

A Randomized, Prospective Comparison of the Nissen Fundoplication *Versus* the Toupet Fundoplication for Gastroesophageal Reflux Disease

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Objective

A prospective, randomized trial was performed to determine which of two antireflux procedures, a complete wrap (Nissen) or a 200° wrap (Toupet), was more effective with fewer sequelae.

Summary Background Data

Laparoscopic procedures for gastroesophageal reflux disease appear to be as effective as those done by open laparotomy. The Nissen fundoplication is used most frequently, but postoperative bloating, inability to belch, and dysphagia occur. The partial wrap has been said to be as effective with less unfavorable postoperative symptoms.

Methods

Patients with reflux esophagitis were approached laparoscopically using a six-port technique. After division of the short gastric vessels and dissection of the terminal esophagus and fundus of the stomach to allow performance of either procedure, patients randomly were assigned one of the procedures by a card drawn in the operating room.

Results

Forty patients underwent operation, but 1 was excluded when an open procedure became necessary. Twenty-three patients received a complete wrap and 16 received a partial wrap. The average operating time was 155 minutes for the Nissen procedures and 162 minutes for the Toupet procedures. The postoperative stay averaged 2.7 days for the Nissen procedures and 2.5 days for the Toupet procedures. There were no deaths. Including the patient converted to an open procedure, three patients had operative complications. At follow-up, Visick scores after the complete wraps were I-13, II-8, III-2 and after the partial wrap were I-12 and II-3. Two patients indicated they would not have the operation again.

Conclusions

A partial or a complete wrap after division of the short gastric vessel offers effective therapy for reflux esophagitis with >90% patient satisfaction. The authors' study shows no clear advantage of one wrap (partial or complete) over the other.

Symptomatic gastroesophageal reflux troubles a large portion of the population with 30% of Americans experiencing occasional heartburn. Ten percent may have heartburn on a monthly or more frequent basis. Acid reflux into the esophagus may cause esophagitis, tracheobronchitis, pain, stricture, or Barrett's esophagus. Eighty-five percent of persons with symptomatic reflux will have a sliding hiatal hernia, but most persons with sliding hiatal hernias (probably 2%–5% of the population) do not have disabling gastroesophageal reflux.

Over the past 20 years, the Belsey transthoracic repair, the Hill operation, and the Nissen fundoplication have been found to create effective barriers to reflux at the esophagogastric junction with alleviation of symptoms. The Nissen fundoplication, probably because of the ease with which it can be taught and learned, is favored by most surgeons around the world. Unfavorable postoperative sequelae, principally "gas bloat," inability to belch, or dysphagia, have concerned a number of workers. Luostarinen¹ noted dysphagia in 47 of 109 patients. Postoperative reported problems of these sequelae probably constitute one of the major reasons for reticence on the part of many physicians and patients to use effective antireflux procedures. More recently, the Toupet procedure, a partial posterior wrap as opposed to the 360° Nissen procedure, has been reported to be as effective as the Nissen procedure with fewer postoperative sequelae.^{2,3} This study was undertaken to compare our usual complete wrap to a 200° posterior partial wrap in a prospective, randomized manner.

MATERIALS AND METHODS

This study was approved by the Institutional Review Board of Carraway Methodist Medical Center. Patients were admitted to the study only after being instructed properly about the trial and signing the appropriate informed consent form.

All patients considered as candidates for the study had recalcitrant reflux esophagitis with 43% having undergone esophageal dilation, usually multiple times. In addition to history and physical examination, patients received upper gastrointestinal endoscopy, esophageal motility study, 24-hour esophageal pH study, and barium swallow. Patients with esophageal dysmotility were excluded from the study.

Operation was undertaken on 40 patients who were

Antireflux Operation

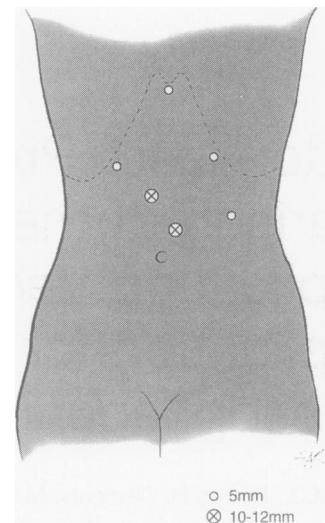


Figure 1. Six cannulas were used. A Hasson cannula was placed above and to the left of the umbilicus. An additional 10- to 12-mm cannula was inserted midway between the right costal margin at the anterior axillary line and the Hasson. Four 5-mm cannulas were used: one in the anterior axillary line at the right costal margin for the surgeon's left hand, two in the left upper quadrant for the assistant, and a subxyphoid cannula for passage of a liver retractor.

