

How Satisfied Are Chronic Heartburn Sufferers with Their Prescription Medications? Results of the Patient Unmet Needs Survey

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- **Objective:** To assess satisfaction with treatment among chronic heartburn sufferers using prescription medication to treat their heartburn.
- **Design:** Survey.
- **Setting and participants:** 20,000 individuals selected from a U.S. household database who identified themselves as chronic heartburn sufferers and who used prescription medication to treat their heartburn.
- **Measures:** Satisfaction with heartburn medication was measured by 3 survey items. A direct query asked respondents to rate their overall satisfaction on a 10-point scale in light of the amount of relief obtained from their medication. Secondary measures were participants' willingness to recommend their heartburn medication to a friend and concomitant use of over-the-counter (OTC) medication with their prescription medication.
- **Results:** 11,064 valid questionnaires were returned (response rate, 58%). Less than half (46.2%) of respondents reported being totally satisfied with their heartburn medication. The proportion of totally satisfied respondents varied by drug class; those taking proton-pump inhibitors (PPIs) reported the highest level of satisfaction (57.9%), followed by those taking histamine₂-receptor antagonists (H₂RAs) (46.1%) and those taking prokinetics (42.4%). H₂RA users reported the highest level of OTC antacid use (42.1%), followed by prokinetic users (37.8%) and PPI users (36.5%) ($\chi^2 = 26.52$; $P < 0.001$). Overall, 58% of respondents reported that they would definitely recommend their medication to a friend.
- **Conclusion:** Observed levels of satisfaction with heartburn medication indicate that heartburn sufferers taking PPIs are more satisfied with treatment than those taking H₂RAs. However, there is room for improvement in therapy outcomes across drug classes.

patients who experience upper gastrointestinal (GI) symptoms of heartburn and dyspepsia will consult a family physician about their symptoms [2]. These patients can account for up to 5% of a family practitioner's workload and necessitate considerable expenditure of health care resources [3,4]. Further, more than 2 million outpatient visits per year and almost 40% of referrals to gastroenterologists are associated with heartburn [5]. It is estimated that the over-the-counter (OTC) antacid market represents \$900 million in annual sales, and more than \$10.2 billion per year is spent overall on heartburn medications [6].

A number of nonpharmacologic and pharmacologic methods are available to treat heartburn [7]. Some patients may derive benefit from lifestyle modifications, including decreased fat intake, smoking cessation, avoidance of certain foods, not eating within 3 hours of going to bed, and raising the head of the bed. OTC antacids and low-dose histamine₂-receptor antagonists (H₂RAs) may be used as initial patient-directed therapy for episodic heartburn, but generally are insufficient when heartburn is frequent (occurring 2 or more days per week) and persistent [8]. Prokinetic agents have been shown to be an effective treatment for patients whose heartburn is due to a motility disorder. Prescription H₂RA therapy was the treatment of choice prior to the development of proton-pump inhibitors (PPIs). This therapy is still used and may be effective in patients with less severe gastroesophageal reflux disease (GERD) [7]; however, evidence from clinical trials indicates that PPIs produce greater acid control than either H₂RAs or prokinetics [9], and there has been growth in the use of PPIs by primary care physicians in the last several years.

Although PPIs and H₂RAs are effective to varying degrees, an area of interest is whether patients treated with these medications are completely satisfied with their therapy or whether

In the United States, more than 60 million adults experience heartburn at least once a month, and about 25 million suffer heartburn daily [1]. Approximately 40% of

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there is further need for improvement. The Patient Unmet Needs Survey (PUNS) was conducted to determine the level of unmet need in patients treated for chronic heartburn with currently available prescription medications. It sought to answer the question: what proportion of individuals with heartburn currently being treated with prescription medications are less than totally satisfied with their treatment?

Methods

Patients

The survey was conducted by NFO Research, Inc. (Toledo, OH), a leading U.S. consumer market research company. NFO maintains a database of approximately 3.1 million individuals from over 600,000 households who have volunteered to participate in survey-based research. Occupants of these households completed a questionnaire, providing demographic information concerning individuals in the household and whether they experience any of a number of common symptomatic complaints or have been diagnosed by a physician with a particular disease. Households that persistently do not respond to periodic surveys are removed from the NFO database and replaced; approximately 30% are replaced every 2 years. Participants represent a broad range of socioeconomic groups and are demographically representative of the general U.S. population; however, as participants must complete self-administered questionnaires, the level of literacy is likely higher than that of the general population.

