A Mixed-Methods Study of Patient Views on Reflux Symptoms and Medication Routines

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Summary: Objectives. Gastroesophageal reflux disease is a chronic disorder often accompanied by laryngopharyngeal reflux. Speech-language pathologists are tasked with treating these patients with voice, dysphagia, and/or reflux therapy. This study investigated patient-reported reasons for reduced compliance with recommended reflux treatment and the top symptoms in patients with reflux, dysphagia, and voice symptoms.

Study Design. This study used a cross-sectional qualitative and quantitative mixed-methods design to identify and describe patients' reflux symptoms and reflux medication routines.

Methods. Fifty-one patients completed a face-to-face, semistructured interview, a questionnaire, and the Reflux Symptom Index (RSI). Interview transcripts were coded by authors for concepts in two cycles.

Results. During the 51 interviews, the top four reported symptoms were *heartburn* (n = 17), *mucous* (n = 11), *dysphagia*, and *globus* (n = 10). Further, 62.7% (n = 32/51) described an incorrect routine in taking their proton pump inhibitor (PPI): taking it with other pills, taking it with food/drink, and uncertainty about which pill is for reflux. RSI scores were moderately correlated with patient-reported reflux severity ($r = 0.62$, $P < 0.0001$, $r^2 = 0.34$). Correct compliance with PPI timing was not enough to significantly lower RSI scores more than those who did not comply (an average RSI of 20.0 *vs*. 25.9, $P = 0.1252$).

Conclusions. Literature has not described the most relevant reflux-related symptoms and why PPI compliance is notoriously poor, from the patients' perspective. The results of this study confirm that PPI compliance is poor, and the reasons for poor compliance could have been prevented with patient education. Even when PPI compliance was adequate, symptoms like globus, mucous, voice dysfunction, and dysphagia persisted. Other interventions such as evidence-based diet and behavioral changes should be a part of voice/dysphagia/reflux therapy.

Key Words: reflux–PPI–voice–dysphagia–qualitative.

INTRODUCTION

Formally defined in 2006 by international consensus, gastroesophageal reflux disease (GERD) is a condition experienced in approximately 20% of the population, which develops when refluxed materials from the stomach cause troublesome symptoms such as heartburn, globus sensation, voice dysfunction, and dysphagia.[1,2] Laryngopharyngeal reflux (LPR) is a type of reflux that has been coined "silent reflux" owing to the absence of frank reflux symptoms.[3] LPR usually occurs while upright, unlike the classic reflux that is likely to occur while supine.[4–6] LPR also differs from GERD in that it often does not include esophagitis and resulting symptoms like heartburn. Instead, LPR irritates the throat with symptoms such as voice complaints, throat clearing, chronic coughing, and postnasal drip.[4] Further, the majority of patient-reported symptoms were of the throat (voice symptoms, dysphagia, mucous) rather than the stomach or chest (heartburn, indigestion).

Voice complaints are a common outcome of reflux, characterized by reduced vocal quality and changes in laryngeal function. Another common symptom of reflux is dysphagia, described by the patient as food sticking in the throat or globus. As a result, speech-language pathologists (SLPs) are tasked with treating patients with dysphagia secondary to GERD or LPR. They work with these patients with behavioral and diet modifications, education, and reinforcement of compliance with physicians' prescription for medication (ie, taking a proton pump inhibitor [PPI] 30 minutes before eating). What is missing from the literature is an investigation of patient's perspective of reflux to allow for a closer look at what bothers them the most and how they do (or do not) manage it.

Reflux and dysphagia symptoms

Multiple studies have postulated that the oral, pharyngeal, and esophageal stages of swallowing operate as one intricately interrelated system in which the dysfunction of one stage correlates to dysfunction in another. However, this complex relationship is still not fully understood. The innervation of the pharynx, larynx, and esophagus *via* the vagus nerve certainly confirms the interconnectivity of the swallowing systems. Evidence suggests that individuals who have esophageal motility disorders also have significantly altered oropharyngeal function, and those who have oropharyngeal dysphagia also have altered esophageal peristaltic function.[7] Cassiani et al[8] found that bolus transit duration through the upper esophageal sphincter was longer in subjects with GERD. Reflux was also found to be one of the most common causes of dysphagia.[9] Another study found a significant association between LPR and edema of the posterior larynx resulting in laryngeal sensory deficits.[10] These authors observed an increased risk for laryngeal penetration and aspiration

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that were five and four times greater, respectively, than those without any sensory deficits. Furthermore, reflux-related dysphagia has been identified to negatively impact patient's perception of their quality of life. Mesallam and Farahat[11] found that compared with patients without LPR, those with LPR scored significantly higher on the Dysphagia Handicap Index, suggesting that LPR significantly impacts patient-reported swallowing difficulties. Reflux-related dysphagia is clearly a well-studied symptom. But what is missing is the link between better identification of reflux-related dysphagia and evidence-based therapy.