intended to be included in the trial. One patient had a laceration of the fundus of the stomach, and the operation was converted to an open procedure. Therefore, he was excluded from the study. There were 19 men and 20 women, of which 9 men and 7 women received the Toupet procedure. The average age of the patients was 51.1 years. Those undergoing the Nissen fundoplication averaged 45.5 years, and those undergoing a Toupet procedure averaged 55.5 years. Thirty-nine patients were randomized to 23 Nissen fundoplications and 16 Toupet procedures.

Technique

The patients were placed supine on the operating table. With the surgeon standing to the right of the patient and the assistant and camera operator standing to the left of the patient, six ports were used (Fig. 1). The initial abdominal entry for the Hasson trocar was gained 4 to 5 cm above and 2 to 4 cm lateral to the midline in the left upper quadrant. In patients who were tall, the initial port was sometimes placed even higher. An additional 10- to 12-mm cannula was inserted in the right upper quadrant midway between the Hasson cannula and the right subcostal margin. Four 5-mm cannulas were used: a right subcostal midclavicular line cannula for the surgeon's left hand, two 5-mL cannulas in the left upper quadrant for the assistant, and a 5-mm cannula in the subxyphoid for

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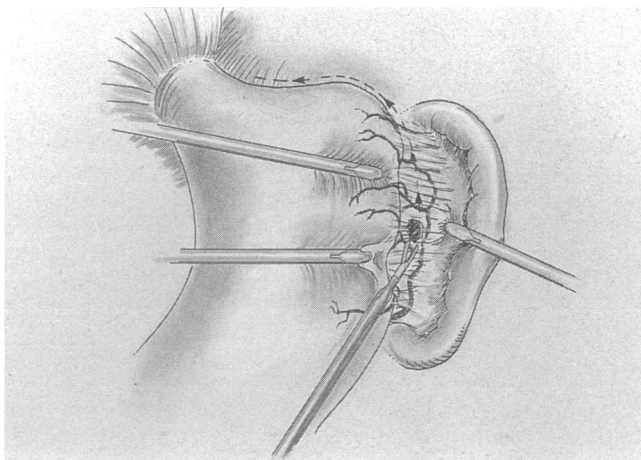


Figure 2. The short gastric vessels were divided from below upward.

the liver retractor. After abdominal insufflation, the patient was placed in the head-up position with the bed turned somewhat to the right. To effect retraction of the left lobe of the liver, a 5-mm McKernan (Allis-type) clamp was passed under the liver via the subxyphoid cannula and locked on the hiatus or the diaphragm anterior to the hiatus effectively holding the liver out of the way. The short gastric vessels from the midspleen up were divided in every patient (Fig. 2). Attention then was turned directly to the hiatus. The phrenoesophageal ligament was divided, usually beginning in the gastrohepatic omentum superior to the vagal branch to the liver (Figs. 3 and 4). An attempt was made to preserve this nerve whenever feasible. The stomach was reduced back into the abdomen if necessary, and the esophagus was cleared circumferentially, with care being taken not to injure the vagus nerves. A 5-mm blue vessel loop was passed around the esophagus, tied with an endloop, and

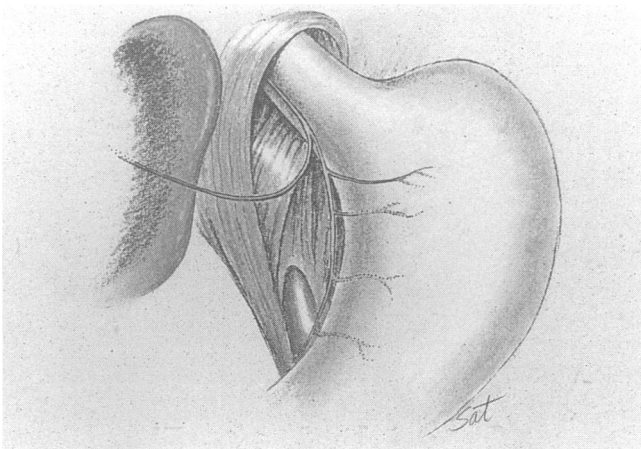


Figure 3. The vagal branch to the liver can be seen in the gastrohepatic omentum.

