

# Improving Health-Related Quality of Life in Gastro-Oesophageal Reflux Disease

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## Abstract

Gastro-oesophageal reflux disease (GORD) is a common, chronic disorder that can progress to erosive or ulcerative oesophagitis and other complications. Uncomplicated GORD can be defined using criteria that combine symptom assessment and the impact of symptoms on well being or quality of life. The extent of impairment of health-related quality of life (HRQL) in GORD patients has been evaluated using generic HRQL questionnaires, GORD-specific quality of life questionnaires or a combination of the two types of instruments. The impact of GORD on HRQL in affected individuals is proportional to the frequency and severity of heartburn, and is greater than that associated with many other chronic diseases. In the treatment of GORD, the goal should be complete symptom resolution as this has been shown to be associated with a clinically significant improvement in HRQL. Both drug treatment and surgical intervention have been successful in improving HRQL of patients with GORD when complete symptom resolution can be attained

Significant advances have been made over the past decade in understanding the epidemiology and symptomatology of gastro-oesophageal reflux disease (GORD, or GERD in the US). Reflux symptoms such as heartburn are common in the general adult population. The US National Institutes of Health reported that more than 60 million American adults experience heartburn at least once a month and about 25 million experience heartburn daily.<sup>[1]</sup> The Domestic/International Gastroenterology Surveillance Study (DIGEST),<sup>[2]</sup> conducted among 5581 respondents from seven European countries, Canada, the US and Japan, found that heartburn was experienced several times a week by 18.0% of respondents and daily by 8.2% of respondents. Heartburn was rated as severe by 14.0% and very severe by 2.0% of these respondents.

GORD is one of the most common conditions that primary care physicians encounter.<sup>[3]</sup> The condition is likely to be more common than documented because many patients self-medicate with antacids and over-the-counter strength histamine H<sub>2</sub>-receptor antagonists.<sup>[4]</sup> Despite this, 5% of people in a community-based study reported seeing a physician in the previous year for reflux complaints.<sup>[5]</sup> In that survey, 86% of individuals had experienced symptoms for at least 1 year, and 59% had experienced symptoms for 5 years or more.

On the basis of endoscopic findings, GORD can be categorised into erosive and nonerosive disease.<sup>[6]</sup> The erosive form of GORD (erosive oesophagitis) is more prevalent than expected in patients with symptoms of GORD. In a recent study of over 10 000 patients screened by endoscopy for entry into a US clinical programme for a new proton pump inhibitor, 65% were diagnosed with erosive oesophagitis.<sup>[7]</sup> Although effective medication is available to control symptoms and heal underlying mucosal injury in patients with erosive oesophagitis, relapse occurs in 80% of patients over a 1-year period after acid suppression treatment is discontinued.<sup>[8]</sup>

Thus, GORD is a chronic, relapsing condition that generally requires continuous pharmacological treatment and/or surgical intervention in order to maintain a normal or near normal level of quality of life.

### **1. Physical Complications of Gastro-Oesophageal Reflux Disease (GORD)**

Serious oesophageal complications of GORD include erosion, ulceration, stricture, haemorrhage, perforation and Barrett's oesophagus. Chronic oesophagitis has been associated with oesophageal stricture in 1.2% of patients in a case series presented by Ben Rejeb et al.<sup>[9]</sup> The intensity and frequency of heartburn and other symptoms of reflux are poor predictors of the presence or severity of oesophageal manifestations.<sup>[10,11]</sup> Although heartburn may not be life threatening, patients typically seek treatment when symptoms become severe enough to impair quality of life or alarm them about potentially more serious disease. Effective control of GORD symptoms can improve quality of life, reduce morbidity and may prevent complications arising from GORD.<sup>[12-14]</sup> Unlike erosive oesophagitis, nonerosive GORD is a difficult condition to diagnose and treat. An empirical diagnosis is often made on the basis of the response to acid suppressive therapy.<sup>[15]</sup> There is little evidence that nonerosive GORD progresses to more complicated oesophageal disease.<sup>[11]</sup>

