

Laparoscopic Fundoplication: Not a simple wrap

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Abstract

Introduction

Laparoscopic fundoplication (LF) has been emerging as the procedure of choice for selected patients with symptomatic and problematic reflux disease. The aim of this study was to investigate post-operative complications associated with LF. Furthermore we wanted to look at the impact of a surgeons learning curve on post operative morbidity and investigate patient satisfaction after LF.

Methods

A single surgeon's series of 75 patients who underwent laparoscopic fundoplication were included in the study. The data was collected prospectively but analysed retrospectively. A satisfaction survey was performed with one to eight years follow-up.

Results

Laparoscopic fundoplication was associated with a learning curve. One of the major aims of the study was to record post-operative complications. Interestingly, post-operative dysphagia occurred in up to 40/75 of our patients. Our initial policy was to perform an OGD and dilate prophylactically; however, this was abandoned halfway through the study as it was found that the dysphagia settled in all patients with conservative management.

Conclusion

Our study confirms a real learning curve for LF. Furthermore, it has also clearly highlighted that post operative dysphagia is common and affects a significant number of patients. In our study we found that this was best managed conservatively.

Laparoscopic fundoplication (LF) has been emerging as the procedure of choice for selected patients with symptomatic and problematic reflux disease since the first described case by Dallemagne in 1991 (1). This was followed by a rapid expansion into routine clinical practice shortly afterwards. With increased acceptance and availability of laparoscopy as a safe surgical modality there has been a huge increase in the number of patients undergoing LF. This has probably been due to increased willingness of patients and referring doctors to consider the less invasive procedure, rather than the older 'open' surgical treatment, with its more rapid recovery, smaller incisions and earlier return to work and to normal daily activities.

Patient referral patterns have also changed over the last decade with the main indication for consideration of LF being patient choice, a general unwillingness to take long term medication as well as ineffective or intolerance of medications and relapse of symptoms (5-6). Several advantages of LF have been described by recent data including shorter hospital stay, less requirement for analgesia, and sooner return to work (7-9). These have to be offset against procedure specific complications including gastro-oesophageal perforation, pneumothorax, dysphagia, and bleeding (2-4). However, the other main downside to LF is the learning curve during which there are an increased number of complications. Previous reports have suggested the learning curve to be around 20 for an individual surgeon and 50 for an institution (10-12).

In a recent meeting of the Upper GI group at the Royal College of Surgeons there was discussion concerning the incidence and management of dysphagia following laparoscopic fundoplication (13 Bill Owen Day RCS (Eng) 2004). There is a paucity of data available in this regard with a general paucity of negative or unequivocal results in the literature equating to a selection bias towards only positive data and positive reporting of good results.

Therefore the aim of the present study was to look critically at the learning curve and, with respect to operative complications, with specific regard to the incidence and management of dysphagia in a personal series of patients who underwent a laparoscopic fundoplication in a District General Hospital in the United Kingdom.

Patients and Methods

From December 1997 to February 2004, 75 patients who underwent laparoscopic fundoplication under the care of a single consultant surgeon in a district general hospital were included in this study. It became routine practice for LF to be performed by one dedicated surgical team (JMT) who kept a complete prospective list of procedures. This series was complete and the hand written records of all the procedures were used to identify patients undergoing operations for LF with or without reduction and repair of Para-oesophageal hernia during the study period. These records were cross-checked with the theatre logbook, hospital computer system as

well as with the surgeon's own record. This ensured full inclusion in the analysis of patients.

The groups were not randomised and 'all comers' were included in the study. However, Group 1 consisted of the first 20 LF whereas Group 2 included LF (numbers 21-75). Informed consent was obtained in writing prior to surgery. At least a single dose of prophylactic antibiotics (of either a third generation cephalosporin or co-amoxiclav) was administered at induction; all patients received standard thromboprophylaxis (subcutaneous clexane, TEDS, intermittent pneumatic calf compression).