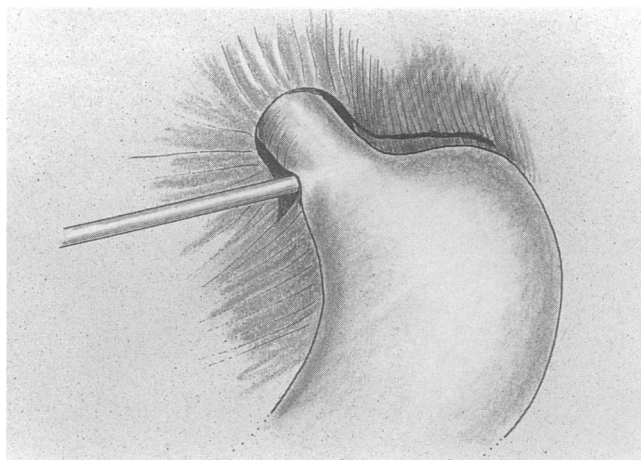


Figure 4. The upper gastrohepatic ligament, the phrenoesophageal ligament, and the attachments of the fundus were divided.

used for retraction (Fig. 5). The vagal nerves were included within the vessel loop and within the esophageal wrap.

Dissection then was completed to free the fundus so that it would pass easily around the esophagus and remain so without tethering retraction (Fig. 6). After determining that either operation was feasible, a card was drawn to select a complete wrap or a partial wrap.

In effecting the Nissen procedure, the crura were closed posteriorly with one or more 0-Dacron sutures to re-establish a normal diameter hiatal opening (Fig. 7). A 38-French Bougie together with an 18-French Levine tube were passed into the stomach of patients during the earlier part of the study, and a 40-French Ewall tube (Lavacuator Mallinckrodt, St. Louis, MO) was used in later cases. The fundus then was brought around the stomach and sewn

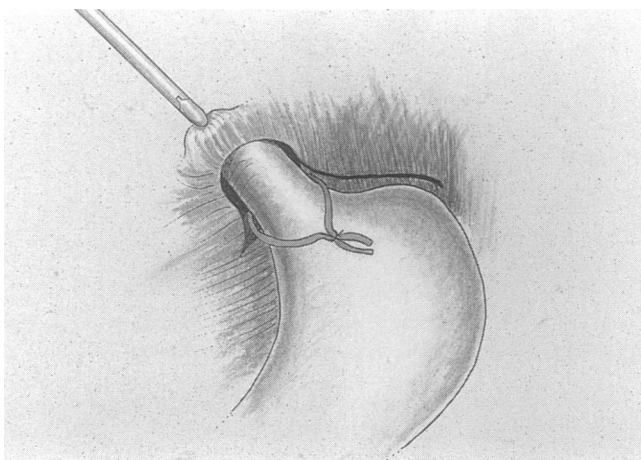


Figure 5. After the esophagus had been cleared circumferentially, it was encircled with a 5-mm vessel loop. The vessel loop was tied with an endloop and used for traction.



Figure 6. A generous portion of fundus was brought behind the esophagus. The arrows show a fundus lying freely to the right of the esophagus.

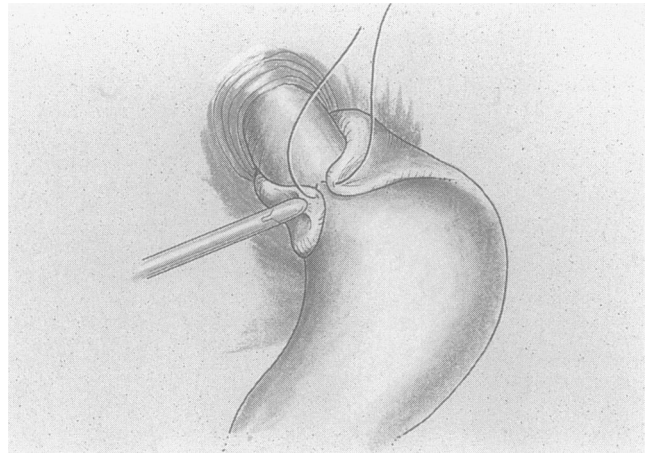


Figure 8. Zero-Dacron stitches were taken including the anterior wall of the stomach, the esophagus, and the wrap.

