

Randomized clinical trial of laparoscopic total (Nissen) versus posterior partial (Toupet) fundoplication for gastro-oesophageal reflux disease based on preoperative oesophageal manometry

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Background: Laparoscopic fundoplication is an accepted treatment for symptomatic gastro-oesophageal reflux disease. The aim of this study was to clarify whether total (Nissen) or partial (Toupet) fundoplication is preferable, and whether preoperative oesophageal manometry should be used to determine the degree of fundoplication performed.

Methods: Preoperative oesophageal manometry was used to stratify 127 patients with established gastro-oesophageal reflux disease into effective (75) and ineffective (52) oesophageal motility groups. Patients in each group were randomized to Nissen (64) or Toupet (63) fundoplication.

Results: No significant differences between the operative groups were seen in heartburn, regurgitation or other reflux-related symptoms up to 1 year after surgery. Dysphagia of any degree (27 versus 9 per cent; $P = 0.018$) and chest pain on eating (22 versus 5 per cent; $P = 0.018$) were more prevalent at 1 year in the Nissen group. There were no differences in postoperative symptoms between the effective and ineffective motility groups. Surgery failed in eight patients on postoperative pH criteria, three in the Nissen group and five in the Toupet group.

Conclusion: Any differences in the symptomatic outcome of laparoscopic Nissen and Toupet fundoplication appear minimal. There is no reason to tailor the degree of fundoplication to preoperative oesophageal manometry.

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Introduction

Laparoscopic fundoplication is an established treatment for symptomatic gastro-oesophageal reflux disease. It effectively controls heartburn and regurgitation, but can be associated with unwanted effects, principally postoperative dysphagia, postprandial fullness, inability to belch (gas bloat) or vomit and increased passage of flatus¹. The choice of surgical technique to provide optimal reflux control while minimizing side-effects remains controversial. Some authorities postulate that side-effects are reduced by forming a partial rather than a total fundal wrap². Some believe that preoperative oesophageal body motility may affect surgical outcome, advising patients with oesophageal dysmotility to undergo partial rather than complete

fundoplication in order to reduce the perceived likelihood of postoperative dysphagia³⁻⁵.

There have been comparisons of laparoscopic total and partial fundoplication, but few randomized studies. A study comparing laparoscopic Nissen and anterior 180° fundoplication in 107 patients found that the anterior hemifundoplication group experienced significantly less dysphagia for solid food, and were more likely to express satisfaction with the clinical outcome than the Nissen group⁶. A trial that randomized 39 patients to laparoscopic Nissen or Toupet fundoplication found no differences in postoperative dysphagia rates or Visick scores, although these numbers were too small to make meaningful comparisons⁷. Fibbe and colleagues⁸

carried out a randomized trial of laparoscopic Nissen *versus* Toupet fundoplication involving 200 patients. A separate randomization was performed between patients with normal preoperative oesophageal body motility and those with ineffective oesophageal motility, resulting in four groups of 50 patients each. Although primarily focusing on oesophageal motility findings before and after surgery, this study found that Nissen fundoplication caused a greater increase in swallowing difficulties in patients with normal preoperative motility, and a lesser improvement in dysphagic symptoms in patients with oesophageal dysmotility than Toupet fundoplication. Clinical follow-up in this trial was, however, reported only to 4 months. A more recent randomized trial involving 163 patients undergoing laparoscopic Nissen or anterior partial fundoplication found significantly less postoperative dysphagia in the anterior partial group 24 months after surgery, although with a higher incidence of recurrent reflux⁹.

The aim of the present study was to compare laparoscopic 360° (Nissen) fundoplication with laparoscopic 270° posterior partial (Toupet) fundoplication in a prospective randomized clinical trial, in patients separated into normal and ineffective oesophageal motility groups before surgery.

Methods

All patients aged between 18 and 80 years undergoing surgery for pH-proven symptomatic gastro-oesophageal reflux disease were eligible for inclusion. Exclusion criteria were a history of previous oesophagogastric surgery, the presence of a manometrically proven primary oesophageal motility disorder and pregnancy. Between October 1998 and July 2001, of 166 patients potentially eligible for laparoscopic fundoplication for symptomatic gastro-oesophageal reflux, 127 were randomized in the trial. All clinical and laboratory data were recorded in a prospective database. Details of individual assessments and their timing are indicated below. No changes were made to medical management in the time interval between preoperative investigations and surgery. The trial was approved by the local ethics committee.

