Laparoscopic Fundoplication: The Alternative to Long-term Medical Therapy for Severe Gastroesophageal Reflux Disease

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Gastroesophageal reflux disease is common. Fundoplication is very effective for those patients who fail medical therapy, particularly those with an incompetent lower esophageal sphincter. Open surgery is reported to achieve cure rates in excess of 90 percent. Laparoscopic fundoplication has been performed since 1991. The early experience with this procedure is reviewed. Results: 1992 cases were reported in the literature. The mortality rate was 0.1 percent. Operative complications occurred as follows: 0.9 percent esophagogastric perforation rate; 0.6 percent bleeding rate (requiring transfusion); and 0.6 percent pneumothorax rate. No splenectomies were reported. 4.8 percent of patients required conversion to the open procedure. As experience with the procedure is gained this conversion rate decreases. Recurrent reflux postoperatively is 3.4 percent, but follow-up is short (range: 0 to 36 months; mean: two years). Dysphagia requiring dilation occurs in 3.5 percent of patients. Gas bloat occurs in 0 to 24 percent of patients. These results compare favorably with the published results of medical therapy and the open fundoplication.

Conclusions: The early experience with laparoscopic fundoplication appears promising and provides an attractive alternative to long-term medical therapy and to open surgery in appropriate patients. Long-term follow-up is awaited.

INTRODUCTION

The lower esophageal barrier against reflux of gastric acid into the esophagus relies on several factors. The most important is the maintenance of a continuous resting pressure at the lower esophageal sphincter area. This pressure is produced by a complex interplay of lower esophageal smooth muscle tone, the effect of the diaphragmatic crura, intra-abdominal pressure and the anatomic configuration of the esophagogastric angle. Almost all patients with severe gastroesophageal reflux disease who fail medical therapy are found to have a subnormal lower esophageal sphincter pressure \cite{1}. Medical therapy is aimed at the suppression of gastric acid secretion since there are no drugs that effectively increase lower esophageal sphincter tone or significantly speed gastric emptying sufficient to keep the gastric reservoir empty of acid for reflux. The healing rate of reflux esophagitis is poor with \textsubscript{H}\textsubscript{2} blockers and somewhat better with omeprazole (Table 1) \cite{2, 3}. However, even on continuous omeprazole therapy at a dose of 20 to 40 mg per day, the relapse rate of esophagitis is extremely high, with 50 percent of patients relapsing during the first 200 days of therapy \cite{4}. The cost of medical therapy is high, with estimates in the range of $2000 per year for severe reflux disease \cite{5}. With the high relapse rate on medical therapy combined with the cost, inconvenience and need for continuous treatment, it is not surprising that patients are willing to seek the surgical alternative.

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Table 1. Healing rate of $H_2$ blocker therapy on esophagitis.

|              | 6 weeks | 12 weeks |
|--------------|---------|----------|
| Mild esophagitis | 65-70%  | 80-90%   |
| Moderate esophagitis | 40-45%  | 60-65%   |
| Severe esophagitis    | 20-30%  | 30-50%   |

Surgery for gastroesophageal reflux disease began in the 1940s with the realization that the presence of a hiatal hernia was associated with reflux of acid into the esophagus and resultant mucosal damage. Early surgical procedures concentrated on reducing the herniated stomach and tightening the crura. This was met with varied success. As knowledge of the anatomic and physiologic mechanisms of reflux developed, it became clear that it was possible to surgically reconstruct the lower esophageal sphincter barrier against reflux. Several operations have been developed including the Nissen 360° fundoplication, the Hill gastropexy, the Belsey transthoracic "inkwell" procedure and the Toupet posterior or partial fundoplication. Thoracic surgeons have proposed an esophageal lengthening operation for the rare condition of esophageal shortening due to reflux damage. The most popular operation has been the Nissen fundoplication. The reasons why this procedure is such an effective antireflux procedure are shown in Table 2. Until 1991, all of these procedures required either a laparotomy or thoracotomy, with their attendant morbidity and mortality. Largely due to poor selection of surgical cases and surgeon inexperience, the results of surgery were not uniformly successful. However, excellent results with 90 percent success at 10 years were reported by surgeons with extensive experience with these procedures [6].

