

# The Validity and Reliability of the Reflux Finding Score (RFS)

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**Background:** The evaluation of medical and surgical outcomes relies on methods of accurately quantifying treatment results. Currently, there is no validated instrument whose purpose is to document the physical findings and severity of laryngopharyngeal reflux (LPR). **Objective:** To evaluate the validity and reliability of the reflux finding score (RFS). **Methods:** Forty patients with LPR confirmed by double-probe pH monitoring were evaluated pretreatment and 2, 4, and 6 months after treatment. The RFS was documented for each patient at each visit. For test-retest intraobserver reliability assessment, a blinded laryngologist determined the RFS on two separate occasions. To evaluate interobserver reliability, the RFS was determined by two different blinded laryngologists. **Results:** The mean age of the cohort was 50 years ( $\pm 12$  standard deviation [SD]). Seventy-three percent were women. The RFS at entry was 11.5 ( $\pm 5.2$  SD). This score improved to 9.3 ( $\pm 4.7$  SD) at 2 months, 7.3 ( $\pm 5.5$  SD) at 4 months, and 6.1 ( $\pm 5.2$  SD) at 6 months of treatment ( $P < .001$  with trend). The mean RFS for laryngologist no. 1 was 10.8 ( $\pm 4.1$  SD) at the initial screening and 10.8 ( $\pm 4.0$  SD) at the repeat evaluation ( $r = 0.95$ ,  $P < .001$ ). The mean RFS for laryngologist no. 2 was 11.1 ( $\pm 3.8$  SD) at the initial screening and 10.9 ( $\pm 3.7$  SD) at the repeat evaluation ( $r = 0.95$ ,  $P < .001$ ). The correlation coefficient for interobserver variability was 0.90 ( $P < .001$ ). **Conclusions:** The RFS accurately documents treatment efficacy in patients with LPR. It demonstrates excellent inter- and intraobserver reproducibility. **Key Words:** Laryngopharyngeal reflux, LPR, extraesophageal reflux, proton pump inhibitors, treatment outcomes, reflux finding score.

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## INTRODUCTION

Laryngopharyngeal reflux (LPR) is the retrograde movement of gastric contents into the larynx, pharynx, and upper aerodigestive tract. The symptoms and manifestations of LPR include dysphonia, globus sensation, cough, subglottic stenosis, muscle tension dysphonia, laryngospasm, vocal process granuloma, asthma, and possibly chronic sinusitis, laryngeal carcinoma.<sup>1–10</sup> The treatment options available to patients with LPR include combinations of dietary and behavior modification, antacids, H<sub>2</sub>-receptor antagonists, proton pump inhibitors, and fundoplication surgery. The evaluation of these medical and surgical therapies relies on methods of accurately quantifying treatment results. Currently, there is no validated instrument whose purpose is to document the physical findings and severity of LPR.

The reflux finding score (RFS) is an 8-item clinical severity scale based on findings during fiberoptic laryngoscopy (Table I). The scale ranges from 0 (no abnormal findings) to a maximum of 26 (worst score possible). The 8 items were derived from a pool of the most common laryngeal findings of patients with LPR seen at our voice center. The final items included in the scale include subglottic edema, ventricular obliteration, erythema/hyperemia, vocal fold edema, diffuse laryngeal edema, posterior commissure hypertrophy, granuloma/granulation tissue, and excessive endolaryngeal mucus. The purpose of this investigation was to evaluate the validity and reliability of the RFS.

## MATERIALS AND METHODS

Forty consecutive patients with a clinical diagnosis of LPR that was confirmed by dual-probe (simultaneous esophageal and pharyngeal) pH monitoring were enrolled. The technique of dual-probe monitoring has been described elsewhere and will not be reiterated other than to emphasize that the proximal probe was placed immediately above the upper esophageal sphincter under manometric guidance.<sup>11</sup> All study patients were prospectively evaluated before treatment and 2, 4, and 6 months after treatment with proton pump inhibitors (PPI). All patients were treated with 20 mg omeprazole, 30 mg lansoprazole, or 20 mg rabeprazole twice daily. Each subject underwent a comprehensive history and physical examination including transnasal fiberoptic laryngoscopy (TFL) with laryngeal photodocumentation and determination of the RFS at every visit. The RFS is shown in Table I.

