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Outcome of medical and surgical therapy of GERD: Predictive role of quality of life scores and instrumental evaluation

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ABSTRACT

Introduction: Aim of this study is to determine whether quality of life (QoL) assessment in association with instrumental evaluation can help to identify factors predictive of outcome both in surgically and medically treated GERD patients.

Methods: Between January 2005 and June 2010, 301 patients affected with GERD were included in the study. QoL was evaluated by means of GERD-HRQL and SF-36 questionnaires administered before treatment, at 6 months, at 1 year follow-up and at the end of the study. The multivariate analysis was used to detect if variables such as sex, age, heartburn, acid regurgitation, dysphagia, presence of esophagitis, percentage of total time at pH < 4, symptom index score (SI), the SF-36 and HRQL scores before treatment, at 6 months and 1 year could affect the QoL questionnaires scores at the end of the study.

Results: One hundred forty-seven patients were included in the surgical group and 154 in the medical group. No differences with regard to gender, age, mean SF-36 and HRQL scores before treatment were documented. At the end of the study, quality of life was significantly improved for SF-36 and HRQL scores, either for surgical or medical group. The multivariate analysis showed no factors individually affected the SF-36 and the HRQL scores, but symptom index score (SI) and QoL questionnaires scores at 6 months and 1 year follow-up.

Conclusions: The combined use of pHmetry with evaluation of SI and QoL questionnaires can predict the outcome of GERD patients managed either by medical or surgical therapy.

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1. Introduction

Gastroesophageal reflux disease (GERD) develops when the reflux of stomach contents causes troublesome symptoms and/or complications [1]. The aims of treatment are symptoms resolution, esophagitis healing, prevention of complications and relapse. During the past two decades, quality of life (QoL) assessment has become an important end point in the treatment of many chronic diseases such as GERD. Although proton-pump inhibitors (PPI) are effective in the treatment of esophagitis and symptoms' control, studies have demonstrated that up to 40% of patients continue to experience abnormal acid reflux on 24-h pH testing [1] and up to 35% of them present a relapse of symptoms during a 3-year follow-

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up [2]. This latter group of patients requires treatment with increasing doses of PPIs to control symptoms and some of them also a surgical definitive treatment. To date, the role of laparoscopic total fundoplication (LTF) is well established in chronic GERD and efforts to develop QoL instruments that effectively demonstrate patient satisfaction and perceived well-being after operation represents an active research field. Short Form 36 (SF-36) [3] is a validated, reliable, generic instrument utilized in the follow up of GERD patients. However, the Gastroesophageal Reflux Disease-Health-Related Quality of Life (GERD-HRQL) questionnaire developed by Velanovich et al. is a disease specific QoL instrument proposed to be more responsive to the effects of treatment and more sensitive to changes in symptoms [4–6]. Aim of this study is to determine whether QoL measurement in association with instrumental evaluation can help to identify factors predictive of outcome both in surgically and medically treated patients.

2. Methods

A prospective electronic database of all patients treated for GERD at the Digestive Surgical Unit of the Second University of Naples were reviewed. The diagnostic workup for GERD for patients who had typical or atypical symptoms of GERD included barium swallow, esophagogastroduodenoscopy, stationary esophageal manometry and esophageal 24-h pH monitoring. At this last instrumental examination the symptom index score (SI) was evaluated. A positive SI (>50%) was defined when more than 50% of symptoms reported by the patients were associated with documented reflux episodes. Inclusion criteria were: the patient had to be over 16 years of age, had to have a diagnosis of GERD based on the presence of esophagitis at upper GI endoscopy or abnormal esophageal exposure at 24-h ambulatory pH testing, patients successfully treated with medical therapy who accepted the alternative of undergoing antireflux surgery, no continuous treatment with any acid-suppressant drug for more than seven days in the four weeks before study entry. The symptoms and their influence on the QoL were evaluated by means of the GERD-HRQL questionnaire [4–6]. It consists of 10 questions that assess the severity of heartburn in orthostatic and supine position, in post-prandial and night time, the effects on dietary habits, dysphagia, odynophagia, abdominal distension in the post-prandial period, discomfort in drugs intake and how the patients define their general statement. The final score is obtained by adding the value assigned to each question and it varies from 0 for asymptomatic patients to 50 for patients with significant limitations in QoL.