A stratified random sample of 20,000 self-identified individuals with chronic heartburn from within the NFO cohort was selected. To be included in the sample, individuals had to have reported experiencing heartburn and related symptoms and using a prescription medication to treat heartburn. A subset ($n = 1320$) of heartburn sufferers in the sample reported that their doctor had told them that they had GERD. Subjects were required to be 18 years of age or older in order to give consent to participate. Minority groups were underrepresented in the sample, so the information obtained from this database is more representative of the U.S. Caucasian householder population.

Data Collection and Satisfaction Measurement

The 3½-page, 22-item PUNS questionnaire was sent to the sample of 20,000 heartburn sufferers on 14 May 1999; the period for returns ran until 14 June 1999. The survey collected data concerning patient characteristics, GI symptoms, heartburn medication use, general health perceptions, and satisfaction with heartburn medication. No external criteria for diagnosing a GI disorder were applied. The questionnaire did ask respondents to indicate which of the following symptom(s) they had experienced in the past 4 weeks: daytime heartburn, nighttime heartburn, acid reflux, difficulty

swallowing, and abdominal pain. Patients were also asked to list OTC and prescription medications they had used to treat their heartburn symptoms in the previous 4 weeks.

Three measures were used to assess patient satisfaction. Participants were asked an overall assessment question to ascertain their satisfaction with their medication given the amount of heartburn relief obtained by use of their medication. Heartburn relief was measured using a 5-point Likert scale: for amount of relief obtained, participants could respond None (symptoms continue without any change), A Little (some change occurs), A Moderate Amount, A Lot (still some symptoms but under control), or Complete (all symptoms gone). Overall satisfaction with medication was measured using a 10-point scale ranging from 1 (Totally Unsatisfied) to 10 (Totally Satisfied). For analysis, the response scale was reduced to 5 points: Totally Satisfied (9 to 10 points); Somewhat Satisfied (7 to 8); Neither Satisfied or Unsatisfied (5 to 6); Somewhat Unsatisfied (3 to 4); and Totally Unsatisfied (1 to 2).

Satisfaction was also assessed on the basis of intent to undertake a particular action: participants were asked whether they would recommend their current heartburn medication to a friend. Responses were measured using a 5-point scale ranging from Definitely Yes to Definitely Not. A third measure assessed satisfaction on the basis of real action taken. The use of OTC heartburn medication in addition to a prescription drug was taken as a surrogate measure of lack of satisfaction. It was reasoned that acceptance of the increased financial burden of purchasing OTC medications and the inconvenience of taking additional medication was an expression of less than complete satisfaction with the relief obtained from prescription medications. The 2 types of OTC heartburn medication currently available—OTC-strength H₂RAs (eg, Zantac 75, Pepcid AC, Tagamet HB) and common antacids (eg, Tums and Rolaids)—vary in cost, efficacy, and popularity and were evaluated separately.

Information on work absenteeism and reduced productivity while on the job was collected during a telephone follow-up interview. This topic will be covered in a separate publication. All respondents to the mail survey who stated that they had used a prescription drug to treat heartburn in the previous 4 weeks were sent a diary, which participants were asked to complete for a 30-day period. Analysis of these data is also discussed in another report.

The PUNS was pretested for patient comprehension of questions and relevance to sufferers' experience with heartburn. Pretesting was done in patient focus groups during the week of 19 April 1999.