In addition to the oesophageal complications of GORD, several supra-oesophageal complications have been identified. Approximately 75% of asthmatics have symptoms of GORD and 40% have reflux oesophagitis; both microaspiration and a vagally mediated mechanisms appear to be involved.<sup>[16]</sup> Aspiration pneumonia has been associated with aspiration of refluxed gastric acid. Multivariate logistic regression analysis of data from more than 100 000 US veterans determined that erosive oesophagitis and oesophageal stricture

were associated with an increased risk of a development of sinus, pharyngeal, laryngeal and pulmonary inflammatory diseases.<sup>[17]</sup>

## 2. Diagnosis of GORD

GORD can be diagnosed symptomatically and, often, by endoscopy. A diagnosis of GORD based on endoscopy can be established for individuals who have acute or chronic oesophageal tissue damage secondary to chronic acid exposure.<sup>[11]</sup> An expert panel of the American College of Gastroenterology wrote that the combination of symptoms and endoscopic changes enables virtually complete (97%) diagnostic specificity.<sup>[18]</sup> However, in primary care, where most patients with complaints of heartburn and other GORD symptoms initially present, performance of endoscopy is unnecessary if initial empirical therapy effectively controls symptoms.<sup>[19]</sup>

The Genval Workshop, a multinational group of gastroenterologists, primary care physicians, health economists and surgeons, proposed a diagnostic definition of GORD that includes individuals "who experience clinically significant impairment of health-related well-being (quality of life) due to reflux-related symptoms, after adequate reassurance of the benign [non-malignant] nature of their symptoms".<sup>[11]</sup> The Genval Workshop suggested that GORD is likely to be present when heartburn occurs on 2 or more days a week, although less frequent symptoms do not preclude disease.<sup>[11]</sup> Because of the emphasis on well being and quality of life in defining GORD, the measurement of quality of life and the impact of therapies on quality of life in patients with GORD assume greater importance.

## 3. Quality of Life Measurements in GORD

Evaluation of health-related quality of life is becoming more important in medical outcome assessment. The term 'quality of life' is used in general to describe the ability to conduct an economically and socially productive life, and is not solely concerned

with health. It reflects the individual's perceptions of various life dimensions, including physical, psychological, social, economic and spiritual. Health-related quality of life refers to the physical, psychological and social domains of health that influence quality of life, and are highly individual concepts, influenced by a person's own experiences, beliefs, expectations and perceptions.<sup>[20]</sup>

There are two broad types of instruments that may be used to measure health-related quality of life: generic instruments and disease-specific instruments.<sup>[21]</sup> Generic instruments assess general health issues pertinent to quality of life in all populations of patients. Such instruments are particularly helpful in the cross-sectional comparison of groups of patients with different diseases within the population. However, generic instruments may not be sensitive to change in a particular disease, and physicians and/or patients may not find them relevant to the illness of interest. Disease-specific instruments focus on the pertinent disease, and offer greater sensitivity to change.<sup>[21]</sup> As such, they are particularly well suited to the longitudinal assessment of individuals or groups of patients with the same disease. The choice of an appropriate health-related quality of life instrument, among the several reliable and valid instruments currently available, depends upon the objectives of the proposed research.<sup>[21]</sup>

Several valid and reliable generic quality-of-life instruments have been used to assess quality of life in patients with GORD, such as the short form 36 (SF-36), the Psychological General Well-Being Index (PGWB), the Impact on Daily Activity Scale (IDAS) and the Sleep Scale<sup>[22]</sup> (table I). Additionally, the reliability and validity of several GORD-specific questionnaires have recently been reported, including the Health-Related Quality of Life (HRQoL) instrument,<sup>[23]</sup> the Quality of Life in Reflux and Dyspepsia (QOLRAD),<sup>[24]</sup> and the Gastroesophageal Reflux Disease-Health-Related Quality of Life (GERD-HRQL)<sup>[25]</sup> (table I). Because the

