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Prospective Double-Blind Randomized Trial of Laparoscopic Nissen Fundoplication With Division and Without Division of Short Gastric Vessels

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Objective
To determine whether division of the short gastric vessels (SGVs) and full mobilization of the gastric fundus is necessary to reduce the incidence of postoperative dysphagia and other adverse sequelae of laparoscopic Nissen fundoplication.

Summary Background Data
Based on historical and uncontrolled studies, division of the SGVs has been advocated during laparoscopic Nissen fundoplication to improve postoperative clinical outcomes. However, this modification has not been evaluated in a large prospective randomized trial.

Methods
One hundred two patients with proven gastroesophageal reflux disease presenting for laparoscopic Nissen fundoplication were prospectively randomized to undergo fundoplication with (52 patients) or without (50 patients) division of the SGVs. Patients with esophageal motility disorders, patients requiring a concurrent abdominal procedure, and patients who had undergone previous antireflux surgery were excluded. Patients were blinded to the postoperative status of their SGVs. Clinical assessment was performed by a blinded independent investigator who used multiple standardized clinical grading systems to assess dysphagia, heartburn, and patient satisfaction 1, 3, and 6 months after surgery. Objective measurement of lower esophageal sphincter pressure, esophageal emptying time, and distal esophageal acid exposure and radiologic assessment of postoperative anatomy were also performed.

Results
Operating time was increased by 40 minutes (median 65 *vs.* 105) by vessel division. Perioperative outcomes and complications, postoperative dysphagia, relief of heartburn, and overall satisfaction were not improved by dividing the SGVs. Lower esophageal

sphincter pressure, acid exposure, and esophageal emptying times were similar for the two groups.

Conclusion

Division of the SGVs during laparoscopic Nissen fundoplication did not improve any clinical or objective postoperative outcome.

Laparoscopic techniques are being applied widely to the treatment of gastroesophageal reflux disease, with reports describing the outcome of many large series now published.[1-3] Before laparoscopic surgery, the Nissen 360° fundoplication was the most commonly performed procedure, although a smaller number of surgeons advocated the routine use of a partial fundoplication to minimize the risk of postoperative difficulties.[4,5] Nevertheless, the Nissen procedure has been the most widely accepted and applied, achieving long-term success in approximately 90% of patients.[6,7] To reduce the risk of postoperative problems such as dysphagia, this procedure has been progressively modified during the last 20 years from that originally described by Nissen. Operative modifications advocated have included routine repair of the esophageal hiatus, shortening of the fundoplication's length, and division of the short gastric vessels (SGVs).[6,8,9] None of these modifications have been assessed in a prospective randomized trial.

With the advent of laparoscopic fundoplication, the finer details of surgical technique have become more controversial. Because the laparoscopic technique does not eliminate all complications and is still associated with a low incidence of poor longer-term outcomes, many surgeons have expressed concern that time-honored rules have been broken to facilitate the application of laparoscopic techniques.[2,10,11] Analysis of some initial series appears to confirm this: some published results have improved after altering laparoscopic techniques to avoid initial shortcuts.[11-13]

Arguably, the most controversial issue is whether the SGVs should be divided to minimize the likelihood of dysphagia.[6,10,13] Good results have been reported at both laparoscopic and open surgery with and without division of these vessels.[1,2,14,15] Many of the proponents of laparoscopic division of the SGVs did not divide these vessels while they were learning laparoscopic Nissen fundoplication; subsequently, they divided them and then compared their early and late experience.[11,13] Because of the inherent problem of a learning curve bias associated with such an analysis, the outcome in the latter group is usually better, leading to the conclusion that the SGVs should always be divided. Other surgeons, however, argue that they have achieved equally good results without dividing these vessels.[14,15]

To determine whether division of the SGVs and full mobilization of the gastric fundus is necessary to reduce the risk of postoperative dysphagia and other adverse sequelae, we undertook a prospective double-blind randomized trial of division *versus* no division of the SGVs during laparoscopic Nissen fundoplication.

METHODS

Participant Assignment

Patients undergoing laparoscopic Nissen fundoplication for gastroesophageal reflux disease were randomized to undergo fundoplication with or without division of the SGVs. Informed consent was obtained from all participants. Randomization was performed by opening one of 120 sealed opaque envelopes and occurred in the operating room after general anesthesia had been induced. A research officer not directly involved in the trial prepared the envelopes before the study; the envelopes were selected by a departmental secretary, at a surgeon's request.

Patient Selection and Preoperative Investigation

All patients with proven gastroesophageal reflux disease who presented for primary antireflux surgery by the laparoscopic technique were considered for entry into this trial. Patients were excluded from consideration only if they had an esophageal motility disorder that precluded a 360° fundoplication, required a concurrent abdominal procedure at the same time as fundoplication (*e.g.*, cholecystectomy), or had undergone previous antireflux surgery. All patients underwent preoperative investigation with esophageal manometry and endoscopy. Preoperative manometric testing also included an acid reflux provocation test and Bernstein test. Twenty-four-hour pH monitoring was performed routinely for patients who did not

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have unequivocal reflux disease demonstrated by preliminary endoscopic and manometric studies. Most patients also underwent preoperative barium meal X-ray examination.