To establish normative RFS data, 40 age-matched asymptomatic control subjects with no history of voice disorder, gastroesophageal reflux disease, or LPR were prospectively examined. Study subjects were matched by age category (within 72 mo) to each of the 40 patients with pH-documented LPR. Each patient underwent a comprehensive history and physical examination including TFL with laryngeal photodocumentation and RFS determination.

For validity assessment, the pretreatment RFS was compared with the RFS at 2, 4, and 6 months of therapy. For test-retest intraobserver reliability assessment, the RFS of the photodocumented larynxes was determined by a single-blinded laryngologist on two separate occasions (at least 24 h apart). To evaluate interobserver reliability, the RFS of the photodocumented larynxes was determined by two different single-blinded laryngologists.

All data were coded and entered into SPSS 6.1.1 for the Macintosh (SPSS Science, Chicago, IL). The Pearson product-moment correlation coefficient was used to determine test-retest intraobserver and interobserver reliability of each individual item as well as the total RFS score. The paired-sample *t*-test was used to assess differences in the RFS at entry and at 2, 4, and 6 months of therapy with PPIs.

## RESULTS

The mean age of the cohort (N = 40) with pH-documented LPR was 50 years ( $\pm 12$  standard deviation [SD]). Seventy-three percent was female and 92% was white. The mean RFS at entry was 11.5 ( $\pm 5.2$  SD). This score improved to 9.3 ( $\pm 4.7$  SD) at 2 months, 7.3 ( $\pm 5.5$  SD) at 4 months, and 6.1 ( $\pm 5.2$  SD) at 6 months of treatment ( $P < .001$  with trend). The median time of RFS completion was 32 seconds.

The mean age of the 40 age-matched control subjects (no history or symptoms of LPR) was 52 years ( $\pm 10$  SD). There was no age, gender, or race differences between the persons with LPR and the age-matched control subjects ( $P > .05$ ). The mean RFS for the control subjects was 5.2 (95% confidence interval = 3.6, 6.8). Thus, we can be 95% confident that a person with a RFS greater than 7 has LPR.

The mean RFS for laryngologist no. 1 was 10.8 ( $\pm 4.1$  SD) at the initial screening and 10.8 ( $\pm 4.0$  SD) at the repeat evaluation ( $r = 0.95$ ). The mean RFS for laryngologist no. 2 was 11.1 ( $\pm 3.8$  SD) at the initial screening and 10.9 ( $\pm 3.7$  SD) at the repeat evaluation ( $r = 0.95$ ). The correlation coefficient was greater than 0.90 for each individual item. The correlation coefficient comparing laryngologist no. 1 to laryngologist no. 2 was greater than 0.90 for each individual item as well as the total RFS score.

## DISCUSSION

The RFS was developed to standardize the laryngeal findings of LPR so that clinicians may better diagnose, evaluate clinical improvement, and assess therapeutic efficacy of patients with LPR. This outcome instrument successfully documents treatment efficacy and thus displays good criterion-based validity. The mean RFS of patients with pH-documented LPR improved from 11.5 at entry to 6.1 after 6 months of treatment. This falls within the normal range established by the control subjects. The

TABLE I.  
Reflux Finding Score (RFS).

Subglottic edema	0 = absent 2 = present
Ventricular	2 = partial 4 = complete
Erythema/hyperemia	2 = arytenoids only 4 = diffuse
Vocal fold edema	1 = mild 2 = moderate 3 = severe 4 = polypoid
Diffuse laryngeal edema	1 = mild 2 = moderate 3 = severe 4 = obstructing
Posterior commissure hypertrophy	1 = mild 2 = moderate 3 = severe 4 = obstructing
Granuloma/granulation tissue	0 = absent 2 = present
Thick endolaryngeal mucus	0 = absent 2 = present

RFS normative data suggests that subtle findings of LPR are present in most individuals. Statistically, we can be 95% certain, however, that an individual with a RFS greater than 7 has LPR.

