERD patients for Barrett's esophagus. There was general confusion about any relationship between *H. pylori* infection and GERD; 80% of PCPs tested for the

infection in at least some patients who only had symptoms of GERD.

CONCLUSIONS: Our survey has identified a number of areas of controversy and confusion related to the

management of GERD. We hope that our findings can assist in the development of educational

materials on GERD for PCPs.

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INTRODUCTION

Of the gastrointestinal diseases that primary-care physicians (PCPs) face in their practices, gastroesophageal reflux disease (GERD) is one of the most common. The prevalence of GERD varies in different studies based upon the frequency of symptoms necessary to define an individual with disease. Farup and colleagues reported that frequent heartburn occurred in 14% of the U.S. population (1). In a 1999 survey of 10 U.S. cities, the prevalence of GERD was estimated to be 18.6 million (2). A study based upon a number of national databases found that, in 2000, GERD led to the highest total direct and indirect costs (\$9.8 billion) among 17 selected GI and liver diseases (3). Drug costs were responsible for 63% of the direct costs for GERD.

This work has been presented in part at the annual meeting of the American College of Gastroenterology in Seattle, WA, in October 2002, and at the annual meeting of the American Gastroenterological Association at Digestive Disease Week in Orlando, FL, in May 2003. Parts of this work have, therefore, been published in abstract form (Chey et al., Am. J. Gastroenterol. 2002: 97: S231–2; Chey et al., Gastroenterology 2003; 124: A-108, Chey et al., Gastroenterology 2003; 124: A-505).

Although GERD occurs commonly, adversely affects quality of life (4), and consumes a large amount of health-care resources, very little is known about the current state of knowledge of PCPs pertaining to GERD. In the current study, we sought to better understand PCPs perceptions' regarding the treatment of GERD in the hopes of identifying areas of confusion or misconception.

METHODS

Questionnaire Development

Item generation was performed by a group of gastroenterologists and a primary-care physician with an interest in GERD. Items elicited information on PCPs' practices and perceptions regarding GERD, and were formulated to address issues with which there might be confusion on the part of PCPs. The initial instrument was piloted in a separate group of gastroenterologists, PCPs, and house officers and revised to the final 30-item survey. The questionnaire was developed without influence or financial support from the pharmaceutical industry. Further, nothing beyond logistical support (mailing

of the survey to participants, collection of surveys, data organization, and mailing to the authors) was accepted to conduct this study.

Specific items addressed the ability of PCPs to prescribe a proton pump inhibitor (PPI) without first using an H₂-receptor antagonist (H₂RA), the ability to prescribe longterm PPI treatment (defined as three or more months continuously) without prior authorization, and any specific advice that they gave to patients concerning the timing of PPI administration. PCPs were asked if they advised patients to take a PPI before, with, or after food, or if they gave no specific advice about time of dosing. PCPs were also asked for their main reason for selecting a specific PPI; they were asked to select one response from a list that included price, availability on formulary, coverage by patient's drug plan, safety, efficacy, FDA-approved indications, drug interactions, and "other." They were then asked to assume that all PPIs cost the same and to give their main reason for selecting a particular PPI. For this, they were asked to select one response from a list that included safety, ability to control stomach pH, speed of the onset of action, effectiveness in controlling the symptoms of GERD, effectiveness of healing erosive esophagitis, FDA-approved indications, drug interactions, and "other." They were asked about a hypothetical patient with typical GERD whose symptoms were incompletely controlled on a PPI given once daily and who was still having some heartburn in the late evening and at night. They were asked to choose one management option from a list that included increasing the PPI dose but continuing to give it once daily, switching to another PPI and giving it once daily, continuing the same PPI but giving it twice daily, continuing the same PPI once daily and adding an H₂RA at bedtime, or referring to a gastroenterologist. They were also asked to indicate the proportion of their GERD patients taking the combination of a PPI and an H₂RA from a list of options comprising <10%, 10–20%, 21-50%, and >50%.

Regarding the surgical management of GERD, participants were asked if they had referred patients for anti-reflux surgery; if so, they were asked whether they referred directly to a surgeon or if they first obtained a gastroenterological opinion. They were also asked about the patients that they referred for surgery; reasons for surgical referral, from which they were asked to select one, included the lack of response to medical therapy, response to medical therapy but unwillingness to take long-term medication, and "other."