Preoperative assessment

Endoscopic oesophagitis grade was scored using the classification of Savary and Miller¹⁰. Hiatal anatomy was recorded. Before initial oesophageal physiology tests, patient symptom information was obtained using a standardized questionnaire that included a DeMeester symptom score¹¹, details of duration of symptoms

and medication taken for reflux symptoms. Dysphagia was scored from 0 (no dysphagia) to 3 (severe, with frequent, troublesome dysphagia for solids and liquids). Heartburn and regurgitation were also each scored from 0 (no symptoms) to 3 (severe, with frequent, troublesome symptoms). Oesophageal physiology studies were performed as outpatient procedures following a 6-h fast. Manometry was performed using a three-channel solid-state manometry catheter (Gaeltec, Isle of Skye, UK) and traces were analysed according to Castell's criteria¹². In brief, 80 per cent of waves in response to wet swallows had to be of 30–180 mmHg in the two distal pressure sensors and to be propagated between these two sensors for oesophageal body motility to be classified as effective. If 30 per cent or more of waves were low in amplitude (less than 30 mmHg in at least one of the two distal sensors) or non-propagated, oesophageal body motility was classified as ineffective. Patients underwent 24-h pH monitoring by a single-use antimony pH catheter with an internal reference electrode (Zinetics™ 24; Medtronic, Salt Lake City, Utah, USA) and a portable digital data recorder (Flexilog™; Oakfield Instruments, Oxford, UK). The pH data were analysed using a commercial software program (Flexisoft™ II; Oakfield Instruments).

Randomization

Two groups were created for patients with effective and ineffective oesophageal body motility. After induction of general anaesthesia, patients were randomized from these stratified groups by the sealed envelope technique to undergo laparoscopic 360° fundoplication (Nissen group) or laparoscopic posterior 270° fundoplication (Toupet group).

Surgical technique

Laparoscopic Nissen fundoplication was performed by fashioning a floppy 360° wrap over a 56-Fr oesophageal bougie, with routine division of the short gastric vessels. A 2-cm wrap was created with three non-absorbable sutures, the proximal two of which included the anterior oesophageal wall. The completed wrap was anchored to the right pillar of the crus with a further non-absorbable suture. Laparoscopic Toupet fundoplication was performed by fashioning a posterior 270° wrap, again over a 56-Fr oesophageal bougie and with routine division of the short gastric vessels. Each limb of the wrap was sutured to the oesophagus using three non-absorbable sutures and to the respective pillar of the crus with a further suture. All patients had a posterior crural repair using non-absorbable sutures. A single surgeon performed all operations.

Postoperative assessment

Patients completed a structured symptom questionnaire at 6 weeks, 6 months and 1 year after surgery along with a modified Visick score ranging from 1 (excellent) to 4 (poor)¹³. All patients were asked to undergo postoperative oesophageal manometry and 24-h pH tests. In those who consented these were performed 6 months after surgery. All patients remained blinded to the surgical procedure performed until after the 1-year postoperative assessment.

Statistical analysis

Non-parametric data were compared using a two-tailed Mann–Whitney *U* test. An unpaired Student's *t* test was used for parametric data. Fisher's exact test or the χ^2 test was used to compare 2×2 contingency tables. Analyses were performed using SigmaStat® 2.03 (SPSS, Chicago, Illinois, USA). All analyses were performed on an intention-to-treat basis.

Results

Manometry showed that 75 patients had effective and 52 had ineffective oesophageal motility. After randomization, 64 patients had laparoscopic Nissen fundoplication and 63 had laparoscopic Toupet fundoplication. A total of 125 patients (98.4 per cent) were contactable for follow-up at 6 weeks, 121 (95.3 per cent) at 6 months and 117 (92.1 per cent) at 1 year after surgery (Fig. 1).