The high correlation coefficients for each individual item as well as the overall RFS score indicate that the instrument is highly reproducible both between different observers and within the same observer. The evaluation of interobserver reproducibility, however, involved a laryngology fellow and the professors who are training him. Additional studies involving observers from other institutions are necessary to confirm this level of reproducibility.

The most frequent finding of persons with LPR was posterior laryngeal hypertrophy, which was documented in 85% of all patients before the initiation of treatment. A detailed explanation of each item is included in the subsequent discussion.

Koufman first described subglottic edema, also called pseudosulcus vocalis, in 1995.<sup>12</sup> It refers to subglottic edema that extends from the anterior commissure to the posterior larynx. It can be differentiated from sulcus vergeture, which is caused by adherence of the vocal fold epithelium to the vocal ligament secondary to the absence of the superficial layer of lamina propria. While true sulcus stops at the vocal process and is in the midportion of the vocal fold striking zone, pseudosulcus vocalis extends all the way to the back of the larynx (Fig. 1). Its presence contributes 2 points to the RFS.

Ventricular obliteration is a relatively frequent finding in patients with LPR (80%). Swelling of the true and false vocal folds causes this space to be poorly visualized

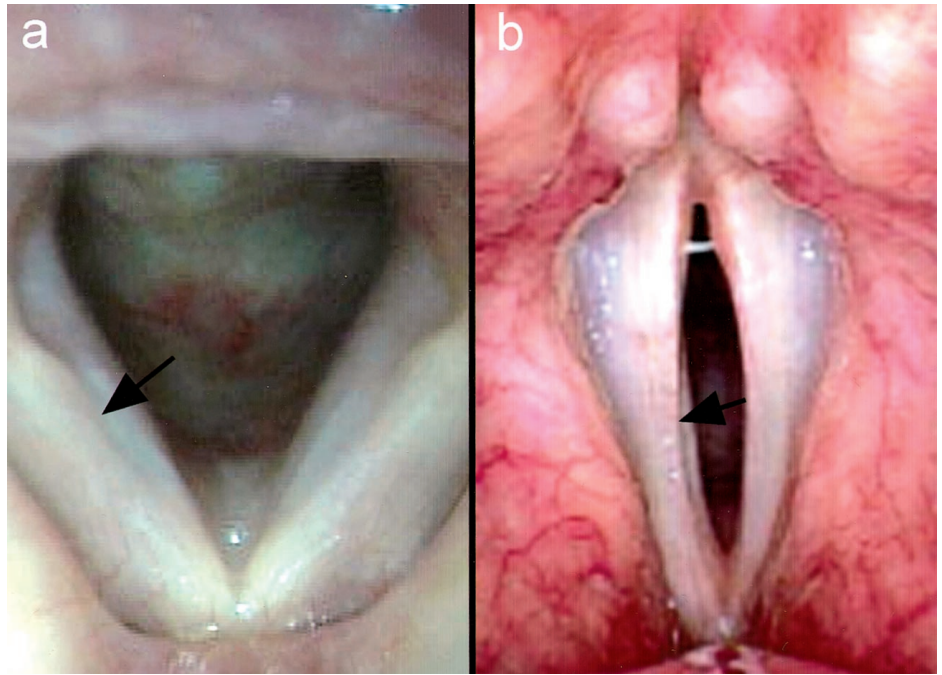


Fig. 1. Comparison of pseudosulcus versus true sulcus vocalis. (A) Bilateral pseudosulcus vocalis (arrow). Notice the subglottic edema extends past the vocal process all the way to the posterior larynx. Also present are posterior commissure hypertrophy, vocal fold edema, diffuse laryngeal edema, and partial ventricular obliteration. (B) True sulcus vocalis of the right vocal fold (arrow). Notice that the sulcus is present in the midportion of the striking zone and stops at the vocal process of the arytenoid.

(obliterated). With partial ventricular obliteration the ventricular space is reduced and the false fold edge is indistinct. With complete ventricular obliteration, the true and false folds appear to touch and there is no true ventricular space (Fig. 2). This finding is noticeably reversed with successful antireflux treatment. Partial obliteration contributes 2 points and complete obliteration contributes 4 points to the RFS.

