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Long-term outcomes following laparoscopic anterior and Nissen fundoplication

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Abstract

Background: Limited evidence exists to which operation gives best long-term outcomes for gastro-oesophageal reflux disease. This study aimed to assess long-term symptomatic outcome and satisfaction following laparoscopic anterior (LA) or Nissen fundoplication in a specialist upper gastrointestinal unit.

Methods: Patients who underwent primary LA or Nissen (LN) fundoplication between May 1994 and June 2010 were identified from a prospectively collected database. DeMeester, modified DeMeester, 'Gastrointestinal Symptom Rating Scale' scores and patient satisfaction were assessed by questionnaire.

Results: A total of 387 patients underwent surgery and 246 patients (65%) completed questionnaires, with 181 LA patients and 65 LN patients. Median follow-up was 83 months for LA and 179 months for LN ($P < 0.001$). A total of 218/245 (89%) reported major improvement in symptoms and 27 (11%) reported poor outcomes. There was no differences between LA and LN for symptom scores at short (<5 years) or long-term follow-up (>5 years). Women reported significantly higher DeMeester scores and lower satisfaction ($P = 0.012$). One hundred and eighteen (48%) patients were taking proton pump inhibitors (PPI) at follow-up despite high satisfaction rates.

Conclusion: LA and LN have similar long-term results with patients reporting high satisfaction levels. Women reported more symptoms and less satisfaction than men. Despite high satisfaction rates a high percentage of patients take PPIs.

Introduction

Laparoscopic fundoplication is an accepted treatment for gastro-oesophageal reflux disease (GORD). Nissen (360°) fundoplication was the initial procedure and although providing effective reflux control, complications included dysphagia, nausea, gas bloat and flatulence. The laparoscopic partial (anterior) fundoplication (LA) was developed to reduce side effects. Several studies support LA as an alternative to laparoscopic Nissen fundoplication (LN).[1] A recent meta-analysis suggests LA is superior to LN with reduced side effects and similar outcomes.[2] However, American guidelines describe a paucity of information comparing LA and LN in the long term.[3] The aim of this study was to compare outcomes of LA and LN in a single unit over a 16-year period.

Methods

Study

Patients undergoing laparoscopic fundoplication for proven GORD in a specialist upper gastrointestinal unit between May 1994 and June 2010 were studied. Patients who underwent surgery for an intra-thoracic stomach (>50% of stomach within chest) and those undergoing revisional surgery as their first operation in the unit were excluded. All patients had documented evidence of GORD preoperatively, either oesophagitis on endoscopy or proven reflux on 24-h pH studies. The type of fundoplication performed was not tailored to the severity of GORD or the preoperative investigations. A validated questionnaire study was sent to all patients identified from the prospectively collected Lothian Surgical Audit database.

Regular but intermittent postal follow-up questionnaires are sent to all patients undergoing fundoplication approximately every 5 years.

Two procedures were analysed: LN and LA. All procedures were performed or directly supervised by consultant surgeons. From 1994 to 2001, LN was routinely performed. From 2001 to 2010, LN or LA was performed depending on surgeon preference.

Surgical technique

The technique for LN is described elsewhere.[4] It involved reduction of any hiatus hernia, mobilization of the lower oesophagus and upper part of the stomach, division of the short gastric vessels and a posterior crural repair. The mobilized gastric fundus was brought posterior to the oesophagus and sutured anteriorly to the remainder of the fundus, producing a 360° posterior wrap. In the majority of occasions a 55-F bougie was used.

The technique for LA is described elsewhere.[5] It involves reduction of any hiatus hernia, mobilization of the lower oesophagus and posterior crural repair. The gastric fundus is then sutured to the left pillar of the right crus (to accentuate the angle of His), over the front of the oesophagus and then to the right pillar of the right crus incorporating the right side of the oesophagus, creating a 180° anterior wrap. A bougie was not routinely used.

Patient questionnaire

Patients were sent follow-up postal questionnaires with expert advice available. Patients completed four validated questionnaires: DeMeester symptom score, modified DeMeester symptom score, Gastrointestinal Symptom Rating Scale (GSRS) and modified GSRS.

