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

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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 α 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 score 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.