Operating Technique

Laparoscopic Nissen fundoplication was performed using a previously described technique.[1,16] In brief, this consisted of dissection of the hiatal pillars followed by full esophageal mobilization and routine posterior hiatal repair. If the SGVs were to be divided, this was performed next. Vessels were dissected, secured by metal clips, and divided. Division usually commenced at the level of the inferior pole of the spleen and progressed superiorly along the greater curvature of the stomach until the left pillar of the hiatus was seen. Division of the SGVs was considered adequate if the superior part of the gastric fundus could be brought loosely around the esophagus for construction of the fundoplication.

If the SGVs were not divided, the anterior wall of the gastric fundus was pulled behind the esophagus for construction of the fundoplication. Occasionally, when the SGVs had not been divided, the first piece of fundus selected appeared tight. By repositioning instruments and grasping an adjacent piece of fundus, a much looser wrap could be constructed. Care was taken to ensure that the completed fundoplication was not tight by having a 52 Fr bougie within the abdominal esophagus. Three or four 2/0 Prolene interrupted sutures were used to secure the wrap, which was 1.5 to 2 cm long.

If the laparoscopic procedure was converted to an open procedure because of intraoperative difficulties, the SGVs were still divided or not divided according to the randomization schedule, with the patient remaining in the trial.

Postoperative Care

Nasogastric tubes were not used in any patients. Patients were allowed oral fluids on the evening of the day of surgery and soft solid food the next day. Discharge from the hospital was encouraged after the second postoperative day. Patients were instructed to avoid bread and lumpy foods for 3 to 4 weeks after surgery, and then to increase the consistency of their diet gradually. A barium meal examination was usually obtained on the second postoperative day to detect any problems amenable to early laparoscopic reintervention (*e.g.*, acute paraesophageal hernia, tight fundoplication, or hiatus).

Masking

Patients did not know whether their SGVs had been divided during laparoscopic fundoplication. Because they had no direct access to case notes or trial records, and both laparoscopic procedures used identical operative wounds, all remained unaware of the exact procedure for the duration of the trial follow-up period. Although operating surgeons were aware of the exact procedure performed, all follow-up was obtained by a scientific officer who was blinded to the randomization of each patient. Because he was not involved in the initial surgery, he remained unaware of the allocated group for each patient throughout the follow-up period. Participant data were entered into a computerized database by another research assistant who was not involved in direct patient follow-up. Final data analysis was performed independently by both the scientific officer and a surgeon investigator.

Table 1. DYSPHAGIA SCORE

1	Water
2	Milk (or thin soup)
3	Custard (or yoghurt or pureed fruit)
4	Jelly
5	Scrambled egg (or baked beans or mashed potato)
6	Baked fish (or steamed potato or cooked carrot)
7	Bread (or pastries)
8	Apple (or raw carrot)
9	Steak (or pork or lamb chop)

The presence of any dysphagia for each liquid or solid substance is first determined and scored; dysphagia always = 1 point, sometimes = 1/2 point, never = 0 points. A score from 0 (no dysphagia) to 45 (severe dysphagia) is then determined by multiplying the score for each substance by the adjacent line number, and then summing all nine lines.

Clinical Follow-Up

Patients were interviewed before surgery and then 1, 3, and 6 months after surgery by a scientific officer using a structured questionnaire. Although longer-term follow-up will be sought, it is unavailable for reporting in this paper. The presence or absence of each of the following symptoms was sought: heartburn, epigastric pain, regurgitation, dysphagia for lumpy solids, soft solids, and liquids, odynophagia, early satiety, inability to belch, epigastric bloating, anorexia, nausea, vomiting, nocturnal coughing, and wheezing. The ability to relieve bloating and whether a normal diet was being consumed were also determined.

Heartburn was scored using a visual analog scale (0 = no heartburn, 10 = severe heartburn). Dysphagia was scored by several methods. Visual analog scales (0 = no dysphagia, 10 = total dysphagia) were independently applied for solids and liquids, as well as a previously validated score[17] (0 = no dysphagia, 45 = severe dysphagia) that combines information about difficulty swallowing 9 types of liquids and solids (Table 1). This latter

Table 2. MODIFIED VISICK GRADING

1	No symptoms
2	Mild symptoms easily controlled by simple care such as avoiding certain foods or small meals, etc.
3	Moderate symptoms not controlled by simple care but not interfering with social or economic life
4	Moderate symptoms interfering with social or economic life
5	Symptoms as bad or worse than preoperatively

score was reversed from that originally described so that the numerical score increased with the severity of dysphagia. Overall outcome was determined using three further scales. Patients ranked the outcome of surgery using a modified Visick grading (Table 2) and were asked to score the outcome as excellent, good, fair, or poor (Table 3). An overall assessment of satisfaction with the operative outcome was scored by a further visual analog scale (0 = dissatisfied, 10 = satisfied).

