

ORIGINAL RESEARCH—GENERAL OTOLARYNGOLOGY

Dosing of proton pump inhibitors is suboptimal among otolaryngologists treating reflux-induced upper-respiratory disease

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OBJECTIVE: To evaluate the practice of otolaryngologists treating reflux-induced upper-respiratory disease in a nationwide survey.

STUDY DESIGN: Survey study using an anonymous questionnaire containing clinical vignettes.

SUBJECTS AND METHODS: The survey was mailed to all 6,899 board-certified fellow members in practice in the American Academy of Otolaryngology–Head and Neck Surgery residing in the United States.

RESULTS: One thousand seven hundred twenty questionnaires were returned. Respondents empirically treated reflux-induced upper-respiratory disease with proton pump inhibitors once daily and twice daily 63% and 31%, respectively. Fifteen percent did not instruct their patients on how to take the proton pump inhibitors. Of those who instructed their patients, 22% advised dosing before breakfast, 32% before breakfast and again before dinner, and 46% recommended other timings. When prescribing twice-per-day dosing, 64% responded to give before breakfast and dinner and 28% responded before breakfast and at bedtime.

CONCLUSION: Suboptimal dosing of proton pump inhibitors is prevalent among otolaryngologists treating reflux-induced upper-respiratory disease.

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Gastroesophageal reflux is increasingly implicated as a cause for upper-respiratory disease. These conditions include reflux-induced asthma and what has been termed laryngopharyngeal reflux (LPR); reflux laryngitis; or ear, nose, and throat reflux. It is estimated that up to 10% of the patients that otolaryngologists see are presenting with symptoms or illness related to gastroesophageal reflux disease (GERD).¹ The most common otolaryngologic symptoms possibly caused by GERD are chronic cough, hoarseness, dysphagia, globus, sore throat, laryngospasm, otalgia, postnasal drip, apnea, excessive throat clearing, and dysphonia.² It is estimated that 5% to 10% of all cases of hoarseness, 10% to 20% of chronic cough, 25% to 50% of globus, and up to 60% of patients with chronic laryngitis

and persistent sore throat refractory to treatment are caused by GERD.²

Currently, empiric proton pump inhibitor (PPI) therapy is the preferred treatment in patients with GERD-related disease.^{2,3} This is consistent with the recommendations of the American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS) in treating LPR.⁴

Despite the widespread use of PPI therapy, physicians often dose these medications suboptimally. PPIs are most effective in suppressing acid secretion when dosed before a meal.^{3,5,6} Dosing after a meal or more than an hour before a meal significantly limits PPI efficacy.^{5,7} Our previous study showed that 54% of patients referred to a gastroenterologist with persistent GERD symptoms despite treatment were dosing their PPI suboptimally.⁵ This finding suggests that patients with acid reflux–induced diseases may have persistent symptoms despite treatment because of suboptimal PPI dosing and not necessarily because of refractory disease. The aim of this study was to assess the PPI dosing habits of otolaryngologists in the treatment of reflux-induced upper-respiratory disease. We hypothesize that suboptimal PPI use among otolaryngologists will be prevalent.

METHODS

Data for this study were collected by using an anonymous questionnaire (<http://journal.entnet.org>) developed by an experienced otolaryngologist using cognitive survey development techniques. The questionnaire was piloted on a sample of four experienced otolaryngologists and modified based on their feedback. Survey reliability was measured by using test-retest methodology. Four otolaryngologists and 10 medical residents completed the survey and were readministered the survey approximately one week later. All responses were reproduced exactly.