The QoL was also evaluated using the Italian version of SF-36 questionnaire [3] which investigates about perceived health status and provides information on health and well being, through eight functions: physical function, role limitations (physical, bodily pain, vitality, general health perceptions, social functioning), emotional and mental health. The Italian translation of the questionnaire was previously validated using objective psychometric criteria. The score ranges from 0 to 100 with the maximum that indicates the best perception of QoL. Both questionnaires were administered to patients in presence of the same physician before treatment, at 6 months, at 1 year follow up and at the end of the study.

2.1. Medical treatment

Medical treatment involved any one of the four different PPIs: rabeprazole 10 mg (Janssen Pharmaceuticals, New Jersey, USA), pantoprazole 20 mg (Knoll Pharmaceuticals, New Jersey, USA), lansoprazole 15 mg (Wyeth Pharmaceuticals, New Jersey, USA) and omeprazole or esomeprazole 20 mg (Astra Zeneca, Sodertalje, Sweden). The daily dose of PPI was kept at or adjusted to a level that abolished all reflux symptoms and expressed as multiples of the above doses.

2.2. Surgical therapy

Patients addressed to surgery underwent LTF with the technique previously described [7–14]. Briefly, the procedure began with the section of the anterior peritoneal reflection of the gastroesophageal junction. After identification of the anterior vagal nerve, the gastrophrenic ligament was divided. The dissection was then continued from right to left behind the esophagus until the crura was exposed, and the angle of His was abolished, with particular care taken to avoid injury to the posterior vagus. At this point a posterior window was created large enough to accommodate fashioning of the wrap. The esophagus was widely mobilized in its mediastinal portion until the esophagus laid in the abdomen without tension. The cruroplasty was accomplished by one simple extracorporeal non absorbable knot. The 2-cm-long total fundoplication was fashioned with the anterior wall of the gastric fundus. The short gastric vessels were always preserved. The two gastric hemi-valves were sutured with two stitches that never incorporated the esophageal muscular layer. In all cases, to check the calibration of the wrap, at the end of the procedure an intraoperative manometry and an endoscopic control were performed.

2.3. Statistical analysis

Statistical analysis was performed on the patients who completed the postoperative evaluation using SPSS for Windows (version 17.0; SPSS, Inc., Chicago, IL). Results are expressed as the mean ± SD unless otherwise indicated. Continuous variables were compared by the unpaired and paired Student *t* test and dichotomic variables were compared by the chi-squared test. Two general linear models were constructed with postoperative SF36 and GERD-HRQL questionnaires in the medical and surgical group as dependent variables each including all the covariates that previously had been shown to be significant at the α level of less than 0.05.

The multivariate analysis was used to detect if variables such as sex, age, heartburn, acid regurgitation, dysphagia, presence of esophagitis, percentage of total time at pH < 4, the symptom index score, the SF36 score and HRQL score pre-treatment, at 6 months and 1 year could affect the QoL questionnaires score at the end of the study either in medical and surgical group.

3. Results

Three hundred and one out of 315 selected patients completed the study. They were divided in two groups according to the type of treatment: Surgical group, comprising 147 patients (67 males, 80 females, mean age 42.9 ± 14.2) who underwent LTF; medical group, comprising 154 patients (61 males, 93 females, mean age 40.5 ± 15.2) who underwent treatment with PPI. Demographic and preoperative data are summarized in Table 1. No statistically significant differences between the two groups with regard to gender, age, incidence of typical symptoms (heartburn and acid regurgitation), mean SF-36 and HRQL scores were documented. Postoperatively, quality of life was significantly improved either for SF-36 (mean 74.3 ± 7.1; $p < 0.0001$) or HRQL scores (mean 10.6 ± 5.3; $p < 0.0001$) in the surgical group. Similarly, better SF-36 (mean 72.1 ± 17.1; $p < 0.0001$) and HRQL (mean 11.5 ± 6.4; $p < 0.0001$) scores were recorded in the medical group. Moreover, no differences were observed in both questionnaires scores SF-36 ($p = 0.14$) and HRQL ($p = 0.18$) between the two groups at the evaluation at

Table 1
Demographic and preoperative data.