Objective Follow-Up

Objective investigation with esophageal manometry, 24-hour pH monitoring, barium meal examination, and a radionuclide esophageal emptying study were performed 3 to 4 months after surgery. The investigation assessed lower esophageal sphincter function, control of reflux, postsurgical anatomy, and the presence of any postsurgical esophageal obstruction caused by a tight wrap or any other cause.

Esophageal Manometry

Patients fasted for 6 hours before each study, and all medications affecting esophageal motility were discontinued 3 days earlier if necessary. Esophageal manometry was performed using an eight-lumen water-perfused catheter incorporating a sleeve sensor (Dent Sleeve, Adelaide, Australia) with signals recorded on a polygraph chart recorder (Model 7D; Grass Instrument Company, Peabody, MA). The lower esophageal sphincter (or postfundoplication high-pressure zone) was located by the station pull-through technique, and the center of the sleeve was positioned at the central point of the lower esophageal sphincter. Each lumen of the catheter was connected in series with a pressure transducer (Stratham P231D; Gould, Oxnard, CA) and was constantly perfused with degassed distilled water at 0.5 mL/min by a low-compliance pneumohydraulic pump (Arndorfer Medical Specialities, Greendale, WI). The resting lower esophageal sphincter pressure was measured over a 5-minute period, followed by measurement of the amplitude and propagation of primary peristalsis and residual relaxation pressure of the lower esophageal sphincter during 10 swallows of 5-mL water boluses.

Table 3. OUTCOME ASSESSMENT

Excellent	Complete recovery
Good	Major improvement with minor problems
Fair	Major improvement with still significant problems or adverse effects
Poor	Minor or no improvement or deterioration

Ambulatory 24-Hour pH Monitoring

A glass pH probe (Radiometer, Copenhagen, Denmark) was positioned 5 cm above the lower esophageal sphincter measured by esophageal manometry and was connected to a Digitrapper (Synectics Medical, Stockholm, Sweden). The patient was encouraged to continue with normal activities for 24 hours. The results were analyzed for the percentage of time during which pH was <4 and for the correlation between reflux symptoms and measured reflux events.

Radionuclide Esophageal Emptying Study

This test measured esophageal emptying of three swallows of a solid meal of cooked ground beef containing 10 to 12 MBq of 99m-technetium sulfur colloid dispersed in egg white. Esophageal emptying was measured as the average time taken for 95% of each of three 10-g solid boluses to clear from the esophagus. The normal emptying time for this test is 7 to 93 seconds.

Barium Swallow Examination

Swallowed radiopaque barium contrast was used to image the distal esophagus, fundoplication, and stomach. Imaging determined any gross delay in esophageal emptying, the site of the fundoplication (abdominal *vs.* thoracic), the presence or absence of any paraesophageal herniation, and any abnormal distortion of gastric anatomy. Prone oblique views were obtained specifically to examine for paraesophageal herniation.

Statistical Analysis

The primary clinical outcomes the trial was designed to evaluate were postoperative dysphagia and control of reflux symptoms. Before the trial began, it was determined that 84 patients (42 per group) would be needed to demonstrate a 20% difference in these outcome measures, at a significance level of $p < 0.05$ and power of

Table 4. PREOPERATIVE PARAMETERS: MEAN (95% CONFIDENCE INTERVAL)

	Vessels Not Divided	Vessels Divided	Value
Number of patients	50	52	
Age (yr)	46.7 (42.7, 50.8)	45.3 (41.8, 48.8)	0.50
Sex	31M; 19F	31M; 21F	0.84
Height (cm)	170 (167, 173)	172 (169, 175)	0.39
Weight (kg)	83.5 (79.4, 87.5)	84.5 (80.0, 88.9)	0.74
Cigarette smoker (%)	20	12	0.38
Alcohol consumed (%)	67	66	1.00
Previous abdominal surgery (%)	38	40	0.84
Duration of symptoms (yr)	9.1 (6.7, 11.5)	8.2 (5.6, 10.8)	0.38
Preoperative medications (%)			
Omeprazole	68	66	0.83
H2 blocker	78	84	0.44
Cisapride	18	20	0.80

90%. To ensure that this was achieved, we decided to recruit 100 patients, allowing for an estimated 20% of all patients who would refuse the objective postoperative investigations. All analyses were performed on an intent-to-treat basis, with all patients remaining in their initial allocated group for this analysis.

Before the trial began, we decided to publish the initial outcomes and results of postoperative testing (this paper) after all patients had been followed for an initial 6-month period. This period was considered adequate to allow the assessment of any differences in the incidence of postoperative dysphagia between the two groups. Medium- to long-term outcomes are more important for determining the efficacy of reflux control and will be reported after follow-up has matured further.

