GENERAL THORACIC SURGERY

EARLY EXPERIENCE AND LEARNING CURVE ASSOCIATED WITH LAPAROSCOPIC NISSEN FUNDOPLICATION

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Background: Laparoscopic approach for hiatal hernia repair is relatively new. Information on the learning curve is limited. **Methods:** From January 1994 to September 1996, 280 patients underwent antireflux surgery at our institution. A laparoscopic repair was attempted in 60 patients (21.4%). There were 38 men and 22 women. Median age was 49 years (range 21 to 78 years). Indications for operation were gastroesophageal reflux in 59 patients and a large paraesophageal hernia in one. A Nissen fundoplication was performed in all patients; 53 (88.3%) had concomitant hiatal hernia repair. **Results:** In eight patients (13.3%) the operation was converted to an open procedure. Median operative time for the 52 patients who had laparoscopic repair was 215 minutes (range 104 to 320 minutes). There were no deaths. Complications occurred in five patients (9.6%). Median hospitalization was 2 days (range 1 to 5 days). Median operative time and median hospitalization were significantly longer in the first 26 patients than in the subsequent 25 patients (248 vs 203 minutes and 2 days vs 1 day, respectively; $p = 0.03$). Seven of the first 30 patients (23.3%) required laparotomy as compared with two of the second 30 (6.7%) ($p = 0.07$). Follow-up in the 51 patients who had laparoscopic fundoplication for reflux was complete in 50 (98.0%) and ranged from 7 to 38 months (median 13 months). Functional results were classified as excellent in 34 patients (68.0%), good in 6 (12.0%), fair in 7 (14.0%), and poor in 3 (6.0%). Three patients were reoperated on for recurrent reflux symptoms at 5, 5, and 11 months. **Conclusions:** We conclude that laparoscopic Nissen fundoplication can be performed safely. The operative time, hospitalization, and conversion rate to laparotomy are higher during the early part of the experience, but all are reduced after the learning curve. (J Thorac Cardiovasc Surg 1998;115:281-5)

Surgical treatment for gastroesophageal reflux disease (GERD) traditionally has been performed through either a thoracotomy or laparotomy. Although laparoscopy was first introduced

more than 6 years ago,^{1,2} controversy still exists regarding the indications for this approach. Moreover, despite an ever-increasing number of laparoscopic procedures being performed, long-term functional results are not yet available. The purpose of this report is to describe our initial experience with laparoscopic Nissen fundoplication for GERD.

Patients and methods

From January 1994 to September 1996, 280 patients underwent antireflux surgery at the Mayo Clinic. A laparoscopic repair was attempted in 60 of these patients (21.4%). All patients were operated on by two surgeons (C.D., M.S.A.) to concentrate experience. The records of these 60 patients were analyzed for age, sex, symptoms, preoperative evaluation, operative approach, morbidity and mortality, and functional outcome.

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All patients were placed in a dorsal lithotomy position. Pneumoperitoneum was instituted with carbon dioxide insufflation. A total of five ports were used, with the locations being in the supraumbilical, right flank, epigastrium, left subcostal, and left flank areas. A 30-degree Storz rigid laparoscope (Karl Storz, Tuttlingen, Germany) was placed through the supraumbilical port and the liver retractor through the right flank. The surgeon used the epigastrium and the left subcostal ports to perform the operation while the assistant retracted the stomach through the left flank port. The hepatogastric ligament was partially divided and the crura were mobilized. The hernia was reduced when present and the crura were reapproximated posteriorly with nonabsorbable sutures. The short gastric vessels were divided in all patients, initially with hemoclips or an ENDO GIA 30 stapler (Auto Suture Company Division, United States Surgical Corporation, Norwalk, Conn.) but later with the Harmonic Scalpel LCS (Ultra Cision, Smithfield, R.I.). The fundoplication was performed around a 50F or 58F bougie with the use of two or three nonabsorbable sutures. The vagus nerves were identified with minimal manipulation in all patients and were included in the fundoplication. All ports were closed in layers under direct vision with nonabsorbable sutures. The operation was usually performed in the morning and the patient was allowed a liquid diet the night of the operation. A soft diet was started on the next postoperative day, and most patients were dismissed within 48 hours of the operation.

Data were acquired from outpatient visits and from questionnaires sent both to the patient and to the referring physician. Functional status was considered excellent if the patient was free of symptoms and not receiving medication; good if the patient had mild symptoms without medication or needed only one postoperative dilatation; fair if symptoms were controlled with medication or periodical dilatations; and poor if the patient's condition was unimproved after the operation or warranted reoperation because of complication.³ All hernias were classified according to the method of Skinner.⁴ Operative time, length of hospitalization, and laparotomy rate were compared by means of the two-sample *t* test.⁵ The threshold for statistical significance was $p = 0.05$.