Regarding Barrett's esophagus and the risk of esophageal adenocarcinoma, we asked if they thought that screening EGD was appropriate, whether screening EGD should be performed before or after the initiation of medical treatment for GERD symptoms, and whether they thought that PPI therapy and/or anti-reflux surgery would reduce the likelihood of the development of esophageal adenocarcinoma. Concerning any possible relationship between *Helicobacter pylori* (*H. pylori*) infection and GERD, we asked if they tested patients who only had typical GERD symptoms for the presence of the infection; respondents were asked to select from a list of options

that comprised "never," "sometimes," "most of the time," and "always." We also asked what—if any—effect the cure of *H. pylori* infection would have on GERD symptoms; options to choose from were "worsens GERD symptoms," "has no effect on GERD symptoms," "improves GERD symptoms," and "not sure/don't know."

Study Cohort

After the development of the questionnaire, attempts were made to identify a suitable means by which to administer it to a valid and representative sample of PCPs. After considering a number of options, we decided to administer it to a geographically diverse group of PCPs attending a series of industry-sponsored consultants' conferences on GERD. As part of the registration materials for these conferences, participants were sent a brief letter of explanation and the questionnaire. They were asked to fill out the questionnaire and to return it at the time of on-site registration for the meeting. If conference participants had forgotten their questionnaire, they were asked to fill one out on site as part of the registration process. All questionnaires were collected before the beginning of the conference in an attempt to minimize bias introduced by educational materials on GERD presented at the conference. Questionnaires were completed anonymously and no form of financial inducement was offered for participation.

Statistical Analysis

Descriptive statistics were used to present responses to survey items. Logistic regression was employed to detect significant associations between multiple independent variables and dichotomous dependent variables and to control for confounding. Geographic regions were defined by the state in which the respondent practiced, which was not necessarily identical to the location of the conference. Five regions were analyzed as follows: Northeast (NE): New York, New Jersey, Massachusetts, Pennsylvania, Maryland; Southeast (SE): North Carolina, South Carolina, Virginia; South (S): Mississippi, Alabama, Louisiana, Tennessee, Arkansas, Georgia, Florida, Texas; Midwest (MW): Michigan, Ohio, Illinois, Minnesota, Wisconsin, Indiana, Kansas, Nebraska, Missouri; West (W): California, Arizona.

RESULTS

From December 2001 until June 2002, completed questionnaires were collected from 1046 participants attending 23 regional conferences. Using the process for questionnaire collection outlined in the Methods section, we were able to collect survey data from 97% of the PCPs who attended the meetings. The mean (\pm SD) age of PCPs was 48 (\pm 9) yr; 85% were male. For the majority of items, no significant difference in response between genders was noted, and the aggregate response is reported. For those items in which significant differences in response between genders was seen, the

segregated analyses are reported in the text. Their mean $(\pm SD)$ number of years in practice was 17 (± 8) . Forty-three percent practiced Internal Medicine, while 46% practiced Family Medicine. Thirteen percent resided in the Southeast (SE), 32% in the Northeast (NE), 20% in the Midwest (MW), 20% in the South (S), and 15% in the West (W).

Issues Concerning the Medical Treatment of GERD

Eighty-three percent of respondents indicated that they were able to prescribe a PPI for a patient with GERD without first using an $\rm H_2RA$. Twenty-one percent in the SE, 13% in the NE, 14% in the MW, 13% in the S, and 18% in the W reported the need for a trial of an $\rm H_2RA$ prior to prescribing a PPI in their patients with GERD (no significant differences among regions).

Eighty-seven percent of PCPs were "very comfortable" with prescribing long-term PPI therapy. When asked whether they needed prior authorization before prescribing a PPI for 3 or more months, 64% said that this was not required, 32% said that it was, and 4% were unsure. Compared to respondents from the NE (25%), MW (27%), and S (25%), PCPs from the W (54%) and SE (44%) were significantly more likely to need prior authorization before prescribing a PPI for 3 or more months (p<0.001). Sixty-four percent of respondents correctly advised their patients to take a PPI before food, while 36% suggested taking a PPI with food, after food, or provided no specific direction in this regard (Fig. 1).