Patients underwent a laparoscopic fundoplication as briefly described below. The patient was placed in the lithotomy position with reversed Trendelenburg tilt; a pneumoperitoneum was created and 4 ports inserted. The liver was elevated using a 'Nathanson' liver retractor placed through a 5 mm epigastric incision. Initially the right and left limbs of the right crus are dissected alongside the pancreaticogastric and phrenogastric ligaments. A window is created behind the distal oesophagus. A Penrose drain is passed through the gap. The short gastric vessels are divided using a harmonic scalpel (Ethicon, USA), if required. The crural limbs are approximated using 2, 2-0 ethibond sutures to leave a hiatus 1 cm wider than the oesophagus. A laparoscopic babcock is placed behind the oesophagus and the gastric fundus is brought left to right behind the oesophagus and brought round to meet with the remaining portion of the fundus anteriorly. Two (or rarely three) sutures of 2-0 ethibond were used for the fundoplication. The upper suture included a bite of the anterior hiatal margin to anchor the wrap. Of note, the important feature of the procedure is the creation of a 'floppy' tension free fundoplication. This is hugely aided by good mobilisation of the gastric fundus with its associated ligaments and if required, division of the short gastric vessels. Notably, one must carefully create a window behind the oesophagus and an overlap of no longer than 3 cms length and one must stay high up on the fundus in order to avoid the creation of a '2' compartment stomach syndrome'.

Post-operatively all patients were treated in an identical manner. As soon as tolerated after the operations the patients were allowed the consumption of water; diet and analgesia were made available as soon after surgery as required by individual patients. Complications were noted as they occurred during the follow-up period. Both general and specific complications were documented for at least 6 months. Furthermore, patient demographics, details of operations, all complications and follow-up data were kept. Follow up for the purpose of this audit involved completion of a proforma at a minimum post operative period of one year and a maximum of eight years.

All patients were regularly reviewed daily on the ward whilst they were in-patients and in the outpatients at 4-6 week intervals or sooner should the need arise by the surgical team.

Thereafter they were given a "see on request" appointment. Data on patient and procedure related morbidity and acceptability was also collected.

At the time of the study contact was made via the telephone and a questionnaire was completed. A telephone survey asking the patient four questions,

1. Where they happy with the operation
2. Would they recommend the procedure to a friend
3. Had there symptoms resolved
4. If they had had post op dysphagia had it resolved

The data was reviewed and analysed in conjunction with our department of medical statistics. Analysis was performed using the Mann-U test. Multivariate analysis of the means was performed using the Kruskal-Wallis Test.

Results

Overall the 75 patients who underwent laparoscopic fundoplication consisted of 44 males (59%) and 31 females (41%). The mean age was 47.0 years (range 22-80 years). Group 1, which consisted of the first 20 LF cases included 11 male and 9 females. The mean age was 53.25 years (range 32-80). Group 2, which consisted of the LF cases numbering 21-75 included 33 male and 22 females. The mean age was 44.8 years (range 22-78). Both groups were well matched across the above parameters with no statistical differences (Table A). Only 4 patients were obese (5%), smoker (n=10, 14%), 7 patients suffering with Hypertension (10%) and one with diabetes mellitus (2%) and were equivalently represented in both groups (data not shown).

Presenting features are shown in Table B. Notably, the commonest presenting complaints included regurgitation of acid/ food in 79% (n=59), heartburn in 73% (n=55) and pain and discomfort 53% (n=35). Other complaints included dysphagia 21% (n=16), cough/wheeze 19% (n=14) and excess salivation 18% (n=13).

Table A: Patient Demographics

	Group 1	Group 2	P value
Numbers	20	55	NS
Male: Female	9: 11	22: 33	NS
Age range (mean) yrs	32-80 (53)	22-78 (45)	NS
Operating time (median) mins	120-240 (190)	75-195 (144)	<0.05
Sliding/No sliding	11	44	NS
Type II/Type III hiatus hernia	9	11	NS

Patients underwent pre-operative evaluation with Upper GI endoscopy 88% (n=66), pH manometry 47% (n=35) and barium swallow 32% (n=24). Previous to this procedure all patients (100%) were on or had been during some part of their illness on therapeutic doses of proton pump inhibitors.

Table B: Presenting Features

	No. of cases
Regurgitation (acid/food)	59 (79%)
Heartburn	55 (73%)
Dysphagia	16 (21%)
Cough/wheeze	14 (19%)
Excess Salivation	13 (17%)
Nausea	10 (14%)
Epigastric pain	6 (8%)
TOTAL	173 (100%)

There was a significant difference between the operating times in the two groups. Thus in Group 1 the average operating time was 190 minutes (range 120-240 minutes) whereas in Group 2 the average operating time was 144 minutes (range 75-195 minutes, $P < 0.05$).

