

# Quality of life and surgical outcomes following laparoscopic surgery for refractory gastroesophageal reflux disease in a regional hospital

Hamish Hwang, MD

From the Department of General Surgery, Vernon Jubilee Hospital, Vernon, and the Faculty of Medicine, University of British Columbia, Vancouver, BC

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**Correspondence to:**  
Dr. H. Hwang  
#200–3207 30 Ave.  
Vernon BC V1T 2C6  
hamish@interchange.ubc.ca

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**Background:** Gastroesophageal reflux disease (GERD) is a prevalent condition leading to poor quality of life (QOL) in patients with refractory symptoms. Laparoscopic antireflux (LAR) surgery has been shown to improve QOL, and I sought to examine the surgical and QOL outcomes associated with LAR surgery over a 3-year period at a regional hospital.

**Methods:** Patients were given GERD–health related quality of life (GERD–HRQL) and SF-36 questionnaires preoperatively, at 6 months and at 12 or more months after surgery. I collected data on demographic and clinical characteristics and surgical outcomes.

**Results:** Of the 342 patients referred for GERD or dysphagia, 26 received LAR surgery during the study period. All 26 patients had symptoms refractory to medications; 19 had atypical symptoms and 8 had some form of chronic pain syndrome (CPS). The mean duration of surgery was 125 minutes. There were no conversions, complications, 30-day readmissions or deaths. Three patients stayed 2 days in hospital and 23 stayed overnight. One patient required esophageal dilation for persistent dysphagia. Two patients resumed medication for recurrent symptoms and 24 remained medication free. There were significant improvements in GERD–HRQL scores in all patients. Patients with CPS had no improvements in SF-36 scores, whereas patients without CPS showed significant improvement.

**Conclusion:** Excellent surgical outcomes in LAR surgery can be obtained with careful patient selection at a nonacademic regional hospital. Although GERD–HRQL improved in all patients, patients with CPS showed no improvement in general health QOL scores after LAR surgery. Careful patient counselling should be employed when offering LAR surgery to patients with CPS.

**Contexte :** Le reflux gastro-œsophagien pathologique (RGOP) chronique est un problème prévalent qui entraîne une mauvaise qualité de vie (QDV) chez les patients atteints de symptômes réfractaires. Il a été démontré que la laparoscopie antireflux (LAR) améliore la QDV, et j'ai cherché à analyser les résultats chirurgicaux et liés à la QDV associés à une LAR pendant une période de trois ans dans un hôpital régional.

**Méthodes :** Les patients ont eu à remplir un questionnaire sur le RGOP–qualité de vie liée à la santé (RGOP–QVLS) et SF-36 avant l'intervention, et 6 et 12 mois ou plus après celle-ci. J'ai recueilli des données sur les caractéristiques démographiques et cliniques et sur les résultats chirurgicaux.

**Résultats :** Des 342 patients référés à cause d'un RGOP ou d'une dysphagie, 26 ont subi une LAR au cours de la période à l'étude. Ces 26 patients présentaient tous des symptômes réfractaires aux médicaments : 19 avaient des symptômes atypiques, et 8 une forme quelconque de syndrome de douleur chronique (SDC). L'intervention chirurgicale a duré en moyenne 125 minutes. Il n'y a pas eu de conversion, de complication, de réhospitalisation à 30 jours ou de décès. Trois patients sont demeurés 2 jours à l'hôpital et 23 y ont passé la nuit. Un patient a dû subir une dilatation œsophagienne à cause d'une dysphagie persistante. Deux patients ont recommencé à prendre des médicaments pour les symptômes récurrents et 24 ont pu se passer de médicaments. On a constaté des améliorations importantes des scores RGOP–QVLS chez tous les patients. Les scores SF-36 ne se sont pas améliorés chez les patients qui avaient un SDC, mais ils se sont améliorés considérablement chez ceux qui n'avaient pas de SDC.

**Conclusion :** Il est possible d'obtenir d'excellents résultats chirurgicaux d'une LAR en choisissant attentivement les patients dans un hôpital régional non universitaire. Même si les résultats du RGOP-QVLS se sont améliorés chez tous les patients, les scores QDV représentant l'état de santé général ne seront pas améliorés chez les patients qui avaient un SDC après une LAR. Lorsque l'on offre une LAR aux patients qui ont un SDC il faut les conseiller avec prudence.