	Surgical group	Medical group	*P*
N of pts	147	154	NS
Sex (m/F)	67/80	61/93	NS
Age			NS
Mean (stand dev.)	42.9 (14.2)	40.5 (15.2)	
Range (min–max)	19–79	17–78	
Heartburn (%)	84	88	NS
Acid regurgitation (%)	78	79	NS
pH-metry	8 (13.2)	7.3 (11.1)	NS
(%t. tot ph < 4/24 h)			
Mean (Stand. dev.)			
HRQL	30.4 (9.1)	29.2 (8.8)	NS
Mean (Stand. dev.)			
SF-36	55.8 (16.9)	56.9 (20.3)	NS
Mean (Stand. dev.)			
Follow-up			NS
Mean (stand dev)	29.2 (7.5)	28.3 (6.4)	
range (min–max)	12–41	16–41	

the end of the study. The multivariate analysis showed no factors individually affected the SF36 and the HRQL scores, but pHmetry symptom index score (SI) and QoL questionnaires scores recorded at 6 months and one year follow up (Tables 2 and 3). Patients with an SI > 50% at the beginning of the study, either in medical and surgical group, showed a significantly better clinical outcome, in terms of SF-36 and HRQL scores, compared with those with an SI < 50%. Instead, neither typical nor atypical symptoms (heartburn, regurgitation, dysphagia), presence of esophagitis or pathological pHmetry alone influenced the SF-36 and HRQL scores at the end of the study either in medical and surgical group (Tables 2 and 3).

4. Discussion

Although laparoscopic surgery in the last twenty years achieved excellent results in the treatment of GERD, at present no definitive conclusions about the choice between surgical or medical therapy can be drawn. Different randomized prospective trials have been conducted but the argument remains controversial [2,15–20]. In a previous randomized study, Lundell and coworkers [2] found antireflux surgery more effective than omeprazole at a dose of 20 mg per day in controlling GERD measured by treatment failure rates. However, after adjusting omeprazole dose at 40 or 60 mg daily, the differences between the two therapeutic strategies became not statistically significant [2]. In contrast, Spechler et al. [18] did not observe any significant differences in SF-36 scores and satisfaction after surgical and medical therapy at 10 years follow up. A larger recent study with a

Table 2
Multiple regression analysis of factors associated with SF36 at the end of the study in the medical and surgical group.

Factors	Medical group	Surgical group
	($P < 0.05$)	($P < 0.05$)
Sex	0.236	0.151
Age	0.654	0.174
Heartburn	0.456	0.845
Regurgitation	0.478	0.922
Dysphagia	0.663	0.753
Esophagitis	0.223	0.123
pHmetry+	0.666	0.573
SI+	0.02	0.003
SI–	0.123	0.274
SF36 pre-treatment	0.07	0.409
SF36 at 6 months	0.03	0.01
SF36 at 1 year	0.0001	0.0001

Table 3
Multiple regression analysis of factors associated with HRQL at the end of the study in the medical and surgical group.