All data was entered into a computerized database (Filemaker Pro version 2.0; Claris, Santa Clara, CA) and analyzed using a commercially available statistical package (InStat version 2.01; GraphPad Software, San Diego, CA). Fisher's exact test was used to determine the significance of 2×2 contingency tables. A two-tailed Mann-Whitney test was used to assess the significance of nonparametric data sets and an unpaired Student's t test to determine the significance of data sets where it was reasonable to assume a parametric distribution (height and weight). Statistical significance was accepted at $p < 0.05$. Unless otherwise stated, all data are reported as the percentage of the total patients in each group, or as the mean (95% confidence intervals [CI]).

Ethical Approval

The protocol for this study was approved by the Royal Adelaide Hospital Human Research Ethics Committee, and the study was conducted in accordance with the World Medical Association Declaration of Helsinki (revised 1989) and the National Health and Medical Research Council of Australia's guidelines on human experimentation.

RESULTS

From May 1994 to October 1995, 102 patients undergoing a laparoscopic 360° Nissen fundoplication were entered into the trial. Fifty patients were randomized to undergo fundoplication without SGV division and 52 to undergo division of these vessels. During the same period, 38 further patients underwent a laparoscopic Nissen fundoplication performed by surgeons contributing patients to this study. Three of these patients were excluded because of the need to perform a concurrent abdominal procedure (cholecystectomy in two, highly selective vagotomy in one). The remaining 35 patients refused entry into the trial because they had a preference for a specific procedure to be performed or were unwilling to participate in the follow-up protocol. Of the 102 patients entered, 98 (96%) were available for follow-up 1 month after surgery, 99 (97%) at 3 months, and 100 (98%) at 6 months. Although prospectively collected follow-up data were unavailable for a few patients at the specific follow-up intervals, no patient elected to withdraw from the study. Missing data were the result of an inability to contact patients at the specific follow-up intervals. Only 2 patients could not be contacted 6 months after surgery; 1 of them had decided to emigrate to Greece.

Preoperative Assessment

Both groups were similar in age, sex, height, weight, cigarette and alcohol consumption, incidence of previous abdominal surgery, duration of symptoms, and medications consumed before surgery (Table 4). Analysis of the

Table 5. SUMMARY OF PREOPERATIVE AND POSTOPERATIVE SYMPTOMS (%)

	Preoperative		1 mo After Operation		3 mo After Operation		6 mo After Operation	
	Not Divided	Divided	Not Divided	Divided	Not Divided	Divided	Not Divided	Divided
Heartburn	94	88	8	8	4	6	6	10
Epigastric pain	57	56	38	50	31	37	29	18
Regurgitation	90	88	29	26	19	14	14	6
Odynophagia	27	16	10	14	13	8	4	4
Early satiety	37	30	85	90	63	69	41	49
Epigastric bloat	59	44	50	50	33*	55*	35	41
Anorexia	4	6	21	16	8	6	8	2
Nausea	27	16	21	16	2	10	10	2
Vomiting	22	26	4	10	0	0	2	0
Nocturnal cough	39	40	15	14	8	14	12	6
Nocturnal wheeze	16	20	8	10	4	12	8	4
Can relieve bloat	79	79	52	50	63	59	65	57
Unable to belch	0	0	48	42	46	51	38	53
Eats normal diet	55	78	48	48	85	84	92	88

* There were no significant differences demonstrated between trial groups ($p > 0.05$ at all follow-up intervals), except epigastric bloat 3 months after operation ($p = 0.043$, Fisher's exact test).

presence or absence of preoperative symptoms (Table 5), as well as the assessment of heartburn using the visual analog scale (Table 6), revealed no significant differences. A significant proportion of patients in each group experienced preoperative dysphagia to some extent, with an incidence of 43% in the division group, and 52% in the non-division group, when assessed using the dysphagia score (Table 7). Although different methods of scoring dysphagia elicited slightly different rates, there was no clinically or statistically significant difference between the two groups. Preoperative Visick grading was also similar for each group (Table 8)

Endoscopic grading of esophagitis before surgery was similar, with 12 (24%) of the nondivision group and 10 (19%) of the division group having complicated reflux disease, demonstrated by either Barrett's esophagus or stricture formation ($p = 0.80$). A hiatus hernia was seen before surgery in 24 (48%) of the nondivision group *versus* 28 (54%) of the division group ($p = 0.67$). Barium meal examination was performed before surgery in 30 patients in the nondivision group and 32 in the division group. A hiatus hernia was demonstrated in 16 (53%) and 18 (56%) examinations, respectively.

Preoperative esophageal manometry outcomes (Table 9) were similar. No statistically significant differences were seen between the groups, although the mean resting lower esophageal sphincter resting pressure was lower in the nondivision group (6.3 *vs.* 8.3 mm Hg, $p = 0.08$).

Twenty-four-hour ambulatory pH monitoring was performed in 22 patients in the nondivision group and 24 in the division group. The mean percentage exposure to an acid pH <4 was 10.0% (6.4% to 13.7%) and 10.3% (6.1% to 14.5%), respectively ($p = 0.68$).