Laryngeal erythema/hyperemia is a relatively non-specific finding that is significantly dependent on the videoendoscopic equipment. Subtle changes in erythema are difficult to quantify and vary depending on the quality of the fiberscope, video monitor, and light source. Nonetheless, isolated erythema of the arytenoids contributes 2 and diffuse laryngeal erythema contributes 4 points to the RFS.

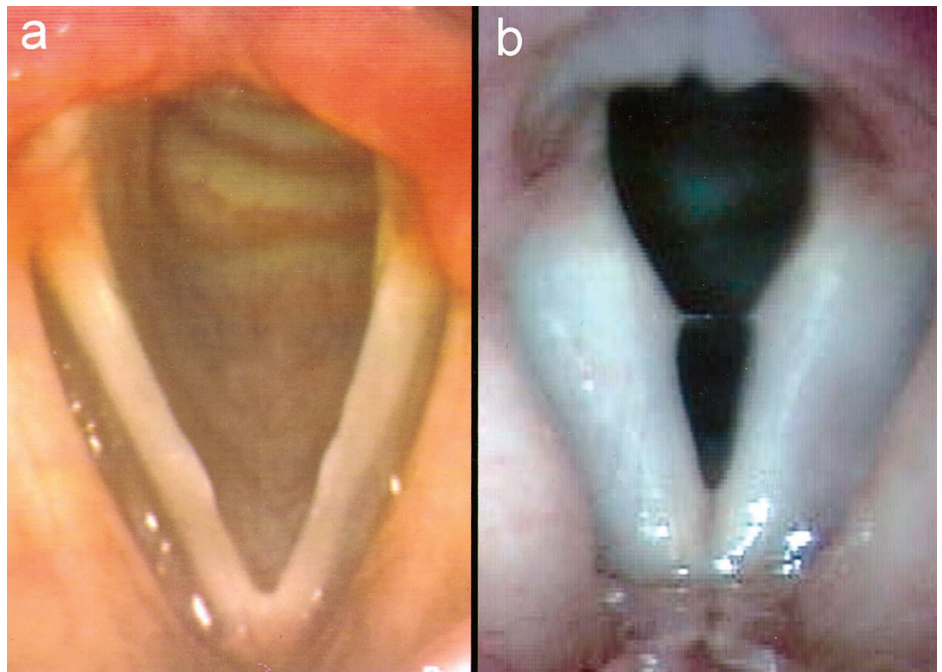


Fig. 2. Ventricular obliteration. (A) Open laryngeal ventricles. Note the sharp ventricular bands and the open space between the true and false vocal folds. Note small prenodule. (B) Ventricular obliteration. Both the true and false vocal folds are swollen, thus obliterating the ventricles. Also present is mild posterior commissure hypertrophy.

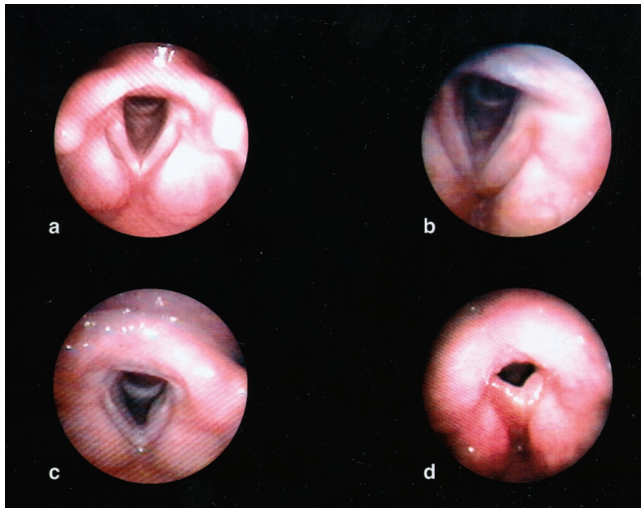


Fig. 3. Vocal fold edema. (A) Mild vocal fold edema. (B) Moderate vocal fold edema. Pseudosulcus vocalis, posterior commissure hypertrophy, and partial ventricular obliteration are also present. (C) Severe vocal fold edema. Sessile changes are noted. Also present are pseudosulcus vocalis, posterior commissure hypertrophy, and partial ventricular obliteration. (D) Polypoid degeneration of the true vocal folds. Also present are severe posterior commissure hypertrophy, total ventricular obliteration, and diffuse laryngeal edema.