Clinical findings. The group comprised 38 men (63.3%) and 22 women (36.7%). The median age at the time of the operation was 49 years (range 21 to 78 years). No patients had a previous operation for either GERD or hiatal hernia. Indications for operation were reflux symptoms in 59 patients (98.3%) and anemia caused by a large paraesophageal hernia in one (1.7%). Pyrosis was present in 53 patients (89.8%), regurgitation in 26 (44.1%), dysphagia in 16 (32.2%), pain in 12 (20.3%), and previous episodes of aspiration in 5 (8.5%). Duration of symptoms ranged from 7 months to 54 years (median 6 years). Of the 59 patients with GERD, 50 (84.7%) were considered unresponsive to optimal medical management and 9 (15.3%) wanted to discontinue omeprazole because of long-term cost despite adequate control of symptoms. Esophageal dilatation had been performed in four patients (6.8%).

Preoperative evaluation included esophagoscopy in all 60 patients, esophageal manometry in 58 (96.7%), barium

swallow in 55 (91.7%), and a pH study in 45 (75.0%). Esophagoscopy findings included esophagitis or a stricture (or both) in 44 patients (73.3%). Barrett's disease was documented histologically in 13 (21.7%). Manometric findings included a hypotensive lower esophageal sphincter in 21 patients (35.0%) and a hypertensive sphincter in one (1.7%). Peristalsis of the body of the esophagus was normal in 55 patients (91.7%) and significantly decreased in three (5.0%). Forty-two patients (70.0%) had abnormal results of an esophageal pH study. Fifty-three patients (88.3%) had an associated hiatal hernia, which was classified as type I in 52 (98.1%) and type III in one (1.9%). A 360-degree Nissen fundoplication was performed in all patients; 53 (88.3%) also had a concomitant hiatal hernia repair and one (1.7%) had a laparoscopic cholecystectomy.

Results

Sixty patients were initially operated on through a laparoscopic approach. In eight of these patients (13.3%), all of whom were undergoing operation for GERD, the laparoscopy was converted to an open procedure. Reasons for conversion to laparotomy included inadequate exposure in four patients, bleeding in two, gastric laceration in one, and a short esophagus in one. The gastric laceration was caused by firing the stapler across the stomach instead of short vessels. Median operative time was 278 minutes (range 186 to 360 minutes). There were no deaths, and complications occurred in only one patient. This patient had acute ischemia of a finger as a result of subcutaneous infiltration of intravenous medication after the operation. Median hospitalization for all eight patients was 6.5 days (range 5 to 23 days). Follow-up was complete in seven patients and ranged from 9 to 32 months (median 27 months). Functional results were classified as excellent in five, good in one, and fair in one.

Fifty-two patients had a laparoscopic Nissen fundoplication (51 for GERD and one for paraesophageal hiatal hernia). Median operative time was 215 minutes (range 104 to 320 minutes). There were no deaths. Complications occurred in five patients (9.8%) and included severe bloating in two (3.9%), bleeding in one, ileus in one, and esophageal perforation necessitating an urgent laparotomy after the initial operation in one. The esophageal perforation occurred in the patient with a paraesophageal hernia. At reoperation, the fundoplication was taken down, a primary repair of the perforation was performed, and the fundoplication redone. This patient later required emergency cholecystectomy for acute acalculous cholecystitis. Hospitalization lasted 18 days. At follow-up this patient remains free of

symptoms 35 months later and has been excluded from further analysis.

Median operative time for the remaining 51 patients for GERD was 205 minutes (range 104 to 308 minutes). Median hospitalization was 2 days (range 1 to 5 days). Median operative time and median hospitalization were significantly longer in the first 26 patients than in the subsequent 25 patients (248 vs 203 minutes and 2 vs 1 day, respectively; $p = 0.03$). Moreover, seven of the first 30 patients (23.3%) required laparotomy as compared with two of the second 30 (6.7%) ($p = 0.07$).

