Reflux Symptom Index and Reflux Finding Score in Otolaryngologic Practice

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Summary: Objectives. To evaluate whether patients with abnormal Reflux Symptom Index (RSI) and Reflux Finding Score (RFS) benefit from proton pump inhibitor (PPI) therapy.

Study Design. Open, multicenter, prospective longitudinal cohort study.

Methods. Patients with suspected reflux-associated laryngologic symptoms were evaluated by 40 community practice otolaryngologists using RSI and RFS. Patients were treated with pantoprazole 40–80 mg/d for 8–12 weeks if RSI was greater than 9 and RFS greater than 7. Pre- and posttherapeutic RSI and RFS were compared using Wilcoxon signed rank test and additionally controlled with the symmetry test of Bowker.

Results. A total of 1044 patients were included over a period of 20 months. Median total score of RSI before therapy was 12 and decreased to 3 ($P \ll 0.001$). Median total score of RFS before therapy was 16 and decreased to 6 ($P \ll 0.001$). Assessment of the treatment effect by otolaryngologists and patients was judged as being excellent in at least 50%. In 2% of the patients, gastrointestinal side effects were documented.

Conclusion. RSI and RSF are easy to administer in the routine care of patients suspected of having laryngopharyngeal reflux. Patients identified by positive results of these tests have a high likelihood of excellent improvement after 8–12 weeks of PPI treatment. By implementation of RFS and RSI in daily use, most patients may not need time-consuming and cost-intensive examinations in the first-line assessment of LPR. These examinations can be reserved for nonresponders, and uncontrolled prescription of PPIs can be restricted.

Key Words: Laryngopharyngeal reflux–Laryngitis–Reflux Symptom Index–Reflux Finding Score.

INTRODUCTION

Reflux of gastric fluid to the pharynx and larynx (laryngopharyngeal reflux [LPR]) may result in symptoms because of laryngeal mucosal damage. A wide variety of otorhinolaryngologic symptoms have been attributed to LPR, although in individual patients, it may be difficult to establish the causal relationship.[1] Reflux may consist of liquid or gas, or both, and its pH may cover a wide range from highly acidic to neutral. In specialized centers, combined pH and impedance measurements have been introduced to identify the reflux of fluid and gaseous contents from the stomach into the pharynx. They have an acceptable sensitivity for detecting laryngopharyngeal acid and nonacid reflux. These tests are currently being evaluated for their use in establishing the causal link between reflux and laryngitis.[2] It is currently unclear whether they are helpful in choosing different treatment options, which may focus on the reduction of acid by proton pump inhibitors (PPIs) or reduction of the volume of reflux, for example, by operative procedures. Whether these tests will ever become widely used in routine clinical care remains doubtful, given the invasive nature of the time-consuming procedures, their limited availability, and the expertise required.

Therefore, markers for LPR and reflux-associated laryngitis are needed. It has been suggested that the Reflux Symptom Index (RSI) and Reflux Finding Score (RFS) may be useful parameters.[3,4] The RSI has been designed to raise the clinical suspicion of LPR in patients presenting with ears, nose, and throat (ENT) symptoms, whereas the RFS has been designed to characterize morphologic lesions presumably associated with LPR. It has remained unclear, however, as of today whether the results of RSI and RSF can be used to guide the treatment of suspected LPR.

In this study, we evaluated the symptoms and signs resolution after 8–12 weeks of acid-suppressive therapy with 40 or 80 mg pantoprazole in ENT patients who were selected for the treatment on the basis of abnormal results of RSI and RFS.

MATERIALS AND METHODS

Between January 2006 and October 2007, 1044 patients attending a community otolaryngology practice for evaluation of otorhinolaryngologic symptoms possibly related to LPR were evaluated. The likelihood of LPR was assessed using a diagnostic questionnaire. Forty community practice otolaryngologists contributed patients to this open, multicenter, prospective longitudinal cohort study. The number of patients contributed by individual otolaryngologists ranged between 4 and 43.

