Review

Quality of life scales for patients with gastroesophageal reflux disease: A literature review

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Abstract

Gastroesophageal reflux disease (GERD) is a common chronic disease of the gastrointestinal tract that occurs in 3.1% of the Chinese population [1]. Heartburn, acid regurgitation and epigastric pain are typical clinical symptoms of GERD. These symptoms can affect patients’ work productivity, sleep, diet and daily activities, thus resulting in a reduced quality of life (QOL) [2]. Although patient QOL is increasingly being considered as a medical outcome index in the evaluation of the impact of GERD symptoms on patients’ health status, measuring patient QOL in clinical trials can be challenging due to the lack of a standard assessment tool. Therefore, we aim to review the commonly used generic, disease-specific and hybrid QOL questionnaires to evaluate patients with GERD to provide a reference for clinical nursing work.

1. Generic quality of life (QOL) scales frequently utilized to evaluate patients with gastroesophageal reflux disease (GERD)

Generic assessment instruments can be broadly applied across various health conditions, with the purpose of investigating the general health status of the subjects. Three different generic scales exist that are extensively used in assessing the QOL of GERD patients: the medical outcomes study 36-item short-form health survey (SF-36), the psychological general well-being index (PGWBI) and the EuroQol 5D (EQ-5D). The SF-36 is one of the most widely used generic instruments, since it contains only 36 items and has proven to be useful in evaluating the clinical curative effect of GERD. It has been well established that the various versions of the SF-36 have acceptable psychometric properties, therefore these scales are the gold standard in the validation of other QOL scales [1–3]. The SF-36 scale does have a somewhat poor sensitivity, so scholars do prefer to combine it with disease-specific instruments in the assessment of a patient’s health status [4].

The PGWBI is specifically designed to measure subjective psychological well-being and depression in the general population. This scale has been confirmed to effectively measure...
the physical condition of patients with gastrointestinal (GI) disease [5,6]. The limitation of the PGWBI is that its emphasis is on the general well-being of patients rather than the development of physiological functions and vitality. Although the findings of Pace et al. [7] determined that the PGWBI is effective in evaluating patients with GERD, further study is needed to demonstrate the sensitivity and specificity of the PGWBI.

Finally, the EQ-5D is an extensively used, multidimensional scale that consists of two parts: the utility value and the questionnaire. The questionnaire is well-documented in terms of its reliability and validity in all available language versions. In addition, it is able to be combined with other instruments to assess the current health status of patients with GERD. The advantage of the EQ-5D scale is its ability to evaluate the cost-effectiveness of clinical interventions via conducting utility value conversions. Therefore, the EQ-5D can offer guidance to health care systems by suggesting clinical therapeutic regimens. Grant and colleagues [8] have conducted a five-year follow-up study of a randomized clinical trial to discuss the long-term clinical effectiveness, cost-effectiveness and safety of laparoscopic surgery among patients with GERD who required long-term medication, surgery and medical management. The results indicated that EQ-5D is a reliable, feasible and validated instrument in the evaluation of GERD patients.

2. Disease-specific QOL scales oftentimes used in the assessment of GERD patients

The scales discussed in this section have been developed specifically for the evaluation of patients with GERD, and therefore demonstrate high sensitivities and responsiveness. One major advantage of these disease-specific scales is that they can monitor small yet significant changes in patient health. The following five questionnaires are the most common disease-specific scales used in clinical work today.

2.1. Health-related QOL scale for GERD (GERD-HRQL)

The GERD-HRQL was developed to survey symptomatic outcomes and therapeutic effects in patients with GERD [9]. The scale has 11 items, which focus on heartburn symptoms, dysphagia, medication effects and the patient’s present health condition. The GERD-HRQL takes approximately one minute to complete. Each item is scored from 0 to 5, with a higher score indicating a better QOL. Velanovich et al. [9] examined the psychometric properties of the GERD-HRQL in GERD patients within a clinical trial. They reported that the Cronbach’s $\alpha$ coefficient for each subscale ranged from 0.89 to 0.94, the test–retest reliability resulted in an intra-class correlation coefficient (ICC) of 0.93 and the responsiveness to clinical change was acceptable. In China, Liu et al. [10] applied the GERD-HRQL to evaluate the efficacy of the Stretta procedure on GERD patients. The main evaluation indices were the GERD-HRQL score, satisfaction of symptom control and medication use. The results showed that there were significant increases in QOL at six and twelve months after treatment when compared to baseline (8.1 vs. 7.3 vs. 25.6, respectively; $p < 0.01$). Onset of relief of GERD symptoms was observed less than two months (70.0%) and two to six months (16.7%) post-treatment, and the percentage of patients with satisfactory GERD control improved from 31.1% at baseline to 86.7% post-treatment. The GERD-HRQL is increasingly being utilized to measure the QOL on morbidly obese patients, however the psychological properties of this scale for these specific patients need to be validated [11].

