

Laparoscopic Nissen fundoplication – 200 consecutive cases

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Abstract

Patients—Laparoscopic Nissen fundoplication was undertaken in 200 patients between 1991 and 1994.

Methods—Pre-operative assessment included symptom score, endoscopy, manometry, and 24 hour pH monitoring of the oesophagus. Patients were evaluated at three and 12 months after surgery with symptom scoring and 96 patients also underwent 24 hour pH studies at three to six months postoperatively.

Results—In the first 100 patients median duration of operation was 155 minutes (range: 70–330), conversion rate to laparotomy was 7%, median hospital stay was three days (range: 2–57), and total morbidity was 16%. This compared with a median operation time of 120 minutes (60–240) ($p=0.0003$, 95% CI 10, 40), a conversion rate of 2% ($p=0.2$), a hospital stay of three days (1–18) ($p=0.0016$, 95% CI 0, 1), and total morbidity of 7% ($p=0.15$) in the second 100 patients. Median total symptom scores fell from 5/9 to 0/9 after fundoplication (<0.0001) while median 24 hour oesophageal acid exposure in 96 patients was reduced from 10% to 1% ($p<0.001$).

Conclusions—Laparoscopic Nissen fundoplication is a safe and effective procedure for gastro-oesophageal reflux disease. With experience, the duration of operation falls and the hospital stay is shorter. Short-term symptomatic and pH results are consistently improved by surgery.

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Keywords: laparoscopy, Nissen fundoplication, pH monitoring, gastro-oesophageal reflux.

The Nissen fundoplication is the most commonly used surgical procedure for correction of gastro-oesophageal reflux.¹ When a short 'floppy' wrap is constructed,² the operation provides longterm symptomatic relief in around 90% of patients^{1 3 4} with low morbidity rates (12–13%) and negligible mortality.^{1 5} The recently introduced laparoscopic approach to Nissen fundoplication offers the potential of reduced postoperative pain and hence a shorter stay in hospital and reduced convalescent times compared with the open approach. Current reports of laparoscopic fundoplication provide encouraging data, but few have presented detailed objective postoperative evaluation of outcome with symptom scoring and 24 hour pH studies of the oesophagus.^{6–9} We have undertaken a

series of 200 laparoscopic Nissen fundoplications using the same surgical principles as those applied to the open operation, and have objectively evaluated patients before and at three and 12 months after operation. The effects of experience with the procedure have been evaluated by comparing outcome after surgery for the first 100 with the second 100 patients. The results show that laparoscopic Nissen fundoplication is a safe and effective procedure for reflux control, and that certain perioperative variables improve with experience.

Methods

Two hundred patients have undergone laparoscopic Nissen fundoplication at the University of Queensland Department of Surgery between November 1991 and October 1994. The median age was 49 years (4–77), 136 were male, and the median weight of the adult patients was 80 kg (50–145). Eight patients were under 10 years of age. The main criterion for operation was symptomatic gastro-oesophageal reflux with either persistent symptoms despite adequate and prolonged medical treatment, or complicated reflux disease (stricture, Barrett's oesophagus). Some patients whose symptoms were controlled by medical treatment elected to undergo laparoscopic fundoplication rather than maintain longterm medical treatment. Operation was precluded by symptomatic coronary artery disease. In those with physical infirmity or comorbid conditions presenting the potential for increased perioperative mortality, the decision to operate was made on the severity of resistant reflux symptoms, especially the severity of respiratory complications from gastro-oesophageal reflux. No patient was excluded on the grounds of obesity, or previous abdominal surgery, including operations in the upper abdomen such as vagotomy. All patients who were submitted to operation had confirmed gastro-oesophageal reflux disease as defined by either Savary/Miller grade II or worse endoscopic oesophagitis, or abnormal acid reflux shown by 24 hour pH monitoring (defined by $>4.2\%$ total acid exposure time over 24 hours, or $>50\%$ symptom correlation with reflux events if total acid exposure was $<4.2\%$).

