

Efficacy of Anti-Reflux Surgery on Refractory Laryngopharyngeal Reflux Disease in Professional Voice Users: A Pilot Study

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Summary: Objectives. Laryngopharyngeal reflux (LPR) is a pervasive disorder that may cause hoarseness, throat clearing, and other symptoms. These symptoms are particularly problematic in professional voice users. Proton pump inhibitors (PPIs) are the mainstay of current medical management for LPR but may be insufficient in managing some patients' symptoms. Laparoscopic Nissen fundoplication (LNF) is well established for treatment of gastroesophageal reflux disease with a high success rate, but its role in the treatment of LPR remains uncertain. This study was designed to investigate the effectiveness of anti-reflux surgery in managing disease refractory to medical reflux therapy (twice of more per day PPIs).

Study Design. Retrospective medical record review.

Methods. This study examined 25 professional voice users, age ranging from 14 to 75 years, diagnosed with refractory LPR treated twice daily or more with PPIs. Reflux finding scores (RFS) were graded by blinded raters and compared for initial, preoperative, postoperative, and final visits. Twenty-four-hour pH-impedance study scores were obtained pre- and postoperatively.

Results. Sixty percent of patients were on no-reflux medications postoperatively and an additional 24% were on less medication. RFS was not significantly different between pre- and postoperative evaluations with good inter- and intra-rater reliability; postoperative examinations occurred on less or no pharmaceutical reflux treatment. Twenty-four-hour pH-impedance testing revealed significant reductions in reflux and a nearly significant reduction in total acid. Ninety percent of positive symptom indices preoperatively were negative postoperatively. Seventy-six percent of patients on BID dosing of PPIs and 86% of those receiving super-high-dose PPI administration who underwent LNF were satisfied with the results for their LPR disease.

Conclusion. LNF should be considered as a treatment option for professional voice users with LPR with symptoms refractory to standard or super-high-dose medical management. LNF may decrease or eliminate the need for postoperative PPI usage. The RFS may not be sensitive enough to monitor changes in LPR severity. Patients, especially those on super-high-dose medication administration, are satisfied with the improvement in LPR symptoms after anti-reflux surgery.

Key Words: Laryngopharyngeal reflux–Reflux–Proton pump inhibitor–Nissen–Fundoplication–Professional voice–Reflux finding score–pH impedance–Super-high-dose proton pump inhibitor.

INTRODUCTION

Reflux of gastric contents to structures that do not produce acid results in substantial morbidity and has been established as a significant public health concern.¹ Extraesophageal reflux of gastric contents (ie, acid and pepsin) with resultant contact injury of the pharyngeal and laryngeal mucosa leads to otolaryngologic manifestations known as laryngopharyngeal reflux (LPR).^{2,3} LPR is characterized by symptoms such as

hoarseness, chronic cough, globus pharyngeus, chronic throat clearing, dysphagia, and excess buildup of intralaryngeal mucus.⁴ Professional voice users find this particularly problematic given the impact on their vocations and may be more prone to this disease process.⁴

Patients with signs and symptoms of LPR are advised about dietary and lifestyle changes and commonly started on proton pump inhibitors (PPIs) as a primary treatment. Some patients respond inadequately to treatment, and persistent symptoms continue to adversely affect quality of life. For others, cost and/or dissatisfaction with long-term medical therapy remains as major issues affecting compliance, and consequently, manifestations of the disease progress.^{5,6} Moreover, long-term PPI usage may be associated with complications.⁷

Laparoscopic Nissen fundoplication (LNF) is a well-established procedure for the treatment of gastroesophageal reflux disease (GERD) with an over 90% success rate in sign and symptom resolution.⁸ Current indications for fundoplication are listed in Figure 1. Fundoplication also has been proposed as a treatment for LPR refractory to standard medical therapy. Many studies have attempted to evaluate the effectiveness of fundoplication for LPR, but results have been mixed with

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Indications for Surgical Management of Reflux
Patients with esophagitis but are intolerant of antireflux medications (PPI's) Persistent esophageal GERD syndrome symptomatology despite reasonable medical management
Relative Indications
Extraesophageal GERD syndromes in whom a reflux causality has been established to the greatest degree possible
Contraindications
Patients with esophagitis well-maintained on medical therapy
<i>Source:</i> Kahrilas PJ, Shaheen NJ, Vaezi MF. American Gastroenterological Association Medical Position Statement on the Management of Gastroesophageal Reflux Disease. <i>Gastroenterology</i> . 2008; 135(4); 1383-91.e5