When asked for the main reason for selecting a specific PPI, 39% indicated that this was based on the drug's efficacy; 30% indicated that this was based on the PPI covered by the patient's drug plan, while 26% stated that this was based on formulary status. The remaining 5% selected a variety of other reasons including perceived safety and number of FDA-approved indications. When asked to assume that all PPIs cost the same and to then identify their main reason for selecting a particular PPI, 69% cited effectiveness in controlling symptoms, 16% cited effectiveness in healing erosive esophagitis, 6% cited safety, 6% cited ability to control stomach pH, 5% cited speed of onset of action, and 4% chose FDA-approved indications or "other." Because a small

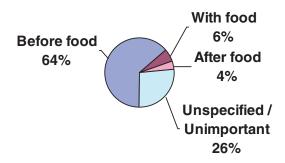


Figure 1. Respondents' answers to the following question: "Do you instruct patients to take a PPI in any particular relationship with meals?"

Table 1. Respondents' Answers to the Following Question: "A Patient with Typical GERD Symptoms Experiences Partial but Incomplete Relief with a PPI Given Once Daily. He/She Still Has Heartburn in the Late Evening and at Night. What Would Be Your Preferred Course of Action?"

Response	Proportion (%)
Increase the dose of the PPI but give it once daily, or switch to another PPI	15
Increase the dose of the PPI but give it twice daily	40
Add an H ₂ RA at bedtime	31
Refer to gastroenterology	14

number of respondents chose more than one answer for this question, the sum of the responses is greater than 100%.

Concerning the management of a hypothetical patient with evening and nocturnal heartburn despite once daily PPI treatment, the most popular management option was to increase the PPI dose to twice daily. Thirty-one percent of respondents reported that they would add an H₂RA at bedtime; a breakdown of the responses is given in Table 1. Eighteen percent of respondents estimated that over 10% of their GERD patients were on the combination of a PPI and an H₂RA.

Issues Concerning the Surgical Treatment of GERD

Seventy-five percent of respondents had referred GERD patients for surgical anti-reflux therapy. Logistic regression revealed that physicians from the NE were significantly less likely to have done so than physicians from other regions (63% vs 85% (SE), 85% (MW), 75% (S), 82% (W), p < 0.001). Male PCPs were more likely than female PCPs to have referred a patient for surgical therapy (OR 2.6, 95% CI 1.8–3.8). Seventy-three percent of those referring patients for anti-reflux surgery indicated that they first referred the patient to a gastroenterologist; 21% stated that they referred directly to a surgeon; the remainder referred to some other specialist or did not provide a response. Regarding the reasons for referring patients for surgical management, 83% stated that their main indication was the lack of response to medical therapy, while 11% gave their main reason as unwillingness on the part of the patient to take long-term medication despite apparently adequate control of symptoms on medical therapy. The remaining 6% of respondents provided a variety of other responses.

Issues Concerning Barrett's Esophagus

Eighty-seven percent of respondents agreed that patients with GERD symptoms for 5 or more years should have EGD to screen for Barrett's esophagus. However, only 50% of respondents indicated that they could order an EGD for patients with presumed GERD without prior consultation with a gastroenterologist. Significantly more respondents from the Midwest were able to order "open access" endoscopy compared to other geographic regions (82% vs 33% (SE), 47% (NE), 47% (S), 30% (W) p < 0.0001). Male PCPs were more likely to recommend endoscopic screening for Barrett's esophagus (OR 2.7, 95% CI 1.3–5.7); however, males were

Table 2. Respondents' Answers to the Following Questions: "Does PPI Therapy Decrease the Likelihood of Progression of Barrett's Esophagus to Esophageal Adenocarcinoma?" and "Does Surgical Treatment for GERD Protect against the Progression of Barrett's Esophagus to Esophageal Adenocarcinoma?"