Statistical Analysis

Frequency distributions of response data and chi-square tests of independence were performed for the primary

patient satisfaction variable of overall satisfaction with heartburn medication and the secondary variables of willingness to recommend heartburn medication to a friend and concomitant use of OTC medication. Significance levels were set at $P < 0.05$ for the chi-square tests. Satisfaction levels were compared between drug classes (H_2 RAs, PPIs, and prokinetics). At the time of the survey, omeprazole (72% of PPI mentions on PUNS) and lansoprazole (28% of PPI mentions) were the only 2 commercially available PPIs. H_2 RAs mentioned by subjects included ranitidine (50%), cimetidine (23%), famotidine (18%), and nizatidine (9%). Since the time of the survey, cisapride (the dominant prokinetic agent) has been withdrawn from the U.S. market; the authors, therefore, have not made prokinetics a focus of the analysis presented here. A comparison between respondents and nonrespondents was performed to ascertain the generalizability of study findings. Information about geographic distribution, age of the head of household, household size, and annual income was available on both respondents and nonrespondents. *T* tests of means were used to compare differences between respondents and nonrespondents, with a significance level set at $P < 0.05$. All questionnaire data were analyzed using the SAS system (SAS, Cary, NC).

Results

Subject Characteristics

Of the 20,000 subjects sent a questionnaire, 14,117 (70.6%) responded; 11,604 questionnaires (58.0%) were considered valid for analysis. To reduce the likelihood of recall bias, questionnaires were considered to be invalid if heartburn sufferers did not report using heartburn medication within the past 4 weeks. No significant differences were observed between respondents and nonrespondents on any of the variables available for comparison (data not shown). The largest observed difference between responders and nonresponders was in household size, with 44.1% of respondents living in a 2-person household versus 41.9% of nonrespondents. Respondents were predominately female (65.0%) and well educated, with more than 90% indicating that they had attained a high school or greater level of education. The cohort was generally middle-aged and older, with 85% of respondents equally distributed among the 4 age-groups 40 to 49 years (20.5%), 50 to 59 years (23.9%), 60 to 69 years (20.0%), and 70 years or older (20.5%). Less than half (45.8%) of respondents reported being employed either full- or part time, and many (30.5%) were retired. The distribution of annual income was similar to that of the U.S. householder population, with two thirds of cohort households reporting an income under \$50,000. Forty-four percent of the 11,604 respondents indicated that they were insured through a managed care plan.

Table 1. Heartburn and Related Symptoms Reported During 4 Weeks of Treatment with Prescription Heartburn Medication

| Symptom | No. of Mentions | % of Total |
|-----------------------|-----------------|------------|
| Daytime heartburn | 7119 | 61.3 |
| Nighttime heartburn | 6762 | 58.3 |
| Acid reflux | 7012 | 60.4 |
| Difficulty swallowing | 2263 | 19.5 |
| Abdominal pain | 3569 | 30.8 |

Symptoms and Medication Use

Among the cohort of individuals who returned valid questionnaires, a wide range of symptom duration was reported (from 1 month to more than 40 years), but all but 4.4% reported experiencing symptoms for more than 1 year. Of heartburn sufferers who saw a physician for their symptoms in the previous year, 21.0% noted that they made 4 or more physician visits during that time period. Heartburn, either daytime or nighttime, was the most frequently occurring symptom (74.3% of participants). The majority of individuals reported both daytime and nighttime heartburn (Table 1). Nighttime heartburn and acid reflux were characterized as severe by more respondents than was daytime heartburn. Nearly one third of the cohort reported experiencing abdominal pain, and 19.5% reported having difficulty swallowing. More than half of the cohort said that symptoms of heartburn were occurring 2 or more times per week despite using prescription medication (62.3% of PPI users, 62.8% of H_2 RA users, and 69.6% of prokinetic users for daytime heartburn).

Of the 11,604 respondents, 8039 reported using prescription medication to treat heartburn in the previous 4 weeks. PPIs were used by more than half of prescription medication users (4109 respondents); 3782 respondents reported using an H_2 RA; and 804 respondents mentioned another prescription medication (primarily cisapride or metoclopramide).

