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Treating laryngopharyngeal reflux: Evaluation of an anti-reflux program with comparison to medications☆

Jin Yang [a,*], Salem Dehom [b], Stephanie Sanders [a], Thomas Murry [c], Priya Krishna [c], Brianna K. Crawley [c]

[a] Loma Linda University School of Medicine, Loma Linda, CA, USA
[b] Loma Linda University School of Public Health, Loma Linda, CA, USA
[c] Voice and Swallowing Center-Loma Linda University Medical Center, Loma Linda, CA, USA

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ABSTRACT

Objective: To determine if an anti-reflux induction program relieves laryngopharyngeal reflux (LPR) symptoms more effectively than medication and behavioral changes alone.
Study design: Retrospective study.
Setting: Tertiary care academic center.
Subjects and methods: A database was populated with patients treated for LPR. Patients were included in the study group if they completed a two-week anti-reflux program (diet, alkaline water, medications, behavioral modifications). Patients were included in the control group if they completed anti-reflux medications and behavioral modifications only. Patients completed the voice handicap index (VHI), reflux symptom index (RSI), cough severity index (CSI), dyspnea index (DI) and eating assessment tool (EAT-10) surveys and underwent laryngoscopy for examination and reflux finding score (RFS) quantification.
Results: Of 105 study group patients, 96 (91%) reported subjective improvement in their LPR symptoms after an average 32-day first follow-up and their RSI and CSI scores improved significantly. No significant differences were found in VHI, DI, or EAT-10 scores. Fifteen study patients who had previously failed adequate high-dose medication trials reported improvement and their CSI and EAT-10 scores improved significantly. Ninety-five percent of patients with a chief complaint of cough reported improvement and their CSI scores improved significantly from 12.3 to 8.2. Among 81 controls, only 39 (48%) patients reported improvement after an average 62-day first follow-up. Their RSI scores did not significantly change.
Conclusion: The anti-reflux program yielded rapid and substantial results for a large cohort of patients with LPR. It compared favorably with medication and behavioral modification alone. It was effective in improving cough and treating patients who had previously failed medications alone.

1. Introduction

The diagnosis of laryngopharyngeal reflux (LPR) is common in clinical practice. It was reported to be present in >50% of patients with laryngeal complaints at an academic voice center [1]. In a recent survey, >60% of a community-dwelling population had either GERD or laryngeal symptoms and >20% had both [2]. Symptoms caused by LPR include chronic cough, dysphonia, dysphagia, post-nasal drip, globus, constant throat clearing, laryngospasm and a multitude of other extraesophageal maladies [3,4].

Empiric treatment of LPR with antireflux medication such as proton pump inhibitors (PPI) has increased in popularity over the past twenty years. Between 1990 and 2001, PPI prescription increased 14 fold, accounting for a significant percentage of healthcare costs [5,6]. A typical treatment for LPR in clinical practice is a course of twice daily PPI for at least 2 months [7]. Many studies have supported the effectiveness of PPIs in treating LPR-related symptoms. One meta-analysis of randomized controlled trials showed that patients treated with a PPI had a significantly higher response rate and reflux symptom index (RSI) improvement than those who received placebo [8]. In a study by Jin et al., treatment with PPIs improved objective voice measures including jitter, shimmer, and harmonic-to-noise ratio after 1–2 months treatment, and maintained results even after 3–4 months [9]. Most studies agree that patients must continue their medication regimen for at least 2–6 months to achieve reduction in symptoms. However, these studies have been contradicted by others in the literature due to discrepancies in method of diagnosis, contributing factors, management regimens, and outcome measures that are often subjective and vary widely.

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* Corresponding author.
E-mail address: jiyang@llu.edu (J. Yang).

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Though some studies support the use of PPIs for LPR, other studies call into question their efficacy or outline the potential dangers of PPI use over protracted periods of time. First, PPIs have been shown to be more beneficial for patients with possible LPR in the setting of typical GERD than for those without it [10]. Second, patients may not universally respond to PPIs: many are PPI resistant or have non-acid reflux [11]. Third, the literature does not conclusively support using PPIs to improve LPR symptoms and objective voice measures. A double-blinded, randomized controlled trial showed no significant difference between PPI and placebo groups in improving RSI and RFS [7] and, in contrast to Jin et al., Hamdan et al. showed that PPI use did not improve acoustic abnormalities [9,12]. In addition, long term use of PPIs has been associated with such adverse effects as osteoporosis, infections, malabsorption, malignancy, kidney disease and dementia, sparking great concern in patients though proof of causation is largely absent [13–16]. But the prescription of anti-reflux medications for LPR treatment continues.

The anti-reflux induction diet was introduced by Dr. Koufman in 2011 [17]. It is comprised of low-acid, low-fat foods to the exclusion of all foods and drinks with a pH less than five for a minimum two week period. The purpose is to provide a basis for what will be a long-term lifestyle change to potentially alter the mechanism and minimize the effects of LPR. The induction diet ends with transition to a similar but less stringent maintenance diet intended to eliminate the need for daily PPIs. This diet/lifestyle approach could provide an alternative for patients refractory to PPIs or who wish to avoid side effects of long term PPI use. In her prospective study of 20 patients who failed PPIs, 19 patients improved on this low acid diet and 3 became completely asymptomatic [16]. Our study sought to address whether this induction diet would be effective in reducing LPR symptoms in a larger patient population. We present the outcomes of a regimen combining the induction diet with anti-reflux medications in a larger group. We compare these results with a group who received standard anti-reflux treatment in our practice.