	Yes	No	Do not Know/Unsure
PPI therapy	65	14	21
Anti-reflux surgery	19	30	51

also more likely to practice in an environment in which open access endoscopy was available (OR 1.6, 95% CI 1.1–2.3), and this was independent from the effect of region. Forty-four percent indicated that the timing of the EGD should be several weeks after starting PPI therapy, whereas 17% thought the EGD should be performed before starting medical therapy. Respondents' views as to the likelihood of PPI therapy or anti-reflux surgery preventing the progression of Barrett's esophagus to esophageal adenocarcinoma are presented in Table 2.

Issues Concerning GERD and H. pylori Infection

Forty-two percent of respondents thought that cure of *H. pylori* infection would improve GERD symptoms, 31% thought it would not affect GERD symptoms, 13% thought it would worsen GERD symptoms, and 14% were unsure or did not know. While 20% of respondents claimed "never" to check for *H. pylori* in patients with only GERD symptoms, 80% reported testing for *H. pylori* at least "sometimes" (Fig. 2). There were no significant variations in responses from different regions of the United States; however, female PCPs and those over the age of 50 were more likely to test for *H. pylori* infection.

DISCUSSION

Although most patients with GERD in the United States are managed by PCPs, relatively little is known about PCPs' attitudes concerning the management of this highly prevalent condition. We have attempted to obtain data on the current practice patterns of a geographically diverse sample of PCPs in the United States.

Most of our respondents indicated that they prescribed a PPI for GERD symptoms without first trying—or being required to prescribe—an H₂RA. Our data suggest that so-called "step-up" therapy for GERD in which patients are initiated on an H₂RA and only given a PPI if or when their symptoms have not been adequately controlled, may have been largely abandoned in the United States. This is gratifying as a controlled clinical trial in a primary-care setting showed that "step-up" therapy was inferior with respect to control of GERD symptoms than the practice of starting a patient on a PPI and continuing it thereafter—the so-called "step-in" approach (5). That most of our respondents could prescribe a PPI for 3 months further indicates that the "step-

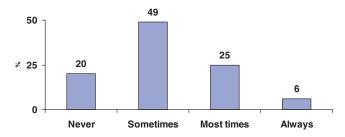


Figure 2. Respondents' answers to the following question: "How often do you check for *H. pylori* in patients with only GERD symptoms?"

in" approach is increasingly accepted in primary care. Most of our respondents appropriately advised their patients with GERD to take their PPI before food, although 36% either gave incorrect advice or did not specify a time of dosing with relation to food intake. PPI absorption is optimal when taken in a fasting state (6) and the subsequent pharmacodynamic effect is maximized if taken before food (7, 8). Eating provides a temporary stimulus to the parietal cell mass and promotes PPI uptake by parietal cells with consequent binding to activated molecules of H⁺/K⁺-ATPase in the secretory canaliculi. It is, therefore, advisable that patients take their PPI before a meal in order to obtain the maximum possible antisecretory effect.

For a patient with persistent nocturnal heartburn despite once daily PPI therapy, 40% of PCPs recommended the addition of a second daily dose of PPI, while nearly a third of PCPs recommended the addition of a nocturnal H₂RA (Table 1). We were somewhat surprised at how commonly PCPs recommended a nighttime dose of an H₂RA for persistent nocturnal heartburn. One reason for this finding may be related to the lower cost of an H₂RA compared to a PPI. Another possibility may be that PCPs are confusing persistent nocturnal heartburn with "nocturnal acid breakthrough" (NAB). NAB is defined as an intragastric pH of below 4 for at least 1 h during the overnight period despite twice daily PPI therapy (9). It remains controversial as to how well NAB and nocturnal heartburn are associated (10, 13)

Most of our respondents had referred some GERD patients for anti-reflux surgery, usually first having obtained the opinion of a gastroenterologist. This may be important as an evaluation by a gastroenterologist can help to divert unsuitable candidates from surgery and—with appropriate diagnostic evaluation—identify patients with esophageal symptoms due to conditions other than GERD. There is general consensus that patients with a poor symptomatic response to PPI therapy are less likely to improve following surgical antireflux therapy as failure of symptoms to improve during PPI treatment may indicate a non-acid related condition such as a functional esophageal disorder. The observation that 83% of our study cohort referred GERD patients for surgical antireflux therapy because of an inadequate response to medical treatment suggests that PCPs are not aware of this important

predictor of surgical outcome. This observation may offer an explanation for the differences in outcomes reported among experienced, high volume surgical centers, and community practice (14–16).