Follow-up was complete in 50 of the 51 patients (98.0%) and ranged from 7 to 38 months (median 13 months). Hospital readmission was required 4 days after the operation in one patient (2.0%) for severe bloating. This patient recovered with nasogastric decompression and was dismissed 2 days later. Three patients (6.0%) required esophageal dilatation within the first 3 postoperative months. Overall, the condition of 47 patients (94.0%) was improved. Functional results (Table I) were classified as excellent in 34 patients (68.0%), good in 6 (12.0%), fair in 7 (14.0%), and poor in 3 (6.0%). A barium swallow was performed in 49 patients after an average postoperative period of 3.2 months (range 1 to 13 months). Forty-four examinations (89.8%) were interpreted as showing normal results; three (6.1%) patients had limited anatomic recurrences of the hiatal hernia and were free of symptoms; two (4.1%) had both significant anatomic recurrence and significant recurrent reflux symptoms. Both of the latter two patients with significant recurrences required reoperation and both are free of symptoms at 12 and 18 months after the second operation. A third patient required reoperation at 5 months for recurrent reflux symptoms after disruption of the fundoplication without herniation. This patient has persistent symptoms 7 months after reoperation.

Discussion

The surgical approach for GERD is evolving. The number of reported laparoscopic series is increasing rapidly and currently outnumbers reports of traditional open antireflux procedures.⁶ Moreover, indications for laparoscopic fundoplication have expanded and both laparoscopic repair of large paraesophageal hernias⁷ and laparoscopic repair of hiatal hernia combined with gastroplasty⁸ for shortened esophagus have been reported. The indication for patients undergoing operation for GERD is also changing. Although open antireflux repair was re-

Table I. Functional results in 50 patients

Symptoms	Excellent (No.)	Good (No.)	Fair (No.)	Poor (No.)
None	34	—	—	—
Reflux	—	3	4	3
Dysphagia	—	1	1	—
Bloating	—	2	2	—
Total	34 (68.0%)	6 (12.0%)	7 (14.0%)	3 (6.0%)

served either for patients with complications⁹ or for those unresponsive to medical management,¹⁰ laparoscopic fundoplication is now considered for patients who are unwilling to take life-long medication. The temptation to offer laparoscopic fundoplication to patients with chronic heartburn is great because patients are attracted to a minimally invasive procedure, especially when they have a choice between several small incisions or life-long medication. Consequently, concerns have been raised that surgeons are inappropriately liberalizing the indications.⁶

Other potential patient-related benefits can be realized with a laparoscopic approach. Hospitalization is clearly shorter and the amount of postoperative pain is less.¹¹⁻¹³ Preliminary reports also suggest that functional outcome is similar to that after open repair.^{11, 13-16} However, mean duration of follow-up in most laparoscopic series is short and has not exceeded 15 months.⁶

The cost-benefit ratio of laparoscopic fundoplication remains to be determined. Whereas Rattner and Brooks¹¹ reported that total hospital charges were significantly less for the laparoscopic approach, Incarbone and coworkers¹⁷ found no difference in total hospital charges. In the report by Rattner and Brooks,¹¹ return to work was earlier than after an open procedure. However, Collard and associates¹⁸ questioned the benefit of returning to work early, because two of their patients had anatomic recurrence of their hernia attributed to premature return to work.

As with other surgical procedures, a period of learning is required,¹⁹ especially when new techniques are involved.²⁰ We had not performed laparoscopy before this report, but our previous thoracoscopic experience has facilitated the transition to another minimally invasive approach.^{15, 21} Forty of our patients (80.0%) had either excellent or good functional outcome after laparoscopic fundoplication. Recurrent reflux symptoms were the cause of fair or poor functional outcome in seven of the remaining 10 patients available for follow-up. Those

results are similar to results from other comparable series.^{12, 14} However, we believe that as experience is gained, a higher percentage of patients will have good to excellent results.

Patients undergoing laparoscopic fundoplication for GERD must be selected appropriately.²² Our early experience suggests that obesity and large hernias are relative contraindications to a laparoscopic approach. Inasmuch as the initial operation for reflux is the best opportunity to achieve an excellent functional result, a reoperation after a failed procedure is not associated with the same gratifying result.²³

In conclusion, laparoscopic fundoplication is feasible and reasonable in selected patients. This approach appears to be as safe as an open procedure; however, a period of learning is required to achieve maximum benefit. As experience is gained, the operative time, hospitalization, and conversion rate to laparotomy will decrease. The extent and significance of patient-related benefits remain unclear. Consequently, continued evaluation and follow-up are necessary to assess the long-term effectiveness of laparoscopic Nissen fundoplication.

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Discussion

Dr. Douglas E. Wood (Seattle, Wash.). Congratulations to Dr. Deschamps and his colleagues at the Mayo Clinic for another outstanding clinical series. We have come to anticipate these large, meaningful clinical reviews from the Thoracic Unit at Mayo Clinic, usually involving larger numbers and better outcomes than most of the rest of us are able to produce. This is a unique series demonstrating the learning curve of experienced surgeons learning a new procedure, surgeons without experience in laparoscopy. What is remarkable is the excellent results obtained by Dr. Deschamps and his colleagues, even in the early portion of their learning curve.