Medical treatment for reflux

There are four general treatment considerations for reflux: medication, behavioral changes, diet changes, and surgery. This study's interest lies in SLPs' role in identifying reflux symptoms and patients' habits and routines in daily management of PPIs. Clinically, we find that the majority of patients with reflux complaints are prescribed medication, specifically PPIs, as a primary treatment. Indeed, the most common treatment for reflux is to control acid production with medication such as antacids, histamine type 2 receptor antagonists (H2RAs), and/or PPIs. Antacids and H2RAs are typically used to treat mild to moderate reflux and are designed for on-demand or as-needed treatment. Antacids rapidly increase the pH of the stomach and its refluxed content to provide relief for about 1–3 hours, whereas H2RAs suppress acid production by temporarily inhibiting the signal to the stomach's acid-producing parietal cells. PPIs, on the other hand, suppress acid production at the terminal step by blocking the proton pumps of the stomach's parietal cells. Unlike H2RAs, PPIs have not been shown to be susceptible to drug tolerance and "can successfully control GERD symptoms and heal [erosive esophagitis] in approximately 80% of patients over 4–8 weeks."[1]

In 2008, Gosselin et al[12] described PPIs as one of the most effective medications for decreasing acid production, supported by another finding of greater effectiveness of PPIs over H2RAs.[10] However, timing is crucial in the management of PPIs to achieve the optimal acid suppression. Because a greater number of proton pumps are activated with a meal, PPIs should be taken approximately 30–60 minutes before the first substantial meal of the day to be effective.[13–15] This timing allows for increased absorption of the drug when the greatest number of proton pumps is likely to be activated. When taken with a meal, after a meal, or after the onset of symptoms, acid suppression is reduced because the damaging acid has already been produced, thus rendering the PPI less effective.[16,17]

Literature suggests that the majority of patients report taking their reflux medication in a routine that differs from the prescribed dosage. Compliance reports have revealed that approximately 40%–50% of those prescribed PPIs take them incorrectly.[18,19] Many patients are either not taking their reflux medication or taking it incorrectly. Multiple studies have documented inconsistent routines of reflux medication,[15,18,20,21] but there are limited data that explore patient compliance and reports of why they take the medication that way. We wanted to investigate reasons for patient-reported noncompliance with PPI medications, considering effectiveness is dependent on careful attention to timing.

We hypothesize, based on literature and clinical experience, that patients will describe low adherence to reflux routines, inaccurate PPI compliance, and limited behavioral modifications to reduce reflux symptoms. The purpose of this study is to describe patient-reported reflux symptoms, as well as patient-reported habits and routines in daily management of PPIs using qualitative and quantitative methods.

MATERIALS AND METHODS

Study design

This study was designed to investigate reflux in a novel manner using mixed-methods research. Although reflux has been widely investigated in quantitative studies, to our knowledge no studies have observed patient-reported reflux symptoms and compliance in a qualitative manner. We chose a mixed-method design (qualitative and quantitative) to optimally capture the complex issue considering patient's perspective.

Recruitment and subjects

The target sample was ambulatory outpatients visiting the radiology and otolaryngology departments at an urban hospital. A member of the study screened patients via chart review, looking for patients with a scheduled appointment with an SLP. The screener looked for documentation of GERD and/or LPR and an active prescription for a PPI (ie, omeprazole), which was typically ordered by the referring otolaryngologist. Dosage amount was not recorded because it was not within the aims of this study to compare effectiveness of dosage. We assume that the ordering physician prescribed an adequate amount to address the patient's symptoms, although this is certainly a limitation to this study. PPIs were selected as an inclusion criterion (as opposed to H2RAs) due to their prevalence as a primary treatment and their effectiveness that is dependent on compliance with timing. We were not able to differentiate between patients diagnosed with GERD and patients diagnosed with LPR because these diagnostic codes are entered into the hospital's documentation system either in tandem or synonymously without attention to specific differences in presentation. Patients who were eligible for the study were noted as potential subjects (Procedure section). Written consent was required for patients who agreed to audio recording of the clinical interview. In the case where patients did not consent to audio recording, the clinical interview and appointment proceeded as standard care without audio recording. We did not include patients who lacked a documented prescription for a reflux medication, even if they reported self-medicating with over-the-counter reflux medication. This study was reviewed by the institutional review board of the hospital and deemed exempt. Our inclusion/exclusion criteria were as follows:

Inclusion criteria:

- a patient (any age, any race) scheduled to see an SLP in the outpatient otolaryngology or radiology clinic
- ≥18 years old
- had GERD and/or LPR documented in the hospital's electronic medical record