The Extended Learning Curve for Laparoscopic Fundoplication: A Cohort Analysis Of 400 Consecutive Cases

J. Gill · M. I. Booth · J. Stratford · T. C. B. Dehn

Abstract Many studies have looked at the learning curve associated with laparoscopic Nissen fundoplication (LNF) in a given institution. This study looks at the learning curve of a single surgeon with a large cohort of patients over a 10-year period. Prospective data were collected on 400 patients undergoing laparoscopic fundoplication for over 10 years. The patients were grouped consecutively into cohorts of 50 patients. The operating time, the length of postoperative hospital stay, the conversion rate to open operation, the postoperative dilatation rate, and the reoperation rate were analyzed. Results showed that the mean length of operative time decreased from 143 min in the first 50 patients to 86 min in the last 50 patients. The mean postoperative length of hospital stay decreased from 3.7 days initially to 1.2 days latterly. There was a 14% conversion to open operation rate in the first cohort compared with a 2% rate in the last cohort. Fourteen percent of patients required reoperation in the first cohort and 6% in the last cohort. Sixteen percent required postoperative dilatation in the first cohort. None of the last 150 patients required dilatation. In conclusion, laparoscopic fundoplication is a safe and effective operation for patients with gastroesophageal reflux disease. New techniques and better instrumentation were introduced in the early era of LNF. The learning curve, however, continues well beyond the first 20 patients.

Keywords Laparoscopic Nissen fundoplication · Learning curve

Introduction

It is well known that there is a learning curve associated with laparoscopic Nissen fundoplication (LNF) for gastroesophageal reflux disease (GERD).[1,2] A number of studies have shown a decrease in the number of complications with surgical experience and with modifications to the surgical technique of fundoplication over time. Watson et al.[2] showed that the individual surgeon's complication rate and conversion rate were highest in the first five procedures and stabilized after the first 20 operations. There are, however, few studies with large patient numbers showing the learning curve of a single surgeon and his/her trainees. We have evaluated this learning curve in our series of 400 consecutive patients undergoing laparoscopic fundoplication.

Materials and Methods

Between January 1993 and August 2002, 400 patients (262 males, 138 females) [mean age: 42.9 years (range 9–86)] underwent laparoscopic fundoplication in a District General Hospital. All procedures were performed or supervised by a dedicated upper gastrointestinal surgeon. Several trainees became the primary surgeons later in the series under direct supervision once they were deemed to have the appropriate laparoscopic skills. The indications for operation were: symptomatic GERD despite prolonged medical therapy; intolerance of medical therapy due to side effects; and volume regurgitation or patient preference for surgery.

Data were collected prospectively on a handheld computer database (Psion, Psion Ltd., England). All patients underwent preoperative endoscopy and 24 h ambulatory esophageal pH monitoring. After the first 75 cases, all

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patients also underwent stationary esophageal manometry using a standardized technique.

The operative technique was modified during the course of the study as new equipment became available. Initially, five 10-mm abdominal ports were used: toward the latter half of the study, two 5-mm and three 10-mm ports were used. For the first 35 patients, a 0° laparoscope was used: all subsequent operations were carried out using a 30° laparoscope. The lower esophagus was mobilized from the crural arch. All patients underwent division of the short gastric vessels initially using individually applied ligaclips: after case 215, a harmonic scalpel (Ethicon, Endosurgery, UK) was used. In the first 40 patients, the crura were repaired (using 2/0 silk) only if a hiatal defect and a hernia were present. After this, all patients underwent crural approximation. A loose wrap of 1–2 cm length was constructed over a 56 French gauge bougie using nonabsorbable sutures (initially silk; later "0" Ethibond) incorporating the anterior esophagus. During the period of the study, 63 patients, who were included in the fourth to seventh cohorts, underwent a laparoscopic partial posterior fundoplication as part of a randomized trial.[3] These patients were included in this study, as there was no difference in symptomatic outcome, complication rate, or operative time between this group and those undergoing a 360° fundoplication. Fourteen pediatric patients underwent an LNF throughout the series. The surgical technique used was the same in adult and pediatric populations. Patients were encouraged to mobilize immediately and commenced on oral fluids, followed by a light diet, as soon as tolerated.