**G**astroesophageal reflux disease (GERD) is a prevalent medical condition for which open or laparoscopic Nissen fundoplication has been shown to be an effective long-term alternative to medical therapy.<sup>1-3</sup> Patients with chronic GERD refractory to medical treatment have a poor quality of life (QOL),<sup>4</sup> and surgery has been shown to improve QOL in these patients.<sup>5-8</sup>

The 36-item short-form health survey (SF-36)<sup>9</sup> and the GERD–health related quality of life scale (GERD–HRQL)<sup>10</sup> have both been validated to quantify generic and disease-specific QOL, respectively, for patients with GERD.<sup>5-8</sup> Excellent outcomes for laparoscopic antireflux (LAR) surgery in the community hospital setting have been previously described.<sup>11</sup> The objective of this study was to examine the surgical and QOL outcomes of all patients who underwent LAR surgery over a 3-year period at a Canadian regional hospital.

## METHODS

I prospectively enrolled patients who were referred to me over a period of 3 years (July 2006 to June 2009) for GERD or dysphagia and underwent LAR surgery. I excluded patients who were naïve to antireflux medications and had full symptom control after starting these medications. I also excluded patients who after investigation were found not to have GERD or who had GERD but elected to be treated medically despite being offered surgery. Patients with a body mass index (BMI) greater than 35 were not offered surgery.

I reviewed the results of all investigations with each patient in detail and obtained informed consent from all patients after an in-depth discussion of potential side effects of surgery, particularly dysphagia and gas bloat syndrome. Patients were scheduled for LAR surgery at the Vernon Jubilee Hospital, a regional hospital with a catchment population of about 130 000. Analysis was performed in March 2010.

Patients were given GERD–HRQL and SF-36 questionnaires at the time of scheduling for surgery or on the day of surgery. The GERD–HRQL scale provides a numeric score from 0 to 50, with 50 indicating the worst severity of symptoms. In addition, the questionnaire assesses whether patients are satisfied, neutral or dissatisfied with their present condition. The SF-36 provides an overall score from 0 to 100, with a low score indicating poor health. The domains of the SF-36 that were analyzed in this study were overall scores for mental health and physical health in addition to the overall composite SF-36 score.

Patients completed the same questionnaires 6 months postoperatively; the returned questionnaires were scanned and stored electronically. At the conclusion of the study, patients who had undergone surgery 12 or more months previously completed a third set of questionnaires. Patients were asked to score their symptoms on the preoperative questionnaires while on antireflux medications; and for the postoperative questionnaires, patients were asked to score their symptoms off antireflux medications.

## Statistical analysis

I recorded data on patient demographic characteristics, clinical parameters, duration of surgery, length of stay in hospital and complications. I used the paired Wilcoxon signed rank test on an Internet-based statistical calculator<sup>12</sup> to compare scores on the pre- and postoperative GERD–HRQL and SF-36 questionnaires. Results were considered to be significant at  $p < 0.05$ .

## RESULTS

A total of 342 patients were referred during the study period: 273 were referred for GERD and 69 for dysphagia. Of these, 37 were treated medically without further investigation as they were naïve to antireflux medications and had full symptoms control after starting medication. In all, 305 patients were investigated with barium esophagogram and/or gastroscopy. Of these patients, 242 were treated medically or were found to have other pathology, including 7 patients with large paraesophageal hernias treated with open operations. The remaining 63 patients were further investigated with esophageal manometry and 24-hour pH studies (patients had to be referred to Vancouver for these studies at their own expense). After investigation, 8 patients were found not to have GERD and 13 with confirmed GERD elected to be treated medically despite being offered surgery. Of the remaining 42 patients, 5 had achalasia and were treated with open ( $n = 1$ ) or laparoscopic ( $n = 4$ ) Heller myotomy, and 1 patient with severe bile reflux post–Bilroth I gastrectomy was converted to a roux-en-Y gastro-jejunostomy. The remaining 36 patients were scheduled for LAR surgery; 10 were waiting for surgery at the time of this study, leaving 26 patients for analysis (Fig. 1).