Following on the success of minimally invasive surgery for the operation of cholecystectomy, surgeons in early 1991 began exploring the possibility of carrying out laparoscopically directed fundoplications [7]. Early success with this operation has led to a reawakening of interest in the surgical therapy of gastroesophageal reflux disease. Between 1991 and 1995, almost 2000 cases have been reported in the literature with some series containing several hundred cases [8-25]. Both patients and referring physicians have been pleased with the minimal morbidity, short hospital stay and rapid return to normal activities offered by the laparoscopic technique. The results after four years are at least as good as those seen after the open operation. In this article, the results of this early experience with laparoscopic fundoplication will be presented.

METHODS

The worldwide published literature was reviewed. Between 1991 and 1995, reports on laparoscopic Nissen fundoplication included 1992 patients. Preliminary data from a French multicenter trial were only available for analysis of mortality, overall morbidity,

Table 2. Reasons why Nissen fundoplication prevents reflux.

- Increased length of intra-abdominal esophagus
- Rise in resting lower esophageal sphincter pressure
- Accentuation of angle of His
- Accentuation of mucosal flap valve at esophagogastric junction
- Angulation of lower esophagus over the fundoplication
- Decreased size of functioning fundus with speeding of gastric emptying
conversion rate and incidence of splenectomy. Other analyses use 1451 patients as the denominator (which excludes the patients in the French multicenter trial). Occasionally the denominator changes if the relevant data were not available in some of the reports. All available data were reported.

RESULTS OF FUNDOPLICATION

Operative complications

The most serious operative complication is that of esophageal or gastric perforation. This has been reported to occur in 13 of 1451 reported cases (0.9 percent). The incidence after the open procedure is reported as one to two percent [6, 26]. If a perforation is identified at the time of surgery, and appropriately treated, this does not lead to any significant problems. A missed perforation results in leakage and peritonitis followed by severe complications and carries a 20 to 50 percent mortality [26]. Bleeding that requires transfusion has been reported in nine of 1451 cases (0.6 percent). Pleural damage and pneumothorax occurred in eight of 1451 cases (0.6 percent). This is usually of no consequence and can be treated by simply reinflating the lungs at the end of the procedure without the need for the placement of a chest tube. The rate of splenectomy is extremely low, with no splenectomies reported in the 1992 cases reviewed in the literature over the last four years. This is a definite improvement on the two to five percent splenectomy rate for the open procedure [6, 26-28]. The long-term benefits of this are self-evident.

The need for conversion to the open procedure has occurred in 4.8 percent (96/1992) of cases. This has been reported as being due to difficulty with exposure, bowel perforation, bleeding, CO₂ retention and pneumothorax. This was necessary in five of our first 32 cases, but in our last 300 consecutive cases we have not found the need to convert any of our cases to the open procedure. There is a definite "learning curve" indicating the need for proctoring in at least the first 10 cases of a surgeon's experience.

The mortality for the procedure is somewhat less than for the open procedure with only two of 1992 cases (0.1 percent) resulting in mortality. This compares favorably with a mortality rate that is closer to one percent after the open procedure [6, 26-28].

Postoperative course

In our recent experience, we have found no need for nasogastric intubation after surgery and have allowed our patients to drink on the evening of surgery. They are encouraged to eat a light breakfast the next morning, and most patients are able to leave the hospital on the first post-operative day. They may return to work within one or two weeks after the surgery.