Symptom Relief and Overall Satisfaction

All prescription medications were reported to provide at least a moderate amount of relief (95.1% for PPIs, 93.1% for H_2 RAs, and 88.4% for prokinetics). However, few respondents (37.4% of PPI users, 29.7% of H_2 RA users, 25.5% of prokinetic users) reported complete relief of symptoms when using prescribed heartburn medications. Within each medication class, a significant majority of those who reported complete relief of symptoms also reported total satisfaction with their medication (85.9% for PPIs, 77.5% for H_2 RAs, 82.6% for prokinetics). Responses for the overall cohort, without regard to specific medication, indicated that less than half (46.2%) of respondents were totally satisfied with

Table 2. Reported Levels of Satisfaction by Heartburn Medication Class

| | Totally Unsatisfied (1–2 points) | Somewhat Unsatisfied (3–4 points) | Neither Satisfied nor Unsatisfied (5–6 points) | Somewhat Satisfied (7–8 points) | Totally Satisfied (9–10 points) |
|--------------------|-------------------------------------|--------------------------------------|--|------------------------------------|------------------------------------|
| PPIs* | 3.1% | 4.0% | 10.2% | 23.7% | 59.0% |
| H ₂ RAs | 3.4% | 4.6% | 14.8% | 31.1% | 46.1% |
| Prokinetic agents | 3.8% | 7.2% | 16.0% | 30.4% | 42.6% |

NOTE: Percentages in each row total 100%. PPIs = proton-pump inhibitors; H₂RAs = histamine₂ receptor antagonists.

*PPIs versus H₂RAs, $\chi^2_{(4)} = 136.9$ ($P < 0.001$).

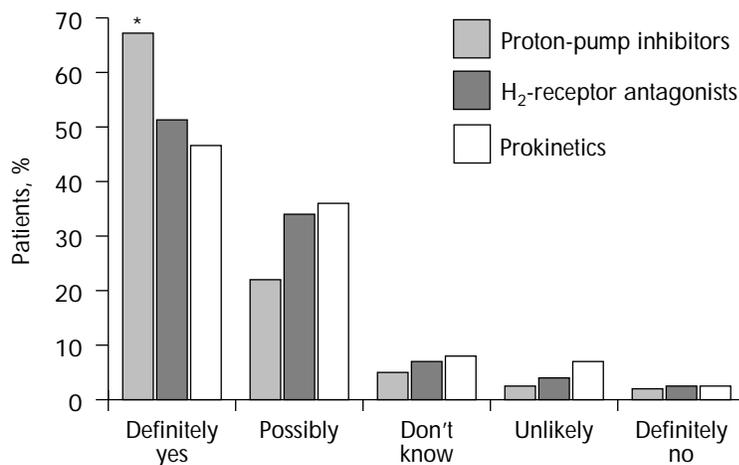


Figure 1. Distribution of responses to the question, "Would you recommend your current prescription heartburn medication to a friend if they were experiencing heartburn," according to drug class. *Chi-square test of independence: $\chi^2 = 255.6$ ($P < 0.001$).

their medication. Very few (3.3%) reported that they were totally unsatisfied. As a class, PPIs were associated with higher satisfaction levels (57.9% totally satisfied) than the next-best class (H₂RAs, 46.1% totally satisfied), with a χ^2 of 136.9 ($P < 0.001$). Among prokinetic users, 42.4% were totally satisfied with their medication. The percentage distribution of respondents' satisfaction levels within drug groups is shown in **Table 2**.

Willingness to Recommend Treatment

Overall, only 58.5% of respondents said that they would definitely recommend their heartburn medication to a friend. However, this was considerably more respondents than those who reported being totally satisfied (46.2%). PPIs ranked highest among recommended treatments, with 67.2% of users indicating that they would definitely recommend treatment compared with 51.3% of H₂RA users and 46.6% of prokinetic users (**Figure 1**). The overall χ^2 was 255.6 ($P < 0.001$).

Use of OTC Heartburn Medications

An approximately equal percentage of respondents from the 3 prescription drug groups reported concomitant use of OTC H₂RAs (11.0% of PPI users, 11.7% of H₂RA users, and

11.3% of prokinetic users). H₂RA users reported the highest level of antacid use (42.1%), followed by prokinetic users (37.8%) and PPI users (36.5%). The difference in antacid use between those taking PPIs and those taking H₂RAs was statistically significant ($\chi^2 = 26.52$; $P < 0.001$) (**Figure 2**).