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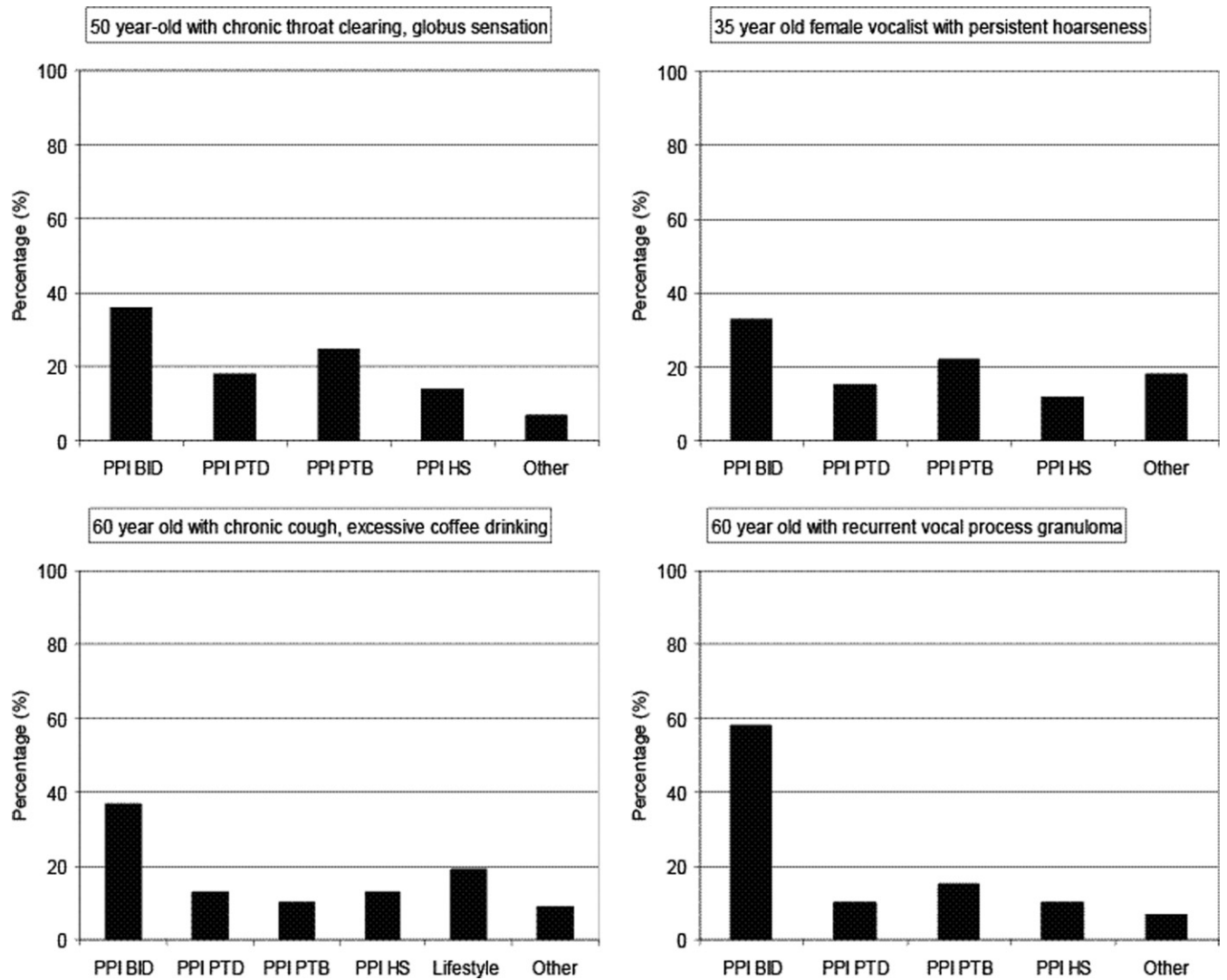


Figure 1 Responses to the 4 clinical vignettes. PTD, prior to dinner; PTB, prior to breakfast; HS, at bedtime.