The overall patient group was divided into eight cohorts of 50 consecutive patients. These cohorts were analyzed separately to compare the following: (1) patient demographics, (2) preoperative symptom length, (3) operative time, (4) length of postoperative hospital stay, (5) conversion to open operation, (6) reoperation rate, (7) postoperative dilatation rate, and (8) perioperative mortality or other early (within 6 months) postoperative complications.

Results

The mean age, weight, and length of preoperative symptoms for each group was similar (see Table 1). This table also shows an overall decrease in the amount of time to accrue each cohort throughout the study period. There was a steady decrease in the mean operative time throughout the study period from 143 min in the first cohort to 86 min in the last cohort (Fig. 1). The mean postoperative hospital stay was reduced from 3.7 days (range 2–25) to 1.2 days (range 1–5) from the first to the last cohort. There were no perioperative deaths.

Figure 1 also shows the rate of conversion from laparoscopic to open fundoplication, the reoperation rate, and the postoperative dilatation rate.

Conversions to Open Operation

The conversion rate in the first cohort of 50 patients was 14%. Compared to this, only one conversion was required in the last 250 patients in the series, and this was necessitated by equipment failure rather than surgical difficulties. Other conversions were undertaken for hemorrhage from short gastric vessels (seven patients), port-site bleeding (one patient), splenic bleeding (one patient), difficult access (two patient), instrumental esophageal perforation (one patient), and adhesions from previous surgery (two patients).

Patients Needing Postoperative Dilatations

In the first 50 patients, 8 of them (16%) needed endoscopic balloon dilatation for persistent dysphagia or gas bloat syndrome between 10 days and 3 months postoperatively. They were dilated between one and three times. Nine patients (18%) were dilated in the second cohort between 9 days and 10 months postoperatively on one to four occasions. In the

Table 1 Demographics and Length of Preoperative Symptoms in Patients Undergoing Fundoplication for GERD

	Patient Numbers							
	1–50	51–100	101–150	151–200	201–250	251–300	301–350	351–400
Time period to accrue cohort (months)	29	21	12	11	11	12	11	10
Mean age (years) (range)	36.3 (13–70)	41.6 (9–82)	43.9 (13–64)	44.5 (12–86)	44.3 (15–66)	43.9 (17–66)	45.4 (18–74)	45.1 (15–81)
Sex (M:F)	34:16	38:12	28:22	32:18	29:21	29:21	34:16	35:15
Mean weight (kg) (range)	71.1 (44–102)	75.7 (29–98)	76.1 (49–104)	74.3 (30–102)	79.5 (51–120)	79.3 (44–103)	78 (48–103)	80.4 (53–100)
Mean preoperative symptomatic period (months) (range)	91 (8–420)	85 (6–540)	106 (3–480)	92 (4–516)	106 (4–430)	96 (12–360)	141 (6–1,152)	140 (4–1,152)

third cohort, six patients (12%) underwent dilatation between 1 week and 7 months, whereas in the fourth cohort, five patients (10%) were dilated between 3 weeks and 2 months postoperatively. They were all dilated once or twice. Two patients (4%) had two dilatations each between 2 and 9 months in the fifth cohort. No dilatations were needed by the last 150 patients to undergo laparoscopic fundoplication.

Patients Needing Reoperation

Figure 1 illustrates a decline in the number of patients requiring reoperation from seven patients (14%) in the first 50 to three patients (6%) in the last 50 patients. Table 2 shows the number of reoperations that took place for any given reason in our overall patient group. It also highlights the number of reoperations that occurred within 3 months of the original fundoplication.

