



Original article

Laparoscopic fundoplication: learning curve and patient satisfaction

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Aims: Laparoscopic fundoplication is now accepted as the optimal surgical option for the management of selected cases of gastro-oesophageal reflux disease. The principal aim of this study was to evaluate the learning curve experience of two consultant surgeons in the technique of laparoscopic fundoplication (LF). Additional variables assessed were total number of cases, pre-operative investigations, conversion rate, duration of operation, ASA grade, morbidity, mortality, necessity of further procedures, and patient satisfaction rate.

Patients and Methods: Retrospective case-note analysis of all adult patients who underwent fundoplication under the care of two consultant general surgeons over a 3-year period from January 1997 to December 1999.

Results: A total of 61 patients were included, 31 males and 30 females, with a median age of 46 years (range, 21–73 years). Of the patients, 90% were either ASA 1 or 2. The mean time for which the 24-h pH < 4 was 20.5% (95% CI, 15.3–25.7). Of the 61 patients, 6 were operated on by open technique, for medical reasons and previous abdominal procedures. Out of the remaining 55 patients, 13 had to be converted (23.6%). Mean operating times were 120 min for LF, 85 min for open operation and 142 min for LF plus conversion. There was a significant decline in conversion rate with time ($P < 0.002$). Mortality was nil. One patient had a perforation of the cricopharyngeus secondary to insertion of a bougie. The mean length of hospital stay following the laparoscopic technique was 3.4 days compared to 8.7 days following the open technique. Overall, 59 patients (96%) were happy with the result, and the operation failed in 2 patients. Five patients (8%) needed endoscopic dilatation in the first few weeks after the operation.

Conclusions: The results show that LF is a safe procedure, takes longer than open procedure, and has an acceptable morbidity. Experience with the technique reduces the need for conversion. The mean length of hospital stay is significantly less and there is a high level of patient satisfaction.

Key words: Laparoscopic fundoplication – Learning curve – Patient satisfaction – Complications

Gastro-oesophageal reflux disease (GORD) is a significant health concern, usually being managed medically and often needing life-long treatment. In adults, 30% experience reflux once a month and at least 10% experience

significant reflux once every day. Only a small number eventually seek surgical advice. Patients who benefit from surgery are those who are young and well controlled on proton pump inhibitors who do not want long-term acid

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suppression therapy and those refractory to medical treatment.

The role of surgical therapy in the management of GORD continues to evolve in the laparoscopic era.¹ Laparoscopic anti-reflux surgery has been shown to be superior to medical management for treatment of GORD.² Good results for anti-reflux surgery are obtained when patient selection is careful and trained surgeons perform the operation.^{3,4} Open anti-reflux surgery has been practised for at least 4 decades prior to the introduction of the laparoscopic approach in 1991. Many of the surgeons who are currently undertaking laparoscopic procedures have had experience in open anti-reflux surgery. However, any new approach is always associated with a learning curve. It is important to have an understanding of this learning curve, which can only be obtained from analysis of individual experience. There have been reports in the literature about the learning curve for laparoscopic anti-reflux surgery,⁵ but there is disagreement about its true length. This is essentially a safe operation with a mortality of 0.1%. Serious postoperative morbidity is also uncommon.⁶

The principal aim of this study was to evaluate the learning-curve experience of two consultant surgeons in the technique of laparoscopic fundoplication (LF). The variables assessed were the total number of cases, pre-operative investigations, conversion rate, duration of operation, American Society of Anesthesiology (ASA) grading regarding their fitness, morbidity, mortality, necessity for further procedures, and, most importantly, this being an operation for symptoms – the patient satisfaction rate.

Patients and Methods

This was a retrospective study by case-note analysis evaluating all adult patients who underwent fundoplication under the care of two consultant surgeons working in two neighbouring hospitals in a single city managed by the same National Health Service (NHS) trust over a 3-year period from January 1997 to December 1999. This includes the time frame when both these surgeons started undertaking laparoscopic anti-reflux surgery. Each of the 2 surgeons had undertaken more than 50 open anti-reflux procedures beforehand and had attended approved courses on the same. All patients underwent upper gastrointestinal endoscopy to: (i) confirm the diagnosis; (ii) rule out other pathology; and (iii) help in patient selection. 24-h oesophageal pH and manometry was attempted in all patients with varying success. We did not modify the type of wrap carried out depending on the pre-operative manometry. The two consultant surgeons were the principal operators in all cases, assisted by specialist registrars and senior house officers. Consultant anaesthetists were responsible for administration of anaesthesia in all cases.

One of the surgeons routinely performed a full 360° wrap, whereas the other performed a partial posterior wrap (180–270°). We did not divide the short gastric vessels routinely and an intra-oesophageal bougie was used by one surgeon in approximately the first half of his patients. The laparoscopic approach involved using either 5 or 6 ports, 2 of them being 10 mm and the remainder 5 mm, including one for the Nathanson liver retractor. All patients had a nasogastric tube left in overnight after the procedure. Patient satisfaction was assessed by means of a telephone interview or in the out-patient clinic. They were asked questions about their symptoms, medications, and whether they would have the operation done again given the opportunity.