The diagnostic questionnaire and examination comprised the following parts:

1. General demographic data (exclusion criteria: noncompliance, malignant diseases, intolerance to PPIs, current medication with PPI, or a washout period of at least 6 weeks since a former PPI treatment).
2. RSI pre- and posttherapy.[4] As shown in Table 1, the symptom history and different symptom characteristics

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TABLE 1.
The Reflux Symptom Index[3]

Symptoms	Within the Past Month, How Did the Following Problems Affect? Ordinal Scale: 0–5 (0 = No Problem, 5 = Severe Problem)					
Hoarseness or other voice problems	0	1	2	3	4	5
Clearing throat	0	1	2	3	4	5
Excess throat mucus or postnasal drip	0	1	2	3	4	5
Difficulty swallowing food, liquid, or pills	0	1	2	3	4	5
Coughing after eating or after lying down	0	1	2	3	4	5
Breathing difficulties or choking episodes	0	1	2	3	4	5
Troublesome or annoying cough	0	1	2	3	4	5
Sensations of something sticking in throat or lump in throat	0	1	2	3	4	5
Heartburn, chest pain, indigestion, or stomach acid coming up	0	1	2	3	4	5

were evaluated by using the structured questionnaire of RSI in a German translation.

3. RFS pre- and posttherapy.[5] Otorhinolaryngologists were advised to use a rigid endoscope for the evaluation of the larynx (as in daily routine). Video documentation was not required. The criteria of examination are listed in Table 2.
4. Evaluation of the therapy based on its effectiveness and tolerance by physicians and patients (ordinal scale with five levels: IV = excellent, III = good, II = satisfactory, I = poor, and 0 = negative).
5. Evaluation of the change in quality of life (ordinal scale with four levels: III = significantly improved, II = improved, I = no change, and 0 = worse).
6. Reasons for unscheduled stop of therapy (descriptive: low efficacy, low tolerance, noncompliance, and other reasons).
7. Observed side effects.

If RSI was greater than 9 (of a possible maximum of 45) and RFS greater than 7 (of a possible maximum of 26), a treatment with pantoprazole 40 mg daily was started for a total treatment duration of 12 weeks (minimal treatment period was 8 weeks). If the treatment effect was considered to be inefficient after 6 weeks, the patient consulted the ENT specialist again, and together with the patient, the otolaryngologist decided whether to increase the dosage of pantoprazole to 40 mg twice a day or not.

On the last day of treatment, patients were reevaluated by their otolaryngologist and the RSI and RFS scores were determined again. The otolaryngologist was blinded to the result of his first evaluation and was able to access the results of his first reexamination only under emergency medical conditions, which was not required in a single case.

Single data entry with comprehensive range and consistency checks was used. All data from the questionnaires were collected and fed into the statistical analysis database. The very few illegible data entries were treated as missing in the database. All variables of the questionnaires were analyzed descriptively. Statistical analysis was based on the "intention-to-treat" principle. For analysis of efficacy, only data for which both time points existed in the patient data log where used (observed cases technique). All error probabilities presented are two-sided and refer to each individual test.

The change in efficacy parameters was determined using the Wilcoxon signed rank test and additionally controlled with the symmetry test of Bowker, as in some cases the required continuity assumption of the data was not fully warranted. Results with an error probability of $P < 0.05$ were considered significant and those with $P < 0.01$ as highly significant.

The statistical software was developed by the company Neumann+Team (Vienna, Austria) and is written in IBM APL2 version 2 service level 6 (IBM, Armonk, NY). This software was

TABLE 2.
The Reflux Finding Score[4]

Laryngoscopic Findings	Ordinal Scale
Infraglottic edema (pseudosulcus)	0 = absent, 2 = present
Ventricular obliteration	0 = none, 2 = partial, 4 = complete
Erythema/hyperemia	0 = none, 2 = arytenoids only, 4 = diffuse
Vocal fold edema	0 = none, 1 = mild, 2 = moderate, 3 = severe, 4 = polypoid
Diffuse laryngeal edema	0 = none, 1 = mild, 2 = moderate, 3 = severe, 4 = obstructing
Posterior commissure hypertrophy	0 = none, 1 = mild, 2 = moderate, 3 = severe, 4 = obstructing
Granuloma/granulation	0 = absent, 2 = present
Thick endolaryngeal mucus	0 = absent, 2 = present