

Quality of life in patients with gastroesophageal reflux disease following pharmacotherapeutic, endoscopic, and surgical treatment

Jakość życia pacjentów z chorobą refluksową przełyku leczonych farmakologicznie, endoskopowo i operacyjnie

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Abstract

Gastroesophageal reflux disease (GERD) is associated with bothersome symptoms. Their chronic and recurrent character has a negative impact on the physical and mental status of the patients. Improvement in health-related quality of life (HRQOL) of GERD patients along with decreasing the severity of symptoms remain the main aims of therapy. This paper reviews literature regarding HRQOL in GERD patients, as well as the impact of various treatment modalities on the patient's status, the incidence and severity of symptoms thereof, and subjective quality of life. Additionally, the factors that may influence the treatment outcome are also discussed. Several studies showed that the improvement of HRQOL is greater after surgical treatment than with pharmacological therapy. However, long-term studies are still needed to determine if surgery can constitute the equivalent of lifelong medical therapy.

Streszczenie

Choroba refluksowa przełyku (GERD) wiąże się z występowaniem uciążliwych objawów. Ich przewlekły i powtarzający się charakter negatywnie wpływa na stan fizyczny i psychiczny pacjentów. Poprawa jakości życia związanej ze zdrowiem (HRQOL) pacjentów z GERD oraz zmniejszenie nasilenia objawów są głównymi celami terapii. W pracy dokonano przeglądu piśmiennictwa dotyczącego HRQOL u pacjentów z GERD, wpływu różnych metod leczenia na stan pacjentów, częstości występowania objawów i ich nasilenia oraz subiektywnej jakości ich życia. Dodatkowo omówiono czynniki, które mogą mieć wpływ na wyniki terapii. Wyniki wielu badań wykazały, że poprawa HRQOL jest większa po zabiegu chirurgicznym w porównaniu z terapią farmakologiczną. Nadal jednak potrzebne są długoterminowe badania, aby ustalić, czy zabieg chirurgiczny może stanowić odpowiednik terapii farmakologicznej.

Introduction

Gastroesophageal reflux disease (GERD) is diagnosed if the reflux of gastric content causes troublesome signs and/or complications [1]. The most typical manifestations include heartburn and regurgitation. The word “troublesome” is a key component of the definition because it may correspond to the signs that negatively affect the overall status and diminish the quality of life of the patient [1]. One recent study showed an inverse correlation between patient

self-rated visual analogue scale (VAS) scores for both heartburn and regurgitation and each dimension of the Quality of Life in Reflux and Dyspepsia (QOLRAD) questionnaire. Moreover, both heartburn and regurgitation's troublesome ratings proved to be associated with the overall QOLRAD score on regression analysis; these relationships were independent of pH data and frequency of reflux episodes [2].

Gastrointestinal reflux disease is a frequent syndrome. It is estimated that GERD occurs in 10–20% of the population in Western Europe and the United

States, and in 10% of South Americans. The disease is diagnosed less often in Asian and African countries, where it affects about 6% of the population [3]. Due to its chronic character and recurrent symptoms, GERD represents an important social and economic liability, requiring long-term, sometimes even life-long, treatment. Principal therapeutic goals include resolution or attenuation of the symptoms. Furthermore, the therapy is aimed at healing of oesophagitis and prevention of the complications of reflux disease, such as aspiration of gastric content during sleep, metaplasia of oesophageal mucosa, and oesophageal ulceration or constriction. The therapeutic strategy of GERD should be adjusted individually, depending on the current needs of the patient and the severity of symptoms. The treatment includes elimination of factors that can promote reflux, pharmacotherapy, and endoscopic and surgical procedures [4].

The concept of quality of life was introduced into medical science in the 1970s [5]. Health-related quality of life (HRQOL) can be evaluated with generic and/or condition-specific questionnaires. The generic questionnaires used in the assessment of GERD patients include SF-36 (Medical Outcomes Study 36-item Short Form), PGWBI (Psychological General Well-Being Index), and Euro-QOL. These questionnaires address the overall health status, physical symptoms, and functional and emotional dimensions of health, enabling the assessment of the differences in the quality of life of patients with various conditions, as well as in healthy individuals. Although the SF-36 questionnaire is reproducible and can be used to detect treatment related changes, it is not useful in the analysis of such issues as sleeping disorders or social, family, and sexual functions [6–9].