Factors	Medical group	Surgical group
	($P < 0.05$)	($P < 0.05$)
Sex	0.278	0.3613
Age	0.865	0.8263
Heartburn	0.338	0.3938
Regurgitation	0.603	0.6136
Dysphagia	0.356	0.246
Esophagitis	0.07	0.09
pHmetry+	0.0654	0.0724
SI+	0.03	0.008
SI–	0.288	0.323
SF36 pre-treatment	0.512	0.5143
HRQL at 6 months	0.003	0.0001
HRQL at 1 year	0.006	0.005

5 year follow up [19] documented no differences between medical and surgical groups in terms of postoperative GERD remission (85% vs 92%, respectively) (p = NS). However, an universally accepted definition and evaluation of treatment success/failure of GERD is still controversial as stated in a recent study [21]. Authors observed that the most consistent parameter to better define treatment success was patient's satisfaction, with a reported mean satisfaction rate as high as 88.9%. In the present study, the employment of both general and health related QoL questionnaires was based on previous evidence supporting these outcome measures as able to well define long term outcome of GERD patients. Specifically, we found medical and surgical treatments were comparable in terms of postoperative QoL outcomes. Instead, instrumental evaluation such as 24-h esophageal pH monitoring may be not helpful, since no correlation between symptoms response and esophageal acid exposure at postoperative evaluation had been detected [22–24]. In fact, Jenkinson et al. [24] have found that among 30 patients becoming asymptomatic after medical treatment, eighteen still presented a pathologic GERD at pHmetric study. At the same time, among 19 patients who reported persistent symptoms after surgery, only two presented a real pathologic gastroesophageal acid reflux at pHmetry. These contradictory results have been confirmed also in more recent studies [25,26]. Several Authors showed that QoL scores evaluation is strictly related to clinical outcome of GERD patients [27–30]. Persistent reflux symptoms on PPI therapy seem associated with worse physical and mental HRQL, whereas patients responders to PPI therapy report a significant improvement of HRQL. Another question might be on what objective and subjective variables are able to predict patients response to either medical or surgical treatment. The present study showed that neither the presence of typical or atypical symptoms, nor the esophagitis as well as a pathological pHmetry alone in the preoperative evaluation, influenced clinical outcome of either medical and surgical groups. Instead, preoperative positive SI and a good short-term postoperative QoL were independent factors associated with a better long-term QoL. Our findings are in line with those previously reported by Shimatani et al. [31], who found that the satisfactory heartburn-relief rate after 4 weeks of medical therapy with a standard dose PPI was significantly higher in patients with a positive SI, compared with those with a negative SI. However, we extended their conclusions even to surgically treated patients, suggesting that preoperative pH monitoring and confirmation of a positive SI can help to predict the efficacy either of medical or surgical GERD therapy. On the contrary, Zerbib et al. [32] reported that no reflux pattern detected at 24 h pH-impedance monitoring was predictive of response to medical

treatment. Other studies evaluating the impact of surgery on GERD population reported conflicting results regarding the role of 24-h pHmetry in predicting postoperative outcome [33–36]. At last, the most interesting finding of the present study is the predictive value a positive SI may have on long-term QoL after medical or surgical treatment.

In conclusion, we support the combined use of pHmetry with evaluation of SI and QoL questionnaires to assess and predict long-term outcome in GERD patients managed either by medical or surgical therapy.

Ethical Approval

This is a retrospective study based only on the analyses of recorded data and no Ethical Approval was necessary.

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Author contribution

Gianluca Rossetti: Partecipated substantially in conception, design, and execution of the study and in the analysis and interpretation of data; also partecipated substantially in the drafting and editing of the manuscript.

Paolo Limongelli: Partecipated substantially in conception, design, and execution of the study and in the analysis and interpretation of data.

Marco Cimmino: Partecipated substantially in conception, design, and execution of the study and in the analysis and interpretation of data; also partecipated substantially in the drafting and editing of the manuscript.

Domenico Napoletano: Partecipated substantially in conception, design, and execution of the study and in the analysis and interpretation of data; also partecipated substantially in the drafting and editing of the manuscript.

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Landino Fei: Partecipated substantially in conception, design, and execution of the study and in the analysis and interpretation of data; also partecipated substantially in the drafting and editing of the manuscript.

Conflicts of interest

All Authors have no conflict of interests.

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