The GERD-HRQL is thought to be simple to use, easy to understand and sensitive to treatment effects. The disadvantage of this scale is that it focuses on disease symptoms, ignoring the importance of psychological status and social function in QOL [3]. Therefore, this scale should be used in conjunction with a generic questionnaire [12].

2.2. QOL questionnaire for GERD (GERD-QOL)

The GERD-QOL was developed by Chan et al. [3] in 2009 to measure the impact of symptomatic GERD on QOL before and after medical therapy. The original questionnaire of 30 items was carefully reformulated leading to a new 18-item scale. Removal of items with loadings 0.3 or lower and deletion of arcane statements led to the generation of the final version of the GERD-QOL questionnaire. This new scale consisted of 16 items clustered into the following four subscales: daily activity, treatment effect, diet and psychological well-being. The total score of this questionnaire is the average of the four subscale scores. The final score can range from 0 to 100, with a higher score indicating a better QOL. The results of the psychometric characteristic analysis of the GERD-QOL demonstrated that the subscale scores were consistent between the two visits (ICC 0.73–0.94, $p < 0.001$). The reliability coefficient (Cronbach’s $\alpha = 0.64–0.88$) was greater than 0.7 except for the diet subscale. Pearson’s correlation between the GERD-QOL total scale and the eight domains of the SF-36 was fair, but significant ($r = 0.23–0.49$, $p < 0.001$). Additionally, a significant difference existed in GERD-QOL scores between baseline and eight weeks post-esomeprazole treatment ($p < 0.001$) [3]. The GERD-QOL scale was translated into English for broader use, however further validation of this measurement tool needs to be conducted with English-speaking patients. Furthermore, the stability of this scale for multinational or multiethnic studies still requires verification.

Two additional points should be considered when using the GERD-QOL. First, it is important to consider that the dimension of psychological well-being has only two items on this scale, so special attention should be taken when interpreting this specific subscale score. Moreover, additional studies should be performed on GERD patients with Barrett’s esophagus and the GERD-QOL, because this specific group of patients was excluded in the development and validation of this scale.

The GERD-QOL is a valid, reliable and acceptable scale for respondents and is simple to administer in both clinical and research contexts. This scale can be applied to patient populations with wide age ranges and various educational levels. Furthermore, with its multidimensional nature, the GERD-QOL lacks the flaws of the GERD-HROL, which is more focused on symptom severity [3]. Unfortunately, practical application of the GERD-QOL is not ideal.
2.3. Quality of reflux questionnaire (Reflux-Qual)

In 1999, Raymond et al. [13] designed the Reflux-Qual questionnaire, which is a patient-centered, self-administered postal questionnaire. The Reflux-Qual was developed to evaluate the outcomes of GERD patients receiving surgery or medical treatment in the randomized evaluation of laparoscopic surgery for reflux (REFLUX) trial. It was confirmed that this questionnaire contained acceptable psychological properties with 37 items covering seven dimensions. Applying multiple stepwise regression analysis, Raymond et al. [13] showed that the QOL in GERD patients decreased with the aggravation of severe endoscopic lesions, and increased gradually when frequent symptoms declined. These results demonstrate that the Reflux-Qual can determine factors that influence QOL and provide prevention priorities for clinical intervention. Another study [14] showed that the Reflux-Qual can also be used for comparing differences in QOL between GERD patients and other patients with diseases of the digestive tract.

