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## Quality of Life After Anti-Reflux Surgery in Adults

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### 1. Introduction

Concepts of validity are of vital importance in the contemporary health care environment where outcome and Quality of Life (QoL) constructs are seen as relevant end points for evaluating the success of treatment and justifying continued intervention. QoL assessments, though sometimes subtle, have always played a central role in the therapeutic objectives of medicine. While the evaluation of surgical interventions focus primarily on outcomes, judgment regarding the success of the intervention should also take into account the functional, physiological, and social aspects of the disease and its treatment. Particularly, in chronic disease states, patients' QoL may be the most important parameter in assessing the efficacy of surgical treatment.

As in gastroesophageal reflux disease (GERD), most surgical operations target the correction of physiological or anatomical derangements that lead to a disease process. Hence anti-reflux operations are designed to prevent pathological amounts of gastric reflux that create typical (heartburn, regurgitation, dysphagia) and atypical (cough, hoarseness, chest pain, asthma and aspiration) symptoms and signs of damage (esophagitis and Barrett's epithelium). Reflux-related symptoms contribute substantially to patients' decreased QoL. Successful anti-reflux surgery should ameliorate these symptoms, arrest the progression of esophageal damage, and reinstitute lower esophageal sphincter (LES) function (24-h pH or impedance monitoring).

In the postoperative period, objective tests (esophageal manometry, endoscopy, pathological examination of esophageal mucosa, 24-h pH studies) that evaluate the fulfillment of surgery objectives may be needed. However, from the patients' standpoint, the results of these objective tests have little impact on their QoL, as they seek relief for heartburn or regurgitation. Thus, QoL will be improved to the extent that reflux-related symptoms are relieved and surgery-related new symptoms (bloating, difficulty in vomiting, dysphagia, etc.) are not acquired. In the postoperative period, patients should be able to sleep without head elevation, and be able to return to normal dietary routines with little or no need for acid suppression medications.

In order to assess QoL in upper gastrointestinal disease, questionnaires have been developed. The Gastrointestinal Symptom Rating Scale (GSRS), which concentrates on

gastrointestinal symptoms (Länroth, 2000), the Psychological General Wellbeing index (PGWB), which gives a general measure of patients' well-being) (Länroth, 2000), and the Visual Analogue Scale (VAS) (Broeders et al., 2011; deBoer et al., 2004; Länroth, 2000; Nord, 1991) Visick grading system (Rijnhart deJong et al., 2008; Velanovich & Karmy-Jones, 1998; Visick, 1948; Zeman & Rózsa, 2005) GERD-Health Related Quality of Life (GERD-HRQL) (Velanovich, 1998), Short-Form 36 (SF-36), and gastrointestinal quality of life index (GIQLI) (Yano et al., 2009), have all been studied for QoL assessment. Questionnaires like GSRS and PGWB may be hard to validate and to apply to different populations, but they may have a role, particularly in prospective randomized studies. The visual analogue scale ranges from 0 (worst possible health status) to 100 and has been validated for QoL assessment after esophageal surgery (deBoer et al., 2004 & Nord, 1991). The Visick grading system is used to evaluate a patient's appreciation of anti-reflux surgery (Table 1 and Table 2). Visick scores correlate well with heartburn (Rijnhart deJong et al., 2008) and a validated questionnaire for reflux symptoms (Velanovich & Karmy-Jones, 1998 & Zeman & Rózsa, 2005). The SF-36 is one of the most frequently used generic tools, and measures eight domains of QoL; namely, physical functioning, role-emotional, level of perceived pain, vitality, mental health, social functioning, and general health. GERD-HRQL and SF-36 have been reported to be reliable, validated, responsive, and appropriate in the assessment of patients with GERD (Amato et al., 2008; Trus et al., 1999; Velanovich, 1998; Velanovich, 1999; Ware et al., 1993). The GIQLI was developed for measuring QoL, especially in patients with gastrointestinal disorders, and is well established and validated. It includes 36 items (the general response to GIQLI is graded from 0-144 points), and five sub-items: gastrointestinal symptoms, emotional status, physical functions, social functions, and stress by medical treatment. Scores for each sub-item are range between 0 and 4; higher scores reflect better QoL.