with 0-Dacron sutures. The anterior wall of the stomach, the anterior esophagus (care being taken not to injure the anterior vagus nerve), and the gastric wrap were included in these stitches (Fig. 8). The goal was to achieve a 2-cm wrap, which usually required three sutures (Fig. 9). Wraps were measured before closure and averaged 2.2 cm in length, varying from 1.6 to 3 cm. No additional sutures were taken between the diaphragm and the wrap or between the diaphragm and the esophagus. The wrap then was tested with a 1-cm probe to ensure it was loose; the length of the wrap was measured, and 300 to 500 mL dilute methylene blue solution was instilled within the stomach to check for any leaks.

For the Toupet operation, a generous wrap was brought behind the stomach. A suture was taken posterior to the

wrap incorporating the upper posterior aspect of the wrap to the left crus of the diaphragm as high as could be conveniently taken from behind the esophagus (Fig. 10). Staples then were applied from this point down to the confluence of the crura.

With mild traction on the esophagogastric junction, another suture was taken incorporating the right side of the esophagus, the upper aspect of the wrap, and the right crus as high as the wrap could be readily placed (Fig. 11). A third suture was taken between the posterior, inferior aspect of the wrap and the confluence of the crura. Again, staples were placed attaching the posterior aspect of the wrap to the right crus between these two sutures. An additional suture was taken between the posterior aspect of the wrap and the right crus as needed. The same esophageal tubes used during the Nissen then were passed.

The left crus anterior to the wrap then was visualized,

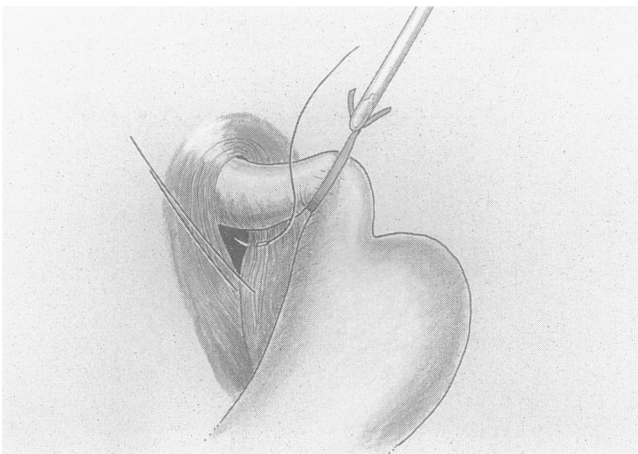


Figure 7. When a complete wrap was to be done, the crura were approximated posteriorly as necessary to re-establish a normal-sized hiatus using 0-Dacron sutures.

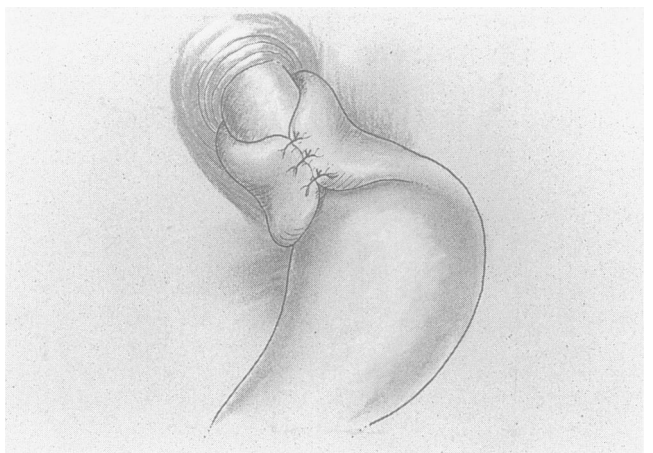


Figure 9. A loose wrap, 2 cm in length, was created with three or more 0-Dacron sutures.