For the purpose of objective evaluation, patients were investigated preoperatively with the DeMeester symptom score,¹⁰ where a score of 0–3 was allocated each for heartburn, regurgitation, and dysphagia (Table I). Endoscopy and grading of oesophagitis using a Savary-Miller scale was undertaken,¹¹ and patients underwent standard oesophageal

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TABLE I Modified symptom scoring based on DeMeester scores for heartburn, regurgitation, and dysphagia¹⁰

Symptom	Description	Score
Heartburn	None	0
	Occasional brief episodes; controlled by antacids	1
	Frequent episodes (>2/week); moderate discomfort; requires H ₂ receptor antagonists	2
	Daily pain; nocturnal attacks interfering with sleep; interference with work, social activities	3
Regurgitation	None	0
	Occasional episodes, mostly postprandial and not predictable	1
	Frequent episodes (>2/week); predictable by posture	2
	Daily episodes interfering with work/social activity; nocturnal episodes; aspiration	3
Dysphagia	None	0
	Occasional transient sensation of food sticking	1
	Episodes of dysphagia requiring liquids to clear	2
	Progressive dysphagia for solids requiring medical attention; need for dilatation; bolus obstruction requiring hospital admission	3
	Total	9

motility studies and 24 hour ambulatory intraoesophageal pH monitoring (Digitrapper mk3, Synectics Medical, Sweden). A group of 25 subjects with no history of gastrointestinal disease has previously undergone 24 hour pH monitoring and was used to define normal limits.¹²

Postoperatively, 112 of 200 patients (56%) agreed to undergo re-evaluation by symptom score and 96 (48%) by 24 hour oesophageal pH monitoring at three to six months, and a further independent symptom score was obtained at one year in 170 patients. Patients with symptoms potentially related to recurrent gastro-oesophageal reflux were evaluated additionally by endoscopy and barium swallow radiography.

Operative technique

The operation was carried out through five abdominal ports placed along a subcostal arc, and a 30° laparoscope was placed through the left subcostal port. After mobilisation of the cardia and lower oesophagus with preservation of the vagus nerves, short gastric vessels were clipped and divided when appropriate. Where a hiatus hernia was present, the stomach was reduced and the crura were approximated with several sutures posteriorly. For the second 100 patients in the series, on the basis of three episodes of wrap migration into the chest, all patients had their crura sutured snugly behind the oesophagus. A loose, 1–2 cm wrap was constructed (over a 48 FG intraoesophageal bougie) above the level of the hepatic branches of the vagus nerve and was secured with

TABLE II Summary of patients' symptoms preoperatively and at three and 12 months after surgery. A total of 192 patients were studied before surgery, 112 at three months, and 170 at one year after fundoplication

	0	1	2	3	Total
Heartburn (%)					
Before operation	6 (3)	6 (3)	38 (20)	142 (74)	192
3 Months	101 (90)	9 (8)	2 (2)	0	112
1 Year	130 (76)	29 (17)	3 (2)	8 (5)	170
Regurgitation (%)					
Before operation	25 (13)	44 (23)	63 (33)	60 (31)	192
3 Months	105 (94)	6 (5)	0	1 (1)	112
1 Year	143 (84)	20 (12)	7 (4)	0	170
Dysphagia (%)					
Before operation	88 (46)	69 (36)	25 (13)	10 (5)	192
3 Months	93 (83)	15 (13)	4 (4)	0	112
1 Year	107 (63)	46 (27)	16 (9)	1*	170

*Patient with grade 3 dysphagia as a result of pharyngeal carcinoma.

sutures incorporating the fundus, phreno-oesophageal ligament, and oesophagus. A nasogastric tube was used to decompress the stomach intraoperatively, but was withdrawn at the end of the procedure.

Patients were mobilised on the first post-operative day and started a fluid diet. On day 2, after a normal breakfast, patients were usually discharged if well.

Statistical evaluation

Operation times, hospital stay, and morbidity rates were compared using the Wilcoxon rank sum test. Comparative data from individual patients (symptom score, pH studies) were analysed using the Wilcoxon signed rank test.