Grade I	No symptoms
Grade II	Mild symptoms, relieved by age
Grade IIIa	Symptoms relieved by care but patient satisfied with results
Grade IIIb	Symptoms not relieved by care and patient unhappy
Grade IV	No improvement

Table 1. Visick Classification of peptic ulcer surgical results

Grade I	No symptoms, perfect results
Grade II	Patient states that results are perfect, but symptoms can be elicited
Grade III	Mild to moderate symptoms, patient and surgeon satisfied with results
Grade IV	Mild to moderate symptoms, patient and surgeon dissatisfied

Table 2. Modified Visick Classification

## 2. Results of open fundoplication and follow up

In the pre-laparoscopy era, a large number of clinical reports were published about consecutive patients who were operated on by open fundoplication techniques.

In one study, the authors (Polk & Zeppa, 1971) reported that 994 patients underwent open fundoplication and were followed-up with for 2.5 years postoperatively. Patients had 96% good results symptomatically.

In another study of open surgery, the authors (Bushkin et al., 1977) treated 165 patients with reflux esophagitis by Nissen fundoplication with an average follow-up period of 4 years, during which time 92% of patients remained free of reflux-related symptoms. The prevalence of gas bloat syndrome, which decreased surgery-related patient satisfaction, was 13% in the early postoperative period. However, this symptom either disappeared or was clinically insignificant in 87% of patients during the follow-up period. The authors concluded that Nissen fundoplication was so initially successful that late occurrence symptoms appeared to be uncommon.

Rossetti and colleagues (Rossetti & Heill, 1977) reported long-term results of fundoplication for the treatment of GERD in hiatal hernia in 590 patients, and showed that 87.5% of patients were symptom-free. In 44 patients with complicated GERD, fundoplication produced clinical healing in 84.1% of patients.

In a study in which 100 consecutive patients were treated with Nissen Fundoplication for GERD (DeMeester et al., 1986), of 89 of patients with complete data, 11 cited heartburn and aspiration as their primary symptoms. Data analysis revealed that fundoplication was successful in 91% of patients in controlling reflux symptoms over a 10-year period. The incidence of postoperative gas bloat and increased flatus was lower in patients with preoperative abnormal distal esophageal manometry. The authors thus concluded that Nissen fundoplication can re-establish a competent cardia and control reflux symptoms with minimal side effects.

### 3. Laparoscopic anti-reflux operations

The long-term results of conventional anti-reflux surgery have been very successful at attaining the desired goal of diminishing reflux-related symptoms (Bushkin et al., 1977; DeMeester et al., 1986; Polk & Zeppa, 1971; Rossetti & Heill, 1977). This proven success stimulated the application of laparoscopic techniques. In 1991, Dallemagne described and reported the results of laparoscopic Nissen fundoplication (Dallemagne et al., 1991). Since then, several studies have demonstrated the safety and efficacy of laparoscopic fundoplication (Hallerbäck et al., 1994; Hinder et al., 1994; Hunter et al., 1996; Jamieson et al., 1994; Watson et al., 1996) (Table 3).

Authors	No. of patients	Follow up (months)	Improvement in reflux related symptoms (%)
Watson (1996)	320	3-24	91
Hunter (1996)	300	12-36	97
Hallerbäck (1995)	142	12	90
Hinder ((1994)	198	6-32	>90
Jamieson (1994)	137	>3	97

Table 3. Reported results of laparoscopic fundoplication

A prospective randomized controlled study comparing laparoscopic and open fundoplication was published by Laine and colleagues in 1997 (Laine et al., 1997). Of the 110 patients enrolled in the study, 55 were randomized to laparoscopic and 55 to open Nissen fundoplication groups. Postoperative recovery, complications, and outcomes at the 3 and 12 month follow-up were compared in the two groups. In both groups, the most common

complaints three months after surgery was dysphagia and gas bloating which disappeared by the 12 month follow-up examination. The authors reported that all patients in the laparoscopy group, and 86% of patients in the open group were satisfied with the results (Table 4).