Table 1
Characteristics of otolaryngologists

Demographic	No. of respondents	Proportion of respondents	Proportion of entire AAO-HNS membership
Male	1,487	89	89
Female	191	11	9
Practice type			
Group	941	58.0	47
Solo	411	25.2	34
University/Medical School	208	12.7	16
Staff Model HMO	45	2.8	0.8
Local/State/Federal Government Hospital	21	1.3	1.8
Non-government Hospital/Facility	8	0.5	0.5
	Mean	Standard deviation	
Age (years)	49	9.5	
Years in practice	17	9.5	
# of patients seen per week	93	41	
# of patients seen per week with GERD related disease	15	11.8	

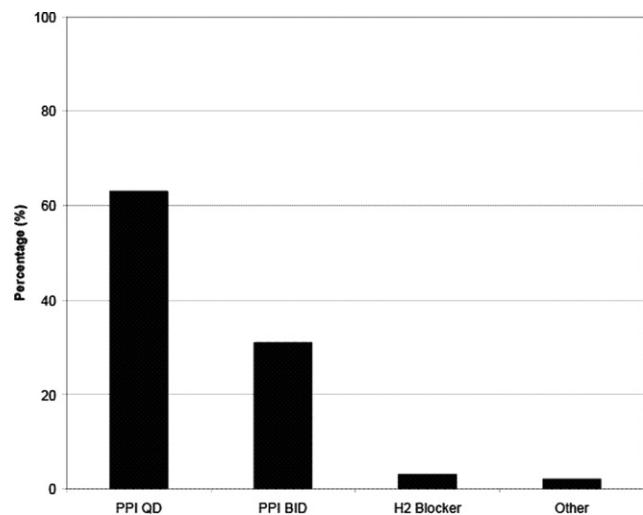


Figure 2 Medication that respondents were most likely to initially prescribe for treating reflux-induced upper-respiratory disease.

Four short clinical vignettes of patients with upper-respiratory disease followed by management questions were used to assess PPI-prescribing habits of the physicians. They encompassed the following scenarios: a 50-year-old man with chronic throat clearing and globus sensation, a 35-year-old female vocalist with persistent hoarseness, a 60-year-old woman with chronic cough who is an excessive coffee drinker, and a 60-year-old man with a recurrent vocal process granuloma (Fig 1). Prescribing patterns were also assessed with direct questions.

The study was approved by the Saint Joseph Mercy Health Systems Institutional Review Board. The survey was mailed to all 6,899 board-certified fellow members in practice in the AAO-HNS residing in the United States. AAO-HNS is the largest nationwide organization of otolaryngologists and was believed to be a representative sample of the entire field. A cover letter was sent along with a postage-paid, business reply envelope. The cover letter detailed the purpose of the study, explained that the subject's participation was voluntary and that responses were anonymous, and provided instructions for completion of the survey. To maintain confidentiality, we did not track responses and only one mailing was done.

Data were entered by using double data entry procedures by trained data entry staff at Trinity Information Systems. Chi-square tests and *t* tests using SPSS (SPSS Inc, Chicago, IL) were used to explore relationships between practice characteristics, physician characteristics, and PPI utilization patterns.

Role of the Funding Source

There was no involvement by the study sponsor in the study design, data collection, data analysis, data interpretation, manuscript preparation, or decision on submission for publication.

RESULTS

One thousand seven hundred twenty questionnaires were returned for a 24% response rate. Table 1 summarizes the demographics of the respondents. Eighty-nine percent of responders were male, the mean age was 49, and the mean years in practice was 17 (Table 1). Response demographics for this study corresponded to the demographic data of the AAO-HNS suggesting that the respondents were a representative sample of the membership.

The otolaryngologists were asked what medication they were most likely to initially prescribe to treat reflux-induced upper-respiratory disease (Fig 2). Sixty-three percent responded that they would prescribe a once-daily (QD) PPI and 31% responded a twice-daily (BID) PPI.

For all of the vignettes, respondents primarily chose some form of PPI therapy and most frequently selected BID therapy. Of note, 9% to 14% of all respondents used a PPI at bedtime (QHS) for treatment. The frequencies of the other methods of PPI therapy and other treatment modalities were varied among the vignettes. The only significant individual write-in response to the "other" answer category was to the third vignette where 19% advocated lifestyle modification. Insignificant "other" responses included the use of H₂-blockers, steroids, further testing, Botox (Allergan, Inc., Irvine, CA) injections, reflux precautions, and allergy testing.