**Table 1.** Instruments for measuring quality of life (QoL) in patients with gastro-oesophageal reflux disease (GORD)

<b>Generic QoL instruments</b>	
Short form 36 (SF-36)	A questionnaire comprising 8 domains with good reproducibility, internal consistency, validity, sensitivity to changes in health status and the ability to detect QoL impairment in a variety of conditions <sup>[26]</sup>
Psychological general well-being index	22 items are combined into the categories of anxiety, depressed mood, positive well-being, self-control, general health and vitality; measures well-being or distress; <sup>[27]</sup> commonly used in Europe
Impact on daily activity scale	Six questions concerning housework, sport or leisure activities, sleep, daily life and work, which measure ability to carry out daily activities <sup>[28]</sup>
Sleep scale	Four items associated with falling asleep, restless sleep and awakening during sleep time <sup>[28]</sup>
<b>Disease-specific QoL instruments for GORD</b>	
Health-related QoL instrument	A 57-item questionnaire containing the short form 12 (SF-12: a shorter, yet valid, alternative to the SF-36) and items pertaining to symptom frequency/bothersomeness and problems related to activities, sleep, work disability, overall health-related QoL and treatment satisfaction <sup>[23]</sup>
QoL in reflux and dyspepsia	A 25-item questionnaire depicting problems with emotions, vitality, sleep, eating/drinking and physical/social functioning <sup>[24]</sup>
GORD health-related QoL	A nine-item ordinal-scaled questionnaire that evaluates GORD symptoms such as severity, position when heartburn occurs, nocturnal heartburn and association with meals <sup>[25]</sup>

GERD-HRQL focuses on symptoms, and does not actually assess overall quality of life, many researchers combine it with generic quality-of-life instruments.<sup>[21]</sup>

#### 4. Impact of GORD on Quality of Life

Heartburn is the most predominant symptom of GORD, and health-related quality of life is impaired in proportion to the frequency and severity of heartburn, regardless of the presence or absence of oesophagitis.<sup>[11]</sup> Compared with the general population, patients with GORD have significantly poorer scores on the SF-36 across all eight domains, including physical, mental and social functioning, vitality, and general health perception ( $p < 0.05$ ).<sup>[29-31]</sup> Individuals reporting GORD-like symptoms also have significantly ( $p \leq 0.0001$ ) poorer scores than the general population on the PGWB.<sup>[2]</sup>

The quality of life of patients with GORD is worse than that of patients with untreated diabetes mellitus, angina pectoris, mild heart failure and hypertension. Patients with untreated GORD reported worse pain, social functioning and emotional well

being than those with diabetes or hypertension.<sup>[32]</sup> As measured by the PGWB, untreated patients with GORD reported more impaired general well being than patients with untreated hypertension, mild heart failure or angina.<sup>[33]</sup> In addition, patients with gastrointestinal disorders rated the impact of their condition on well being, mental health and functional status as exceeding that of patients with back problems, diabetes, chronic lung problems, hypertension and arthritis.<sup>[34]</sup>

#### 5. Impact of Current Therapies on Quality of Life

Drug treatment is usually employed first-line to treat both the erosive and nonerosive forms of GORD. Non-response to drugs such as proton pump inhibitors is an indication that the symptoms may not be an acid-related problem.<sup>[6]</sup> Surgery is recommended for patients with severe symptoms that do not respond adequately to medication or for those who wish to decrease their need for lifelong drug therapy.<sup>[19]</sup> More recently, the advent of non-inva-

**Table II.** Open-label studies of the impact of current therapies on quality of life in patients with gastro-oesophageal reflux disease

