The demographic characteristics and health-related quality of life in a large cohort of reflux esophagitis patients in Japan with reference to the effect of lansoprazole: the REQUEST study

Michio Hongo¹, Yoshikazu Kinoshita², Hirotó Miwa³, and Kiyoshi Ashida⁴

¹Department of Comprehensive Medicine, Tohoku University Hospital, 1–1 Seiryo-machi, Aoba, Sendai, 980-8574, Japan
²Department of Gastroenterology and Hepatology, Shimane University School of Medicine, Izumo, Japan
³Division of Upper Gastroenterology, Department of Internal Medicine, Hyogo College of Medicine, Nishinomiya, Japan
⁴Department of Gastroenterology and Hepatology, Saiseikai Nakatsu Hospital, Osaka, Japan

Background. Patients with reflux esophagitis (RE) in Western countries have impaired health-related quality of life (HRQOL). However, few data are available concerning HRQOL in Asian patients with RE. Aim. To determine the demographic characteristics, HRQOL, and the impact of lansoprazole treatment in a large cohort of RE patients in Japan. Methods. Patients with RE were enrolled. Lansoprazole was administered for 8 weeks and HRQOL assessed using the SF-8 and a newly developed questionnaire for RE-specific HRQOL (RESQ) at baseline and after 4 and 8 weeks of treatment. Results. Among enrolled patients, 2320 patients with the Los Angeles classification grade A to D esophagitis at enrollment to the study were analyzed. A higher proportion of older women was observed (in the group of patients aged ≥60 years, 61.3% were women). Prevalence of obesity was 4.7%. At baseline, HRQOL scores of RE patients were well below the mean for the Japanese general population in all domains of the SF-8. After 8 weeks of treatment with lansoprazole, these scores significantly improved to the levels of the general population (P < 0.01). Scores of RESQ also significantly improved (P < 0.01). Conclusions. Demographically, RE patients in Japan differ from those in Western countries with an increased proportion in older women and lower prevalence of obesity. RE has a marked negative impact on HRQOL, which is significantly improved by treatment with lansoprazole.

Key words: quality of life, reflux esophagitis, proton pump inhibitor, lansoprazole

Introduction

Reflux esophagitis (RE) is one of the most common disorders treated in general practice, and it is estimated to occur in 10%–20% of Western populations and in 2.5%–6.7% of Asian populations,¹ ² and the overall prevalence appears to have increased in recent years.³ In terms of demographics there are some important differences between Western and Asian patients with RE. For example, gastric acid secretion is generally lower in Asian populations than in Western populations.⁴ ⁵ An epidemiological study conducted in the United States reported that the prevalence of RE peaked in middle age regardless of sex.⁶ In contrast, in the East Asian populations, the number of women increases with advancing age, while there are few age-related differences among men.⁷–¹⁰ In addition, the prevalence of obesity [body mass index (BMI) >30 kg/m²], one of the major risk factors for RE, is only about 3% in Japan whereas it is 30% in the United States.¹¹ ¹²

With regard to patient well-being, health-related quality of life (HRQOL) of patients with RE has been found to be impaired in physical, psychological, and social aspects. Clinical studies conducted in Western countries have revealed that all dimensions of HRQOL in patients with RE are impaired compared with the general population, and improvement of HRQOL was achieved during treatment with proton pump inhibitors (PPIs).¹³ ¹⁴ RE patients in Japan also complained of impaired HRQOL in general practice, reporting improvement in HRQOL with antisecretory therapy. However, to our knowledge, no quantitative analysis of HRQOL in a large cohort of Asian patients with RE has been published to date. Therefore, we conducted the REQUEST (Re-assessment of Quality of Life on Reflux Esophagitis Treatment) study, an open-label, multicenter, postmarketing observational study, to determine the characteristics and HRQOL of RE patients in Japan and to evaluate the effects of a short
course of antisecretory therapy with lansoprazole (LPZ) in the clinical practice setting.