Patients were asked whether they had undergone further investigations (endoscopy, barium swallow, manometry or pH monitoring) since their operation and whether they had required oesophageal dilatation. Patients who subsequently underwent revisional surgery during follow-up were identified from the prospectively collected database.

The overall success of the operation was subjectively rated as excellent (complete recovery), good (major improvement with minor problems), fair (major improvements but significant symptoms and/or adverse effects) or poor (minimal improvement or worse than before operation). The final question asked the patients to list all current prescription and over-the-counter medications.

Statistical analysis

Follow-up times were divided into short-term (<5 years) and long-term (>5 years). Mann–Whitney *U* and Kruskal–Wallis tests were used to compare continuous variables between the different operation types. Chi-squared test was used to compare categorical variables, with Yates' correction and Fisher's exact test used where appropriate. Spearman's rank correlation was used to analyse the relationship between continuous variables. Analyses were completed using PASW version 17.0.2 (SPSS, Chicago, IL, USA).

Results

Patients

A total of 387 patients underwent primary laparoscopic fundoplication between May 1994 and June 2010. Completed questionnaires were received from 246/380 (65%) alive patients (Fig. 1). Seven patients died during follow-up of unrelated causes. The study included 13 patients who required revisional anti-reflux surgery during the study; 10 out of 13 responded. There was a difference in response rate between the LA and LN groups (Fig. 1; $P = 0.001$) and between sexes: 121 of 159 women (76%) returned questionnaires, compared with 125 of 221 men (57%) ($P < 0.001$). Sixty-five respondents underwent LN (35 male; 30 female) and 181 respondents underwent LA (90 male; 91 female). There was no statistical difference between sexes undergoing LA/LN ($P = 0.664$).

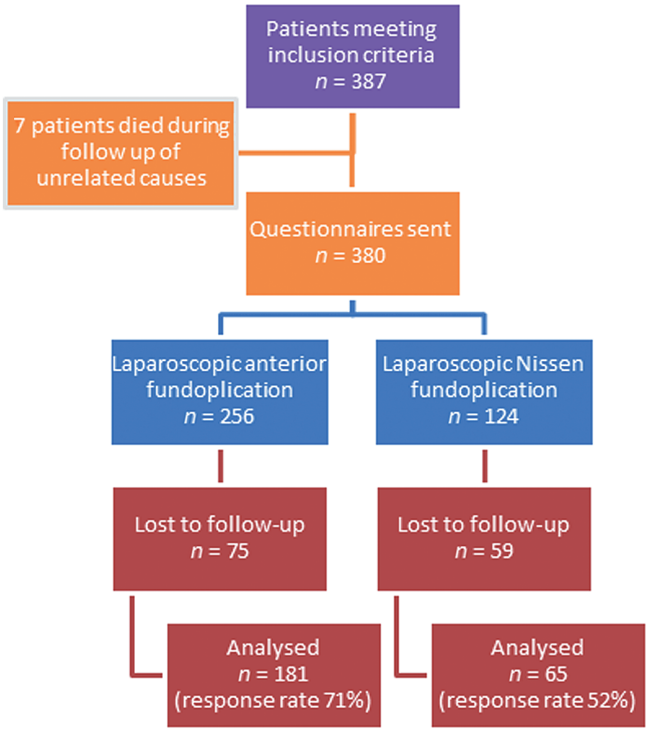

Fig. 1. Cohort diagram of study patients.

Follow-up

Post-operative follow-up ranged from 12 to 193 months (mean 70.6 months). The mean (standard deviation) follow-up after LA was 58.2 (33.7) months compared with 121.9 (52.5) months after LN ($P < 0.001$).

Relationship between symptom scores and operation

There were no significant differences between both surgical techniques in terms of post-operative symptoms (Table 1).

Relationship between symptom scores and gender

Women had higher DeMeester (2.7 versus 1.9 ($P = 0.012$)), modified DeMeester (3.6 versus 2.6 ($P = 0.009$)) and GSRS scores post-operatively. Women had increased mean age compared with men at the time of operation (51.5 versus 43.9 years ($P < 0.001$)) (Table 2).