Table C: Post Op Mild and Moderate Complications

	Cases (n=75)
Dysphagia	40
Regurgitation	7
Nausea	4
Diarrhoea	3
Heartburn	5
Excess Salivation	2
Portsite discomfort	6
Gas Bloat	4
Total	71

One of the major aims of the study was to record post-operative complications. Table C shows all mild and moderate complications which resolved completely with conservative management. Of note Table F shows that dysphagia occurred in up to 40 of our patients. Table F shows the distribution of dysphagia in both groups. In group A (n=20) there are 15 patients who complained with dysphagia (75%) of which 5 settled spontaneously and 10 required further investigation with OGD +/- dilation. In group B (n=55), 25 patients suffered with dysphagia all of which settled with conservative management. Our initial policy was to perform an OGD and dilate prophylactically; however, this was abandoned halfway through the study. It was found that the dysphagia settled in all patients with conservative management. Furthermore, other mild/moderate complications, of note included regurgitation of stomach contents (7/75) and port-site discomfort (6/75), all of which also resolved spontaneously.

Table D: Major Complications Groups 1 & 2

	Group 1	Group 2	P value
PE	1 (5%)	0	NS
Pneumonia	1 (5%)	1 (2%)	NS
Oesophageal Perforation	1 (5%)	1 (2%)	NS
Stomach perforation	0	1 (2%)	NS
Pneumothorax	0	1 (2%)	NS
Major desaturation	0	1 (2%)	NS
TOTAL	3 (15%)	5 (9%)	NS

Major complications are shown in Table D. Of note there are three conversions to 'Open' surgery in Group 1 and five in Group 2 (Table E).

Table E: Conversion to Open Surgery

	Group 1 (n=20)	Group 2 (n=55)	P Value
Desaturation	0	1 (2%)	NS
Perforation viscus	1 (5%)	1 (2%)	NS
Pneumothorax	0	1 (2%)	NS
Technical (Obese/previous surgery)	2 (10%)	2 (4%)	NS
TOTAL	3 (15%)	5 (9%)	NS

In detail, four cases (two in each group) were converted early because of poor or very difficult access. They included difficulty in reducing the stomach and omentum from the mediastinum into the abdomen, unable to reach the hiatus despite placing the ports as high as possible, dense adhesions between the liver and stomach and G-O junction thereby leaving no access to the hiatus and simply impossible access to the upper stomach. Further, oesophageal perforation which was caused by intra-operative insertion of a nasogastric bougie (Group 1), this was repaired laparoscopically with no sequelae. Other reasons for conversions included perforation of the greater curve of the stomach due to the fact that there was thickened fatty tissue around the greater curve of the stomach and spleen which produced a perforation while dissecting the stomach free. Also in Group 2 there was one pneumothorax and in another patient there was marked desaturation on creation of the pneumoperitoneum and in both cases it was deemed safer to open the patient.

Table F: Dysphagia Group

	Group 1 (n=20)	Group 2 (n=55)	P value
Dysphagia	15	25	NS
Resolved Spontaneously	5	25	<0.05
Investigated (swallow and OGD)	10	0	<0.05

Relaparotomy occurred in three patients; one developed severe pain and clinical shock at 24 hours and it was found on laparotomy to have a perforated oesophagus, the second patient we found disruption of the wrap (requiring re-operation and refashioning the wrap) and a final patient developed small bowel obstruction.

Finally a telephone survey at the conclusion of the study managed to contact 70/75 patients. It was found that overall 68/70 patients were satisfied with their procedure and would recommend the procedure to a relative or friend.

Discussion

Gastro-oesophageal reflux disease (GORD) is the commonest disorder of the Upper GI tract affecting approximately between 10-40% of most western populations and with rising incidence (11). In Australia it has shown to consume around 10% of the national expenditure on prescription drugs. Fortunately the majority of patients settle with simple measures including weight loss and reductions in smoking, caffeine and chocolate consumptions. Furthermore, better timing of meals as well as increasing the number of pillows and raising the head end of the bed can lead to improved symptoms. The advent of H₂-receptor antagonist (H₂RA) and later proton pump inhibitors (PPIs) has led to symptom control in the majority of patients. However, patients on maximum therapy who remain symptomatic or who develop complications (i.e. haemorrhage, oesophagitis, strictures) or those who refuse long term medication are deemed candidates for surgical intervention.