Patients and methods

Patients and treatment

A total of 1809 hospitals and clinics throughout Japan participated in the REQUEST study, which was performed between May 2005 and June 2006. Attending physicians made a diagnosis of RE by endoscopy or recent patient history. Patients enrolled in the study included those with newly diagnosed RE at enrollment, those who had a relapse of RE following previous antisecretory therapy, and those who agreed to switch to LPZ from their current medication for RE regardless of presence of symptoms. We did not set a washout period from prior medications because this study was mainly conducted by general practitioners and it was difficult to set a washout period in their daily practice. At baseline, physicians recorded a complete history of RE characteristics for each patient. Physicians assessed the presence of kyphosis, obesity, and hiatal hernia; no criteria for the diagnosis of these conditions were defined, diagnosis being left to the discretion of the physicians. Following this initial assessment, patients were treated with LPZ 15 or 30 mg/day for 8 weeks. The dose was left to the discretion of individual physicians because this study was conducted in an actual clinical setting. The use of additional drugs except PPIs was not restricted during the treatment period. Before enrollment, the purpose and methodology of this study were explained to all patients.

HRQOL

HRQOL was assessed by self-administered questionnaire, the Japanese version of the 8-item Short-Form Health Survey (SF-8) and a newly developed questionnaire for RE-specific HRQOL (RESQ), at baseline, and after 4 and 8 weeks of treatment.

The SF-8 is a generic questionnaire that is derived from the longer 36-item Short-Form Health Survey (SF-36), and was developed to estimate HRQOL based on the scores from eight domains. Importantly, results obtained from the SF-8 demonstrate a high correlation with the SF-36. The Japanese version of the SF-8 was developed using a cross-cultural adaptation method that requires translation of the original English version into Japanese, followed by back-translation into English, and its validity was confirmed using the Japanese general population. The SF-36 was used to evaluate HRQOL in patients with RE included in clinical trials conducted in Western countries; however, we used the SF-8 in the present study for the convenience of both patients and physicians in primary care because it is easier, quicker, and more convenient to use in everyday practice. Scores for the eight domains—“general health,” “physical functioning,” “role: physical,” “bodily pain,” “vitality,” “social functioning,” “mental health,” and “role: emotional”—and the physical (PCS) and mental (MCS) component summaries were calculated according to the manual for the Japanese version of the SF-8. A score of 50 is the mean for the Japanese general population across the eight domains and two summary scores; higher scores indicate a better HRQOL.

Although eating and sleep are known to be impaired in RE patients, the SF-8 does not include questions that directly address these conditions. Questionnaires compiled specifically for the evaluation of HRQOL in RE patients have been developed, but as yet there is no standard form and Japanese versions of these questionnaires were not available at the start of this study. To assess HRQOL in RE patients in Japan more specifically, and using a smaller number of questions, we developed the RESQ, which comprises five questions. The grade of “difficulty in daily life,” “dissatisfaction with limitation in eating amount,” “dissatisfaction with avoiding favorite food,” “dissatisfaction with disturbances in falling asleep,” and “dissatisfaction with interrupted sleep” were assessed using a 5-point Likert scale (5, not at all; 4, slightly; 3, moderately; 2, quite a lot; or 1, extremely). We selected the 5-point Likert scale for the RESQ because this scale was used in six of eight questions of the SF-8. The “difficulty in daily life” score was used for the “daily life” domain, while mean scores of “dissatisfaction with limitation in eating amount” and “dissatisfaction with avoiding favorite food” were used for the domain of “eating.” The mean score of “dissatisfaction with disturbance in falling asleep” and “dissatisfaction with interrupted sleep” were used for the “sleep” domain. The mean score of these three domains was defined as the RE-specific summary (RES) score. Thus, the score for each domain and RES ranged from 1 to 5, with higher scores indicative of better HRQOL. The validity of RESQ was assessed using the data from this study. Cronbach’s alpha for each domain and RES score ranged from 0.841 to 0.917, indicating a high internal consistency. Spearman’s correlation coefficients between SF-8 and RESQ ranged from 0.406 to 0.601 for each domain and summary score. These values are equivalent to those documented when comparing other RE-specific HRQOL questionnaires and the SF-36.

After 4 and 8 weeks of treatment, each patient also answered the recall questions that assessed “chest/abdomen discomfort,” “comfort in daily life,” “eating condition,” and “sleep condition” in comparison to baseline (much better than before, better than before,