Population	Treatment (no. evaluable patients)	Results: SF-36
Heartburn (at least weekly) and grade II–III oesophagitis <sup>[37]</sup>	Omeprazole 20mg twice daily × 8wk (77)	All 8 dimensions improved vs baseline ( $p = 0.06$ for mental health and $p < 0.05$ for all others); improvements did not differ between the subgroups of patients with healed vs unhealed oesophagitis
Symptomatic reflux disease for ≥1 months <sup>[38]</sup>	Ranitidine 150mg twice daily × 2wk, then 2–4 times daily × 2wk (333)	All 8 dimensions improved for the group as a whole ( $p < 0.01$ ) and for the 78% of patients responding (defined as resolution or improvement of symptoms) at week 2 ( $p < 0.001$ ). Nonresponders at week 2 had no statistically significant change in quality of life
Moderate-to-severe heartburn for ≥6 months, including ≥4 of 7 days prior to enrolment <sup>[32]</sup>	Ranitidine 150mg twice daily × 6wk (465)	The 24% of patients who responded (defined as no heartburn for 7 days) had better scores than nonresponders for mean body pain, physical and social function, and vitality (all $p < 0.001$ ), as well as better scores for the other dimensions ( $p = 0.05$ – $0.005$ )

**SF-36** = short form 36 quality-of-life instrument; **wk** = week.

sive laparoscopic fundoplication has increased patient acceptance of a surgical treatment option.

### 5.1 Pharmaceutical Approaches

Treatment with proton pump inhibitors or H<sub>2</sub>-receptor antagonists has been shown to improve the health-related quality of life of patients with symptomatic GORD, both in open-label, non-comparative studies (table II) and in controlled clinical studies (table III and table IV). These drugs are generally well tolerated and have been confirmed through post-marketing surveillance to have a good safety profile with no clinically important long-term adverse consequences.<sup>[35,36]</sup>

The positive effect of proton pump inhibitors and H<sub>2</sub>-receptor antagonists on health-related quality of life in patients with GORD (with or without endoscopically confirmed oesophagitis) was confirmed in several placebo-controlled studies (table III). For example, proton pump inhibitors were significantly superior to placebo in improving baseline values of the overall score and the dimensions of anxiety, self-control and depressed mood according to the PGWB,<sup>[27]</sup> and most scales of the HRQoL.<sup>[29]</sup> Ranitidine 150mg administered twice daily was superior to placebo for the physical functioning, bodily pain and vitality dimensions of the SF-36, and for all dimensions (role-physical, heartburn pain, sleep, diet, social functioning and mental health) of a

GORD-specific questionnaire designed by the investigators.<sup>[41]</sup>

H<sub>2</sub>-receptor antagonists have been shown to be less effective at improving health-related quality of life than proton pump inhibitors as confirmed in randomised, double-blind studies that directly compared ranitidine and omeprazole (table IV). Omeprazole 20mg or 10mg daily provided superior improvement in health-related quality of life than ranitidine 150mg twice daily in patients with GORD, with or without endoscopically confirmed oesophagitis. Specifically, omeprazole was superior for the total score of the PGWB,<sup>[28]</sup> as well as the scores for the dimensions of positive well being, anxiety and general health.<sup>[28]</sup> Omeprazole was also superior to ranitidine as assessed by the IDAS health-related quality of life instrument.<sup>[28]</sup>

A relationship between improvement in health-related quality of life and response of GORD symptoms to ranitidine therapy with respect to heartburn has been reported (table II).<sup>[32,38]</sup> The proportion of patients who were non-responders in both of these ranitidine studies (22% and 78%, respectively; see table II)<sup>[32,38]</sup> suggests that H<sub>2</sub>-receptor antagonists are not an optimal choice for improving health-related quality of life in patients with GORD. Although the present generation of proton pump inhibitors does not completely resolve symptoms in all patients, direct comparisons of ranitidine and

**Table III.** Randomised, double-blind, placebo-controlled studies of the impact of current therapies on quality of life in patients with gastro-oesophageal reflux disease (GORD)