Table 1 Symptoms scores following anterior and Nissen fundoplication

Symptoms scores	All patients		LA		LN		*P*†
	n	Mean (SEM)	*n*	Mean (SEM)	*n*	Mean (SEM)	
Age at operation (years)	246	47.7 (0.9)	181	49.2 (1.1)	65	43.4 (1.5)	0.009
DeMeester (0–9)	245	2.3 (0.1)	180	2.4 (0.2)	65	2.1 (0.3)	0.213
DeMeester heartburn (0–3)	246	1.9 (0.1)	181	1.9 (0.1)	65	1.9 (0.1)	0.442
DeMeester regurgitation (0–3)	245	1.7 (0.1)	180	1.8 (0.1)	65	1.6 (0.1)	0.113
DeMeester dysphagia (0–3)	245	1.7 (0.0)	180	1.7 (0.1)	65	1.6 (0.1)	0.450
DeMeester bloating (0–3)	246	1.7 (0.1)	181	1.7 (0.1)	65	1.9 (0.1)	0.237
Modified DeMeester (0–12)	245	3.1 (0.2)	180	3.1 (0.2)	65	3.0 (0.3)	0.442
GSRS (1–7)							
Abdominal pain	245	2.2 (0.1)	180	2.2 (0.1)	65	2.0 (0.2)	0.214
Reflux	244	2.1 (0.1)	179	2.2 (0.1)	65	2.0 (0.2)	0.612
Diarrhoea	244	2.1 (0.1)	179	2.2 (0.1)	65	2.1 (0.2)	0.670
Indigestion	243	2.6 (0.1)	178	2.6 (0.1)	65	2.5 (0.2)	0.665
Constipation	245	2.3 (0.1)	180	2.4 (0.1)	65	2.0 (0.2)	0.061
Inability to vomit (1–7)	246	1.6 (0.1)	181	1.7 (0.1)	65	1.3 (0.1)	0.301
Inability to belch (1–7)	246	1.6 (0.1)	181	1.6 (0.1)	65	1.7 (0.2)	0.787

†Mann–Whitney *U*-test. GSRS, Gastrointestinal Symptom Rating Scale; LA, laparoscopic anterior fundoplication; LN, laparoscopic Nissen fundoplication; SEM, standard error of the mean.

Table 2 Comparison of symptom scores between men and women undergoing fundoplication

Symptoms scores	Male		Female		*P*†
	n	Mean (SEM)	*n*	Mean (SEM)	
Age at operation (years)	125	43.9 (1.1)	121	51.5 (1.3)	<0.001
DeMeester (0–9)	125	1.9 (0.2)	120	2.7 (0.2)	0.012
Modified DeMeester (0–12)	125	2.6 (0.2)	120	3.6 (0.3)	0.009
GSRS (1–7)					
Abdominal pain	125	1.9 (0.1)	120	2.4 (0.1)	0.014
Reflux	125	1.9 (0.1)	119	2.4 (0.2)	0.128
Diarrhoea	125	2.2 (0.1)	119	2.1 (0.1)	0.239
Indigestion	124	2.4 (0.1)	119	2.8 (0.1)	0.035
Constipation	125	2.1 (0.1)	120	2.6 (0.2)	0.042
Inability to vomit (1–7)	125	1.7 (0.1)	121	1.6 (0.1)	0.902
Inability to belch (1–7)	125	1.6 (0.1)	121	1.7 (0.1)	0.561

†Mann–Whitney *U*-test. GSRS, Gastrointestinal Symptom Rating Scale; SEM, standard error of the mean.

Relationship between symptom scores and follow-up

There was no correlation between symptom scores and length of follow-up in the LA or LN groups between short-term (<5 years) and long-term (>5 years) follow-up ($P = 0.913$).

Operation success for anterior and Nissen fundoplication

For operation success, excellent or good results were reported by 169/245 patients (69%), fair results by 49/245 patients (20%) and poor results by 27/245 patients (11%).

There was no significant difference in reported operation success between LA and LN groups ($P = 0.654$). There was no difference in reported operation success between patients with short-term (<5 years) ($n = 123$) versus long-term follow-up ($n = 122$) ($P = 0.948$).