Questionnaire compliance was 100% for the preoperative questionnaire (though 1 patient forgot to fill in the SF-36 component). Twenty-three of 24 patients completed the 6-month postoperative questionnaire for a compliance

rate of 96%, and 17 of 18 patients completed the questionnaire 12 or more months after surgery for a compliance rate of 94%. One patient did not return the questionnaire at 6 months but did at 12 or more months.

Of the 26 patients who had surgery, the mean age was 50.6 (range 17–79) years, 9 patients were male, the mean American Society of Anesthesiologists (ASA) class was 2.19 and the mean BMI was 27.7 (range 22–35). All patients in this study had reflux symptoms refractory to medical therapy. Nineteen of 26 patients had atypical symptoms such as chest pain, choking, reactive airway disease and coughing. No patients had only atypical symptoms. Eight patients were noted to have some kind of chronic pain syndrome (CPS) identified by a separate

office questionnaire or through medical history. One had nonvascular leg pain, 2 had noncardiac chest pain, 1 had arthritis, 2 had vague abdominal pain, 1 had neck pain and 1 had fibromyalgia with multiple sites of pain. Six of these 8 patients had atypical reflux symptoms.

All patients were investigated with gastroscopy, barium esophagogram, esophageal manometry and pH studies. One patient could not tolerate the manometry catheter but had pathologically confirmed esophagitis so was offered surgery on that basis. Seventeen patients were noted to have a hiatal hernia. Three patients had Barrett esophagus and 5 had esophagitis, confirmed by pathology. No patient had delayed gastric emptying.

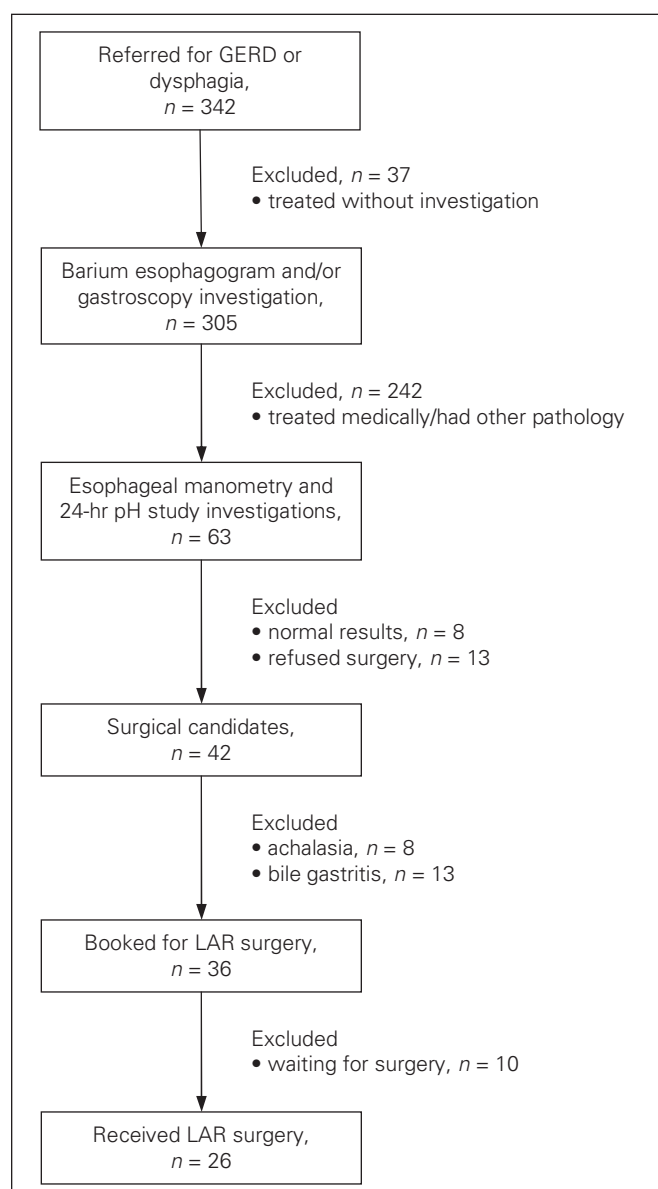
Two patients had severe esophageal dysmotility and were offered partial funduplications of the Dor type. One patient had intermittent dropped propulsion and another was noted to have nutcracker esophagus, and these patients underwent standard Nissen fundoplication. The remaining patients had normal or near-normal motility, and all underwent Nissen fundoplication. The mean lower esophageal pressure was 9 (0–22) mmHg and the mean DeMeester score was 40 (5.1–227.3). Of the 8 patients who had a DeMeester score lower than 14.7, all had a positive symptom association index of 71.3% or greater.