In the first cohort, five patients underwent reoperation for mediastinal "wrap" herniation between 9 and 80 months postoperatively. Two patients required revisional surgery; one underwent a Watson fundoplication, whereas the other undertook a redo Nissen fundoplication at 2 and 6 months, respectively, for persistent dysphagia failing to respond to endoscopic dilatations. One reoperation for "wrap" herniation was attempted laparoscopically but was converted to an open procedure. All other reoperations were carried out as open procedures.

In the second cohort, three patients were reoperated on "for mediastinal "wrap" herniation and wrap disruption at 2, 30, and 47 months postoperatively: one by open surgery and two laparoscopically. One patient underwent laparos-

Table 2 Total Number and Timing of Patients Undergoing Reoperation after Laparoscopic Fundoplication

Cause of Reoperation	Total Number of patients	Early (within 3 months)	Late (after 3 months)
Mediastinal wrap herniation	16	1	15
Persistent reflux	1		1
Dysphagia despite dilatation	2	1	1
Gas bloat	3		3
Perforation of wrap	1	1	
Port-site hernia	1		1

copic conversion of a 360° to 270° "wrap" for "gas bloat" at 11 months despite two endoscopic "wrap" dilatations.

There was one reoperation in the third cohort of patients for gas bloat 92 months later. The wrap was found to be mildly attenuated and was taken down laparoscopically. In the fourth cohort, one patient underwent laparoscopic conversion to a 270° "wrap" for "gas bloat" syndrome 12 months later, and one patient was converted from a 270° to a 360° wrap for a persistent reflux. Two patients underwent open reoperations in the fifth cohort: one for a perforation of the "wrap" at 4 days, the other for a port-site hernia repair at 9 months.

In the sixth cohort, two patients underwent a redo LNF for wrap herniation and disruption at 23 and 36 months postoperatively. In the seventh cohort, two patients were found to have a wrap herniation, and one patient was found to have a large crural defect with wrap herniation at 18, 19, and 23 months, respectively. All underwent redo LNF; the patient with the large crural defect had a hiatal mesh placed.

Figure 1 Showing operative conversions to open procedure, rates of reoperation, and rates of dilatation in patients undergoing laparoscopic fundoplication for GERD.
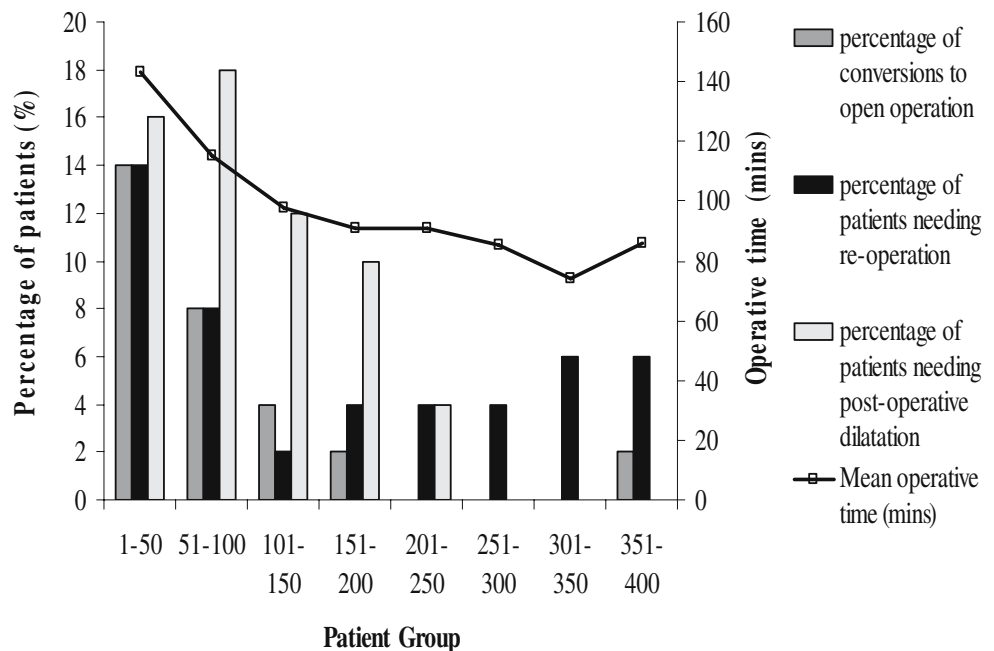
In the last cohort, three patients underwent redo LNF (two with hiatal mesh placement) for wrap herniation at 20, 27, and 36 months postoperatively.