Results

Preoperative studies

Endoscopically, 38% of patients had Savary-Miller grade 0–I, 30% grade II, 26% grade III oesophagitis, and 6% had strictures. Eight patients had Barrett's oesophagus. One hundred and thirty four patients had preoperative manometric assessment of the oesophagus; all but 26 had either reduced or an undetectable lower oesophageal sphincter pressure, and 16 (12%) had reduced oesophageal peristalsis defined by 80% or more of contractions being less than 20 mm Hg in pressure.

Preoperative symptom scoring and 24 hour intraoesophageal pH monitoring was undertaken in 192 (96%) and 157 (79%) of patients respectively. Most patients had heartburn as their predominant symptom, although in over half of them regurgitation remained a serious or disabling problem despite full medical treatment (Table II). More than half of the patients complained of at least intermittent (non-obstructive) dysphagia. Median scores for heartburn (3/3), regurgitation (2/3) and dysphagia (0/3) gave a total median score of 5/9 (range: 1–9). Twenty four hour pH studies showed a median of 53 (range: 6–643) reflux episodes (normal 10; 1–21), and a median acid exposure time of 10% (2.2–49) (normal 1.7%; 0.1–6.1).

Operative details

Median duration of operation was 140 minutes (60–330). Short gastric vessels were divided in 75% of cases, and nine procedures (5%) were converted to open operation. The reasons for conversion were: bleeding short gastric vessels (n=3), splenic injury (n=2), colonic injury (previous surgery) (n=1), and equipment failure (n=3). No patient required splenectomy as a result of intraoperative injury. Previous abdominal operation did not preclude surgery by the laparoscopic route, and no patient required conversion to open operation as a result of peritoneal adhesions. Median post-operative stay was three days (1–57).

Morbidity

Sixteen patients (8%) suffered early (30 day)

TABLE III A list of morbidity incurred in 200 patients undergoing laparoscopic Nissen fundoplication

Early (<30 days)	8%	Late (>30 days)	4%
Total dysphagia – conversion to 270° wrap	n=1	Dilatation	n=2
Wrap migration	n=2	Bolus obstruction	n=2
Bolus obstruction	n=4	Wrap migration	n=1
Respiratory failure	n=1	Recurrent reflux	n=1
Pneumothorax	n=2	Dysphagia (conversion)	n=1
Perforated oesophagus (bougie)	n=1		
Pneumonia	n=1		
Ulnar nerve paresis	n=1		
Mediastinitis	n=1		
Pulmonary embolus	n=1		
Atelectasis	n=1		
Total	16	Total	7

postoperative morbidity; there were no deaths (Table III). A case of total dysphagia was returned to the operating theatre at day 4 and a 360° wrap was converted to 270°. Wrap migration through the diaphragmatic hiatus causing severe lower retrosternal chest pain and oesophageal obstruction, experienced by one patient, was corrected at laparotomy. Another case of proximal wrap migration was corrected laparoscopically. Bolus obstruction causing complete dysphagia in patients was usually caused by ingestion of meat during the first week postoperatively (despite contrary dietary instructions) and either resolved spontaneously or required endoscopic intervention. An oesophageal perforation was caused during bougie insertion. This was repaired laparoscopically and the fundoplication was completed. In one patient, a perforation of the wrap occurred resulting in mediastinitis requiring laparotomy and mediastinal drainage four days postoperatively. Respiratory failure requiring a period of mechanical ventilation followed operation in a patient with cystic fibrosis. Intraoperative pneumothorax occurred on two occasions and was caused by perforation of the left pleura behind the diaphragmatic crus while encircling the oesophagus. These were manifested by an increase in ventilation pressure requirements during anaesthesia and treated by temporary insertion of an 18 G cannula into the thorax for the remainder of the operation. Formal intercostal catheter drainage was not required in either case. A pulmonary embolus occurred in one patient, requiring a period of anticoagulant treatment. Seven patients (3.5%) have suffered delayed morbidity (>30 days). Gastric obstruction after wrap migration into the lower mediastinum necessitated re-operation in one patient. Two additional patients experienced bolus obstruction; in each case the bolus passed into the stomach without intervention. One patient had persistent dysphagia for solids after 10 months, which did not respond to balloon dilatation. Laparoscopic conversion of a 360° wrap to 270° resolved the dysphagia. One patient with recurrent symptoms of heartburn and regurgitation had an acid exposure time of 21% of total study time on 24 hour oesophageal pH monitoring at three months postoperatively. At laparotomy, the wrap was found to be partially disrupted, and was reconstituted to 360° with correction of reflux at follow up. Two patients with benign oesophageal stricture preoperatively required

further dilatations after fundoplication before satisfactory swallowing was achieved.