Population	Treatment (no. evaluable patients)	Results
Heartburn ( $\geq 2$ days/week) but no oesophagitis <sup>[27]</sup>	Omeprazole 20mg once daily $\times$ 4wk (163); omeprazole 10mg once daily $\times$ 4wk (163); placebo (82)	GSRS: reflux dimension improved with omeprazole 20mg <sup>†</sup> and 10mg <sup>†</sup> ; PGWB: improved overall with omeprazole 20mg <sup>*</sup> and 10mg <sup>†</sup> ; all dimensions improved, but anxiety, self-control and depressed mood improved significantly vs placebo
Heartburn and/or regurgitation, but normal oesophageal mucosa or nonerosive oesophagitis <sup>[39]</sup>	Omeprazole 20mg once daily $\times$ 4wk (98); placebo (111)	Omeprazole recipients had significantly greater improvements from baseline in GSRS total score <sup>‡</sup> , a lifestyle questionnaire <sup>‡</sup> , and the anxiety <sup>†</sup> component, but not the depression component, of a validated anxiety and depression questionnaire <sup>a</sup>
GORD symptoms with or without mucosal breaks in the oesophagus <sup>[10]</sup>	Omeprazole 20mg once daily $\times$ 4wk (213); omeprazole 10mg once daily $\times$ 4wk (211); placebo (82)	GSRS total score improvement: omeprazole 20mg <sup>*</sup> ; GSRS reflux dimension improvement: omeprazole 20mg <sup>†</sup> and 10mg <sup>†</sup> (patients without mucosal breaks); omeprazole 20mg superior to omeprazole 10mg (all patients; $p < 0.007$ ); PGWB score improvement: all dimensions improved vs baseline with omeprazole 20mg and 10mg therapy
Oesophagitis $\geq$ grade II <sup>[29]</sup>	Lansoprazole 15mg once daily $\times$ 8wk (183) <sup>b</sup> ; lansoprazole 30mg once daily $\times$ 8wk (368) <sup>b</sup> ; omeprazole 20mg once daily $\times$ 8wk (367) <sup>b</sup> ; placebo (183) <sup>b</sup>	HRQoL: the active treatment groups improved more than the placebo group ( $p < 0.05$ ) on most scales beginning at week 2, but improvement among each active treatment group did not differ to a statistically significant extent
Heartburn for $\geq 3$ months and $\geq 4$ of the 7 days prior to enrolment <sup>[41]</sup>	Ranitidine 150mg twice daily $\times$ 6wk (301); placebo (289)	Ranitidine scores were superior ( $p < 0.05$ ) to placebo scores for SF-36: physical functioning, bodily pain and vitality dimensions; GORD-specific questionnaire <sup>c</sup> : all dimensions (role-physical, heartburn pain, sleep, diet, social functioning and mental health)

a Described by Goldberg et al.<sup>[40]</sup>

b Number of evaluable patients at week 4 of treatment.

c This questionnaire was specifically designed for the study. The study methodology stated that the questionnaire was subjected to psychometric testing to provide support for its validity and reliability.

**GSRS** = gastrointestinal symptom rating scale (which focuses on symptoms rather than quality of life); **HRQoL** = health-related quality of life instrument; **PGWB** = psychological general well-being index; **SF-36** = short form 36 instrument; **wk** = week; \* =  $p \leq 0.05$  vs placebo;  $\dagger$  =  $p \leq 0.01$  vs placebo,  $\ddagger$  =  $p \leq 0.001$  vs placebo.

