Changes in the Quality of Life of Patients With Laryngopharyngeal Reflux After Treatment

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Summary: Objective/Hypothesis. To assess changes in the symptoms and quality of life (QOL) of patients diagnosed with laryngopharyngeal reflux (LPR) after proton pump inhibitor (PPI) treatment.

Study Design. Prospective study.

Methods. One hundred eighty patients diagnosed with LPR were evaluated. All patients were prescribed Lansoprazole (15 mg) twice daily for 12 weeks. The Reflux Symptom Index (RSI), Reflux Finding Score (RFS), Short-Form 36-Item Health Survey version 2.0 (SF-36), and LPR–health-related quality of life (HRQOL) were collected from each patient at the initial visit and at 4- and 12-week follow-up visits.

Results. Significant improvement was observed in RSI and RFS scores after treatment. The LPR-HRQOL score also showed gradual improvement after PPI treatment in the voice, cough, throat clearing, swallowing, and overall impact of acid reflux. Although each domain of the SF-36 had a low score at the baseline visit, seven domains of the SF-36 had improved, except for the physical functioning domain.

Conclusions. We found that RSI, RFS, and most categories in the LPR-HRQOL and SF-36 improved 12 weeks after initiating PPI treatments. These findings indicate that PPI treatment for 3 months could improve the QOL of patients diagnosed with LPR.

Key Words: Laryngopharyngeal reflux–Quality of life–Proton pump inhibitor–Change–Symptom.

INTRODUCTION

Laryngopharyngeal reflux (LPR) is distinct from gastroesophageal reflux disease (GERD) and has been extensively studied over the recent 10–15 years. This disease has been shown to be related to the laryngopharyngeal segment and gastrointestinal tract. The symptoms of LPR mainly result from irritation of the laryngopharynx due to gastroduodenal content, particularly gastric acid. These symptoms result in chronic and intermittent symptoms such as dysphasia, hoarseness, cough, globus sensation, throat clearing, and laryngospasm. In addition, due to these irritations, erythema, vocal fold edema, subglottic edema, posterior pachydermia, laryngeal edema, ventricular obliteration, endolaryngeal mucus, and granuloma can be observed from an endoscope evaluation in patients with LPR.[1,2] Most GERD patients report heartburn as the main symptom, but in LPR patients, there are no primary symptoms or some symptoms can appear alone or simultaneously. It has been reported that less than 40% of LPR patient complained of heartburn and less than 25% of the patients had esophagitis.[3–5] Therefore, the presence of heartburn in patients with LPR is not an important symptom for diagnosis.[3,5,6] LPR is a highly prevalent disease, and 10% of patients who visited an otolaryngologist are diagnosed with this disease. More than 50% of patients complain of a chronic cough and voice disorder, and LPR patients experience more discomfort during their daily life than patients with other conditions.[3] Therefore, LPR treatment primarily focuses on improving these symptoms, with the ultimate goal of improving the quality of life (QOL) for patients. Most studies on LPR have compared GERD and LPR or have attempted to identify a correlation between GERD and QOL. For example, in a Medical Outcomes Study Short-Form 36-Item Health Survey (SF-36), the morbidity of LPR was shown to negatively affect the social functioning and vitality of patients and even the Voice Handicap Index was reported to be higher in patients with LPR.[7,8] Several studies have reported the negative effects of acid reflux on the laryngeal mucosa.[5,9] However, because of nonspecific physical examination findings, symptom overlap with common voice disorders, and a lack of consensus about diagnostic methods, empiric proton pump inhibitor (PPI) has been recommended for patients with suspected LPR.[10] Studies have also reported improved symptoms when patients receive PPI two to three times a day for 2–3 months.[11] However, very few studies have examined the degree to which this treatment improves the symptoms associated with LPR and overall QOL. Therefore, in this study, we evaluated the effect of PPI treatment on the subjective symptoms using Reflux Symptom Index (RSI) and assessed the effects on the QOL of patients using LPR–health-related quality of life (LPR-HRQOL) and SF-36 over a 3-month period.

METHODS

Patients

We evaluated patients who visited an otolaryngologist at three different hospitals (Samsung Changwon Hospital, Kyung Hee University Hospital at Gangdong, Seoul Veterans hospital) and were diagnosed with LPR between November, 2010 and February, 2012. All patients received an otolaryngologic

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examination including laryngoscopy, and LPR was diagnosed based on the following symptoms and signs: (1) having at least one of the following symptoms: hoarseness, chronic cough, throat irritation, laryngospasm, chronic throat clearing, and dysphasia; (2) confirmed signs such as erythema, vocal fold edema, subglottic edema, posterior pachydermia, laryngeal edema, ventricular obliteration, and also endolaryngeal thick mucus and granuloma from the findings of laryngoendoscope; and (3) symptoms were not due to postnasal drip or laryngitis that originated from respiratory infections and/or allergies in the past month. Additional exclusion criteria included age (younger than 18 years), patients suffering from GERD symptom but not LPR symptoms, patients who had malignancy or chronic wasting disease or major psychosis, patients who had a history of radiation treatment, and patients that received gastrointestinal tract surgery or treatment with PPI in the past month. The enrolled group included all patients newly diagnosed with LPR during the past month who had not received any treatment. Diagnosis was determined by otolaryngologic experts from three different hospitals.