Postoperative assessment

Three months – all adult patients (n=192) were invited to undergo both postoperative symptom scoring and 24 hour pH monitoring of the oesophagus after three months. One hundred and twelve patients agreed to these studies (Table II). Median symptom scores were reduced from 5/9 to 0/9 ($p<0.0001$) by three months postoperatively. Patients who complained of clinically significant heartburn or regurgitation (DeMeester score >1) were investigated by gastroscopy and barium swallow radiography in addition to 24 hour pH monitoring. Of these patients, one displayed objective evidence of recurrent acid gastro-oesophageal reflux (1%). After three months four patients had persistent, troublesome dysphagia where liquids were required to aid swallowing of meals. Ninety six patients attended postoperative evaluation with 24 hour pH monitoring. Median total number of reflux episodes was reduced from 53 (6–643) to seven (0–330) ($p<0.0001$). Prolonged reflux episodes (>5 min) were reduced from five (0–30) to 0 (0–18), and total acid exposure time fell from 10% (2–81) to 1% (0–21) postoperatively ($p<0.0001$).

Twelve months – one hundred and seventy patients have been followed up with independent symptom scoring at 12 months (Table II). Clinically significant heartburn or regurgitation (DeMeester score >1) was reported by 11 patients (7%). Repeat 24 hour pH monitoring studies showed acid exposure within normal limits (<4.2%) in 10 patients. In four patients postprandial episodes of heartburn were correlated with acid reflux, and in six there was no symptom correlation with acid exposure. Sixteen patients (9%) had episodic dysphagia that required fluid ingestion to clear the oesophagus. One patient had grade 3 dysphagia as a result of recurrent pharyngeal carcinoma previously treated with radiation therapy.

Effect of experience

The first 100 patients undergoing laparoscopic Nissen fundoplication (18 November 1991 to 15 September 1993) were compared with the second 100 patients in the series (16 September 1993 to 5 October 1994) (Table IV). Both length of hospital stay and duration of operation fell with experience. A trend toward a lower rate of conversion to open operation was apparent in the second half of the series (7 versus 2). Early morbidity rates remained constant, but similar to those reported for open surgery.^{1 5} Delayed morbidity has been absent in the second half of the series (9% versus 0% $p=0.02$).

Discussion

The results of this series show that laparoscopic Nissen fundoplication, using the same

TABLE IV Comparison of first and second hundred patients undergoing laparoscopic Nissen fundoplication. Comparisons between the two groups were made with the Mann-Whitney U test for non-parametric data

	18/11/91-15/9/93 (n=100)	16/9/93-5/10/94 (n=100)	p Value (95% CI)
Duration of operation (min)	155 (70-330)	120 (60-240)	0.0003 (10, 40)
Hospital stay (days)	3 (2-57)	3 (1-18)	0.0016 (0, 1)
Conversion	7 (7%)	2 (2%)	0.2
Weight (kg)	80 (50-145)	80 (60-115)	0.28
Morbidity (30 days)	8 (8%)	8 (8%)	>0.9
Morbidity (>30 days)	7 (7%)	0	0.02

surgical principles as those applied to the open operation, can be performed safely with a low morbidity rate and no mortality. The results also show that there is an initial learning experience, after which operative time and postoperative stay can be expected to fall.