Our survey found that there was general acceptance by PCPs of the desirability of screening patients with longstanding GERD symptoms for Barrett esophagus; 87% indicated that they would arrange EGD for a patient with symptoms for 5 or more years. However, only half of the respondents were able to order an EGD without prior consultation with a gastroenterologist. Despite published recommendations (17), fewer than half would arrange the EGD after the patient had been on medical therapy for several weeks. In a recent clinical guideline, the American College of Gastroenterology suggested providing PPI therapy for several weeks before EGD to maximize the likelihood of identifying Barrett's esophagus, which is more difficult to diagnose in the setting of active esophagitis. There was disagreement among our respondents about whether PPI therapy or anti-reflux surgery prevents or delays the progression of Barrett's esophagus to esophageal adenocarcinoma (Table 2). While 65% of respondents felt that PPI therapy reduced the likelihood of progression to esophageal adenocarcinoma, fewer than 20% felt the same to be true for antireflux surgery. Though controversial, it is unclear whether either form of therapy leads to regression of Barrett's esophagus or prevents progression to dysplasia or adenocarcinoma (15, 18-20).

There was confusion among PCPs concerning any possible interrelationships between GERD and H. pylori infection. When we constructed questions to address this issue, we were careful to ask specifically about testing for H. pylori in patients with only GERD symptoms including heartburn and regurgitation. Although the professional gastroenterological societies have not recommended that physicians check GERD patients for H. pylori infection (21-23), 80% of our respondents claimed to be doing so at least some of the time. This may reflect confusion about the upper gastrointestinal conditions with which H. pylori is causally associated or difficulty in distinguishing symptoms of GERD from those of dyspepsia. There was a broad range of opinion concerning the effect—if any—of the eradication of H. pylori infection upon GERD symptoms. There is, in fact, no consensus on this difficult issue. Current opinion is that any change in symptoms is likely dependent on the distribution of H. pylori-related gastritis and the presence or absence of GERD symptoms prior to eradication (24, 25). It is not surprising that our respondents had a variety of opinions on this difficult and controversial issue.

Several methodological issues are noteworthy when considering the relevance and generalizability of our results to the overall population of PCPs from the United States. Our study cohort consisted of PCPs invited to a series of industry-sponsored educational conferences on GERD. We acknowledge that the physicians invited to these conferences may or may not be representative of the overall population of PCPs

in the United States. Given the nature of the conferences, it is likely that the PCPs invited had considerable experience treating patients with GERD and with using acid suppressive therapies. As such, one could speculate that the opinions and practices concerning GERD expressed by this group of PCPs represent a level of sophistication at least equivalent to the overall population of PCPs in the United States. We would also point out that there is no perfect way to select a study cohort when conducting survey research. Using a mass mailing to the membership of organizations such as the American Medical Association (AMA) or American College of Physicians (ACP) may not be truly representative of PCPs. For example, surveying members of the ACP would capture primarily internists and would largely ignore family medicine physicians and general practitioners. Further, survey research studies that rely on mass mailings are often associated with poor response rates, which raise issues of generalizability of results. The strengths of our study cohort include a broad representation of primary-care providers (internists, family medicine, and general practitioners), a response rate of over 95%, and the large geographically diverse sample

Another issue worthy of mention is that 85% of our study cohort were male. In contrast, data from the AMA in 2000 reported that 76% of its membership was male (26). In a subgroup analysis, we found few differences in survey responses between male and females. Moreover, multiple comparisons between subgroups such as gender increases the possibility of reporting chance associations. As such, we do not think that the differences in gender demographics diminish the validity of our results.

In summary, this study provides current information on the views of US-based PCPs concerning the management of GERD. Our survey has identified a number of areas of controversy and confusion including the proper dosing of PPI therapy, indications for surgical anti-reflux therapy, the impact of PPI therapy and surgery on the natural history of Barrett's esophagus, the treatment of nocturnal heartburn, and the role—if any—of *H. pylori* infection in GERD. We hope that our results can provide direction for future educational efforts on GERD directed at PCPs.

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