Symptoms	Open	Laparoscopic
No symptoms	70	83
Bloating	7	17
Heartburn	7	0
Dysphagia	13	0
Upper abdominal pain	3	0

Table 4. Postoperative symptoms at 12 month follow up exam.

Since a symptom is a perception derived from various sources, including psychosomatic factors, objective tests may inadequately assess patients' well-being in the postoperative period (Länroth, 2000). This theory is supported by the findings obtained from a study (Kamolz & Pointner, 2002). The authors evaluated the expectations of 70 patients with GERD awaiting laparoscopic anti-reflux surgery. Only two patients stated that they would expect normalization of pH values and healing of esophagitis. The rest of the patients had expectations related to their QoL. Hence, QoL assessment should essentially be implemented in order to evaluate a patient's postoperative satisfaction level. In 1995, Swedish authors Glise and colleagues presented QoL assessments for the first 40 consecutive patients undergoing laparoscopic Rossetti fundoplication (Glise et al., 1995). They used PGWB and GSRS questionnaires 3 months and 8-12 months after operation, and concluded that patients had good QoL scores postoperatively, thus showing that QoL ratings can be used to assess laparoscopic anti-reflux operations. The results also showed that laparoscopic fundoplication was better than no treatment and as good as optimal medical treatment.

In the last two decades, laparoscopic anti-reflux surgery has been shown to improve the QoL in patients with GERD (Bloomston et al., 2003; Broeders et al., 2010a & 2011; Dallemagne et al., 2006; Draisma et al., 2006a & 2006b; Fein et al., 2008; Fernando et al., 2002 & 2003; Gee et al., 2008; Gillies et al., 2008; Kamolz et al., 2003 & 2005; Morino et al., 2006; Papasevas et al., 2003; Pessaux et al., 2005; Ravi et al., 2005; Rosenthal et al., 2006). In addition to general QoL assessments, several authors also used QoL measurements to compare the effectiveness of different anti-reflux procedures. For example, Draisma and colleagues (Draisma et al., 2006a) randomized 177 patients with GERD into groups undergoing either laparoscopic (LNF) or conventional Nissen fundoplication (CNF). The authors found no difference in overall patient satisfaction rates, which were 88% and 90%, respectively, and concluded that both procedures were equally effective in achieving successful objective and subjective results (Table 5).

Although the Nissen procedure produces excellent reflux-related symptom control, it may be associated with a high postoperative dysphagia rate and specific side-effects such as the inability to belch and vomit, and gas bloat syndrome. The Toupet procedure is thought to produce less postoperative side-effects than the Nissen procedure (Broeders et al., 2010b) (Figure 1), but the recurrence rate of reflux symptoms may be higher after this procedure,

though not every author agrees with this. In two study (Radajewski et al., 2009 & Sgromo et al., 2008), a comparison of QoL outcomes was made between Nissen and Toupet fundoplication. The authors concluded that QoL scores, overall symptom improvement, and patient satisfaction were equivalent.

		LNF (n = 79)	CNF (n = 69)	Redo Surgery (n = 20) <sup>†</sup>
	General QoL (Mean VAS score 0-100)	67.1 (2.8)	60.5 (3.2)	63.3 (7.0)
	Increase in general QOL (% of preoperative)	27.3%	28.6%	41.9%
Self rated change in reflux symptoms vs preoperative state	Resolved (n)	39	31	7
	Improved (n)	36	30	11
	Unchanged (n)	3	3	2
	Worsened (n)	1	5	0
	Satisfied with outcome [n(%)]	69 (87.3%)	62 (89.9%)	16 (80%)

Table 5. Subjective outcome after LNF and CNF at 5 years after surgery. (Draisma et al., 2006a). LNF: Laparoscopic Nissen Fundoplication, CNF: Conventional Nissen Fundoplication. † Including 1 patient with cicatricial hernia correction.