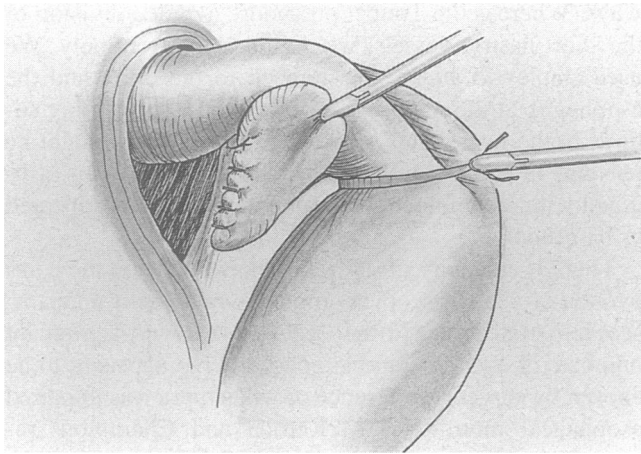


Figure 10. The posterior aspect of the wrap was sewn to the left crus as high as a stitch could be taken readily. Staples then were placed between the stomach wrap and left crus.

and a suture was taken between the crus, the wrap and the esophagus on the left side of the hiatus at approximately the 2 o'clock position (Fig. 12). A row of staples then was placed from the suture on either side of the esophagus down to the junction of the esophagus into the fundus, first on the right side of the esophagus and then on the left side (Fig. 13). Again, 300 to 500 mL dilute methylene blue was instilled within the stomach to check for leakage.

No tubes were left in the esophagus after operation. Patients were offered clear liquids the night after the operation or the next morning depending on their desire for oral intake. The diet usually was advanced to full liquids or regular diet on the second day. Patients were discharged when comfortable swallowing and voiding.

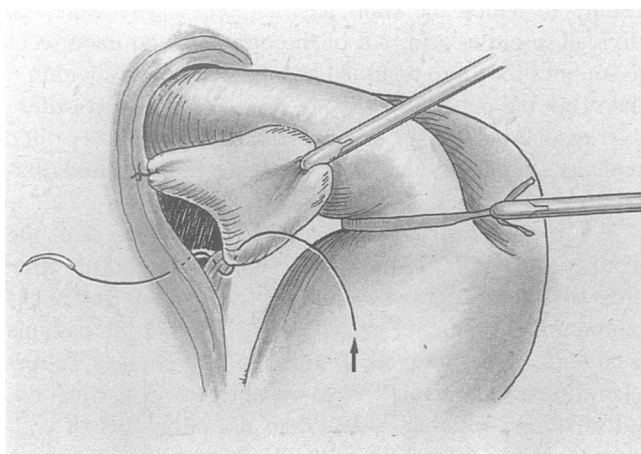


Figure 11. A second stitch was taken including the esophagus, the wrap, and the right diaphragm at the 10 o'clock position. A third stitch was taken between the posterior aspect of the wrap and both crura as they came together. Staples then were placed attaching the wrap and the right crus between the two stitches.

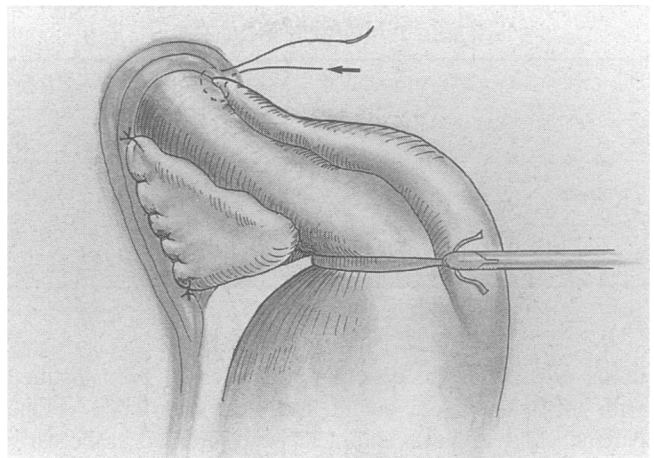


Figure 12. A fourth stitch was taken at the 2 o'clock position between the left diaphragmatic crus, the upper aspect of the wrap, and the esophagus.