Surgery

Surgery was performed by one of seven surgeons. All patients randomized to the nondivision group had a loose fundoplication successfully fashioned without resorting to vessel division. One patient randomized to undergo

Table 6. ASSESSMENT OF HEARTBURN BY VISUAL ANALOGUE SCALE: MEAN (95% CONFIDENCE INTERVAL)

	Vessels Not Divided	Vessels Divided	p Value
Preoperative	4.8 (3.7, 5.8)	3.7 (2.8, 4.7)	0.18
1 mo after operation	0.21 (−0.10, 0.51)	0.20 (−0.01, 0.41)	0.88
3 mo after operation	0.11 (−0.11, 0.32)	0.47 (−0.06, 0.98)	0.63
6 mo after operation	0.33 (−0.03, 0.69)	0.48 (−0.04, 1.00)	0.75

Table 7. DYSPHAGIA ASSESSMENT: PERCENTAGE OF TOTAL OR MEAN (95% CONFIDENCE INTERVAL)

	Preoperative		1 mo After Operation		3 mo After Operation		6 mo After Operation	
	Not Divided	Divided	Not Divided	Divided	Not Divided	Divided	Not Divided	Divided
Dysphagia for								
Lumpy solids (%)	31	36	56	56	48	49	33	29
Soft solids (%)	4	8	17	16	8	13	2	2
Liquids (%)	6	2	15	18	13	10	6	16
Visual analogue scale								
Solids	1.7 (0.9, 2.5)	2.5 (1.5, 3.4)	3.4 (2.6, 4.2)	3.2 (2.4, 4.0)	2.2 (1.4, 3.0)	2.1 (1.3, 2.7)	1.4 (0.8, 2.0)	1.3 (0.7, 1.9)
Liquids	0.74 (0.1, 1.4)	0.78 (0.2, 1.3)	1.4 (0.6, 2.3)	0.9 (0.4, 1.4)	0.60 (0.06, 1.2)	0.61 (0.2, 1.1)	0.39 (−0.07, 0.9)	0.48 (0.1, 0.8)
Dysphagia score								
Overall result	9.5 (5.5, 13.6)	7.6 (4.5, 10.8)	14.5 (10.8, 18.2)	13.5 (10.2, 16.8)	8.3 (5.1, 11.5)	7.9 (5.2, 10.5)	4.8 (2.4, 7.2)	4.6 (2.3, 6.9)
Scored 0 only (%)	48	57	26	27	43	39	63	61

No tests for significance between groups at comparable follow-up intervals were significant ($p > 0.05$ at all follow-up intervals).

division did not have the SGVs divided because intraoperative anesthetic difficulties meant it was necessary to complete the procedure as rapidly as possible. This patient remained in the division group for subsequent analysis. One patient in the division group sustained an intraoperative perforation of the anterior gastric wall because of an injury from a grasping instrument. This was successfully repaired laparoscopically.

Three to eight SGVs (median, five) were divided between metal clips when required. There was some variation in the number of vessels clipped by different surgeons, with some using electrocautery and others clips for smaller vessels. Bleeding sufficient to impair visibility was encountered during SGV division in 3 patients (6%). This was overcome in all instances, with no need for conversion to open surgery. However, the laparoscopic procedure in 4 (8%) of the patients in the division group was converted to open surgery during esophageal dissection. The reasons for conversion were obesity and liver hypertrophy in two patients, large hiatus hernia in one patient, and the inability to manipulate an instrument safely behind the esophagus because of periesophagitis in one patient. All procedures in the nondivision group were successfully completed laparoscopically.

Table 8. OUTCOME, SATISFACTION, AND VISICK GRADING

	Preoperative		1 mo After Operation		3 mo After Operation		6 mo After Operation	
	Not Divided	Divided	Not Divided	Divided	Not Divided	Divided	Not Divided	Divided
Outcome (%)								
Excellent	NA	NA	17	14	23	19	29	25
Good	NA	NA	60	60	64	67	59	69
Fair	NA	NA	23	24	11	12	10	4
Poor	NA	NA	0	2	2	2	2	2
Visick grade (%)								
1	0	0	11	12	23	15	25	23
2	0	0	53	46	60	70	57	69
3	26	29	25	30	11	9	10	2
4	74	71	11	8	4	4	6	4
5	0	0	0	4	2	2	2	2
Satisfaction score								
Mean score	NA	NA	8.3	7.9	8.7	8.5	8.5	8.6
95% CI	NA	NA	7.6, 8.9	7.2, 8.6	8.2, 9.2	7.8, 9.1	7.8, 9.2	8.0, 9.2

NA = not applicable; CI = confidence interval.
No tests for significance between groups at comparable follow-up intervals were significant ($p > 0.05$ at all follow-up intervals).