The mean duration of surgery was 125 (70–161) minutes, and total operative time was 168 (115–210) minutes. In all cases, a 48- or 50-French bougie dilator was used, except the 2 patients who had Dor anterior funduplications. There were no conversions or intraoperative complications. The length of stay in hospital was 2 days for 3 patients and overnight for the remaining patients.

There were no apparent postoperative complications, and the 30-day readmission rate was zero. There were no deaths. One patient required esophageal dilation for persistent dysphagia more than 3 months after surgery. Two patients had to resume medication for recurrent reflux symptoms, but the remaining 24 were off medications at the time of analysis. The symptom recurrences were not confirmed with pH studies because of the travel barrier.

Figure 2 summarizes patient satisfaction with their present condition. It should be noted that some patients who indicated they were dissatisfied postoperatively explained that this was owing to other conditions, such as depression or diabetes, and not GERD; these patients wrote comments on their questionnaires to this effect.

Table 1 summarizes overall QOL scores. Compared with preoperative scores, there was a significant improvement in the GERD–HRQL and overall SF-36 scores 6 months postoperatively. However, when the SF-36 was broken down into physical health and mental health scores, only the physical health component showed significant improvement at the 6-month mark. Of the patients who were at a follow-up stage of 12 or more months postoperative at the conclusion of the study, the mean length of



**Fig. 1.** Selection of patients for laparoscopic antireflux (LAR) surgery referred for gastroesophageal reflux disease (GERD) or dysphagia.

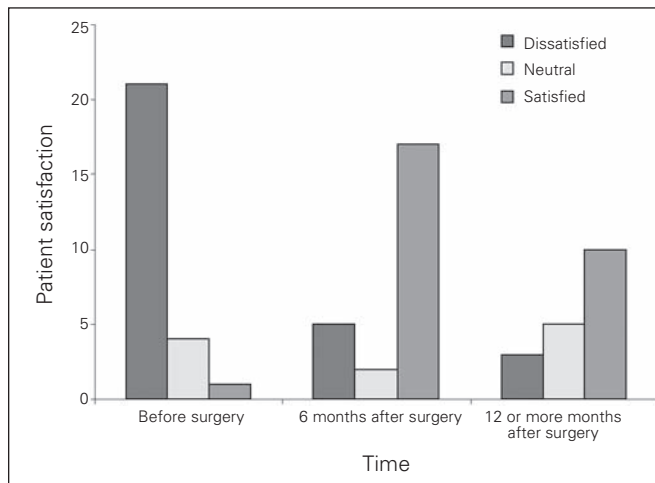
follow-up was 21 (range 12–34) months. Compared with the preoperative scores, there was significant improvement in the GERD–HRQL scores but not in any of the SF-36 scores.

Table 2 compares the GERD–HRQL and SF-36 scores between patients with and without CPS. The GERD–HRQL scores improved significantly in both groups at 6 and 12 or more months postoperatively. The SF-36 overall score and the physical health and mental health component scores all improved significantly in patients without CPS at 6 and 12 or more months postoperatively; however, in patients with CPS, there was no improvement at the 12 or more month mark.

The mean preoperative gas bloat score was 2.9 (out of 5). The mean score was 1.9 at 6 months and 2.3 at 12 or more months. These differences were not statistically significant. Similarly, the mean dysphagia score was 2.0 preoperatively, 1.1 at 6 months and 1.6 at 12 or more months; none was significant.