The condition-specific questionnaires are used to assess the quality of life related to a given clinical condition. The selection of questions included in a given test enables the study of the effect of disease, impairment, and/or employed therapeutic methods on the functioning of the person in various areas of life, i.e. in physical, social, professional, and emotional spheres. The detailed questionnaires enable assessment of minute, but clinically important factors that play a significant role in a given condition. Specific questionnaires developed for the examination of GERD patients include GIQLI (Gastrointestinal Quality of Life Index), GSRS (Gastrointestinal Symptoms Rating Scale), GERD-HRQL (Gastroesophageal Reflux Health Related Quality of Life Scale), GERQ, HBQOL, QOLRAD, and GERD-QOL [9]. GIQLI is an example of a GERD-specific questionnaire with a structure enabling the objective comparison of health-related quality of life in patients with various alimentary conditions. It is a useful instrument preferred in the assessment of quality of life in GERD patients prior to and after surgical fundoplication [6]. Another ques-

tionnaire, GERD-HRQL, addresses the influence of the most typical and frequent signs of gastroesophageal reflux disease, e.g. the presence of heartburn in relation to ingested meals, position of body, and time of day. The authors of this questionnaire did not include questions related to respiratory and laryngeal symptoms, since they are observed only in a small group of patients. Although the questionnaire addresses solely the severity of disease symptoms, according to its authors it satisfies the basic criteria for the instruments used in quality of life assessment [10]. Due to the character of the included questions, addressing such issues as diarrhoea, constipation, indigestion, reflux, and pain, GSRS is particularly useful in assessing HRQOL in patients prior to and after anti-reflux procedures [10]. GERD-QOL is another GERD-specific questionnaire, which comprises 16 questions grouped into four categories: everyday activities, results of treatment, diet, and general mental status. According to Chan *et al.*, it constitutes a reproducible tool for the quality of life assessment in GERD patients, both prior to and after pharmacotherapy [11].

Quality of life in patients with gastroesophageal reflux disease

Although GERD is a mild condition, HRQOL in GERD patients is significantly lower than in the general population [12–14]. Revicki *et al.* [12] observed that GERD impairs HRQOL in all areas of health analysed with the SF-36 questionnaire. The patients experienced stronger subjective bodily pain and showed more pronounced limitation of physical functioning than the general population of the United States. Moreover, pain experienced by the patients, their social functioning, and emotional wellbeing were poorer than those experienced by individuals with diabetes, arterial hypertension, and arthritis, irrespective of the presence of oesophageal inflammatory lesions [15, 16]. Dimenäs *et al.* [17] analysed the psychological index of the overall status and showed that the quality of life of GERD patients was lower than in the case of arterial hypertension, ischaemic heart disease, gastric and duodenal ulcers, and menopause. Furthermore, they revealed that the quality of life diminished in concert with the severity of heartburn and regurgitation. The ProGERD study, involving more than 6000 GERD patients, showed that the quality of life in this group is lower than in the general German population, but similar to that of patients with acute coronary episodes. The psychological component measured with the generic SF-36 questionnaire in the GERD group was lower than in patients with markedly more severe conditions, such as cancer or diabetes. Therapy with proton pump inhibitors (PPI) was reflected by an increase in psychological and physical status measured with SF-36. Among others, the improvement was more evident in patients with more severe oesophagi-

tis (C and D according to the Los Angeles scale) as well as in those with more severe manifestations [13]. The level of quality of life in reflux disease was comparable to that observed in mild-degree heart failure [18]. Also, the analyses conducted in Italy, China, Japan, and Australia confirmed that the HRQOL of GERD patients is markedly lower as compared to the general populations of those countries [14, 19–21].

All aspects of life are impaired in GERD patients, irrespective of the presence of ulcerative oesophagitis accompanying the subjectively perceived symptoms [13, 22, 23]. Many studies [24–26] revealed that the occurrence of gastrointestinal symptoms significantly impairs the status and everyday functioning of patients. The negative influence of heartburn, the predominant symptom of gastroesophageal reflux disease, on the quality of life of patients was also confirmed by Polish studies. These studies revealed that heartburn has the strongest impact on such SF-36 domains as “experiencing pain”, “vitality”, “physical functioning”, and “limitations due to somatic health”, compared to the reference level developed for the Hungarian population [22]. Another multicentre study involving more than 20,000 participants revealed that patients with GERD are characterised by more frequent comorbidities, lower quality of life measured in the SF-8 scale, and lower efficiency of work assessed with the Work Productivity and Activity Impairment questionnaire [27]. A recent systematic review that included 19 studies showed that compared to patients with less pronounced reflux symptoms, patients with frequent and severe reflux symptoms of GERD are characterised by worse quality of sleep (1.5 times more frequently), more frequent (2.4-fold) absence from work, and lower average score of general and psychological status [28]. Talley *et al.* revealed that the most frequent causes of diminished quality of life in 984 patients with non-erosive reflux disease (NERD) were associated with such areas as ingestion of meals and fluids (45–81%), sleeping disorders (39–49%), weakness (41–58%), and poor general status (45–55%). The most frequent activities of daily living were impaired in nearly 20% of the subjects [29]. The presence of extra-oesophageal signs of GERD such as “globus”, hoarseness, and throat clearing may also be reflected by diminished quality of life, particularly with regards to vitality and social contacts [30]. A systematic review of literature conducted by Gerson and Fass suggests that dyspeptic symptoms are common in patients with GERD and impact their HRQOL [31].