Discussion

The postoperative complications most commonly associated with open fundoplication are dysphagia and gas bloat syndrome. The advent of the laparoscopic approach to fundoplication, first described in 1991,[4] has introduced a number of procedure-specific complications, including pneumothorax, pneumomediastinum, major-vessel injury, mesenteric thrombosis, and gastrointestinal perforation.[5]

The first prospective randomized study comparing laparoscopic and open Nissen fundoplication[6] showed similar complication rates and a better symptom outcome in those who had undergone laparoscopic surgery. There has, however, been a concern as to the severity of the reported complications in the laparoscopic approach.[7]

Before the commencement of this study, the surgeon had a 6-year experience with open fundoplications. In the early 1990s, formal courses were not available to learn laparoscopic fundoplication: consequently, the surgeons pioneering this procedure were mentored for the first few cases. After this, the surgeon would operate independently.

Our study shows that as the surgeon's experience of laparoscopic fundoplication increases, the mean operating time becomes comparable to that of an open operation. The mean postoperative length of stay in hospital was 1.2 days in the last 50 patients compared with an average stay of 7 days in those having an open fundoplication.[8] The decrease in postoperative length of stay in hospital, which was seen throughout this series, can be partly attributed to increased knowledge of recovery from laparoscopic procedures and from patient feedback of their postoperative recovery.

The high conversion rate to an open operation in our first 50 patients (14%) can be attributed to the surgical learning curve and poorer quality equipment leading to reduced quality of vision and the reduced ability to secure bleeding. Similarly, high conversion rates were seen in other early laparoscopic series.[9,2] Only 1 of the last 150 patients needed conversion to an open procedure, and this was due to equipment failure. One patient underwent a splenectomy (0.3% of all patients) due to splenic bleeding, which is comparable to other studies.[10] This compares with a splenectomy rate of 3.6% in open Nissen fundoplications in one study.[6] Of the 15 patients requiring conversion throughout the series, 14 were in the preharmonic scalpel era. Nine of these were converted due to bleeding. The harmonic scalpel has greatly enhanced the ease of fundal mobilization in comparison to the application of individual ligaclips to the short gastric arteries. A decreasing trend in conversion rate can, however, be seen within the first four cohorts before the introduction of the harmonic scalpel.

The number of patients undergoing endoscopic dilatation decreased significantly from 17% in the first 100 patients to none in the last 150 patients. This was probably due to a number of factors. First, none of the last 250 patients had symptomatic "wrap" disruptions/slippages causing dysphagia. The patients who were found to have wrap herniation presented with heartburn and not dysphagia. Secondly, it is now recognized that early dysphagia (less than 2 months postoperatively) is present in a significant proportion of patients but settles with time without the need for intervention.[11] The exception to this is in children who are less tolerant of dysphagia after laparoscopic fundoplication and hence are more likely to require early endoscopic dilatation.[12] Two studies[12,13] have shown dilatation success rates of 56 and 67%, respectively, in resolving postfundoplication dysphagia. The study by Malhi-Chowla et al.[13] also found that the only symptom that responded to dilatation was dysphagia.