Discussion

Among survey respondents, 46.2% were totally satisfied with their current heartburn medication and an additional 25.7% were somewhat satisfied. The highest levels of total satisfaction were reported by PPI users; however, only 57.9% were totally satisfied with these agents (versus 46.1% for H₂RAs and 42.4% for prokinetics). Further, only 37.4% of PPI users achieved complete symptom resolution (versus 29.7% for H₂RAs and 25.5% for prokinetics). Respondents who reported complete heartburn resolution within each medication class also reported higher levels of total satisfaction with their medication (85.9% for PPIs, 77.5% for H₂RAs, and 82.6% for prokinetics).

The percentage of PPI users and H₂RA users also taking OTC heartburn medication is comparable to rates observed in a prospective health economic study previously conducted by one of the authors [10]. This study demonstrated that

one third to one half of individuals with heartburn symptoms supplement their prescription medications with OTC drugs.

These findings should be considered generalizable to the population of Caucasian heartburn sufferers in the United States being treated by a physician. As discussed in the Methods section, members of the NFO Research household cohort are demographically representative of the U.S. population. The characteristics of the cohort differ from that of the general U.S. population in that participants need to be literate and to have expressed a willingness to participate in consumer market research. The sample size of 20,000 allowed the investigators to compare results between medication classes after excluding for invalid responses.

The PUNS study was structured so that all information was obtained directly from individuals with heartburn, without involving physicians or accessing medical records to confirm a specific diagnosis [11]. One might argue that symptom-based inclusion criteria are not valid without the “gold standard” of a diagnosis. However, functional GI disorders do not have clear physiologic findings, and in standard practice GI diagnoses are made empirically on the basis of symptoms reported by patients when they seek care.

Practitioners may ask, “If survey respondents are representative of all heartburn sufferers using prescription medication, why were so many less than totally satisfied when I know that my own patients are satisfied?” According to Fleming [12], most patients are unlikely to criticize any aspect of their health care in the presence of their primary care provider. When patients are asked if they are satisfied with care, they tend to say yes [12,13]. When asked to quantify the extent of their satisfaction, however, a different picture may begin to emerge.

Patient satisfaction ratings that are less than “excellent” or “complete” should be considered a red flag [14]. Pelletier [15] states that any aspect of health care that receives a satisfaction score below 75% from any individual needs to be examined closely by the health system or provider. Nearly 40% of PUNS participants rated their satisfaction with heartburn medication below the 75% level. Patient satisfaction is an extremely relevant issue in today’s competitive health care environment. Various studies indicate that satisfied patients are more likely than unsatisfied patients to continue using medical services [16–18], maintain a relationship with a specific provider [19–21], and comply with medical regimens [22–25]. In addition, some studies demonstrate a clear relationship between patient satisfaction and the patients’ intent to recommend a health care service to friends and relatives [26–28].

The PUNS data identify an unmet need in heartburn patients and suggest that better pharmacotherapy is needed to provide more heartburn sufferers with complete symptom

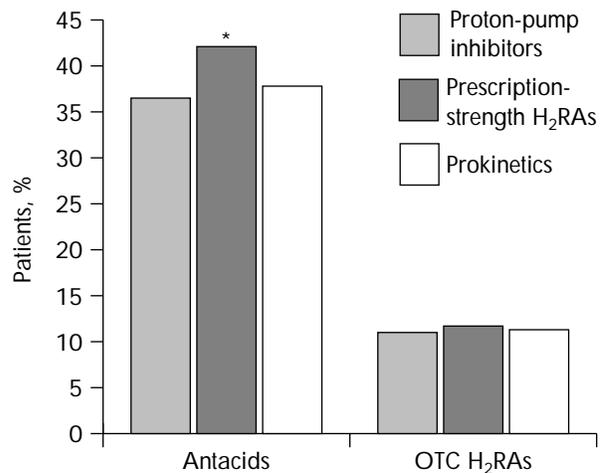


Figure 2. Supplemental over-the-counter (OTC) medication use by individuals with heartburn using prescription medications. H₂RAs = histamine₂-receptor antagonists. *Chi-square test of independence: $\chi^2 = 26.52$ ($P < 0.001$).

resolution. Optimal health outcomes can likely be achieved if patients and providers work collaboratively to identify the most effective treatment for each patient.

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