

# The Effect of Antireflux Therapy on Phonomicrosurgical Outcomes: A Preliminary Retrospective Study

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**Summary: Objective/Hypothesis.** Currently, no clinical standards exist with regard to antireflux medications in the perioperative period for patients undergoing surgery for benign vocal fold lesions. The present study sought to determine the clinical yield of these medications on operative outcomes in patients who underwent surgical treatment for benign vocal fold lesions.

**Study Design.** Retrospective, outcomes study.

**Methods.** Medical records were reviewed from a single surgeon database between January 2011 and June 2012 to quantify outcomes in patients taking antireflux medications compared with subjects not taking medications at the time of surgery. Voice Handicap Index (VHI)-10 and Reflux Symptom Index (RSI) scores were the primary dependent variables. The *t* test analyses were conducted to compare VHI-10 and RSI scores. Additional multivariate regression analyses were conducted to evaluate medication effects on VHI and RSI, adjusting for potential confounds.

**Results.** A total of 51 patients met inclusion criteria. Of these patients, 12 (23.5%) were using antireflux medication(s) at the time of surgery and 39 (76.5%) were not. The mean shifts in VHI-10 and RSI after surgery for the antireflux therapy (ART) group were  $-14.75$  and  $-7.5$ , respectively. For the non-antireflux therapy (non-ART) group, mean  $\Delta$ VHI-10 and  $\Delta$ RSI values were  $-9.87$  and  $-5.05$ , respectively. Both *t* test and regression analyses confirmed no statistical difference between the ART and non-ART groups for both  $\Delta$ VHI-10 and  $\Delta$ RSI. Additional regression analysis revealed a positive correlation between preoperative RSI score and  $\Delta$ RSI score.

**Conclusion.** Antireflux medications did not significantly alter postoperative outcomes in this preliminary cohort of patients.

**Key Words:** Voice–Dysphonia–Phonomicrosurgery–Laryngopharyngeal reflux.

## INTRODUCTION

Benign vocal fold lesions, such as vocal fold cysts, nodules, and polyps are common and typically require comprehensive medical, behavioral, and often surgical therapy. With regard to surgical intervention, several patient-related factors warrant consideration; preoperative voice therapy, postoperative voice conservation,<sup>1</sup> surgery type (laser vs microflap excision), and perioperative medications. These factors are particularly relevant as there is likely no one clear etiology underlying these benign vocal fold lesions. Clearly, in many cases, mechanical injury to the vibratory margin of the musculomembranous vocal folds results in subsequent lesion formation.<sup>2,3</sup> However, phonotrauma as the sole etiology for these lesions is questionable. Laryngopharyngeal reflux (LPR) has also been associated with benign lesion formation. Several studies have observed an association between LPR and vocal fold nodules,<sup>4</sup> polyps, and Reinke edema.<sup>5</sup> More globally, pH

probe–confirmed LPR was present in 50% of patients presenting with primary vocal complaints and in 70% of patients with phonotraumatic lesions.<sup>6</sup>

Considering the high concordance between LPR and benign vocal fold lesions, it may be difficult to determine the degree to which LPR contributes to clinical disease severity. Furthermore, the impact of LPR on surgical outcomes remains unknown, although one may hypothesize a deleterious effect of refluxate on the healing process. Additionally, recent data from our group suggest that most patients who reported to a specialty laryngology clinic with an established diagnosis of reflux as the sole etiology of their vocal symptoms, from either an otolaryngologist or primary care physician, were noted to have clear non-LPR–related mucosal pathology.<sup>7</sup> These data may suggest that reflux is an overdiagnosed entity potentially accompanied by overtreatment. Sulica and Behrman<sup>8</sup> reported that otolaryngologists frequently prescribe antireflux medications in the setting of benign lesions, yet there are no data to suggest this practice is warranted.

It is, therefore, difficult to justify antireflux therapy (ART) as a perioperative, complimentary treatment for patients with benign lesions. Kantas et al<sup>9</sup> previously reported that the Reflux Finding Score and Reflux Symptom Index (RSI) improved in patients undergoing phonomicrosurgery on proton pump inhibitors (PPIs) compared with controls. That study, however, did not include any voice-related end points in their analyses. The goal of the present study was to determine the potential role for reflux medications on postoperative, global vocal function as quantified by the Voice Handicap Index (VHI)-10, which

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is not intrinsically linked to reflux itself. We hypothesized that reflux medications would not have a significant effect on voice outcomes after surgical resection of benign vocal fold lesions in our preliminary cohort.