This study was developed using the LPR evaluation and treatment algorithm described by Ford.[12] In addition to lifestyle modifications (avoidance of caffeine, alcohol, smoking, fatty food, and meals close to bedtime), LPR patients were administered 15 mg of Lansoprazole (Jeil Pharmaceutical Co., Ltd, Seoul, Korea) two times a day for 12 weeks. Patients were instructed to take the PPI 30 minutes before each meal. The changes in subjective symptoms were assessed using the RSI, SF-36 version 2.0, and LPR-HRQOL.[13–15] The surveys were recorded three times over the study period at first visit and 4-week (1 month) and 12-week (3 month) follow-up visits. In addition, the Reflux Finding Score (RFS) of Belafsky was conducted by three otolaryngologic experts to evaluate the objective findings of the laryngeal condition.[16] This work was performed as a multicenter study with approval by an Institutional Review Board at the centers of three different hospitals.

All patients provided signed informed consent.

Laryngeal examination

All enrolled patients received laryngoscopy to find objective signs of LPR based on the RFS.[16] Three experts performed the examination using a Strobolaryngoscope and 70° rigid endoscope. When a clear appearance of the vocal folds and other surrounding structures were not visible in the rigid endoscope, a flexible laryngofiberscope was instead used to increase the accuracy. Enrolled patients were taught how to pronounce "Yee" in a high-pitched tone, low-pitched tone, and regular-pitched tone. Through this procedure, diagnosis on the LPR and RFS, which is the rating scale of clinical advanced disease of LPR, were recorded. The RFS ranged from 0 (normal) to 26, with a higher score indicative of a deteriorated laryngeal condition. A consensus meeting among all three clinics was carried out to obtain a higher inter- and intrarater reliability in RFS scoring. This investigation was performed according to standard protocol and was scored by observers blinded to the patient's identity.

The questionnaires

We evaluated the QOL and subjective symptoms reported by patients using three surveys: SF-36 version 2.0, LPR-HRQOL, and RSI. We analyzed the level of QOL in SF-36 comprised eight different categories and 11 questions, which included physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, and mental health. The gradient of the eight different criteria were measured to better understand the common health condition and the degree of LPR in each patient. SF-36v2 Health Survey Scoring Demonstration (Quality Metric, Inc., Lincoln, RI) was used to calculate score. Using the score conversion method of Ware et al,[15] the values were added by considering the portion of its weight. The total calculated score was 100 (0 is the worst health condition and 100 is the highest health condition).

LPR-HRQOL is a reliable and valid QOL rating scale described by Carrau et al.[14] This method can be used to evaluate the QOL of LPR patients through a simple survey comprising 43 questions across five different categories including hoarseness, cough, throat clearing, swallow, and overall impact of acid reflux. The questionnaire uses a basic seven-point Likert scale question in four categories, except for the 10-point Likert, which involves the overall impact of acid reflux. A high score indicates more severe symptoms, whereas a score of 0 indicates no symptoms.

The RSI not only evaluates the severity of LPR symptoms but is also a highly validated survey and includes nine questions that assess the response to treatment. The survey evaluates the level of symptoms and its severity through a six-point Likert scale, which ranges from 0 to 5. A high score indicates that patients have more severe symptoms, where 0 means no symptom. Generally, when the total score is greater than 10, the LPR is considered severe. The survey was given three times through the course of treatment.

Statistical analysis

SPSS 18.0 (SPSS Inc., Chicago, IL) was used for statistical analysis and mean ± standard deviation was calculated for all data. A paired *t* test was used to compare the RFS, RSI, SF-36, and LPR-HRQOL results between the first visit and 4-week follow-up visits as well as the first visit and 12-week follow-up visits. A difference was considered statistically significant when the *P* value was less than 0.05.

RESULTS

A total of 180 patients were diagnosed with LPR: 98 men (54.4%) and 82 women (45.6%). The survey was completed without omission by all 180 patients during the follow-up period. The mean age of the patients was 52.8 ± 14.5 years and ranged from 19 to 85 years. We determined the degree of improvement by comparing the mean symptom scores between the first visit and 4- and 12-week follow-up visits for all three surveys. In addition, the mean RSI scores were compared between three visits for each patient.

The RSI score was 13.15 ± 8.68 at the first visit, 10.03 ± 8.97 after 4 weeks of treatment ($P < 0.01$), and 7.56 ± 9.08 after 12 weeks of treatment ($P < 0.01$). The difference between the