Eighty-five percent of otolaryngologists responded that they instructed their patient on the time of day to take the PPIs. Of those that did instruct their patients, 32% advised taking before breakfast and then before dinner, 22% advised before breakfast only, 17% advised before dinner only, 11% advised before breakfast and then at bedtime, 10% advised at bedtime only, and 8% advised something else (Fig 3). Fifty-four percent of respondents advocated premeal dosing before the first meal (optimal dosing), and, therefore, the remaining 46% of responses were considered suboptimal.

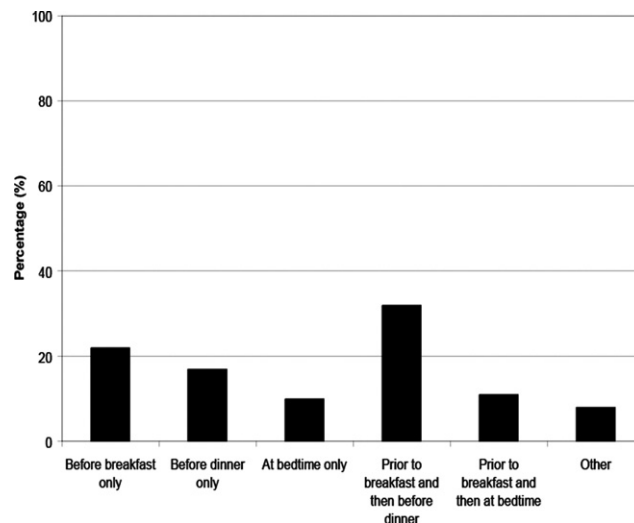


Figure 3 The time of day that the respondents instructed the patient to take the PPI.

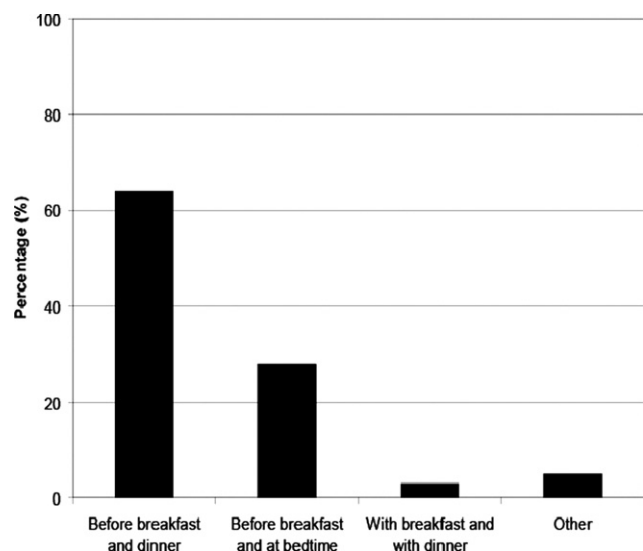


Figure 4 The dosing schedule of BID PPI that respondents felt worked best to suppress acid.

When asked which BID PPI dosing schedule works best, they responded before breakfast and dinner 64% of the time and before breakfast and at bedtime 28% of the time (Fig 4). The respondents' age did not significantly influence how they prescribed a PPI.

DISCUSSION

When managing reflux-induced upper-respiratory disease, 94% of respondents use PPIs for empiric treatment, with 63% recommending QD regimens and 31% BID regimens. Fifteen percent did not instruct their patients on how to dose the medication, and 46% of those instructing patients recommended suboptimal dosing schedules. Up to 10% of physicians used PPIs only at bedtime for treatment. These findings show that significant numbers of respondents who treat reflux-induced upper-airway disease are using PPIs suboptimally, which, in turn, may lead to refractory symptoms.