**Table IV.** Randomised, double-blind studies directly comparing the impact of different classes of gastro-oesophageal reflux disease (GORD) treatments on quality of life in patients with GORD

Population	Treatment (no. evaluable patients)	Results
Heartburn unresponsive to ranitidine <sup>a(28)</sup>	Omeprazole 20mg once daily × 8wk (117); ranitidine 150mg twice daily × 8wk (120)	Sleep scale scores did not differ significantly between groups, but omeprazole had superior mean scores for – GSRS: overall†, reflux‡, abdominal pain† and indigestion pain†; PGWB: total scores*, positive well-being*, anxiety* and general health†; IDAS‡
Heartburn for ≥3 months and ≥2 days/week × 2 weeks, with or without erosive oesophagitis <sup>a(2)</sup>	Omeprazole 10mg once daily × 2wk; omeprazole 20mg once daily × 2wk; ranitidine 150mg twice daily × 2 wk	Treatment groups did not differ in improvement in the reflux dimension of the GSRS, but omeprazole improved the following more so than ranitidine – GSRS: total score (omeprazole 10mg†); PGWB: total score (omeprazole 10mg†, omeprazole 20mg*)
Symptomatic reflux oesophagitis grades I or II <sup>(43)</sup>	Omeprazole 20mg once daily × 8wk <sup>b</sup> ; ranitidine 300mg once daily <sup>b</sup> × 8wk	GSRS: omeprazole group had significantly better scores for the dimensions of swallowing and eating problems†, and reflux-related problems†
Symptomatic reflux oesophagitis grades I or II <sup>(44)</sup>	Omeprazole 20mg once daily × 4wk (222); ranitidine 300mg twice daily × 4wk (224)	GSRS: reflux dimension†and total score* improved more with omeprazole
Heartburn and/or epigastric pain for ≥1 month <sup>(45)</sup>	Omeprazole 10mg once daily × 4wk (333); antacid/alginate liquid 10mL four times daily × 4wk (337)	Improvements from baseline were superior for omeprazole in both the PGWB‡ and the GSRS‡

a Heartburn unresponsive to ranitidine (150mg twice daily × 6wk) was defined as at least one episode of moderate-to-severe heartburn in the week prior to randomisation.

b A total of 243 patients were enrolled.

**GSRS** = gastrointestinal symptom rating scale (which focuses on symptoms rather than quality of life); **IDAS** = impact on daily activity scale; **PGWB** = psychological general well-being index; **wk** = week; \* =  $p \leq 0.05$  omeprazole vs ranitidine; † =  $p \leq 0.01$  omeprazole vs ranitidine, ‡ =  $p \leq 0.001$  omeprazole vs active comparator.

omeprazole confirm the relationship between heartburn resolution and health-related quality of life,<sup>[12,37]</sup> and demonstrate that the effect of proton pump inhibitors on health-related quality of life is superior to that of H<sub>2</sub>-receptor antagonists (table IV).<sup>[43-45]</sup>

As would be expected, proton pump inhibitors also provide greater benefit in health-related quality of life than antacids. In a randomised comparison of omeprazole 10mg daily and antacid/alginate 10mL four times daily, improvements from baseline favouring omeprazole were highly significant for the PGWB index ( $p < 0.001$ ).<sup>[45]</sup>

## 5.2 Heartburn Relief and Improved Health-Related Quality of Life

Complete resolution of heartburn (i.e. 7 consecutive days without heartburn) has been shown to be clearly associated with improved patient functioning and well being as measured by the SF-36 and PGWB questionnaires.<sup>[12]</sup> This association was evaluated in a secondary analysis of three clinical trials comparing ranitidine and omeprazole. Patients with no heartburn for 7 consecutive days consistently reported improved psychological well being, general health and vitality, regardless of the treatment group. These findings were consistent across all three trials in different patient populations: (i) a relatively healthy managed care population; (ii) a primary care population with co-morbid conditions who were at the lower end of the range of socioeconomic status; and (iii) patients with symptomatic GORD who met the usual inclusion/exclusion criteria of a clinical trial. The authors concluded that sustained complete resolution of heartburn was consistently associated with statistically significant improvement in patients' health-related quality of life. Therefore, optimal improvement in health-related quality of life for patients with GORD is most likely to be achieved with treatment providing complete resolution of heartburn.<sup>[12]</sup>