Influence of pharmacotherapy on the quality of life

A large number of previous trials unambiguously confirmed high efficacy of PPI therapy in attenuating the complaints and improving HRQOL in patients with gastroesophageal reflux disease [13, 32–34]. Usu-

ally the treatment with PPIs lasts for 2 to 8 weeks [14]. No significant differences were observed between various medications from this group [35], but it should be mentioned that PPIs proved more effective than H₂-receptor antagonists [13, 35]. Italian researchers observed a significant improvement in the quality of life of 96% individuals treated with PPIs for 4 weeks [14]. Analysis of therapeutic outcomes recorded in such countries as Germany, Austria, and Switzerland confirmed that even 2 weeks of treatment with PPIs is reflected by significantly improved quality of life [13]. Consequently, the majority of studies have revealed an improvement in quality of life following effective treatment.

The abovementioned studies analysed the influence of relatively short pharmacotherapy on HRQOL, and were usually performed at the end or shortly after completing the treatment. Markedly fewer studies addressed the long-term outcomes of implemented therapies. Application of PPIs was revealed to be reflected by significant improvement, including the resolution of symptoms, healing of inflammatory oesophageal lesions, and prevention of disease recurrence and complications [36]. Only single studies have dealt with the effect of long-term maintenance therapy with PPIs on the HRQOL in GERD patients. It was observed that significant and clinically important improvement in quality of life resulting from initial 4-week therapy with esomeprazole (40 mg; 1 × day) was maintained during a 6-month “continuous” or “on demand” administration of this agent at 20 mg/day [14]. The “continuous” administration of the agent was reflected by slightly better outcome.

Long-term, 12-month maintenance therapy with lansoprazole (15 mg/day) in patients with healed ulcerative oesophagitis enabled maintenance of improved HRQOL resulting from a previous 2-month treatment with the same agent at a doubled dose [35]. The effect of 12-month administration of lansoprazole proved better than ranitidine. During 1 year of follow-up the authors of this study observed that the measures of “health distress” and “comparative assessment of health” improved after the initial 2 months of maintenance therapy as compared to respective baseline values. However, at the third month of the therapy the higher values were observed only in the case of “health status impairment”. The other indices of HRQOL such as “general perception of health”, “general health status”, “energy and vitality”, and “mental health” did not increase markedly over the baseline level during the 12 months of follow-up. Furthermore, it was observed that the quality of life in GERD patients, which improved significantly after 2 months of therapy with PPIs, persisted during a further 5-year follow-up, during which the patients were supervised by their primary physicians [36].

Japanese researchers observed that 8-week therapy with omeprazole at a standard dose (20 mg/day)

efficiently improves the quality of life in patients with GERD. The incidence of heartburn was reduced to no more than one episode per week in 76% of patients treated with this agent. Further 6-month maintenance therapy at 10 mg/day enabled the improved HRQOL to be maintained in 80% of the participants [19].

Patients with NERD constitute the vast majority of subjects with reflux symptoms. One recently published study revealed similar efficacy and degree of improvement in the quality of life assessed with the SF-36 questionnaire in a group of NERD patients given ranitidine or rabeprazole on demand [37].

In recent years, particular attention has been paid to the association of obesity with gastroesophageal reflux disease. One meta-analysis revealed that patients with higher body mass index (BMI) have an increased risk of reflux oesophagitis [38]. In contrast, the reduction of body weight was reflected by the attenuation of symptoms and lower number of acidic reflux episodes [39]. A recently published study conducted in several Japanese centres revealed overweight in 5.8% of 2646 patients with GERD. Compared to individuals with normal BMI, this group of patients is characterised by higher severity of symptoms and poorer quality of life, assessed with F-scale and SF-8 questionnaires, respectively. However, the therapeutic responses to PPI were similar irrespective of the patients' BMI [40]. Another study showed that obese patients are prone to lower HRQOL scores, and obese women present with the poorest mental health.