The treatment groups were well matched for age, sex, weight, preoperative duration of symptoms, indications for surgery, preoperative pH parameters and endoscopic findings. All patients were treated with proton-pump inhibitors before surgery, with similar proportions in each group taking them until surgery (Table 1). Preoperative symptoms of any degree were equally prevalent in the two groups (Table 2), although moderate dysphagia before surgery was significantly more common in the Nissen than the Toupet group (14 of 64 versus five of 63; $P = 0.010$). No patient had severe dysphagia before surgery. Symptom severity and preoperative findings were significantly different between patients with effective and ineffective oesophageal motility (Tables 3 and 4). Patients with ineffective oesophageal motility were older and had a significantly higher prevalence of severe regurgitation before surgery. They also had significantly greater overall acid exposure times and lower resting lower oesophageal sphincter (LOS) pressures. No other preoperative variable showed any significant difference between groups with effective and ineffective oesophageal motility (Tables 3 and 4).

All patients had the assigned procedure. There were no conversions to open surgery. Operating time was slightly longer in the Toupet group than in the Nissen group (median 89 versus 81 min; $P = 0.053$). Median hospital stay was the same in each group (2.0 days; $P = 0.687$). Major morbidity was seen in only one patient who suffered a fundal wrap perforation 4 days after a partial fundoplication, requiring open repair. There were no hospital deaths.

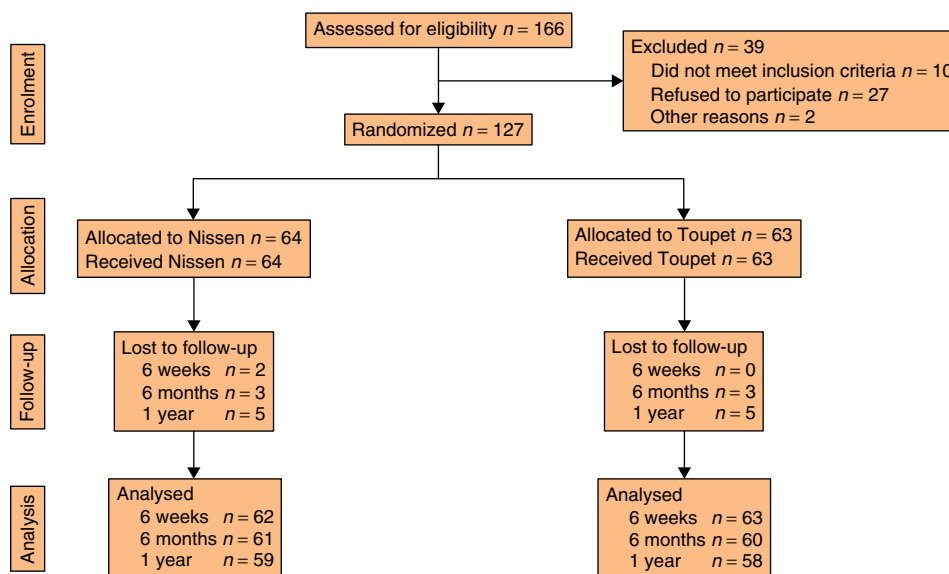


Fig. 1 Patient randomization, allocation and numbers analysed at follow-up

Table 1 Demographic data of 127 patients with gastro-oesophageal reflux disease

	Nissen (n = 64)	Toupet (n = 63)
Age (years)	45.3 (21–86)	44.2 (19–69)
Sex ratio (M:F)	41:23	43:20
Weight (kg)	81.6 (55–103)	80.2 (51–120)
Duration of symptoms (months)	94.5 (7–516)	95.6 (6–248)
Indication		
Failed medical therapy*	48 (75)	46 (73)
Patient preference*	16 (25)	17 (27)
PPI use*	59 (92)	57 (90)
Hiatus hernia*	39 (61)	32 (51)
Erosive oesophagitis*	10 (16)	10 (16)
Barrett's oesophagus*	3 (5)	6 (10)
Preoperative acid exposure time (% total)	6.9 (2.3–28.7)	6.3 (1.3–73.0)
Ineffective motility*	26 (41)	26 (41)
LOS pressure (mmHg)	9.9 (0–27)	10.0 (0–23)
LOS length (cm)	3.9 (2–6)	3.9 (2–5)

Values are mean (range) unless indicated otherwise; *values in parentheses are percentages. PPI, proton-pump inhibitor; LOS, lower oesophageal sphincter.