Table 9. ESOPHAGEAL MANOMETRY RESULTS: % OF TOTAL OR MEAN (95% CONFIDENCE INTERVAL)

	Vessels Not Divided	Vessels Divided	p Value
Preoperative			
Number of propagated swallows*	9.1 (8.6, 9.6)	8.7 (7.9, 9.4)	0.92
Peristaltic amplitude	66.8 (55.3, 78.4)	62.8 (51.1, 74.5)	0.59
% patients with normal peristalsis	89	82	0.39
LES resting pressure (mm Hg)	6.3 (4.5, 8.1)	8.3 (6.2, 10.3)	0.08
LES nadir pressure (mm Hg)	0.52 (0.27, 0.78)	1.06 (0.46, 1.66)	0.46
Resting LOSP < 10 mm Hg (%)	79	66	0.18
Postoperative			
Number of propagated swallows*	7.8 (6.6, 9.1)	8.2 (7.1, 9.3)	0.44
Peristaltic amplitude	60.5 (45.2, 75.7)	79.8 (61.7, 97.9)	0.14
% patients with normal peristalsis	68	72	1.00
LES resting pressure (mm Hg)	24.5 (20.1, 28.9)	20.9 (17.1, 24.7)	0.23
LES nadir pressure (mm Hg)	13.3 (9.4, 17.3)	11.0 (8.4, 13.6)	0.46
Resting LOSP < 10 mm Hg (%)	0	10	0.25

LES = lower esophageal sphincter; LESP = lower esophageal sphincter pressure.
* Swallowing was assessed from 10 wet swallows.

Operating time varied from 35 to 170 minutes (mean 70.6, median 65, CI 63.0 to 78.1) when the vessels were not divided and 59 to 215 minutes (mean 107.9, median 105, CI 99.0 to 116.8; $p < 0.0001$) when the vessels were divided. The corresponding operating room times were 60 to 185 minutes (mean 95.2, median 91, CI 87.5 to 102.9) and 75 to 245 minutes (mean 132.7, median 135, CI 121.7 to 143.8; $p < 0.0001$). Operating surgeons were asked to rate the difficulty of the operative procedure using a scale from 1 to 10. Procedures in which the SGVs were divided (mean score 6.0, CI 5.5 to 6.6) were perceived to be more difficult than when the vessels were not divided (mean score 4.7, CI 4.1 to 5.4; $p = 0.0072$)

Early Hospital Outcomes

The periods between surgery and the commencement of oral fluids and solids and the length of postoperative hospital stay were unaltered by division of the SGVs (Table 10). The incidence of postoperative complications was also unaffected by vessel division (Table 11). Most of the complications were minor and did not affect later outcomes. However, two patients in the nondivision group required laparoscopic revision on the second and fourth postoperative days for acute postoperative paraesophageal herniation. In both instances, a hernia was discovered at a routine barium meal examination on the second postoperative day, facilitating early diagnosis and laparoscopic repair. Three patients in the division group also required surgical revision during the follow-up period. One patient with severe dysphagia underwent laparoscopic reexploration on the fifth postoperative day. The problem in this instance—tight closure of the diaphragmatic esophageal hiatus despite calibration of the closure with a 52 Fr bougie—was rectified by removing the top hiatal suture. The second patient underwent a laparotomy 6 hours after the initial procedure for bleeding caused by slippage of a clip previously placed across a divided SGV. The third patient had persistent severe postoperative dysphagia caused by fibrous stenosis of the esophageal hiatus. Twelve weeks

Table 10. EARLY HOSPITAL OUTCOMES: MEAN (95% CONFIDENCE INTERVAL)

	Vessels Not Divided	Vessels Divided	p Value
Postoperative stay (days)	3.75 (3.16, 4.34)	3.93 (3.35, 4.52)	0.56
Median	3	3	
Days to oral fluids	1.16 (0.80, 1.51)	1.37 (1.03, 1.71)	0.31
Median	1	1	
Days to solids	2.27 (1.82, 2.73)	2.50 (2.16, 2.84)	0.15
Median	2	2	

Table 11. THIRTY-DAY COMPLICATIONS

	Vessels Not Divided	Vessels Divided	p Value
Urinary retention	1	0	
Minor respiratory	0	2	
Ileus (>2 days)	3	2	
Paraesophageal hernia	2	0	
Bleeding short gastric vessel	0	1	
Tight hiatal repair	0	1	
In hospital fall	1	0	
Total number of patients	7 (14%)	6 (12%)	0.77

later, the hiatus was widened at open surgery, relieving the swallowing difficulty. One patient in the nondivision group and two in the division group also required early flexible esophagoscopy for disimpaction of a bolus food obstruction caused by inappropriate early consumption of large lumps of meat.

Patients undergoing division of the SGVs took an average 1.5 weeks longer to return to normal physical activity, possibly because of the conversion of 4 of the procedures to open operations (mean 4.6 weeks (3.4, 5.8) *vs.* 6.3 weeks (4.6, 7.9); p = 0.064).