A recently published systematic review revealed that the persistence of reflux symptoms despite PPI therapy is associated with diminished quality of life. Furthermore, patients with low baseline quality of life have a poorer response to the implementation of PPIs. High level of anxiety seems to constitute a significant factor capable of worsening the therapeutic response. In another study, global satisfaction with life (Satisfaction with Life Scale score > 20) was documented in 63% of non-responders to PPI given twice daily, 78% of non-responders to PPI administered once a day, and 78% of responders receiving PPI once daily. However, lack of response was not associated with anxiety and depression [41]. Another study revealed that the effectiveness of PPIs, manifested by the attenuation of reflux symptoms and improvement in the quality of life, is determined by the causative relationship between reflux and experienced symptoms. The authors used an objective method (oesophageal pH-metry) to verify if symptoms reported by their patients are truly associated with reflux. Patients with physiological oesophageal exposure to acidic content and a lack of symptom-reflux correlation (so-called functional heartburn) were characterised by the lowest quality of life and had a poorer response to PPI treatment than the subjects with abnormal exposure to acid or those with positive reflux-symptom correlation [42].

Heartburn is known to respond well to acid suppression therapy, whereas regurgitation is less responsive to the treatment. Frequent regurgitation, persistent despite acid suppression, negatively affected sleep and work productivity, and was associated with a clinically relevant, incremental decline in QOLRAD scores beyond those associated with heartburn, prior to and after therapy.

Comparison of quality of life in patients treated pharmacologically and surgically

Ciovică *et al.* compared the quality of life in patients with gastroesophageal disease treated pharmacologically and in those subjected to surgical anti-reflux procedures. Overall, 579 patients (including 40% of women) aged between 16 and 81 years (median: 52 years) were examined. The quality of life was assessed with specific HRQOL and GIQLI questionnaires. Endoscopic examination revealed lesions typical for Barrett's oesophagus in 25% of the patients. In total, 351 (61%) patients underwent anti-reflux surgeries, including individuals with long-term history of persistent or recurrent GERD symptoms and/or complications resistant to intense maintenance therapy, as well as those who preferred surgery instead of long-term maintenance therapy. Nissen fundoplication was performed in 91% of patients qualified to surgical treatment, whereas partial posterior fundoplication was performed in the remaining 9%. The perioperative morbidity rate was 7.7%. The quality of life and the severity of symptoms were assessed prior to the treatment as well as 3 and 12 months following the surgery. Patients qualified to pharmacotherapy were given esomeprazole (40 mg/day) for at least 3 months. The dose was increased to 60–80 mg/day if the symptoms persisted despite standard regimen. Significant improvement of HRQOL assessed with both questionnaires was observed in patients treated with PPIs as compared to the pretreatment level ($p < 0.05$). In surgically treated patients, the quality of life normalised in all aspects and was significantly higher as compared to the quality of life of pharmacologically treated individuals (GIQLI and GERD-HRQL, $p < 0.05$). No significant differences were observed between the quality of life of surgical patients with GERD and the quality of life in the general population. Moreover, a marked attenuation of symptoms experienced following the surgery was documented, as confirmed by manometric examination conducted 3 and 12 months post-surgery [43]. In a systematic review of four randomised, controlled trials including a total of 1232 patients, Wileman *et al.* documented a statistically significant improvement in HRQOL at 3 months and 1 year after surgery, when compared to the results of pharmacotherapy alone [44]. Also, another randomised, controlled trial with three years of follow-up revealed that laparoscopic Nissen fundopli-

cation can be reflected by better control of symptoms and more pronounced improvement in the quality of life as compared to PPI pharmacotherapy [45]. Research suggests that surgical treatment can be a more beneficial method for patients who require long-term therapy [45, 46].

The LOTUS (Long-Term Usage of Esomeprazole vs. Surgery for Treatment of Chronic GERD) trial compared the efficacy of pharmacotherapy ($n = 192$) and laparoscopic anti-reflux surgery – LARS ($n = 180$) during 5 years of follow-up of GERD patients from 11 countries. The patients were referred for control visits every 6 months. The quality of life was assessed with QOLRAD and GSRS questionnaires. The average HRQOL score of both groups of patients improved and resembled those of the general population. Surgically treated patients were characterised by better quality of life assessed with both tools as compared to the pharmacologically treated group ($p < 0.001$). The percentage of patients reporting severe adverse events was similar in the conservatively and laparoscopically treated groups (24.1% and 28.6%, respectively) [47]. In another recent randomised, controlled trial (REFLUX) including a total of 357 patients subjected to a 5-year follow-up, SF-scores and European Quality of Life-5 Dimensions scores were generally better after surgery. However, the differences attenuated over time and were not significant at five years [48].