True vocal fold edema is graded as mild (1 point) if only slight swelling exists and moderate (2 points) when it becomes more perceptible. Edema is graded as severe (3 points) when swelling of the cord becomes sessile. Finally, polypoid degeneration of the true vocal fold contributes 4 points to the RFS (Fig. 3).

Diffuse laryngeal edema is judged by the size of the airway relative to the size of the larynx. It is graded as mild (1 point) to obstructing (4 points). Hypertrophy of the posterior commissure is a frequent finding in LPR. It is graded as mild (1 point) when there is a mustache-like appearance of the posterior commissure mucosa and moderate (2 points) when the posterior commissure mucosa is swollen enough to create a straight line across the back of the larynx. Posterior commissure hypertrophy is graded as severe (3 points) when there is bulging of the posterior larynx into the airway and obstructing (4 points) when a significant portion of the airway is obliterated (Fig. 4). The final two items on the RFS are granuloma/granulation tissue and thick endolaryngeal mucus. Patients get 2 points when these entities are present and 0 points otherwise.

## CONCLUSION

Reflux may be present in up to 50% of patients with voice disorders.<sup>13</sup> The ability to determine interval improvement in patients with LPR relies on the clinician's ability to record laryngeal findings. The RFS is an 8-item scale that attempts to document the clinical severity of LPR. It is easily administered, takes less than 1 minute to complete, and manifests excellent inter- and intraobserver reproducibility. Although each item on the RFS is entirely subjective, the overall finding score reliably documents improvement with antireflux therapy.

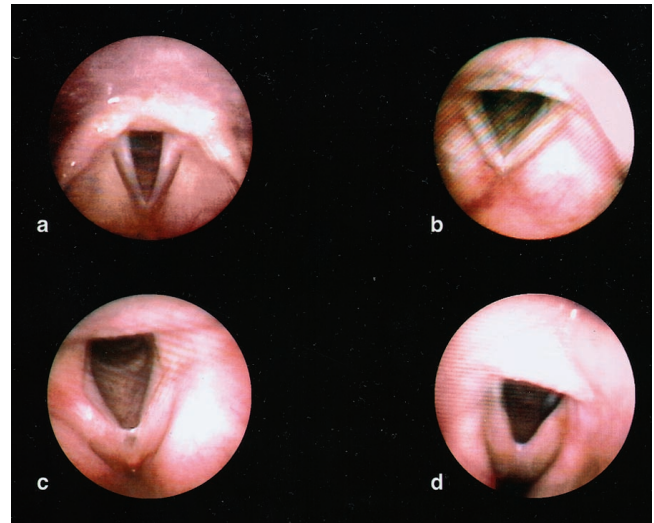


Fig. 4. Posterior commissure hypertrophy. (A) Normal posterior commissure. Cuneiform cartilages can still be visualized. (B) Mild posterior commissure hypertrophy. Slight mustache-like configuration of posterior commissure. Also present are moderate vocal fold edema, pseudosulcus vocalis, and partial ventricular obliteration. (C) Moderate posterior commissure hypertrophy. Straight line across the posterior larynx. Also present are moderate vocal fold edema, pseudosulcus vocalis, partial ventricular obliteration, and diffuse laryngeal edema. (D) Severe posterior commissure hypertrophy. Also present are several vocal fold edema, total ventricular obliteration, and diffuse laryngeal edema.

The independent items on the RFS are not meant to individually predict the presence or absence of LPR. In fact, for the 40 age-matched control subjects without LPR, the mean RFS was 5.2. Thus, findings consistent with reflux are present in asymptomatic individuals without a clinical diagnosis of LPR. Nonetheless, the total RFS accurately predicts treatment efficacy of patients with pH-documented LPR, and we can be 95% certain that an individual with a RFS greater than 7 has LPR.

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