Summary data are expressed as a mean with the 95% confidence interval. Comparison of groups was tested using the χ^2 test with $P < 0.05$ accepted as being significant. Trend analysis was tested with the χ^2 test for trend.

Results

In total, 61 patients were included (31 male and 30 female) with a median age of 46 years. (range, 21–73 years.) Surgeon A operated on 31 patients and surgeon B on 30 – both datasets were pooled to avoid any bias. Of all patients, 90% were graded as either ASA I or II indicating a high level of anaesthetic fitness. Fifty-two (85%) patients underwent 24-h oesophageal pH and manometry. The mean time for which the pH < 4 was 20.5% (95% CI, 15.3–25.7). Eleven (18%) patients had disordered oesophageal peristalsis on manometry, but these patients underwent the standard operative intervention. We have not specifically examined the correlation between pre-operative manometric indices and postoperative results in this study and, therefore, these tests were not repeated routinely postoperatively. All 61 patients underwent pre-operative upper gastrointestinal endoscopy, and this helped us to make the decision to adopt an open procedure in 3 patients due to the presence of a large hiatus hernia. Three other patients had undergone previous abdominal procedures and were also operated on by the open technique. We, therefore, attempted LF on 55 patients, and were successful in 42 (76.4%). The overall conversion rate during this period was 23.6% ($n = 13$) as shown in Figure 1.

The mean operating time for an open operation was 85 min compared to 120 min for laparoscopic fundoplication and 142 min for attempted laparoscopic procedures which were subsequently converted (Fig. 2). The mean length of hospital stay for the laparoscopic procedure was significantly shorter, 3.4 days compared to 8.7 days for the open technique ($P < 0.002$; Fig. 3).

There was no mortality. One of the surgeons initially used an oesophageal bougie routinely for his patients.

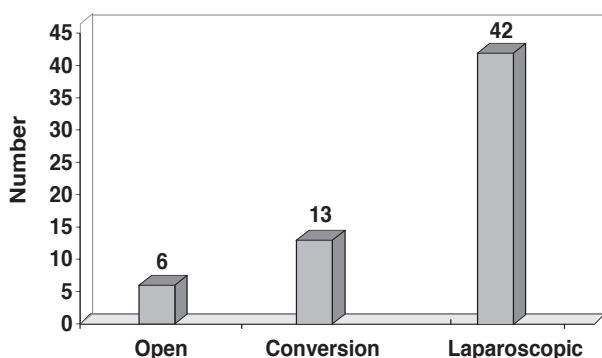


Figure 1 Numbers of various procedures examined ($n = 61$).

One patient had perforation of cricopharyngeus secondary to this, which was detected at the time, and was repaired. We have subsequently given up using this manoeuvre. Another patient developed hiatal fibrosis causing dysphagia within the 30-day period. This was confirmed on laparoscopy, but needed a laparotomy for division of the fibrosis. There were no wound infections or port site herniae.

As regards follow-up, our protocol was to review patients in clinic 2 weeks and then 6 weeks following discharge from hospital. They were then discharged back to the care of the general practitioner if appropriate. Patients with symptoms were followed up for longer in clinic. None of the patients had postoperative 24-h pH monitoring or manometry carried out. Twelve (20%) patients developed early dysphagia in the postoperative period and a small number, 5 (8%), needed endoscopic dilatation in the first few weeks. These figures are comparable to those in published series.⁷ The median interval at which dilatation was carried out was 6 weeks post-procedure, and this was necessary in only a small number. Four of the 5 patients had normal pre-operative manometry and 1 had low oesophageal sphincter pressure. All these patients were quite symptomatic at that stage, and it was doubtful whether they would have improved on further conservative management. Since this is essentially an operation for symptoms, all our patients were asked specific questions to assess satisfaction with the procedure. This was carried out in April 2000, 3 months following the completion of the study and the median period of follow up was 20 months. Fifty-nine (96%) patients were happy with the result. One patient had significant reflux after the operation which was obviously a technical failure and another patient had the wrap disrupted following dilatation for dysphagia. Both of them are currently listed to have an open repair carried out. It is interesting to note that there was no difference in the complication rate or patient satisfaction in patients with a full or partial wrap.

As part of our learning curve, we also looked at our conversion rate as our experience with the procedure increased. We divided the patients into 5 sequential groups of 12 patients and the last group of 13 patients. It was clearly demonstrated (Fig. 4) that the conversion rate falls with experience and this was significant ($P = 0.002 \chi^2$ for trend). In the first set of 12 patients, we converted 7 and in the last subset of 13, there was only 1 conversion.