## METHODS

### Data accrual

The present study was approved by the institutional review board at the New York University School of Medicine. Patients who underwent phonosurgery between January 2011 and June 2012 were queried by Current Procedural Terminology (CPT) code for phonosurgery as well as potassium titanyl phosphate (KTP) laser ablation of benign vocal fold lesions; this query revealed 239 patients who potentially met inclusion criteria; medical records were then reviewed individually. Inclusion criteria were either microflap excision or KTP laser ablation of a benign vocal lesion; cyst(s), bilateral nodules, polyps, granuloma(s), and vascular irregularities. Patients with recurrent or chronic conditions were excluded such as cancer, leukoplakia, and/or recurrent respiratory papillomatosis.

### Patient-based outcome measures

VHI-10 and RSI scores were collected as a component of routine care. Preoperative VHI-10 and RSI scores were collected from the office visit in closest temporal proximity before their procedure. Additionally, VHI-10 and RSI information were collected from the postoperative visit closest to 6 wk following the procedure. Patients were split into two groups, ART or non-antireflux therapy (non-ART), based solely on the use of any antireflux medications both peri- and postoperatively. Reflux medication use was determined via patient report; data regarding compliance with any regimen was not obtained. Reflux medications were defined as either H<sub>2</sub> blockers or PPIs.

### Statistical analyses

The *t* test analyses were conducted to compare mean VHI-10 and RSI scores, separately, between ART and non-ART groups as well as between procedure types. Multivariate regression analyses was performed separately on  $\Delta$ VHI-10 and  $\Delta$ RSI, defined as the difference between presurgical and postsurgical scores, as dependent variables to evaluate the treatment effect of antireflux medication, adjusting for possible cofounders including age, sex, procedure type, days until evaluation, and preoperative RSI and VHI-10 scores.

## RESULTS

Of the 239 patients reviewed, 51 patients met inclusion criteria. Of these patients, 12 (23.5%) were on antireflux medication(s) and 39 (76.5%) were not. Thirty patients underwent KTP laser ablation and 21 underwent microflap excision. Two of the patients who underwent microflap excision had additional KTP ablation during the same procedure for vascular ectasias. Polyps were the most common diagnosis in both the ART and non-ART arms, representing 55% of the total study sample. Cysts were the second most common diagnosis, and together, cysts and polyps represented 76% of the study subjects

**TABLE 1.**  
Study Cohort Demographic Information

	Reflux Medication	Control
Number of patients (%)	12 (23.5)	39 (76.5)
Mean age (SD)	47 ± 18	37 ± 13
Sex		
Male	6	23
Female	6	16
Diagnosis		
Cyst	1	10
Polyp	7	21
Scar*	2	2
Granuloma	1	1
Nodule	1	1
Other†	0	4
Procedure		
Excision	3	18
KTP	9	21
Days until evaluation‡	39.4	40.3

Abbreviation: SD, standard deviation.

\* One control and one reflux medication had scar + bilateral ectasia.

† Other three bilateral ectasia and one submucosal mass.

‡ Days between preoperative and postoperative evaluations.

(Table 1). A statistically significant difference in age was noted between the ART and non-ART groups, but age was not significantly associated with either  $\Delta$ VHI-10 or  $\Delta$ RSI in subsequent multivariate analysis. Of the 12 patients on reflux medications, all were on PPIs, with esomeprazole and omeprazole the most prevalent. Monotherapy was the most common, but two of the 12 patients were on combination therapy (pantoprazole plus esomeprazole and esomeprazole plus ranitidine). In all cases, ART was initiated by a clinician other than the treating phonosurgeon before consultation and this therapy was maintained during the peri- and postoperatively. In no case was ART initiated specifically as a component of operative management.

### Vocal Handicap Index-10

Mean VHI-10 score across all patients decreased from 20.5 ± 8.7 before surgery to 9.5 ± 7.5 postoperatively ( $P < 0.0001$ ). Mean VHI-10 scores in the ART and non-ART groups before surgery were 23.7 ± 9.4 and 19.5 ± 8.5, respectively (Figure 1A). Mean  $\Delta$ VHI-10 scores were -14.75 ± 9.5 and -9.87 ± 8.4 in the ART and non-ART groups, respectively. No statistically significant differences were detected by *t* test between the two groups in either preoperative VHI-10 or  $\Delta$ VHI-10 scores ( $P = 0.15$  and 0.09, respectively). Multivariate regression analysis confirmed that the association between  $\Delta$ VHI-10 score and medication status was not significant ( $P = 0.53$ ), adjusting for cofounders including procedure type, age, gender, days between evaluation, and preoperative VHI-10 score.  $\Delta$ VHI-10 scores were also similar between procedure types; mean  $\Delta$ VHI-10 scores for phonosurgery and KTP ablation were 9.7 ± 9.5 and 11.9 ± 8.4, respectively ( $P = 0.74$ ).

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