FIGURE 1. Current indications for anti-reflux surgery.²⁷

some studies showing clear benefits, whereas others show little improvement. However, most studies suffer from lack of standardization in diagnosis, characterization of symptoms, and physical findings pre- and postoperatively.⁹ Long-term outcomes in LPR patients treated with LNF are also uncertain.¹⁰ The purpose of this study was to elucidate further the effectiveness of LNF in a defined cohort; professional voice users with LPR refractory to treatment with high doses of PPIs, many of whom did not meet criteria for fundoplication surgery, which may be considered inappropriate for this patient cohort.

STUDY GOALS

1. Does reflux surgery effectively treat refractory LPR disease in professional voice users?
2. Does reflux surgery reduce the frequency with which professional voice users with refractory LPR are taking reflux medication?
3. How effective are the tools currently available to determine the severity of LPR disease?
4. Are patients satisfied with the results of anti-reflux surgery?

MATERIALS AND METHODS

Study design and patient population

After obtaining approval from the Drexel University College of Medicine Institutional Review board, a retrospective analysis of medical records was performed, and the pertinent literature was reviewed. All study patients were from the senior author's (R.T.S.) tertiary-care laryngology practice and underwent LNF between 2005 and 2012 for refractory LPR symptoms. All patients were professional voice users defined as those whose voice is essential for them to carry out their profession (ie, singers, teachers, doctors, lawyers, clergy, salespeople). Symptoms refractory to medical management were defined as persistent complaints (eg, throat clearing, throat mucous, globus, and so forth) despite at least 6 months of PPI therapy twice daily or more frequently. All subjects underwent dynamic voice assessment and stroboscopy with flexible and rigid endoscopes, using a previously published protocol.¹¹ LPR was identified initially by characteristic symptoms and laryngeal findings on stroboscopy. Twenty-four-hour pH-impedance testing also was performed. To determine

reflux surgery efficacy in treating LPR disease, stroboscopic findings were compared from four examinations: the presenting examination, the examination immediately preceding surgery, the immediate postoperative examination, and the most recent examination.

Patient's included in the study had persistent symptoms or signs of LPR despite PPIs at least twice-daily and nighttime histamine-2 antagonists, were aged ≥ 14 years, were compliant with medical therapy, had abnormal initial reflux finding scores (RFS), and had undergone reflux surgery for treatment of LPR disease. Patients excluded from the study were aged < 14 years, noncompliant with medical therapy, using breakthrough or other reflux therapies (eg, motility, neutralizing, neurologic, or other homeopathic agents), were difficult to visualize on laryngeal examination, and/or had additional laryngeal pathology.

Twenty-four-hour impedance monitoring

Patients underwent dual probe 24-hour pH-impedance monitoring pre- and postoperatively at an esophageal laboratory for testing. Event diaries were distributed to record pertinent events during the 24-hour monitoring period including symptom occurrence, positional changes (recumbent or upright), and timing of meals. Information about medication regimen and timing, presenting symptoms and demographics (age, gender, etc.) was confirmed and recorded before monitoring.

Twenty-four-hour pH-impedance monitoring was performed using a combined impedance and pH-monitoring device (Sandhill Scientific, Inc, Highlands Ranch, CO). The device consists of a catheter with two pH sensors (gastric and distal esophageal) and six paired impedance sensors. Before placement, each sensor was calibrated using manufacturer-recommended standardized buffer solutions (pH 4.0 and 7.0). Each catheter was placed transnasally at predefined positions (3, 5, 7, 9, 15, and 17 cm) above the lower esophageal sphincter; positioning was confirmed by manometry. Sensors communicated with a wired data recorder (pH Impedance Monitoring; Sandhill Scientific, Inc). Data sampling frequency for both impedance and pH sensors was 50 Hz. At the conclusion of the monitoring period, the catheter was removed, and the data recorder information was downloaded and interpreted using BioView Analysis software (Sandhill Scientific, Inc), and a report was generated.

Timing and positioning (upright or recumbent) of acid (pH ≤ 4) and nonacid (pH > 4) reflux events were identified and recorded after autodetection (Autoscan; Sandhill Scientific,

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