PPIs selectively inhibit actively secreting gastric parietal cell adenosine triphosphatase (ATPase) molecules⁸ and thereby reduce acid secretion. Food ingestion stimulates gastric parietal cell ATPase molecules to secrete acid, allowing PPIs to inhibit acid secretion when they are taken before meals.^{3,6,8-10} When the gastric pH is near the pH of activation of the respective PPI, the PPI is protonated, and the activated form binds covalently with the H⁺/K⁺ ATPase, thus, irreversibly inhibiting acid secretion by the proton pump. H⁺/K⁺ ATPases are regenerated after a period of fasting, and, in the majority of individuals, the H⁺/K⁺ ATPase density is greatest after awakening from sleep. PPIs are, therefore, most effective after a prolonged fast and before eating because this is when there are the largest numbers of H⁺/K⁺ ATPases present.⁷ The American Col-

lege of Gastroenterology guidelines for treating GERD recommend that PPIs should always be dosed before a meal and never at bedtime. The PPI should be first dosed before breakfast, and, if symptoms persist, a second dose before dinner should be added. Empiric use of BID PPI therapy may be considered in patients with noncardiac chest pain and supraesophageal reflux symptoms to assess symptom response.¹¹ The recent introduction of immediate-release omeprazole (Zegerid oral suspension; Santarus, Inc., San Diego, CA) may lead to modification of these recommendations because QD bedtime dosing has been associated with effective acid control for patients with nocturnal acid breakthrough.¹²

It has been hypothesized that prebreakfast dosing maximizes PPI efficacy because ATPase molecules are able to accumulate in parietal cells during a prolonged overnight fast, making more ATPase molecules available for acid-catalyzed conversion to their actively secreting form by food ingestion.³ The importance of premeal PPI dosing has been explored in a number of intragastric pH probe studies. Kuo and Castell¹⁰ revealed that omeprazole 20 mg BID (before breakfast and dinner) provided superior intragastric pH control compared with 40 mg QD before breakfast or dinner, despite the same cumulative daily dose of omeprazole in each group. A comparison of 24-hour intragastric pH data in 19 subjects taking omeprazole 40 mg before breakfast, 40 mg before dinner, or 20 mg twice daily before breakfast and dinner revealed that the 20-mg BID regimen was superior in controlling intragastric pH.⁹ Hatlebakk et al⁶ compared the gastric acidity at the end of two isolated 7-day periods in 21 patients taking omeprazole 20 mg or lansoprazole 30 mg daily.⁶ During one 7-day period, patients took the PPI 15 minutes before breakfast, whereas during the other 7-day period, they took their PPI in the morning with no food or drink (except water) until noon. Nine-hour pH monitoring on day seven showed that the pH was acidic (pH less than 4) 17% of the time in the week in which the PPI was dosed before breakfast versus 42% of the time in the week without breakfast ($P = 0.01$). These studies clearly show that dosing a PPI before a meal (ideally 15-30 minutes before the first meal of the day) optimizes acid suppression.^{3,6,8}

The two generally accepted approaches for the medical treatment of suspected reflux-related disease are the "step-down" or "step-up" therapies. Kamel et al¹³ and Wo et al¹⁴ reported symptomatic response rates for LPR to PPI use of 92% and 67%, respectively. In these studies, 40 mg omeprazole was given at bedtime, and this was increased to BID dosing for nonresponders after two months of treatment. Vaezi¹⁵ reported response rates of 47% and 64% to BID PPI dosing at two and four months, respectively. In a study assessing the role of pH monitoring in refractory GERD patients, Charbel et al¹⁶ showed that BID PPI therapy is 99% effective at suppressing acid production. The use of BID PPI dosing has been recommended in the literature as the initial treatment of LPR.² The AAO-HNS has advocated

the use of BID PPI therapy for an initial treatment of LPR for a period of no less than six months.⁴

However, the AAO-HNS recommendations do not specify a dosing schedule for BID therapy. In the studies by Kamel et al¹³ and Wo et al,¹⁴ the use of bedtime dosing was clearly ineffective and may have biased the study toward poor symptom control in those patients using that schedule. An alternative recommendation is to dose the PPI before the first meal of the day and then add a second dose up to an hour before the evening meal only in those patients who have persistent symptoms.

In our study, 94% of otolaryngologists responded that they would prescribe a PPI for empiric treatment. The widespread use of PPIs is generally known, but this is the first study to actually assess the frequency of use by otolaryngologists. This study shows how PPI therapy and, therefore, “step-down” therapy is believed to be the most important initial medical treatment in managing reflux-induced upper-respiratory disease.