A common cause of Nissen procedure failure is thoracic herniation of the fundoplication. This is particularly more common when the esophagus is short, or the esophagus is inadequately mobilized. Esophageal shortening is a complication of advanced GERD, but is also common in patients with esophageal stricture, paraesophageal hernia, dysphagia, and Barrett's esophagus. A short esophagus is usually confirmed intraoperatively, whereas only 20% of preoperative diagnosis of short esophagus is confirmed intraoperatively. Collis gastroplasty combined with fundoplication may be a good alternative in patients with advanced GERD. In a study in which the researchers compared laparoscopic Nissen Fundoplication plus Collis gastroplasty with Nissen fundoplication alone (Youssef et al., 2006), improvement of QoL in the postoperative period was comparable to that observed with Nissen fundoplication alone. The authors concluded that Collis gastroplasty combined with Nissen fundoplication provided excellent relief of reflux-related symptoms.

Several studies have shown the safety and feasibility of robot assisted anti-reflux surgery. Two randomized controlled trials (Draisma et al., 2006b & Morino et al., 2006) compared robot assisted versus laparoscopic Nissen fundoplication, and found comparable outcomes; however, costs were higher due to longer operation times and the use of more expensive instruments.

As older patients have a greater incidence of co-morbid diseases, gastroenterologists are often reluctant to refer these patients to surgery due to concerns about increased operative risks. This is partly due to the fact that medical therapy with proton pump inhibitors (PPIs) seem to provide a 93% symptom remission (Lundell et al., 2008), and studies that show both medical and surgical treatments are highly effective, safe and well tolerated (Mahon et al., 2005; Ortiz et al., 1996; Parrilla et al., 2003; Spechler, 1992; Spechler et al., 2001) and improve