One- to 6-Month Postoperative Clinical Outcome

A detailed analysis of the outcome of the blinded standardized clinical assessment is summarized in Tables 5, 6, 7, and 8. No differences between groups in the incidence of assessed symptoms were seen at any stage of the initial 6-month follow-up period, with the exception of a higher incidence of epigastric bloating 3 months after surgery in the division group (see Table 5). The ability of patients to relieve symptoms of bloat and their ability to belch were not altered by dividing the SGVs. The incidence and severity of heartburn, as assessed by the visual analog scale, were also identical (see Table 6). Outcomes were similar at all follow-up intervals when assessed by the visual analog satisfaction score, the outcome scale, and the modified Visick scale (see Table 8). Similarly, the incidence and severity of dysphagia assessed 1, 3, and 6 months after laparoscopic Nissen fundoplication were not altered by division of the SGVs (see Table 7). No trend toward improvement in the overall outcome after division of the SGVs could be demonstrated by careful analysis of the different symptom scores.

Objective Postoperative Investigations

Eighty patients (78%) underwent a postoperative esophageal emptying study, 66 (65%) a barium swallow examination, 56 (55%) esophageal manometry, and 46 (45%) postoperative 24-hour pH monitoring. The clinical outcomes in patients who underwent postoperative investigation were similar to the outcomes in the patients who declined investigation.

In the division group, barium swallow examination revealed a small asymptomatic paraesophageal hernia in 4 patients (12%) and delayed emptying of barium from the esophagus in 2 patients (6%). None of these appearances were evident in patients in the nondivision group, except in one patient with delayed esophageal emptying. In all but 1 patient in the nondivision group, the fundoplication lay completely within the abdominal cavity; in 7 patients (21%) in the division group, the wrap partly straddled the diaphragm. No fundoplications in either group migrated fully into the thoracic cavity. All fundoplications appeared to be constructed correctly using gastric fundus, irrespective of operative technique.

Esophageal manometry outcomes after surgery are summarized in Table 9. Esophageal body motility parameters were similar, but mean lower esophageal sphincter resting and nadir pressures were 3.6 and 2.3 mmHg higher, respectively, in the nondivision group; however, this difference failed to reach statistical significance. Twenty-four-hour pH monitoring demonstrated normalization of acid exposure times in all but three patients (one in the nondivision group and two in the division group). All these patients had minimally elevated acid exposure times, and none had any symptom of gastroesophageal reflux.

The mean esophageal emptying time, measured by the radionuclide method, was 109 seconds (86, 132) in the nondivision group and 127 seconds (103, 151; p = 0.26) in the division group. In the division group, 44% of patients had a normal emptying time, compared with 49% in the nondivision group (p = 0.82).

DISCUSSION

Although approximately 90% of patients who undergo a Nissen fundoplication using conventional open techniques achieve good long-term relief of reflux symptoms with no significant postoperative sequelae,[6,7] a few patients develop at least one adverse outcome.[1,6,7] The surgical literature contains many papers that discuss the issues of postfundoplication dysphagia, gas bloat, and recurrent gastroesophageal reflux.[7,18,19] Because of these potential problems, Nissen's original total fundoplication has been progressively modified by calibrating the wrap with a large intraesophageal bougie, shortening the fundoplication length from 5 to 1 to 2 cm, and gaining full mobilization of the gastric fundus by dividing the SGVs.[6,8]

Division of SGVs during open Nissen fundoplication has been advocated in reports from DeMeester et al.[6] and

Donahue et al.[8] It has been suggested that this maneuver reduces the incidence of postoperative dysphagia and enables greater relaxation of the lower esophageal sphincter region during swallowing. Although persuasively argued, scientific data establishing this have been lacking. For instance, Donohue et al.[8] studied an uncontrolled series of 77 patients followed for an average of 4.1 years, with objective manometric follow-up in only 19 (25%). DeMeester et al.[6] studied a nonrandomized series of 100 patients, of whom 36 underwent postoperative manometric assessment.[6]

All modifications to Nissen's original operation have been introduced and advocated without supporting evidence from any controlled clinical trials. This has led to divergent opinions about whether modifications such as SGV division really do reduce the incidence of postoperative dysphagia.[6,7,8,13–15] Assessment outside prospective controlled trials often results in the comparison of different groups of patients who undergo surgery by different surgeons at different stages in their experience. This introduces the possibility of unintentional bias and means that conclusions from such studies should be seen as hypotheses to be tested.

The technique used for Nissen fundoplication in our department has changed over time.[1,20] Initially, we performed an extensive mobilization of the gastric fundus at open surgery. However, this procedure was modified to a fundoplication performed without dividing the SGVs at open surgery. Our anecdotal impression was that after open surgery, the incidence of postoperative dysphagia was not increased by omitting SGV division. Consequently, when laparoscopic Nissen fundoplication was first performed in our department in 1991, the SGVs were not divided. Our initial impression was that the incidence of dysphagia may have been higher after the laparoscopic technique.[16] Because of this, we began to divide the SGVs during laparoscopic fundoplication. This was done before beginning this randomized trial, ensuring that the technique for SGV division was standardized and all learning difficulties were overcome.