Furthermore, a recently published systematic review of 11 studies confirmed that surgical management of GERD is more effective than medical treatment in terms of health-related and GERD-specific quality of life aspects. However, also the authors of this review concluded that long-term studies are still needed to ascertain if surgery is really an equivalent to lifelong medical therapy.

The influence of endoscopic treatment of GERD on quality of life

Although laparoscopic fundoplication is considered to be the gold standard of surgical treatment of GERD, it is associated with the risk of such adverse effects as flatulence, dysphagia, and diarrhoea. Usually, these symptoms resolve within the first few days post-surgery, but can persist for longer, diminishing the quality of life of the patients [49]. Novel endoscopic techniques, regarded as alternatives for surgical treatment of GERD, have been developed during the last decade. These techniques include the Stretta procedure (Stretta System Mederi Therapeutics, Inc., Greenwich, CT), plication of the gastroesophageal junction (NDO Plicator, NDO Surgical, Inc., Mansfield, MA; EndoCinch, CR Bard, Inc., Murray Hill, NJ), and injection of biopolymers into the gastroesophageal junction (Enteryx, Boston Scientific Corporation, Natick, MA; Gatekeeper, Medtronic Foundation, Minneapolis, MN, Plexiglas). Several studies

have shown a significant improvement in HRQOL of patients treated with Stretta procedure [50–52]. In one recent study of 56 patients subjected to Stretta procedure (including 64.2% of males) and followed-up for 48 months [51], the quality of life was determined with the help of the SF-36 generic questionnaire and GERD-specific GERD-HRQL instrument prior to the procedure, and 24 and 48 months thereafter. The severity of heartburn was determined using a Likert-type scale. Both follow-up studies, performed 2 and 4 years post-surgery, revealed significant improvement in the somatic and psychological components of the quality of life, as assessed with either the specific GERD-HRQL questionnaire ($p = 0.003$) or the generic SF-36 instrument ($p < 0.005$). Moreover, the surgery was reflected by significant reduction in the severity of heartburn ($p < 0.003$) [51]. Recently published meta-analysis, including 1441 patients treated with the Stretta method revealed that this procedure results in a marked attenuation of reflux symptoms and improvement of HRQOL, and may constitute an alternative to pharmacotherapy and surgical treatment in a selected group of patients [52]. Currently, endoscopic full-thickness plication seems to be a very promising treatment option due to its documented long-term efficacy in reflux symptoms control in the majority of patients, improvement in the quality of life, and lack of side effects seen after laparoscopic fundoplication [53, 54].

Comparison of quality of life in patients treated endoscopically and surgically

Antoniou *et al.* compared the effectiveness of endoscopic full-thickness plication (29 patients) and laparoscopic anti-reflux fundoplication (27 patients). Both methods were reflected by similar degree of improvement in the HRQOL scores prior to the treatment and 3 and 12 months thereafter. More pronounced reduction in the incidence of heartburn and regurgitation was observed in the surgically treated group, along with an increase in the incidence of dysphagia [54]. Recently, the same authors confirmed that both procedures are associated with similar improvements of general subjective outcome parameters and that laparoscopic anti-reflux fundoplication provides more effective control of reflux-related symptoms. They also suggested that endoscopic therapy may be favoured in terms of side effect symptoms. Another study assessed the efficacy of a new SRSSM Endoscopic Stapling System (Medigus Ltd., Omer, Israel) (11 patients) and compared its outcomes with those of laparoscopic fundoplication (16 patients). Mean GERD-HRQL scores significantly decreased in 64% patients from the SRS group and in 87% of individuals subjected to laparoscopic treatment. Although the first short-term results of this new device are promising, additional studies regarding the side effects are necessary.

Conclusions

The chronic and recurrent character of oesophageal and extra-oesophageal symptoms negatively affects daily functioning in social, professional, and family spheres, leading to a decrease in the quality of life of patients with gastroesophageal reflux disease. Enhancing patient's status, along with decreasing the incidence and severity of symptoms, and improving the quality of life should constitute important goals of gastroesophageal reflux disease management. The results of studies suggest that all pharmacological endoscopic and surgical treatments of gastroesophageal reflux disease exert positive effect with regards to symptom attenuation and quality of life improvement. Moreover, preliminary results of new devices, such as electrical stimulation of lower oesophageal sphincter and laparoscopic magnetic sphincter augmentation, are promising in the treatment of GERD symptoms and improvement of HRQOL.

Conflict of interest

The authors declare no conflict of interest.

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