RESULTS

The operating time averaged 155 minutes for the Nissen procedures and 162 minutes for the Toupet procedures. Post-operative stay after the Nissen repair was 2.7 days and 2.5 for the Toupet repair. There were no deaths. Three serious operative complications occurred. During dissection, the fundus of one patient was lacerated, so the operation was completed by open laparotomy. For this reason, this patient was not randomized. A subphrenic abscess developed in another patient who received a Toupet repair. We think this resulted from excess hematoma left adjacent to the spleen because of difficulty with division of the short gastric vessels. In a third patient, a delayed esophageal leak after a Toupet procedure developed, which necessitated open drainage, and the fistula subsequently closed. At the time of his

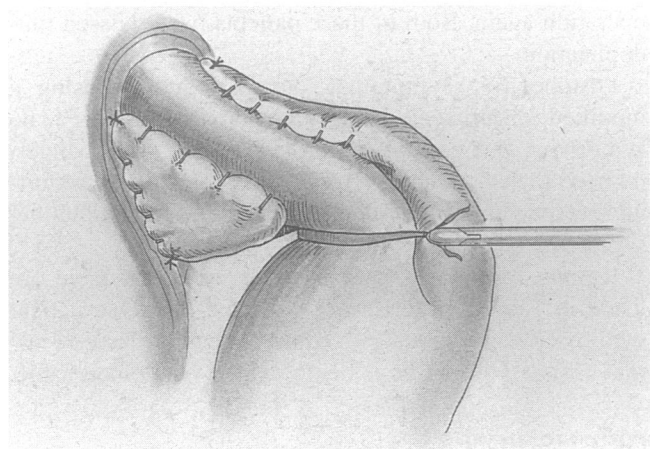


Figure 13. Staples were placed attaching the wrap from the esophageal stitches downward to where the esophagus joins the stomach, first on the right side of the esophagus and then on the left side.

Table 1. VISICK SCORES

	Visick Score		
	I	II	III
Complete	13	8	2
Partial	12	3	0
Total	25	11	2

initial procedure, the patient's stomach had been instilled with methylene blue, but no leak had been shown. One patient who had had a complete wrap returned in the early postoperative period with gastric dilation, which was relieved by a nasogastric tube.

Of 17 patients who had preoperative dilatations, 9 received a complete wrap and 8 received a partial wrap. Two patients with a complete wrap required a total of three dilatations, and one patient with a partial wrap required a single dilatation after operation. No patient had significant dysphagia at last follow-up.

Average follow-up was 27.2 months. All patients were seen by the surgeon and by a masked independent observer who queried for postoperative symptomatology and sequelae. Thirty-eight people were contacted by phone immediately before this meeting. At follow-up, all patients were asked the following questions:

1. Can you swallow?
2. Can you belch?
3. Do you have chest pain?
4. Do you have constipation or diarrhea?
5. Do you have reflux or heartburn?
6. What medications are you currently taking?
7. Would you have the operation again?

Only 2 of 38 patients said they would not have the operation again. Both of these patients had a Nissen fundoplication.

Postoperative symptomatology was judged using a modified Visick scale using the following grades: I, no symptoms; II, minimal symptoms, no lifestyle changes, no need to see a doctor; III, significant symptoms requiring lifestyle changes of doctor's help; and V, debilitating symptoms or reoperation.

Results for the 38 patients who were evaluable are listed in Table 1. There were no grade IVs. One patient who received a Nissen procedure appears to have recurrent esophagitis and he is being treated with omeprazole.

DISCUSSION

Our partial wrap operation differed from that of Toupet's in two significant and potentially consequential

ways. Whereas the Toupet procedure avoided division of the short gastric vessels, we divided them routinely. We used staples to attach the stomach to the crura and the esophagus in the manner of McKernan³ after placing sutures in the four points where we thought there might be tension. In this group of patients, the partial wrap fashioned with a combination of sutures and staples appeared to be effective.

There is a paucity of information available on the comparison of a laparoscopic complete wrap *versus* a laparoscopic partial wrap. In the largest series with significant numbers of each operation, a partial wrap appeared to be chosen by surgeon preference or when there was impaired esophageal motility.⁴⁻⁶ McKernan and Champion⁶ reported 230 Toupet procedures and 37 Nissen procedures with 89% excellent results after the Toupet procedures and 79% after the Nissen procedures.

Hunter et al.⁷ studied postoperative dysphagia in 184 consecutive patients who had received 1 of 3 procedures, the Nissen, the Rosetti-Nissen (without short gastric division), and the Toupet (without short gastric division). The choice of operation was decided by the anatomy and surgeon preference. New onset moderate-to-severe dysphagia in the early postoperative period was present in 30 patients (54%) undergoing the Rosetti-Nissen procedure, 8 (17%) of those undergoing a Nissen procedure, and 13 (16%) of those undergoing a Toupet procedure. The dysphagia persisted after 3 months in 11% of the Rosetti-Nissen procedures but in only 2% of those who received a Nissen or a Toupet procedure, suggesting these two operations gave equivalent results. In two series where the comparison was direct, the Toupet procedure fared better than did the Nissen procedure.