Patients reporting poor outcomes

There was no significant difference in poor outcomes between LN and LA; 21/27 patients who reported a poor outcome underwent LA (12% of LA patients) and six underwent LN (9% of LN patients) ($P = 0.769$). The mean scores for all symptoms were greater in the 'poor' group (Table 3). Of the 27 patients who perceived their operation as poor, the majority (23/27 – 85%) were taking acid-suppressing drugs and 18/27 (67%) had further investigations. Females were more likely to report poor outcomes than males. Eighteen out of 27 were female (15%) and 9/27 were male (7%) ($P = 0.085$).

Patients requiring further investigations

Ninety-eight patients had investigations during follow-up endoscopy (83), barium swallow (34), oesophageal dilatation[6] or oesophageal manometry or pH studies (19). The indication for further investigations was directly related to fundoplication for 31 patients; recurrent reflux symptoms ($n = 26$) and dysphagia ($n = 5$). Other indications included Barrett's surveillance, peptic ulcer disease symptoms and investigation of anaemia. There was no difference between patients from the LA and LN groups in post-operative investigations ($P = 0.225$).

Table 3 Comparison of mean symptom scores between patients reporting poor, fair, good and excellent outcomes

Symptoms scores	Perceived operation success				*P*†
	Poor	Fair	Good	Excellent	
DeMeester (0–9)	5.26	3.49	2.11	0.82	<0.001
Modified DeMeester (0–12)	6.26	4.43	2.9	1.31	<0.001
GSRS (1–7)					
Abdominal pain	3.99	3.07	1.88	1.34	<0.001
Reflux	4.5	3.16	1.58	1.28	<0.001
Diarrhoea	3.16	2.86	1.97	1.53	<0.001
Indigestion	3.33	2.82	2.36	1.6	<0.001
Constipation	3.97	3.24	2.54	1.74	<0.001
Inability to vomit (1–7)	2.33	2.12	1.48	1.29	<0.001
Inability to belch (1–7)	2.11	1.94	1.6	1.27	<0.001

†Kruskal–Wallis test. GSRS, Gastrointestinal Symptom Rating Scale.

Patients requiring revisional surgery during follow-up

The rate of revisional surgery was 3.4% (13 of 380). The need for revisional surgery was similar for both surgical techniques ($P = 0.367$) with seven LA patients (2.7%) and six LN patients (4.8%). Reasons for revision included recurrent reflux (two LA, three LN), para-oesophageal hernia (three LA, one LN), abdominal pain (one LA), dysphagia due to slipped wrap (two LN) and oesophageal motility disorder (one LA). Seven (54%) of these patients were taking a proton pump inhibitor (PPI). Reported operation success was excellent ($n = 3$), good ($n = 3$), fair ($n = 1$), and poor ($n = 2$). The mean DeMeester score was 2.56 compared with 2.3 for other patients ($P = 0.755$).

Patients taking acid suppression medication

A total of 117 patients (48%) reported PPI use. There was a significant increase in medication with poorer perception of operation success ($P < 0.001$).

There was no significant difference in PPI use between LA and LN groups ($P = 0.682$). A higher number of women (56%) were taking PPIs compared with men (39%) ($P = 0.011$).

Patients using PPIs had a mean DeMeester score of 3.21 compared with 1.23 for those not using PPI ($P < 0.001$). There was a positive correlation between DeMeester score and PPI use ($r_s = 0.546$, $P < 0.001$).

Discussion

This study supports both LA and LN for the treatment of GORD. Both procedures resulted in equally high levels of patient satisfaction, with 89% reporting major improvements in symptoms. This high satisfaction rate was despite almost half of patients taking PPI therapy at follow-up. Reasons for PPI use were not evaluated in this study and the proportion of patients with 'true' recurrent reflux is not known. PPI use post-fundoplication does not necessarily equate to patient dissatisfaction or surgical failure. Overall, women were less satisfied and reported more symptoms and side effects than men, which should be considered during preoperative counselling.