Dr. Deschamps, you report 60 attempted laparoscopic Nissen operations out of 280 antireflux procedures performed at Mayo during the 32 months of the study. You appropriately avoided complex anatomy and reoperations for this early experience, and I agree completely with your

efforts to maintain the principles of the open procedure, especially in mobilization of the fundus and short gastric division, which has also been our practice. You report a conversion rate to an open procedure of 13%, considerably higher than the 1% to 3% rate in large, mature series, but I think that this is to be expected in one's early experience. However, your results are comparable with results of other large series of laparoscopic Nissen procedures and to historical results with open procedures, with a greater than 90% improvement in symptoms.

I have two questions and an opinion. In your preoperative evaluation, you report only 75% of patients undergoing pH studies, 92% having radiologic studies, and 97% undergoing esophageal motility. What is your routine preoperative evaluation for patients undergoing antireflux surgery, particularly in regard to objective demonstration of reflux? I was somewhat concerned that some patients did not have pH studies and would be interested in the reasons that they did not.

Second, how do your results compare with your simultaneous series of 220 antireflux procedures? How different were the hospital stay, morbidity, and functional results in this simultaneous series?

Finally, I disagree with you that the indications for antireflux surgery are changing; the indications have always been reflux complications and failure of medical therapy, but they have also included surgery as an alternative to prolonged medical therapy. The difference may be semantic, but what appears to be changing is an increasing acceptance of patients and gastroenterologists for minimally invasive antireflux surgery. Ideally, this will produce an improved quality of life for these patients and is fruitful ground for evaluation of cost-effectiveness and outcomes data between medical and surgical treatment of GERD.

Dr. Deschamps. Thank you very much, Dr. Wood, for your kind comments. The patients who did not have a pH study had Barrett's disease, and we did not think it necessary to prove reflux or to quantify it with a pH study. However, our routine approach is to perform a pH study on all patients except those with Barrett's esophagus. We were particularly scrupulous in this series, because we did not want to be vulnerable to criticism for matters such as selection of patients. Our routine approach for a patient who needs an antireflux procedure at the Mayo Clinic is manometry and an endoscopy. Barium swallow has been done less commonly over the years, although we have tried to use it more with the laparoscopic Nissen operation because we thought it would provide a better outline of the hernia.

May I disagree with your disagreement? I *do* think that the patient population is changing. The 30-year-old patient who is receiving omeprazole and cannot afford it can

justifiably be considered for an operation. Certainly if he has no esophageal damage and weighs 350 pounds, this operation is less of an option. However, the 30-year-old patient with esophagitis who has been treated with omeprazole successfully, but is unable to continue omeprazole, is otherwise a good candidate. Those patients were not coming through the door 10 years ago.

Dr. Wood. Dr. Deschamps, I think we agree. Those indications in the 30-year-old patient existed before laparoscopic antireflux surgery. The difference is that both the patients and the gastroenterologists resisted surgery. My point is that the surgical indications are the same, but there is less resistance to surgery, so that some patients are able to consider surgery at an earlier stage.

Dr. Walter B. Cannon (*Palo Alto, Calif.*). This procedure is being performed with increasing frequency in this country, and the frequency will continue to increase, much the way the frequency of laparoscopic cholecystectomy has increased. I do not think the indications for laparoscopic cholecystectomy or cholecystectomy have changed, but I do think the number of operations has increased because patients are less willing to tolerate the symptoms. That same scenario is likely to be noted with laparoscopic Nissen fundoplication.

Do you think the learning curve would be shortened if there were better instruments or devices to make this procedure easier? That has been true with numerous of endoscopic procedures. Can you think of any instruments that need to be invented or at least produced that would make this procedure easier?

Dr. Deschamps. I do think that the instruments help. I am not sure that they enhance safety, but certainly the Harmonic scalpel has reduced our operative time at least by 15 to 20 minutes. Now, an average laparoscopic Nissen fundoplication will take approximately 90 minutes to perform. We tried to use simple instruments that can be reusable. The Harmonic scalpel in our experience has been the biggest help in decreasing the duration of the operation and making the division of the short vessels swift and safe. We observed no instances of excessive bleeding when the Harmonic scalpel was used.

Dr. Paul F. Waters (*Los Angeles, Calif.*). Dr. Deschamps, how do you determine whether the patient has a short esophagus at operation?

Dr. Deschamps. I wish I could determine that before the operation. In the patient who had a short esophagus and required an open procedure, good judgment on my part should have alerted me before the operation. I cannot give a firm number, but when the esophagogastric junction appears to be less than 30 cm or cannot be reduced without tension, I would not consider that patient for laparoscopic Nissen fundoplication.