Throughout the series, two patients had been reoperated on for persistent dysphagia beyond 2 months. Both were in the first 25 cases, and both were found to have bowstringing of the wrap due to lack of division of the posterior gastric bands. One was converted to a Watson fundoplication, whereas the other underwent a redo Nissen fundoplication. Our low incidence of dysphagia may be in part due to the laparoscopic operation used. Hunter et al.[14] showed that the incidence of early and late persistent dysphagia is significantly lower in both LFNs and Toupet fundoplications than in Rosetti–Nissen fundoplications.

Two patients had undergone reoperation for gas bloat syndrome: both were converted to a 270° posterior wrap and are now either asymptomatic or mildly symptomatic.

All patients in this study had been followed up for a minimum of 4 years. Overall, 6% of our patients required reoperation because principally of wrap herniation. After the first 40 operations, a routine posterior crural approximation was carried out with nonabsorbable sutures to reduce the incidence of thoracic "wrap" migration. Two studies[15,16] have emphasized the importance of a crural repair in reducing the incidence of postoperative paraesophageal hiatus hernia. Basso et al.[17] have proposed a mesh repair of the hiatus to prevent "wrap" migration after finding that in several reoperations, the sutures approximating the crura had cut out with consequent wrap herniation.

Paraesophageal wrap herniation is more common in laparoscopic than in open fundoplication.[16] Several reasons have been proposed for this: (1) the tendency to extend esophageal dissection further into the thorax,[18] (2) the increased risk of breaching the left pleural membrane during dissection,[19] and (3) the reduced postoperative pain allowing increased abdominal pressure when vomiting/coughing

in the laparoscopic procedure.[16] Wu et al.[20] found that routine division of the short gastric arteries and posterior closure of the crura during LNF significantly reduced wrap slippage/migration. This is the procedure that we have undertaken since the 40th patient. Despite of this, 5% of the last 150 patients underwent reoperation (all for heartburn due to wrap herniation). Smith et al.[21] have also concluded that wrap herniation is now the most common mechanism of failure requiring a redo fundoplication.

Of the eight patients reoperated on in the first cohort, only one procedure was attempted laparoscopically. All reoperations are now attempted laparoscopically where possible. This change in approach has occurred with increasing laparoscopic experience. Several studies[22,23] have shown that laparoscopic reoperations are not only possible and safe but also produce good results.

Several studies[24,25,26] have now shown a 90% satisfaction rate at 5-year follow-up after LNF. Our own study[25] on patient satisfaction 2–8 years postlaparoscopic fundoplication revealed that once over the initial problem of early postoperative dysphagia, the satisfaction rate was 91%. Furthermore, 90% remained free of significant reflux symptoms, and only 14% were subsequently taking regular antireflux medication. This has changed little throughout the course of the series.

Our results show a decreasing trend in operative time, postoperative hospital stay, conversion rate, postoperative dilatation rate, and reoperation rate with increasing surgical experience and improved technology. Another factor in this improvement may be due to the increased frequency with which this procedure was performed with time.

Conclusion

Dysphagia is the Achilles' heel of laparoscopic antireflux surgery. To avoid this, the authors have routinely divided the short gastric vessels. This has led to an increased rate of conversion owing to hemorrhage especially during the period when individual ligaclips were used. Short gastric vessel division may, in addition, increase the rate of wrap herniation and clip or thermal injury to the gastric fundus leading to perforation.

The high rate of reintervention in the first two cohorts would not be acceptable a decade later. It must be recognized that at the start of this series, the visual acuity of the optical systems and the quality of the instrumentation were both substantially inferior to those of today. Furthermore, there were no formal training courses available. The pioneers of advanced laparoscopic surgery had to suffer high conversion and complication rates in laparoscopic cholecystectomy,[27] antireflux,[2] and groin hernia surgery.[28,29]

When introducing complex techniques, surgeons tend to underestimate the learning curve: both of themselves and of their institution. Only by maintaining prospective data can these problems be identified and recognized.

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