Recurrence of reflux

DeMeester et al. reported a more than 90 percent efficacy in curing patients (n = 100) of reflux symptoms at 10 years of follow-up with the open Nissen fundoplication. The reported incidence of recurrent reflux symptoms after the laparoscopic Nissen fundoplication is 3.4 percent, with an incidence of 11 out of 1451 (0.8 percent) of re-operation. The follow-up, however, remains short, with a mean time of about two years (range: 0 to 36 months). Re-operation can be carried out via the laparoscopic route with good results. Some of these failures may be due to the "short esophagus," and some surgeons feel that most patients with recurrent reflux symptoms should have a thoracotomy with the option of an esophageal lengthening procedure. There are, however, no clear data to support this contention.
**Dysphagia**

The reported incidence of early postoperative dysphagia varies; however, most patients will usually complain of some dysphagia in the first few weeks after surgery. Late dysphagia, mostly mild and infrequent, is reported in 86 out of 1090 cases (7.9 percent). This can usually be easily treated with esophageal dilatation and rarely will result in the need for reoperation. Of the 1090 patients available for review, 3.5 percent required dilatation after the laparoscopic Nissen fundoplication.

**Other side-effects**

In our series, eight percent (16/198) of patients have required esophagogastroduodenoscopy. This showed no endoscopic abnormality in 56 percent (9/16) of cases, gastritis in 38 percent (6/16) of cases, and one patient had a prepyloric gastric ulcer that healed on medical therapy.

"Gas bloat" syndrome is probably due to the trapping of gas in the stomach and small bowel by the competent anti-reflux barrier at the cardioesophageal junction. These patients may have learned to repeatedly swallow saliva and air before surgery in an attempt to clear the esophagus of refluxed gastric acid. This habit may persist into the postoperative period resulting in aerophagia. This syndrome can be difficult to treat and may be troublesome to some patients. The reported incidence varies between 0 percent and 24 percent [8-25]. Other symptoms include persistent diarrhea, which may be due to inadvertent vagotony or the induction of rapid gastric emptying by the fundoplication, chest pain, bloating and belching.

**HALT OF PROGRESSION OF COMPLICATIONS**

**Strictures**

Fundoplication has been found to be extremely effective in decreasing the need for further dilatation of reflux-induced esophageal strictures. On review of our recent experience, only 11 percent of patients with a documented preoperative stricture have required further dilatations after laparoscopic fundoplication (unpublished data). In other series, 46 percent of patients on H₂ blockers and 30 percent of patients on omeprazole during one year of continuous medical therapy have required further dilatations for esophageal strictures [29].

**Barrett’s esophagus**

It is not clear whether the progression in extent of Barrett’s esophagus or the progress to malignancy can be decreased or prevented by fundoplication. It is, however, evident that the disease does not regress. It is still to be established whether progression to malignancy is slowed. There have been isolated reports of progression to carcinoma of the esophagus after fundoplication. Long-term epidemiologic studies are required to establish the efficacy of fundoplication in this regard.

**COST**

The hospital cost of a laparoscopic Nissen fundoplication has been reported at between $6000 and $28,000 in different geographic areas [5]. The mean hospital cost appears to be in the area of $10,000. This equates to five years of continuous medical therapy. It is, therefore, cost-effective to offer surgical therapy to young patients with severe disease. A further advantage of the laparoscopic procedure over long-term medical therapy is the early return to normal activity after surgery and the decreased need for frequent physician visits and time off work. In this age of cost containment and managed care, these considerations in the management of the disease may become increasingly important.
CONCLUSION

Laparoscopic antireflux surgery has excited the interest not only of surgeons but also that of gastroenterologists and patients suffering from chronic reflux disease. The early results after five years of experience with the laparoscopic Nissen fundoplication indicates that this procedure is an attractive alternative to long-term medical therapy with the benefit of convenience, safety, minimal complications and low cost. The excellent short-term results suggest that the long-term results will be at least as good as for the open procedure. Results from long-term analysis of large numbers of patients after laparoscopic anti-reflux surgery will soon be available to support this statement.

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