Good clinical outcomes have been reported after total fundoplication, both with and without SGV division, using both open and laparoscopic techniques.[1,2,6–8,14,15] Rossetti and Hell,[7] in a report on the 20-year outcomes of 875 patients who underwent fundoplication without division of the SGVs, found that 87.5% had achieved a good or excellent outcome. At follow-up of 1 to 13 years (mean 45 months), DeMeester et al.[6] reported that 91% of patients who underwent SGV division achieved a good or excellent outcome.

Published outcomes of laparoscopic fundoplication are all short term. However, Anvari et al.[14] and Geagea[15] have described substantial experience with Nissen fundoplication without vessel division, reporting dysphagia rates of 5.4% and 0%, respectively. This compares with the initial experience of Hinder et al.,[2] who advocated routine division of the SGVs, in which 23% of 198 patients experienced dysphagia at early follow-up. Peters et al.,[21] who also routinely divide these vessels, reported a 9.4% incidence of dysphagia 3 months after surgery in their initial 34 patients undergoing laparoscopic Nissen fundoplication.

The difficulty encountered when comparing these studies is that different procedures are performed by different surgeons, who may be at different stages in their experience. These problems are compounded by the use of different patient selection criteria and variation in postoperative assessment methodology. Personal follow-up obtained by an operating surgeon may elicit outcomes different from those obtained independently by a nonsurgeon investigator. In our earlier experience,[1] as well as that of Anvari et al.[14] and Geagea,[15] nearly all patients were offered the laparoscopic approach, whereas Peters and DeMeester[10] have recently advocated a more selective approach, excluding patients with Barrett's esophagus and esophageal stricture from consideration. These selection differences are likely to affect the incidence of postoperative dysphagia.

The double-blind prospective randomized trial reported in this paper minimizes the risk of bias inherent in the nonrandomized studies and retrospective reviews published previously. A significantly higher rate of postoperative manometric and other objective investigations was achieved than in these nonrandomized studies.[6,8]

The current trial demonstrated no significant differences between the study groups. Although some minor differences in individual dysphagia scores are apparent, when all criteria used for dysphagia assessment are considered together, the overall results reveal no trend toward an improved outcome in either group, nor any significant difference in lower esophageal sphincter pressure, esophageal emptying time, or barium meal outcome. It might be argued that a trend of difference favoring division of the SGVs has been established between the groups in certain parameters measured at 6 months (*e.g.*, dysphagia for lumpy solids [33% in the non division group *vs.* 29% in the division group], lower esophageal sphincter pressure [24.5 in the non division group *vs.* 20.9 mm Hg in the division group], lower esophageal sphincter nadir pressure [13.3 in the non division group *vs.* 11.0 mm Hg in the division group]) and that these figures may have reached significance in a larger study. Nevertheless, the other dysphagia scores and patient satisfaction were clearly comparable between the two groups, and esophageal emptying was quicker in the nondivision group. If there is any difference, it is likely to be marginal. The overall outcome scores also were not influenced by division of the SGVs. In terms of minimizing the incidence

of postoperative dysphagia, the construction of a loose wrap is probably more important than whether the SGVs are divided.

Outcomes may vary between surgeons with different levels of expertise and experience; indeed, our experience with laparoscopic fundoplication without division of the SGVs may not reflect the experience of other surgeons, especially during their initial learning curve. To achieve an acceptable outcome, the fundoplication must be constructed loosely when not dividing the SGVs. Nevertheless, this study has demonstrated that a sufficiently loose fundoplication can be constructed, irrespective of the status of the SGVs.

The ability of patients to belch after surgery was not improved by dividing the SGVs. Although approximately 40% to 50% of patients claimed they could not belch 6 months after surgery, this apparently high incidence reflects the supercompetent valve produced by the Nissen fundoplication. Other work from our department suggests that effective belching is unlikely after the Nissen procedure.[22] Patients who claim they can belch usually report esophageal belching rather than true gastroesophageal reflux of gas.

Dividing the SGVs was associated with an increase of about 40 minutes in operating time, resulting in increased expense and technical difficulty. The one patient who required early reintervention for bleeding demonstrates the added potential for intraoperative and postoperative hemorrhage that follows division of these vessels.

After short-term clinical follow-up at 6 months and objective investigation 3 to 4 months after surgery, this trial has failed to show any reduction in the incidence or severity of dysphagia after division of the SGVs during laparoscopic Nissen fundoplication. Early correction of reflux symptoms was identical between the groups, but longer-term follow-up will be needed to assess the durability of each operation and the incidence of recurrent reflux. At present, we conclude that division of the SGVs during laparoscopic Nissen fundoplication is indicated only in the uncommon circumstance that a loose wrap of fundus cannot be constructed.

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