



# Evaluation of long-term outcome and quality of life after antireflux surgery

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Patients with frequent and severe symptoms of gastro-oesophageal reflux disease (GERD) require targeted therapy with the most effective treatment strategies. Current treatment options include pharmacological and surgical approaches.

Several randomized trials comparing proton pump inhibitor (PPI) therapy with laparoscopic antireflux surgery have been conducted, particularly over short-medium terms. Some of these trials showed an advantage for surgical therapy in outcome and cost-effectiveness after a few years, whereas the LOTUS trial showed an advantage for modern PPI therapy after 5 years (1). The most recent Cochrane review (2) including four controlled trials concluded that the short-term GERD-specific quality of life (QoL) was better in the laparoscopic fundoplication (LF) group than in the medical treatment group. However, the outcome between LF and medical treatment was imprecise for overall short- and medium-term health-related QoL (HRQoL), medium-term GERD-specific QoL, percentage of people with adverse events, long-term dysphagia, and long-term acid regurgitation. None of the randomized trials comparing LF with PPI therapy has reported long-term (HRQoL) or GERD-specific QoL.

Most studies in the surgical literature have included only patients who respond adequately to PPIs. Patients who do not respond adequately to PPI treatment, however, are often referred to surgery. The available evidence for efficacy of LF in patients who do not respond adequately to PPI treatment was reviewed by Lundell *et al.* (3). Across the included studies, LF offered a substantial and

clinically relevant improvement in GERD symptoms, physiological measures of GERD and QoL parameters in partial responders beyond that provided by PPI treatment alone. Symptoms recurred, however, in around 30–35% of patients a decade after LF in those studies reporting long-term follow-up data. Overall, long-term follow-up studies suggest that the excellent short-term results of antireflux surgery deteriorate over time. Some patients may revert to the use of long-term PPI therapy, or need revision surgery to improve symptom control following recurrent symptoms. Side effects of Nissen fundoplication such as dysphagia, increased bloating and flatulence, and inability to belch or vomit may also limit the success of antireflux surgery.

Broeders *et al.* (4) reported 10 years outcome of a randomized controlled trial on laparoscopic (LNF) and conventional Nissen fundoplication (CNF) in patients with PPI-refractory GERD, with focus on effectiveness and reoperation rate. A total of 148 patients (79 LNF, 69 CNF) participated in this 10-year follow-up study. GERD symptoms were relieved in 92.4% and 90.7% [not significant (NS)] after LNF and CNF, respectively. The effect of surgery on self-rated change in general health was measured on a 3-point scale that ranges from “improved”, to “unchanged”, to “worsened”. A visual analogue scale (VAS), validated for QoL assessment after esophageal surgery, was used to measure the impact on QoL. The scale ranged from 0 to 100, where 0 represented worst possible health and 100 represented perfect health. General health (74.7% *vs.* 72.7%, NS) and QoL (visual analogue scale score: 65.3 *vs.* 61.4, NS) improved similarly in both

groups. The percentage of patients who would have opted for surgery again was similar as well (78.5% *vs.* 72.7%, NS). The authors concluded that the 10-year effectiveness of LNF and CNF is comparable in terms of improvement of GERD symptoms, PPI use, QoL, and objective reflux control.

As a continuum of this randomized trial, Oor *et al.* (5) reported 17-year outcome of these patient series. A total of 111 patients (60 LNF, 51 CNF) participated in this 17-year follow-up study. GERD symptoms were relieved in 90% and 95% (NS) after LNF and CNF, respectively. Both groups demonstrated significant improvement in general health (77% *vs.* 71%, NS) and QoL (75.3 *vs.* 74.7, NS). One or more surgical reinterventions were performed in 18% and 45% after LNF and CNF, respectively ( $P=0.002$ ). Overall, 16% of the patients underwent surgical reintervention for recurrent GERD and/or persistent dysphagia, with no significant difference between the study groups (12% *vs.* 22%). Incisional hernias were more often operated on in the conventional group (3% *vs.* 14%). The percentage of patients who would have opted for surgery again was similar as well (82% *vs.* 69%, NS). Use of daily acid-suppressing medication was relatively high in both groups (42% *vs.* 49%, NS). The authors concluded that the effects of fundoplication on symptomatic outcome and general health remain for up to 17 years after surgery.

How should we interpret these results? Complete resolution of GERD symptoms (Visick I) was observed in 50% *vs.* 53% of the patients in the LNF and CNF groups, and symptom improvement (Visick II) in 45% *vs.* 37% of the patients, respectively. General health and general QoL improved equally in both study groups, but no comparison was made to normal population. The percentage of patients who would have opted for surgery again was some 70–80%. The number of patients on PPI therapy was relatively high, and some 16% of the patients required reoperation for recurrent GERD/dysphagia. Were the patients on PPI-therapy, or those reoperated for recurrent GERD/dysphagia considered as treatment success, if asymptomatic or improved at the end of the follow-up? The significance of the use of PPI therapy in the long term is debatable without objective measurements, and may not be a reliable marker of surgical failure. Redo funduplications are generally carried out for failure of improvement of existing symptoms or new symptoms of GERD. Based on the current knowledge, surgery for failed antireflux procedures is technically demanding, and the success rate does not equal that of the primary procedures.

The evaluation of efficacy of antireflux surgery or medical treatment as a permanent treatment for GERD depends on determining what should be considered a successful or failed outcome. From the patient point of view, it is the symptom response experienced by the patients that ultimately determines the success or failure of antireflux surgery or PPI-therapy. Ideally, long-term outcomes after antireflux surgery should be examined in multiple domains including symptom response, side effects of surgery, endoscopic findings, 24-h pH-metry/pH impedance study to identify patients with true recurrent GERD, patient's subjective perception of overall success of the operation, and general and disease-specific QoL reflecting the functional status of the patients compared to normal population. Complexity of data collection is evident.

Several QoL instruments have been developed, and used to assess general and disease-specific QoL in upper gastrointestinal diseases including GERD (6). A number of studies have demonstrated that HRQoL in patients presenting with reflux disease is significantly impaired in comparison to the general population. Previous studies have also shown that HRQoL of patients with long-term treatment success seems to be similar to that of general population. Failed antireflux surgery and symptom recurrence significantly worsens the QoL in most dimensions. The presence of various QoL instruments used in different studies, however, limits the interpretation and comparison of results.

Although patients reporting relief/improvement of GERD symptoms can be considered as a successful treatment outcome, defining and reporting treatment success or failure more objectively, might give a better insight of the effectiveness of antireflux surgery in the long term. Some studies have defined antireflux surgery failed if at least one of the following criteria is present: persistence or recurrence of moderate to severe heartburn or regurgitation occurring more than once every 2 weeks (grade 2) or daily (grade 3) or both; moderate to severe dysphagia reported in combination with heartburn or regurgitation or both; the use of daily or weekly PPI medication; endoscopic evidence of erosive; pathological 24-h pH monitoring; and necessity to undergo redo surgery. However, no uniform criteria are available.

Laparoscopic approach to fundoplication has become the gold standard for the surgical management of GERD by reducing perioperative complications and facilitating postoperative recovery. For the long term (>10 years), limited data indicate decreasing effectiveness of laparoscopic antireflux

surgery. Symptom assessment, symptom scores and QoL assessment reported in different studies have been dissimilar, making a plea for more uniform symptom scales and QoL tools. Moreover, an accurate and internationally accepted consensus definition of treatment success or failure to evaluate the effectiveness of antireflux surgery is a critical issue.

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