LA was introduced with the aim of reducing dysphagia and gas bloat associated with LN; however, there are reports that LA may have less durable reflux control in the long-term.[6] In the current study, there were no significant differences between LA and LN in symptoms measured by DeMeester, modified DeMeester and GSRS scores. Both techniques provide improvements in symptoms, which have been shown to be durable with time, although the LN group had longer mean follow-up. This supports the efficacy of both techniques in successfully treating GORD, with equivalent levels of satisfaction for short-term and long-term. Eleven per cent of patients described the outcome as poor, with no difference between the two procedures. The subjective assessment of patient satisfaction was validated by the negative relationship between all symptoms (except bloating) and perceived operative success. This suggests that patient satisfaction is dependent on post-operative symptoms. These results are similar to those from Adelaide.[1]

A number of recent meta-analyses have compared different fundoplication techniques. A meta-analysis (2011) supports laparoscopic posterior fundoplication as the optimal procedure for GORD.[7] However, this meta-analysis is severely limited by the authors grouping all posterior approaches (270° and 360°) versus all anterior approaches (90°, 120° and 180°), making the results difficult to interpret. A second meta-analysis (2012) supports LA.[8] A further meta-analysis (2013) of five randomized controlled trials[1,6,9–13] compared LA and LN fundoplication.[2] At 1-year follow-up, dysphagia, bloating and wind-related symptoms were less after LA. Peri-operative outcomes, heartburn, re-operation rates and PPI usage were similar.[2] The benefits of LA remained at 5 years, although satisfaction scores were similar.[2] The variable results of studies and meta-analyses demonstrate that there is no strong evidence to support one type of fundoplication above others. In the present study, patients undergoing LA reported lower symptom scores of bloating and inability to belch. This was not statistically significant, and satisfaction rates were similar.

An important finding of the study was the high PPI use, despite good outcomes following surgery. This is similar to a study that reported 37% of patients were taking anti-reflux medication following fundoplication, and abnormal acid exposure was only identified in 26% of these patients.[14] It would be important to clarify whether the medication was for true reflux symptoms. There was a positive correlation between DeMeester score and anti-reflux medication, suggesting that some patients did have reflux symptoms. However, only 19 patients went on to repeat oesophageal physiology tests and the rate of revisional surgery was low.

The authors suspect the PPI group is a mixture of those with recurrent reflux and other dyspeptic symptoms including gas bloat and poor oesophageal emptying. The results suggest PPI usage is not necessarily an indication of failure of surgery as there was a high satisfaction rate despite PPI use. It does indicate that fundoplication may not prevent patients taking PPIs in the long-term, whatever the indication. This should be taken into account when performing cost-effectiveness comparisons of medical and surgical GORD treatments. Better education for patients and primary care physicians may reduce unnecessary medication use and identify patients requiring reassessment by specialist units.

In this study, women had a higher response rate and reported higher DeMeester, modified DeMeester and GSRS scores, and lower satisfaction. A higher percentage of women took PPIs compared with men. This has been reported following primary and revisional anti-reflux surgery.[15,16] This is an important finding as women should be informed preoperatively about these results when they are deciding whether to undergo fundoplication.[17]

There are a number of limitations to this study. Follow-up was incomplete with a 65% response rate and therefore data may not be representative of the whole population. Similar studies have failed to achieve complete follow-up.[18] Response bias has the potential to skew results, but little is known why patients do not respond to satisfaction surveys. Results were based on the patient responses to the questionnaire, which could lead to incorrect subjective reports of reflux. However, repeat invasive assessments are unpopular with patients. It is not known whether patients requiring medication are a failure of surgery or patient understanding of which symptoms might improve or be present post-operatively. Indications for PPI usage were not recorded and this requires further evaluation. Finally, there was a difference in follow-up between groups as the study was non-randomized with historical cohorts. This was mainly due to the shift in preferred operating technique from LN to predominantly LA in 2001 within the surgical unit. Nevertheless, this is a large single-unit study using validated questionnaires with long-term follow-up.

In conclusion, this study supports the use of LA or LN in the surgical treatment of GORD because of high satisfaction rates and comparable long-term results. Patients reported high levels of satisfaction with surgery despite almost half using PPI at follow-up. PPI use is therefore not a surrogate marker of dissatisfaction. No significant difference between the operation types existed but there was a difference in outcome between the sexes with women reporting more symptoms, side effects and lower satisfaction than men.

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