Another significant finding was that 15% of otolaryngologists responded that they did not instruct their patients on when to dose the medication. Because the timing of administration of a PPI corresponds closely to its effectiveness in suppressing acid production, patient education is critical in ensuring optimal use of PPIs. Guidelines for treatment of reflux-induced upper respiratory disease should also stipulate that the provider should educate the patient regarding the importance of premeal dosing for effective symptom control. Optimal dosing patterns of PPI therapy include before breakfast for QD dosing and before breakfast and dinner for BID dosing.³ Of those otolaryngologists that did instruct their patients on how to take the PPI, 46% recommended a suboptimal dosing pattern. In response to the clinical vignettes, up to 14% of practitioners also used a PPI at bedtime as the only treatment. This dosing regimen clearly results in ineffective acid control and may lead to persistent or refractory symptoms in these patients. This is not a problem common to only otolaryngology, as evidenced in previous studies on PPI dosing patterns.^{5,17,18} Furthermore, when asked about BID PPI dosing, 36% of respondents chose sub-optimal dosing patterns. In response to the clinical vignettes, the otolaryngologists chose BID PPI therapy most frequently. These findings suggest that nearly half of otolaryngologists surveyed who instruct their patients on the use of PPIs do so incorrectly. The combined effect of noninstruction (15%) and incorrect instruction (46%) may contribute to persistent or suboptimally treated disease. Therefore, efforts at educating patients and physicians on the effective use of PPIs should be strongly considered.

In the first prospective study of its kind, Park et al¹⁹ assessed the efficacy of different acid suppressive regimens used for the treatment of suspected LPR. They determined that BID PPI therapy provided a significantly greater reduction in symptoms (50%) after eight weeks than QD PPI therapy (28%) for LPR. Additionally, the study showed that

increasing the dose to BID in QD nonresponders resulted in symptom improvement in 54% of these patients. As a result, the study recommended initiating empiric therapy with BID dosing for at least four months. The responses to the clinical vignettes in our study showed that 31% of respondents use empiric BID therapy. With the trend toward BID PPI therapy for reflux-related disease being a more recent phenomenon, we hypothesized that younger physicians may be more likely to prescribe BID therapy than older physicians. However, this did not turn out to be the case.

There are several limitations to our study that should be considered. First, our findings need to be interpreted with caution because our response rate was limited to 24%. Although this diminishes enthusiasm for our findings, it is important to note that the demographic characteristics of the 1,720 respondents were similar to those of the AAO-HNS membership at large, and, therefore, respondents were believed to be fairly representative of AAO-HNS members (Table 1). Although our response rate did not reach that reported by Karkos et al²⁰ (94%) who looked at the awareness of general practitioners to LPR, it was greater than the 15% reported in the survey study by Barrison et al.¹⁷ Because of time, financial constraints, and respect for privacy, we were unable to engage in multiple follow-up efforts with individuals who did not respond.

Second, it is possible that our survey was biased in its design. Respondents may have overreported that they prescribe a PPI for empiric treatment. The selections for the vignettes primarily offered various PPI dosing schedules because PPI use was the focus of the study. However, respondents could record alternative therapies under the selection of “other.” Based on our results that 94% of respondents use PPIs for empiric therapy, we do not believe that there would have been much difference in the responses to the clinical vignettes if we provided other specific options such as antacids or H₂-blockers.

CONCLUSIONS

Our study shows that PPIs are used by 94% of otolaryngologists for the management of reflux-induced respiratory disease. However, 15% did not instruct their patients on how to dose the medication, and 46% of those who did instruct their patients recommended suboptimal dosing schedules. Thirty-six percent recommend suboptimal BID dosing schedules. Based on the results of our study and recommendations in the literature, otolaryngologists may benefit from educational efforts aimed at increasing their understanding of optimal dosing of PPIs. Given the recommendation of the AAO-HNS of empiric BID PPI therapy for LPR, consideration should also be given to specifying premeal dosing in these guidelines. Optimal dosing of PPIs may improve clinical symptoms control, which, in turn, may decrease health care costs.