Prospective evaluation of the symptomatic status of patients using objective scoring of the three most important symptoms of gastro-oesophageal reflux (heartburn, regurgitation, and dysphagia) has shown relief for most patients up to at least one year postoperatively. Likewise, a fall in acid exposure from 10% to 1% after surgery in those patients who were studied objectively shows the efficacy of the Nissen fundoplication, at least in the short-term. Collectively, the results compare favourably with those of several other recent reports of laparoscopic Nissen fundoplication.^{8 13 14}

Symptomatic evaluation three months after operation consistently showed better results for control of heartburn and regurgitation than were seen at 12 months. To find out if these results pointed to a deterioration in the efficacy of fundoplication with time, patients with DeMeester grade 2 or greater reflux symptoms were objectively evaluated. Of these 11 patients, only one had both symptomatic and pH confirmed recurrent (abnormal) gastro-oesophageal reflux. The acid exposure of this patient doubled to 21% after surgery. Severe retching in the postoperative period causing partial wrap disruption may have accounted for this recurrence, which was apparent within weeks of surgery. At open operation 10 months later, despite disruption, a 270° wrap was found to be maintained by perioesophageal adhesions. Four patients with good correlation between acid reflux on pH monitoring and reflux symptoms but with normal total oesophageal acid exposure represent a small group of patients with a particularly acid sensitive oesophagus. Although symptomatic acid reflux persisted in these patients, all had considerable improvement and were satisfied with the outcome. In the remainder of patients with persistent symptoms of 'heartburn' or 'regurgitation', or both, correlation with acid reflux could not be shown and presumably their symptoms originate from other sources. This finding underlines the necessity for objective assessment of postoperative symptoms before a diagnosis of 'recurrent' gastro-oesophageal reflux is made.

Although all patients were invited to undergo follow up, objective evaluation of postoperative oesophageal acid exposure was only possible in 96 patients (48%). Discomfort

as a result of naso-oesophageal intubation and the time required for pH testing were the most common reasons for non-attendance. Despite the incomplete nature of those data, it is probable that the results give a representative view of the effects of laparoscopic fundoplication on acid reflux, as those with troublesome postoperative symptoms were anxious to undergo evaluation.

Most patients evaluated postoperatively showed a small amount of asymptomatic acid gastro-oesophageal reflux by pH monitoring (median 1%), and this occurred generally in the postprandial period. This mimics the physiological reflux seen with gas venting ('belching') in normal controls and in our view constitutes a desirable outcome. Postoperative oesophageal acid exposure remained abnormal (>4.2%) however, in a further eight patients, but none complain of reflux symptoms. Persistent clinically significant postoperative dysphagia (DeMeester score >1) has been found in 10% of those studied at one year, a small improvement on the proportion with this complaint preoperatively (18%).

Symptomatic proximal wrap migration into the lower mediastinum requiring re-operation in 1-2% of patients seems to be confined to Nissen fundoplication undertaken by the laparoscopic route. Closure of the diaphragmatic hiatus, minimisation of proximal oesophageal dissection, use of 'crown sutures' to secure the wrap to the phreno-oesophageal ligament, and antiemetic prophylaxis have all been proposed as useful adjuncts in prevention of this complication. Distal wrap migration (the 'slipped Nissen') has not been seen in this series, and this may be a result of avoidance of dissection of the lesser curve of the stomach and construction of the wrap above the intact hepatic branches of the vagus nerve.

Fundoplication for gastro-oesophageal reflux has an almost unique place in upper gastrointestinal surgery because it provides a modification of function without resection or ablation. Gastro-oesophageal reflux disease has the special characteristics of being substantially non-life-threatening, is prevalent in a comparatively young age group, and for the most part is at least partially controlled by medical treatment. For these reasons surgical intervention must have low operative morbidity together with high and lasting efficacy. Open surgery for gastro-oesophageal reflux disease has carried all the potential complications associated with laparotomy in addition to a recovery time of up to six weeks.¹⁵ As the laparoscopic approach has reduced postoperative recovery times after cholecystectomy,^{16 17} it has the potential to confer similar benefits to those having fundoplication. The encouraging results of surgery for gastro-oesophageal reflux using the laparoscopic Nissen fundoplication warrant consideration of a randomised trial of medical treatment versus surgery for treatment of chronic gastro-oesophageal reflux in patients not adequately controlled with currently available treatment, with outcome incorporating quality of life assessment in addition to the methods used above.

Future planned follow up of these patients will determine the longterm efficacy of the laparoscopic Nissen fundoplication. We believe that careful patient selection by objective means and attention to operative detail is mandatory. The operation is technically demanding and requires advanced laparoscopic skills, but results can be expected to improve with experience.

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