2. Methods

Loma Linda University IRB granted approval for a retrospective review of patients treated for laryngopharyngeal reflux (LPR) at our academic tertiary referral center. A database was assembled by initially including all patients over age 18 diagnosed with primary LPR from 12/2011 to 6/2016 at the Loma Linda Voice and Swallowing Center (LLVSC). Diagnosis was based on the presence of signs and symptoms or pH probes (nasopharyngeal pH probes at our center with positive Ryan scores and adequate symptom correlation or outside reports of positive pH probe results) demonstrating LPR or GERD (with extraesophageal symptoms). Patients who had negative pH probe results, and who had other contributing pathology (radiation, vocal fold lesions, sinonasal pathology, airway stenosis, etc.) were excluded. Patients who were simultaneously treated for or found to have allergic rhinitis, glottic insufficiency, or vocal fold atrophy were also excluded as these other treatments could cause the LPR-directed treatments to appear more effective. We divided all patients meeting criteria into two groups: those who were prescribed the LPR induction program and those who were prescribed only anti-reflux medications and behavioral modifications.

Patients prescribed the LPR induction program (Table 1) were included in our study group. The LPR induction program consists of a two-week induction diet [17], high dose anti-reflux medications (PPI 40 mg qD and/or H2 blocker 300 mg qHS), with at least 16 oz of alkaline water (pH > 8) daily [18], and behavioral modifications, including weight loss, smoking cessation, alcohol avoidance, and eating no less than 3 h before lying down [19]. If patients preferred or presented with PPI 40 mg BID instead of 40 mg qD, their medication regimen was maintained. At the end of two weeks, these patients were instructed to begin reintroducing foods back into their diet slowly in order to monitor rebound symptoms and to subsequently determine which foods were causing problems so that these could be avoided. They were asked to return within a month of beginning treatment in order to gauge initial success with the induction diet and to help guide transition to the maintenance phase, if appropriate. We retrospectively excluded only patients who failed to follow up within 2 months or who reported to have not been 100% adherent to the treatment protocol. There were no other exclusion criteria for our study group.

Our control group was comprised of the remainder of our patients who were prescribed a course of high dose PPIs (40 mg qD), or both high dose PPIs and H2 blockers (300 mg qHS) with LPR behavioral modifications (Table 2) [19]. If patients preferred or presented with PPI 40 mg BID instead of 40 mg qD, their medication regimen was maintained. These patients were largely seen prior to the introduction of the anti-reflux induction program into our practice and standard follow-up for this group was three months, consistent with reports that treatment requires at least 2 months to take effect [7]. We excluded patients who failed to follow up within 3 months in order to bring this group as close as possible to our study group. Patients were also excluded if they reported being noncompliant with their medications and behavioral modifications. There were no other exclusion criteria for our control group.

For both study and control groups, information including routine demographics, previous treatment with antireflux medication (dosage and duration), medical comorbidities, smoking status, and 24-hour pH probe studies was gathered. At each of their clinic visits, patients were asked to complete the VHI-10 [20] and RSI [21]. Additional questionnaires were added at the time the induction program was introduced and these included the CSI [22], DI [23], and EAT-10 [24]. In addition, an otolaryngologic history and physical exam was completed accompanied by a videostroboscopic exam, which was assigned a Reflux Finding Score (RFS) [25]. Information about patients' subjective symptom improvement was collected during their first follow-up visit.

Two subgroups were isolated from the treatment group for further scrutiny. The first included all patients in the treatment group who had failed a complete course of 40 mg qD or higher dosage PPI for >6 weeks before presenting to our center and completing the LPR induction program. Six weeks was chosen in order to exclude patients who had completed longer courses than the popular 14 day trial. The second group was comprised of treatment group patients presenting with the chief complaint of cough who had also completed the CSI questionnaire pre- and post-induction program. Pre-and post-induction program questionnaire scores and symptom results were analyzed separately for the above two cohorts.

The RFS was assigned to every exam collected from patients in the treatment group. They were not collected from the control group because most exams were not available for review. Two different attending laryngologists performed the scoring blinded to the patient, date of exam, and treatment period. Using only patients who had both pre- and post-induction program exams within two months of each other, overall change in RFS, inter-rater reliability, and intra-rater reliability (20% blinded repeat grading) were calculated.

Table 1
Anti-reflux program.

Two-week induction diet [17]
High dose anti-reflux medications (PPI 40 mg qD and/or H2 blocker 300 mg qHS)
At least 16 oz of alkaline water (pH > 8) daily [18]
Behavior modifications (Table 2)

Table 2
Behavior modifications [19].

Weight loss
Smoking cessation
Alcohol avoidance
Minimizing tight clothing/belts
Eating no less than 3 h before lying down
Taking PPI 30–60 min before meals

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