Since the Reflux-Qual contains 37 items, it was considered to be cumbersome, time-consuming and inconvenient. Therefore, Amourette et al. [15] developed the revised short-form reflux-qual (RQS), which is a short questionnaire based on the Reflux-Qual. The RQS consists of eight items covering four categories, including daily life, well-being, psychological impact and sleeping/eating. A score ranging from 0 to 100, with 100 representing the best health condition and zero the worst health status, can be rapidly obtained using this questionnaire. The Cronbach’s α coefficient of the RQS is 0.84 and the response rate is 98.5%. Furthermore, the questionnaire has the potential to determine both the improvement and deterioration in patients’ QOL for an entire study population. Avaro et al. [16] investigated the QOL of 52 patients who underwent GERD reoperation between 1986 and 2006. Either a transthoracic or transabdominal operation was performed on each patient. A telephone enquiry was completed using a validated French RQS. The results verified that patients who underwent transthoracic GERD surgery had the highest RQS values, a lower complication rate and a lower rate of reoperation. At present, the practicality of the RQS questionnaire has been widely validated, and it has been utilized in several different patient populations. Unfortunately, this questionnaire has yet to be translated into Chinese. In the future, the RQS should be made available in Chinese and subsequently validated in this language.

2.4. QOL questionnaire for patients undergoing anti-reflux surgery (QOLARS)

Zeman et al. [17] designed the QOLARS scale to measure satisfaction and other aspects of daily life for patients undergoing anti-reflux surgery. The researchers combined the European organization of research and treatment of cancer (EORTC) QOL questionnaire (EORTC-QLQ-C30), the Visick score and a modified GERD-HRQL to generate the QOLARS questionnaire. When administered preoperatively, this questionnaire consists of 45 items. Five additional questions concerning surgical complications and efficacy are included when the QOLARS is administered postoperatively. The total one-dimensional Cronbach’s α coefficient of the QOLARS was found to be 0.95, ranging from 0.74 to 96. Higher correlations were found between scales for items measuring the convergent validity, and lower correlations were found measuring divergent validity. In 2007, Zeman and Tihanyi [18] required patients to complete the QOLARS questionnaire before laparoscopic anti-reflux surgery. The patients were also asked to complete the questionnaire six weeks, one year and three years post-surgery to analyze patient QOL and satisfaction. The findings showed that the general QOL and heartburn scores improved significantly within six weeks after surgery, exhibited further improvement at the end of the first postoperative year and then remained stable three years after surgery. Importantly, this study also found that preoperative QOL measurements can predict which patients will be satisfied with anti-reflux surgery.

A majority of items in the QOLARS questionnaire are specifically developed for patients undergoing anti-reflux surgery. This questionnaire has a higher sensitivity and reliability compared to other disease-specific scales and is more descriptive of a patient’s QOL. The QOLARS scale was considered to be more comprehensive than existing measures when administrated to patients who had undergone laparoscopic fundoplication [18].

2.5. The GERD analyzer (GERDyzer)

The GERDyzer is a self-administered questionnaire primarily designed to evaluate the impact of erosive GERD on QOL and to assist medical staff in determining an optimal therapeutic strategy [19]. The GERDyzer consists of 10 dimensions that can be clustered into two factors based on factor analysis. To calculate the total score of the GERDyzer, the first factor is weighted by 1.0 and the second is weighted by 0.5. Holtmann et al. [19] reported that they were able to obtain a consistently high Cronbach’s α coefficient of 0.95, a high test-retest reliability demonstrated by an ICC of 0.91 and a responsiveness of 1.38. In Germany, Monnikes et al. [20] utilized the GERDyzer to confirm the efficiency of Pantoprazole in relieving upper and lower GI symptoms in patients with erosive esophagitis. Another study [21] suggested that the GERDyzer could be regarded as a standardized control to evaluate the psychological characteristics of new questionnaires.

The two biggest differences between the GERDyzer and other GERD QOL questionnaires are the innovative design and the content arrangement. Remarkably, the questionnaire design, which utilizes graphics, seemingly improves response rates and promotes nurse-patient communication. Unfortunately, the complex scoring system and limited use of this questionnaire has hindered the development and extension of the GERDyzer. Future work should focus on expanding the use and applicability of this scale.