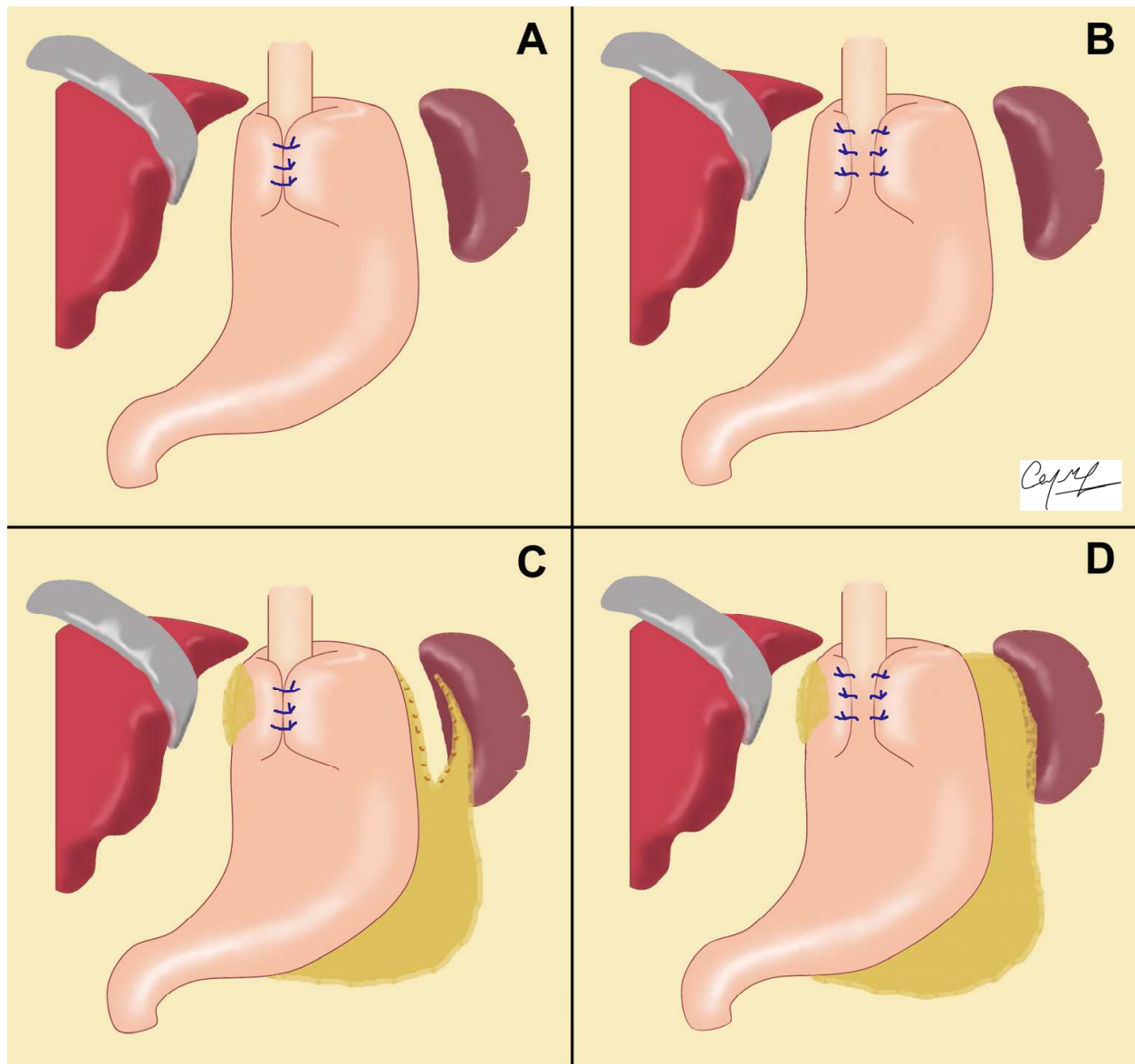


Fig. 1. Illustrated are common kinds of anti-reflux procedures. A: Nissen fundoplication (360 degree fundic wrap), B: Toupet fundoplication (270 degree posterior fundic wrap), C: Nissen fundoplication (short gastric vessels divided), D: Nissen-Rossetti fundoplication (short gastric vessels preserved)

QoL of GERD patients. Gillies and colleagues (Gillies et al., 2008) showed that laparoscopic anti-reflux surgery also improved the QoL of patients whose symptoms were well controlled on medical therapy. In two studies (Fernando et al., 2003 & Wang et al., 2008) in which the investigators compared the outcomes between young and elderly patients who underwent laparoscopic fundoplication, outcomes were similar and QoL scores improved significantly among adult and old patients, despite differences in co-morbid diseases. The authors concluded that laparoscopic fundoplication should be considered as a therapeutic option for older patients with reflux. Paraesophageal hernias are frequently seen in elderly patients, and troublesome heartburn and regurgitation may be present in 23-59% of these patients in addition to obstructive symptoms. Laparoscopic Nissen fundoplication has been found to be equally effective as anti-reflux procedures in both GERD and paraesophageal

hernia patients. However, the improvement in QoL is less in these patients due to age-related co-morbidities (Mark et al., 2008).