LF has emerged as the procedure of choice for GORD. The present study, which is a personal single surgeon series, shows that laparoscopic fundoplication is a safe and effective procedure with low rates of long-term complications. Importantly, post operatively these patients may develop dysphagia which settles with conservative measures in the vast majority of cases (13).

There is no doubt that for LF a 'learning curve' exists but there is debate about the actual numbers. Most studies suggest that it is around 20 for an individual and around 50 for a department (12), thus in the present study we compared our first 20 (classically thought to be within the learning curve) with the next 55 in order to assess major complications, conversions to open procedure. We found that in Group 1 there were 3 major complications (15%) whereas in the next 55 cases there were five (9%). Indeed only one major complication in Group 1 and two in Group 2 could be considered as technical, they were oesophageal and gastric perforations the rest being post operative pneumonia, PE and major desaturation. There were no deaths in either group. This was in keeping with previously published series (14-16).

Previously published data and our own observations revealed that there were significant post operative rates of dysphagia. In the present series dysphagia was the single commonest complication experienced by 53% of patients (n=40). Initially these were investigated with barium swallow and OGD and treated aggressively with early dilation (Group 1) however this strategy was abandoned after it was found that the vast majority of our patients resolved their dysphagia with conservative treatment. From thereon we adopted a very conservative approach reassuring the patient and keeping within close contact until the dysphagia resolved. We reserved dilation for only highly resistant dysphagia or patients who were non-compliant with conservative treatment. We found that clear explanations pre-operatively, regular reassurance and assessment

was generally all that was required. In Group 2 (21-75) none of the patients required dilation for dysphagia. It is almost universal that patients undergoing LF will have a degree of dysphagia. However what is now accepted and reflected from the experience from the present study is that dysphagia after LF should only cause concern if severe, presenting with severe pain, uncontrolled retching and vomiting requiring immediate surgical revision (17). Most commonly this is due to over-tightening of the hiatus or with poor mobilisation and a 360 degree wrap. This may be related to the learning curve, being more common in the earlier cases in a personal series. In our series 53% of patients (n=40) experienced dysphagia. This is comparable to previous reported data (2,16). Notably, Fontaumard et al reported a dysphagia rate of 78% (40/51). The reason for this post operative dysphagia has been thought to be related to the type of procedure. In our series all patients underwent a Nissen type of repair however evidence is now emerging that the incidence of dysphagia and gas related complications are reduced following anterior partial fundoplication (19,20). This is shown from the data of two recent randomised controlled studies. Baigrie et al (18) in a double-blind, randomized study compared laparoscopic Nissen total fundoplication and anterior partial fundoplication. There were no differences in mean heartburn scores between groups but dysphagia scores for both liquids and solids were lower after anterior fundoplication. Also Ludemann et al (19) compared total fundoplication for gastro-oesophageal reflux disease with an anterior 180 degrees partial fundoplication. Both achieved effective reflux control but the partial wrap was associated with fewer side-effects in the short term than total fundoplication. After 5 years, dysphagia, measured by a visual analogue score for solid food and a composite dysphagia score, was worse at 5 years after total fundoplication.

Our study confirms what has previously been shown with the learning curve for LF and its acceptability. It has also clearly highlighted that post operative dysphagia is common and affects a significant number of patients post operatively. However in our study we found that this was best managed conservatively and the almost all resolved spontaneously. There is no evidence to support early intervention unless the symptoms are very severe and occur very soon after surgery, when the patient should be taken back to theatre for another look. The specific causes of the dysphagia are not known but it is postulated that it is due to increased pressure as the upper part of the wrap augments the pressure of the lower oesophageal sphincter causing it to become over competent. Over time this mechanism relaxes leading to an improvement in dysphagia with simple conservative therapy. Furthermore, there was a hugely positive satisfaction score on a simple telephone survey suggesting symptom control from this procedure.

COMPETING INTERESTS

None Declared

AUTHOR DETAILS

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