3. Hybrid QOL scales frequently utilized to assess patients with GERD

Hybrid scales are appropriate for patients with any GI condition. The content of hybrid instruments not only includes GI disease symptoms but also covers general health questions.
Currently, the following two questionnaires for GERD patients are most often used in clinical work.

### 3.1. QOL questionnaire in reflux and dyspepsia (QOLRAD)

Wiklund et al. [22] specifically designed the QOLRAD to evaluate the impact of GERD symptoms and dyspepsia on QOL. Twenty-five questions are included in this scale and cover the following five domains: emotions, vitality, sleep, eating/drinking and physical/social functioning. The internal consistency and discriminant validity were examined for the QOLRAD scale. A total Cronbach’s α for the internal consistency of the scale was reported as being >0.7 (overall α value of 0.97, dimensions 0.89–0.94), and the association between similar constructs in the QOLRAD, the SF-36 and the GRS scores was confirmed. The QOLRAD is one of the most commonly used hybrid scales in evaluating GERD, largely because it addresses influence factors and the effect of clinical treatment [23–25].

In China, Cao et al. [26] translated and revised the QOLRAD and subsequently surveyed Chinese GERD patients. The results of this study showed that the total Cronbach’s α coefficient of the QOLRAD is 0.98. In addition, a high test–retest reliability was determined with an ICC = 0.93. Moreover, the researchers confirmed that all eight of the SF-36 dimensions significantly correlated with the QOLRAD total score. The research team also investigated the QOL status of GERD patients in Shanghai, China. These results revealed that GERD patients have significantly more health problems than healthy subjects of the same age, specifically in the areas of eating disturbance, physical functions and emotional wellbeing. In addition, they found that the severity of reflux symptoms is closely related to physical comfort. To demonstrate that the QOLRAD could be utilized as a discriminant questionnaire to distinguish different populations, Niu and colleagues [24] examined 256 patients with non-erosive reflux disease who were treated with the proton pump inhibitor (PPI) esomeprazole. The patients were divided into symptom-free and residual symptoms groups according to the QOLRAD scale to analyze risk factors for refractoriness to PPIs. Thus, the QOLRAD questionnaire can be routinely used as an evaluation tool for patients with GERD and dyspepsia.

### 3.2. The domestic/international gastroenterology surveillance study questionnaire (DIGEST)

The DIGEST questionnaire was designed to investigate the prevalence of upper GI symptoms in patients and the impact these symptoms had on QOL. Eggleston et al. [27] reported that the DIGEST questionnaire is primarily used as an epidemiological investigational tool with satisfactory psychological properties. The DIGEST questionnaire consists of two parts: the first section is a newly developed instrument containing 27 questions and three dimensions (severity of disease, frequency of symptoms and effect on daily activities), whereas the second part is the PGWB, a validated generic QOL scale. A survey of 5581 participants using the DIGEST questionnaire demonstrated that heartburn, diarrhea and postprandial abdominal distension are common GI symptoms. This study also found that sex, severity of symptoms and medical condition correlate with the degree of impairment of health and daily activities [27]. Tijssen [28] verified the external validity of the DIGEST questionnaire and found that there were no statistically significant differences in age, sex and family income. Therefore, this study can provide the theoretical basis for the comparison of data from different geographical areas to show that the DIGEST questionnaire can be used as a trans-regional, indiscriminate survey.

Currently, the DIGEST questionnaire is primarily used for large, multicenter, cross-sectional survey studies. Although Meier et al. [5] reported that the DIGEST questionnaire could be used as an index to evaluate the effect of drug tests, this study was not in-depth. Therefore, the applicability of the DIGEST scale in evaluating clinical intervention efficiency needs to be verified.

### 4. Conclusions

In summary, although a large variety of disease-specific QOL questionnaires to assess patients with GERD are used worldwide, there is still a lack of a recognized standard scale. Importantly, research on QOL scales to evaluate Chinese patients with GERD is scarce compared to that in western countries. Research on QOL assessment tools for patients with GERD is still at a very early stage in China, and reports in the literature on QOL scales assessing GERD patients are rare. Hence, future clinical studies need to develop an effective QOL assessment tool for Chinese GERD patients undergoing medical therapy.

### Conflict of interest

We declare no potential conflicts of interest with respect to the research and/or publication of this article.

### REFERENCES