### 5.3 Limitations of Current Pharmacological Therapies

Proton pump inhibitors are clearly superior to other currently available medications in relieving GORD symptoms and improving health-related quality of life. Available options for individuals who do not achieve satisfactory responses from their current medications include higher or more frequent doses of older generation proton pump inhibitors, combination treatment, enhanced acid suppression with the later generation proton pump inhibitors such as esomeprazole<sup>[46]</sup> or laparoscopic fundoplication surgery.

## 6. Laparoscopic Fundoplication Surgery

Patient interest in surgery has increased with the availability of laparoscopic fundoplication in which a portion of the gastric fundus is wrapped around the oesophagus and secured, creating a new valve to prevent acid from refluxing into the stomach.<sup>[47]</sup> Unlike pharmaceutical therapy, however, there is disagreement among gastroenterologists about whether surgery is the best option and for which patients it should be recommended.<sup>[4,37]</sup> Although fundoplication should not be first-line therapy for most patients with GORD, it offers an alternative to 'qualified' patients with unequivocal GORD.<sup>[44]</sup> Relief of heartburn and regurgitation has been reported to be maintained for up to 3 years in 90% of patients with GORD in certain case series treated by fundoplication,<sup>[4]</sup> but in a long-term study, more than one half of patients who underwent the procedure had a continued need to use antireflux medications regularly.<sup>[48]</sup>

Several controlled studies have reported improved health-related quality of life following fundoplication surgery in patients with GORD.<sup>[43,45,46]</sup> Both laparoscopic and open fundoplication improved symptoms and normalised overall PGWB scores.<sup>[43,46]</sup> Seventy two patients initially

treated with H<sub>2</sub>-receptor antagonists, omeprazole and/or cisapride were offered fundoplication surgery if they were dissatisfied with pharmacological treatment and had both a hypotensive lower oesophageal sphincter and abnormal results on 24-hour pH monitoring.<sup>[45]</sup> Quality of life was measured with the Gastroesophageal Reflux Data Sheet, a 10-item questionnaire that included an overall assessment of satisfaction. Those who ultimately chose surgery had a greater improvement in quality of life scores from pre-treatment compared with those choosing to remain on pharmacological treatment. In contrast, a recent 10-year follow-up study of patients with GORD found no differences in all but one item on the SF-36 questionnaire (the exception being a small difference in bodily pain) in patients treated with either medication or surgery.<sup>[47]</sup>

As with all surgery, the skill and experience of the surgeon are crucial to success. Fundoplication surgery can be associated with bloating, dysphagia and vomiting in many patients. The high cost of laparoscopic fundoplication (and recovery including lost work days) makes it least cost-effective initially.<sup>[48]</sup> Five-year follow-up of 310 GORD patients with oesophagitis randomised to omeprazole or antireflux surgery also included an assessment of health-related quality of life. The PGWB questionnaire was administered at 2 and 6 months postintervention and then annually. Results indicated there was no difference between patient groups on the basis of quality of life over the 5 year period. Reported scores for the PGWB were within normal range at 2 months postintervention.<sup>[49]</sup>

## 7. Conclusions

Chronic reflux symptoms, with or without objective evidence of physical complications, are common in the general population and have a significant negative impact on health-related quality of life. An expert panel determined that impairment of health-related quality of life is disease defining in the



absence of objective endoscopic findings of reflux. Among the treatment options available, comparative evaluations consistently demonstrated the superiority of proton pump inhibitors over H<sub>2</sub>-receptor antagonists in measures of efficacy and health-related quality of life. Fundoplication surgery is another treatment option for some patients. The ultimate goal of GORD treatment should be rapid and sustained achievement of complete symptom resolution, because this is associated with marked improvement in, or normalisation of, health-related quality of life.

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