McKernan³ compared 14 patients undergoing a stapled Toupet procedure to 14 patients undergoing a Nissen procedure in which the short gastrics necessarily were not divided in either arm. All of the patients who underwent a Toupet procedure resumed normal swallowing within 6 days, but the patients who underwent a Nissen procedure averaged 24 days for normal swallowing. Two of the patients who underwent a Nissen procedure required dilatation.

When the short gastric vessels were not divided, the Toupet procedure appeared to do better than did the Rosetti-Nissen procedure in a prospective trial by Bell et al.⁸ containing 11 patients in each arm. Three of the patients who underwent complete wrap were converted to Toupet operations with resolution of symptoms. Consequently, information available to date does not allow a clear conclusion of the superiority of either operation, but these studies suggest failure to take down the short gastric vessels may be a crucial factor. The partial wrap may be more tolerant of leaving these vessels intact.

The short gastrics were divided in all patients to evalu-

ate only one variable in this study: the difference of a partial wrap as opposed to a complete one. Our bias before this study had been that the short gastric vessels should be divided on a selective basis. Freeing the stomach from the spleen usually is not difficult, but takes approximately 20 minutes on the average. We think two major complications, namely laceration of the fundus and subphrenic abscess, probably occurred secondary to difficulty in freeing the spleen from the greater curvature. Therefore, this step is not completely innocuous. Even so, we now divide the short gastric vessels in every instance.

One group of experts carefully has excluded the posterior vagus nerve from the wrap on all cases.⁹ The authors routinely have included the vagus nerves within the encircling vessel loop, and therefore the wrap, to make injury of the posterior vagus nerve less likely during suturing of the crura. Peillon et al.¹⁰ prospectively randomized the vagi inside or outside the wrap in 42 patients undergoing a "partial Nissen" 270° fundoplication and found no difference. Ten of their patients did have postoperative delayed gastric emptying.

Most surgeons place an esophageal dilator up to 60 French during the suturing of the wrap. We have found large dilators to be rather stiff to work around. Our standard "dilator" during the early part of the study was a 38-French Bougie simultaneously with an 18-Levine tube. Because of recurring difficulty in passing the tubes, we began using a 40-French Ewall tube. The Ewall tube passes more easily and allows irrigation of the stomach and lower esophagus without the passage of another tube. We think a delayed perforation in one patient was because of difficulty passing the Levine tube even though leakage of methylene blue was not evident at the time of operation. Ideally, we would like to have a 50-French Ewall tube if one were available.

Some postoperative reported problems were present in one third of our patients. This is not surprising. In a Veterans Administration multicenter, prospective, randomized trial of medical *versus* surgical therapy for reflux esophagitis, Spechler and colleagues¹¹ found within the first year that 81% of patients undergoing surgery had more than one postoperative reported problem. More important, 60% of the patients in each of the medical groups had more than one "surgical" symptom, even though they had had no operation. Surgery was judged to be superior to medical treatment in the study.

Conversely, two thirds of our patients had no untoward gastrointestinal symptomatology, which compares favorably to the public at large. Muller et al.¹² queried 561 volunteer blood donors about their gastrointestinal symptoms. They found potential blood donors to be 64.5% Visick I, 28.9% Visick II, and 6.4% Visick III even though they had had no gastric surgery. These studies emphasize the frequency of gastrointestinal reported problems in the general population.

Numerous reports show the effectiveness of a variety of current antireflux procedures when performed via the laparo-

scopic approach.^{4,5,9,13-15} Long-term follow-up of laparoscopic procedures is not yet possible, but recurrent symptoms appear to be uncommon.¹⁶ We think the laparoscopic procedures should be as lasting as those formerly done open.

We conclude the complete wrap (Nissen) and the partial wrap (Toupet) fashioned with a combination of sutures and staples are both effective for the treatment of recalcitrant reflux esophagitis with only a small difference in postoperative sequelae. Division of the short gastric vessels may be beneficial with a partial or complete wrap. The need for esophageal dilatation in these patients is reduced dramatically. The frequency of postoperative gastrointestinal symptoms in our patients reflects the status of the population at large.

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