Discussion

The data show that laparoscopic fundoplication is a safe procedure with an acceptable morbidity. The laparoscopic procedure certainly takes longer to perform than an open procedure, but with experience this decreases. Our current mean operating time for laparoscopic fundoplication is 95 min. Similarly, the conversion rate drops to an acceptable level with experience. The mean length of hospital stay is

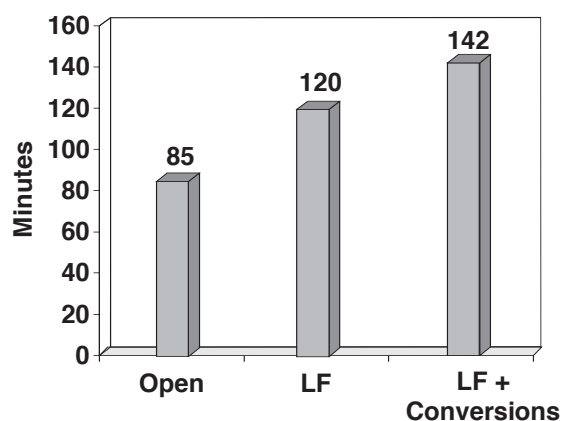


Figure 2 Mean operating time for 3 groups of patients.

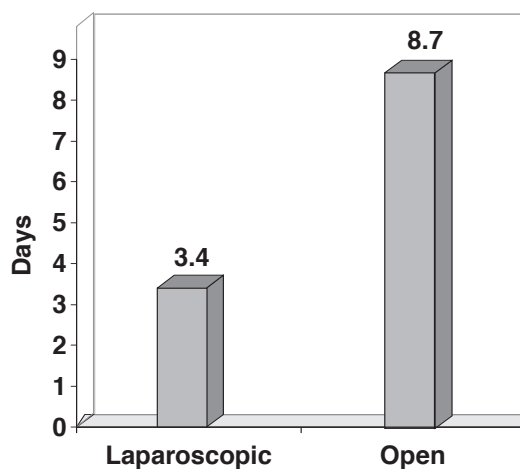


Figure 3 Mean length of hospital stay ($P < 0.002$).

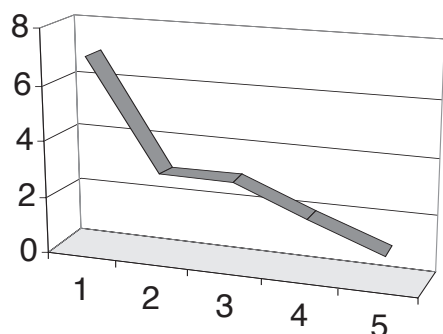


Figure 4 Conversion rate for LF 'learning curve' $P < 0.002$ (χ^2 test for trend). See text for groups of patients.

also less and this results in a higher turnover of patients and reduced bed occupancy. We have not estimated the costs of the operation or that of follow-up as part of this study. Shorter hospitalisation and absence of wound complications makes the laparoscopic approach the preferred method for performing fundoplication.⁸

Our results seem to be acceptable in the short and medium term, but would need assessment for a further period of time to evaluate the long-term results. Most of the recurrences occur early⁹ and our median follow-up at present is 20 months. Other published studies have shown excellent results with 5-year follow-up.¹⁰ Even within the learning curve, the patient satisfaction is quite high and this is likely to remain the same or even improve as the surgeon gains more experience. Our conversion rate of 23.6% during the learning curve compares quite favourably with other published series from North America and Australia^{5,11,12} all of which reported a conversion rate of 20% for the first 100 cases. Their average operating time was 117 min and they argued that it took around 20–25 laparoscopic funduplications per surgeon to surmount the learning curve. The learning curve is very steep up to this point even for experienced surgeons. Improvements as judged by decrease in operative time, conversion rate and intra-operative complications continue to occur even after 100 cases. We currently have no experience with laparoscopic re-operation for failed anti-reflux procedures and this explains why two of our patients for this procedure are on the waiting list for an open operation. However, laparoscopic re-operation has good results in the hands of experienced surgeons.¹³

There was an equal distribution of patients who underwent a complete wrap versus a partial wrap in our series, with no major differences noted in any of the parameters. This confirms with the results of a published clinical trial which dismissed the advantages of tailoring anti-reflux surgery.¹⁴ We do not routinely divide short gastric vessels for mobilisation of the fundus and current evidence suggests that division of the short gastric vessels does not improve clinical or objective postoperative outcome.¹⁵

The published incidence of iatrogenic oesophageal perforation during bougie insertion is 0.8%.¹⁶ Although not common, prevention must focus on either avoiding this technique or, if it is deemed necessary, close communication between surgeon and anaesthetist is mandatory.

The already published series on learning curve experiences in LF does not specifically cover the issue of patient satisfaction. Our study offers insight into this important variable and emphasises the high level of patient satisfaction during a surgeon's learning curve. Moreover, there have not been any other studies looking at learning curve experience in this procedure from the UK. We hope that more surgeons would be trained to perform this operation, which would improve the quality-of-life of patients as well as decrease the cost of long-term medications.

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