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Naresh T. Gunaratnam, study design, writer; **Fawwaz Humayun**, study design, writer; **Paul T. Hoff**, study design, writer; **Eileen Robinson**, study design, conduct, data collection.

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FINANCIAL DISCLOSURE

None.

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A National Survey of Otolaryngologists on the Medical Treatment of
Reflux-induced Upper Respiratory Disease

*Please circle or fill in the blank with the **ONE best answer** that most closely reflects your clinical practice patterns. Answers to the survey are anonymous.*

1. A 50 year old male presents with a 3 month history of chronic throat clearing, phlegm production, and fullness in the lower neck. Examination reveals interarytenoid edema, vocal cord edema, and thick mucous (string sign). Of the following treatment options, your preferred treatment would be: (Please choose only one)

1. Proton pump inhibitor BID
2. Proton pump inhibitor before dinner
3. Proton pump inhibitor prior to breakfast
4. Proton pump inhibitor at bedtime
5. Other _____

2. A 35 year old female professional vocalist comes in with a 3 month history of hoarseness that persists despite vocal therapy for the last 2 months. Examination reveals mild vocal cord edema. Of the following treatment options, you would treat her with: (Please choose only one)

1. PPI BID
2. PPI before dinner
3. PPI prior to breakfast
4. PPI at bedtime
5. Other _____

3. A 60 year old female with a chronic cough is frequently awakened with choking episodes. She states she cannot breathe and feels strangled for 10-30 seconds. This occurs intermittently. She also complains of tightness in the lower neck and hoarseness that worsens as the day goes on. She drinks 10 cups of coffee per day. Of the following treatment options, you would treat her with: (Please choose only one)

1. PPI before dinner
2. PPI prior to breakfast
3. PPI at bedtime
4. PPI BID
5. Other _____

PLEASE TURN OVER PAGE AND CONTINUE ON BACK

4. A 60 year old male with a history of prolonged intubation presents with a 3 month history of hoarseness. This persists despite voice rest and voice therapy. Examination reveals a vocal process granuloma. The mass is excised endoscopically and the patient does well initially. Three months later he is hoarse again and the granuloma has recurred. The patient did not receive a trial of antacids either before or after the surgery. Of the following treatment options, you would treat him with:

1. PPI BID
2. PPI before dinner
3. PPI prior to breakfast
4. PPI at bedtime
5. Other _____

5. What medication are you most likely to initially prescribe for treating gastroesophageal reflux-induced upper respiratory disease?

1. PPI QD
2. PPI BID
3. Other _____

6. Do you usually instruct your patient on when to take the proton pump inhibitor? Please circle your response.

1. Yes
2. No

If your answer is “No”, then skip to question 8. Otherwise, proceed to question 7.

7. How do you usually instruct the patient on the time of day to take the proton pump inhibitor?

1. Before breakfast only
2. Before dinner only
3. At bedtime only
4. Prior to breakfast and then before dinner
5. Prior to breakfast and then at bedtime
6. Other _____

8. Which dosing schedule of BID PPI works best to suppress acid?

1. Before breakfast and dinner
2. Before breakfast and at bedtime
3. With breakfast and with dinner
4. Other _____

Figure E2

9. How influential are outside factors (i.e. insurance coverage, managed care) in how you prescribe the medication to your patients? Please circle the choice that corresponds most closely with your practice.

Not at all		Somewhat		Very strongly
1	2	3	4	5

Your Profile:

10. Gender: 1. M
2. F

11. Age at last birthday _____

12. Number of Years in Otolaryngologic practice _____

13. Practice Type

1. Group
2. Solo
3. University or Medical School
4. Staff Model HMO
5. Local/State/Fed Government Hospital
6. Non-government Hospital/Facility

14. Approximate number of patients that you see in your office per week _____.

15. Approximate number of patients that you treat for GERD-related disease in your practice per week _____.

Thank you for taking the time to complete the survey

Please return the completed survey
in the enclosed envelope to
St. Joseph Mercy Hospital Clinical Research Department

Figure E3