**DISCUSSION**

Surgical outcomes in this study were equivalent or better



**Fig. 2.** Patient satisfaction with quality of life pre- and postoperatively.

**Table 1. Comparison of pre- and postoperative GERD–HRQL and SF-36 scores**

Questionnaire	Time; score*		
	Preoperative	6 months after surgery	12 or more months after surgery
No. completed	26	24	18
GERD–HRQL	27	7†	11†
SF-36	63	72†	69
Physical health	57	68†	63
Mental health	64	71	69

GERD–HRQL = gastroesophageal reflux disease–health related quality of life;<sup>10</sup>  
 SF-36 = 36-item short form health survey.<sup>9</sup>  
 \*Unless indicated otherwise.  
 †p < 0.05.

than those reported in other studies.<sup>1,2,5,7,8,11,13</sup> Careful selection has been recommended for patients with GERD<sup>2,14</sup> and also when introducing other advanced laparoscopic procedures in a nonacademic community hospital setting to ensure excellent outcomes.<sup>15</sup> Some studies have shown poor long-term outcomes after laparoscopic Nissen fundoplication in obese patients,<sup>16</sup> and on this basis no patients with a BMI greater than 35 were offered surgery in the present study. Once good outcomes are established the indications can be broadened to include patients with a BMI greater than 35. Out of 342 referred patients in this study, only 36 were scheduled for laparoscopic antireflux surgery, which indicates a relatively conservative patient selection. As a result, there were no perioperative complications. There was 1 case of dysphagia requiring dilation, a rate of 3.8%, which is in keeping with the range of 0.3%–20% reported in the literature.<sup>13</sup> There were no cases of severe gas bloat syndrome, which is in keeping with the rate of 0%–45% described in the literature. There were 2 cases (7.7%) of recurrent symptoms requiring resumption of medications, which compares with the rate of 3.47% reported in the literature. The length of stay of 1.1 days compared favourably with the reported average of 2.8 days.<sup>13</sup>

Assuming patients answered the questionnaires honestly in this nonblinded study, improvement in disease-specific QOL scores persisted 12–34 months postoperatively. However, the same was not found for SF-36 scores in patients with CPS, though there was a sustained improvement in SF-36 scores in patients without CPS. This phenomenon has been previously described by Velanovich,<sup>17</sup> the same author who developed the GERD–HRQL scale. It is theorized that patients with CPS or psychoemotional

**Table 2. Comparison of GERD–HRQL and SF-36 scores of patients with and without chronic pain syndrome at 12 or more months after surgery**

Patient group; test	Time; score*		
	Preoperative	6 months after surgery	12 or more months after surgery
<b>No chronic pain</b>			
No. questionnaires completed	18	18	10
GERD–HRQL	26	7†	13†
SF-36	63	75†	74†
Physical health	58	74†	71†
Mental health	65	74†	72†
<b>Chronic pain</b>			
No. questionnaires completed	8	6	7
GERD–HRQL	29	7†	9†
SF-36	64	61	62
Physical health	58	51	51
Mental health	64	62	65

GERD–HRQL = gastroesophageal reflux disease–health related quality of life;<sup>10</sup>  
 SF-36 = 36-item short form health survey.<sup>9</sup>  
 \*Unless indicated otherwise.  
 †p < 0.05.

disorders in the absence of reflux symptoms become fixated on persistent or new somatic complaints, leading to a decrease in overall health that overshadows improvement in GERD-specific symptoms. The present study concurs with that of Velanovich, especially with the finding of a significant deterioration in SF-36 physical health scores more than a year after surgery in patients with CPS. The recommendation that LAR surgery should be offered with caution to patients with CPS unless there is objective evidence of refractory esophagitis or Barrett esophagus is supported by this study.

It is difficult to identify which patients will not be satisfied with surgery based on whether they have CPS or not. However, some patients identify with their pain to the point of writing "I have chronic pain" when asked to list their medical illnesses on a preconsultation questionnaire, and it is these patients who seem to have fared poorly in terms of QOL scores after LAR surgery.

## CONCLUSION

In general, careful patient counselling and informed consent should be employed when offering LAR surgery to patients with CPS, including discussing the possibility that their pain may become more pronounced after surgery.

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**Conflicts of interest:** None declared.

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- La Société canadienne des chirurgiens du côlon et du rectum
- La Société canadienne de chirurgie thoracique
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Le *American College of Surgeons*, l'Association canadienne des médecins et chirurgiens spécialistes de l'obésité, l'Association québécoise de chirurgie, le *Canadian Association of University Surgeons*, le *Canadian Hepato-Pancreato-Biliary Society*, le *Canadian Undergraduate Surgical Education Committee*, le *James IV Association of Surgeons* et l'Association canadienne de traumatologie sont au nombre des sociétés qui appuient cette activité.

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