The choice of surgical procedure (a partial or total-360° fundic wrap) in patients with reflux-related esophageal dysmotility is controversial. Theoretically, a 360° wrap may increase the risk of postoperative dysphagia when compared to a partial wrap which decreases the risk of dysphagia, but has a higher likelihood of treatment failure (Baigrie et al., 1997 & Lundell et al., 1996). Reflux-related esophageal disturbances may be improved after successful anti-reflux surgery, possibly due to a compensatory mechanism which overcomes the increased resistance created by fundoplication (Heider et al., 2003 & Scheffer et al., 2004). Ravi and co-workers compared 60 normal esophageal motility patients with 38 esophageal dysmotility patients undergoing laparoscopic Nissen fundoplication (Ravi et al., 2005). Esophageal wave amplitude increased in both groups, and 20 patients (53%) in the dysmotility group reverted to normal motility after surgery. In the postoperative period, 88% of patients with normal motility, and 89% of patients with dysmotility had no symptoms or minor symptoms, with a significant improvement in quality of life six months after surgery. The authors concluded that preoperative dysmotility is not a contraindication for total fundoplication. Total fundoplication may cause dysphagia, gas bloat, and inability to belch as a result of increased resistance at the newly created lower esophageal sphincter function. Some measures have been proposed to prevent these surgery-related complications such as mobilization of the gastric fundus by complete division of short gastric vessels to create a floppy wrap. In a randomized study it was found that both dividing and preserving the short gastric vessels provided long term reflux control with no differences in QoL between the two approaches (Mardani et al., 2009).

GERD can be subdivided into erosive (ERD) and non-erosive reflux disease (NERD) depending upon endoscopy findings. Decreased QoL and symptom severity is similar in both ERD and NERD. However, lower response rates to PPI treatment and higher relapse rates have also been reported for patients with NERD. In a study, the authors compared subjective and objective outcomes of Nissen fundoplication in ERD and NERD patients operated on for PPI refractory disease (Broeders et al., 2011). Heartburn, regurgitation, and dysphagia grades were similar postoperatively at the five year follow-up. Moreover, 89% of NERD patients and 96% of ERD patients reported their reflux symptoms as being resolved or improved (Visick score I or II). There was no difference in QoL between the two groups during the follow-up period. Similar results were reported in another study (Kamolz et al., 2005), however QoL improvement was significantly better in the NERD group because the preoperative QoL score (GIQLI) was worse. The authors concluded that laparoscopic surgery is an excellent treatment option for NERD patients. There is not much evidence about the impact of Barrett's esophagus (BE) on the QoL of patients with GERD. BE is frequently associated with severe reflux disease. Kamolz and colleagues (Kamolz et al., 2003) showed that non-BE patients achieved better QoL than those with BE after laparoscopic anti-reflux surgery, and thus concluded that the surgical procedure improved the QoL significantly in all GERD patients with or without BE.

#### 4. Conclusion

Quality of life assessments have a central role in obtaining rapid communication of surgical outcomes. The aforementioned studies and QoL assessments, in addition to ongoing efforts,



have provided valuable data for the surgical treatment of GERD. Laparoscopic and open anti-reflux surgery effectively controls disease-related symptoms and significantly improves QoL. However, co-morbid psychiatric disorders, dyspepsia, or aerophagia usually complicate QoL assessments despite appropriate surgical therapies. Furthermore, the presence of numerous QoL tools hinders the easy interpretation and comparison of results. The SF-36 is possibly the most frequently used generic QoL instrument. However, there is still no consensus on clearcut changes on scores representing clinical significance. On the other hand, QoL studies in the postoperative period indicate that anti-reflux surgery, especially laparoscopic Nissen fundoplication, is effective in routine clinical practice.

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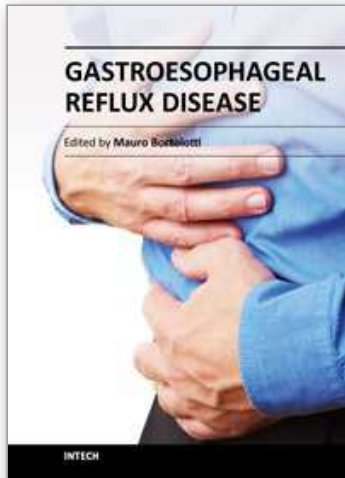
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## **Gastroesophageal Reflux Disease**

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Gastroesophageal reflux disease affects many patients. This disease not only lowers their quality of life, but it also threatens some of them with an underhand risk of cancer. Additionally, it becomes an economic burden for the patients and society. The aim of this book on gastroesophageal reflux disease is to provide advice and guidance to gastroenterologists to help them understand and manage some aspects of this proteiform disease.

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