Symptoms

Heartburn, regurgitation and dysphagia improved significantly after surgery in all groups ($P < 0.001$ all values; *Table 2*). Postoperative symptom severity scores also improved significantly in all subgroups and at all times for heartburn, regurgitation, DeMeester symptom scores, epigastric pain and bloating ($P < 0.001$ all values).

There was no significant difference in the prevalence or severity of symptoms after surgery between the Nissen and Toupet groups except for a greater prevalence of dysphagia

Table 3 Demographic data of 127 patients divided into effective and ineffective oesophageal motility groups

	Effective motility (n = 75)	Ineffective motility (n = 52)
Age (years)	42.8 (19–86)	47.6 (21–69)†
Sex ratio (M:F)	48:27	36:16
Weight (kg)	80.7 (51–120)	81.2 (55–101)
Duration of symptoms (months)	99.5 (9–516)	88.6 (6–300)
Indication		
Failed medical therapy*	55 (73)	39 (75)
Patient preference*	20 (27)	13 (25)
Hiatus hernia*	39 (52)	32 (62)
Erosive oesophagitis*	10 (13)	10 (19)
Barrett's oesophagus*	4 (5)	5 (10)
Preoperative acid exposure time (% total)	6.0 (1.3–42.1)	7.6 (1.5–73.0)‡
LOS pressure (mmHg)	11 (0–27)	7 (0–25)§
LOS length (cm)	4.0 (2–5)	4.0 (2–6)

Values are mean (range) unless indicated otherwise; *values in parentheses are percentages. LOS, lower oesophageal sphincter.

† $P = 0.022$ versus effective motility (unpaired Student's *t* test);

‡ $P = 0.026$, § $P < 0.001$ versus effective motility (Mann–Whitney *U* test).

of any degree and chest pain on eating in the Nissen group 1 year after surgery (*Table 2*).

Similarly, there were no postoperative differences in the prevalence or severity of symptoms between the effective and ineffective motility groups, other than an increased severity score for flatus in the effective motility group 6 months after surgery (2 (interquartile range (i.q.r.) 1.5–2) versus 1 (i.q.r. 1–2); $P = 0.005$).

Overall, dysphagia was present in 52 patients (40.9 per cent) before surgery, rated as mild by 33 and moderate by 19. Of 117 patients followed to 1 year, 47

Table 2 Prevalence of symptoms (of any degree) before surgery, and at 6 months and 1 year after surgery

	Preoperative		6 months		1 year	
	Nissen (n = 64)	Toupet (n = 63)	Nissen (n = 61)	Toupet (n = 60)	Nissen (n = 59)	Toupet (n = 58)
Heartburn	60 (94)	60 (95)	17 (28)*	13 (22)*	14 (24)*	14 (24)*
Regurgitation	56 (87)	57 (90)	13 (21)*	8 (13)*	10 (17)*	7 (12)*
Dysphagia	30 (47)	22 (35)	21 (34)*	12 (20)*	16 (27)*	5 (9)*†
Chest pain on eating	14 (22)	16 (25)	17 (28)	14 (23)	13 (22)	3 (5)†
Epigastric pain	45 (70)	45 (71)	26 (43)*	24 (40)*	15 (25)*	18 (31)*
Bloating	46 (72)	38 (60)	17 (28)*	10 (17)*	11 (19)*	6 (10)*
Postprandial fullness			54 (89)	47 (78)	37 (63)	37 (64)
Restriction in belching			33 (54)	25 (42)	26 (44)	21 (36)
Unable to belch			8 (13)	3 (5)	8 (14)	3 (5)
Increased flatus			55 (90)	48 (80)	44 (75)	39 (67)
Diarrhoea			9 (15)	7 (12)	4 (7)	6 (10)
Abdominal pain			11 (18)	17 (28)	13 (22)	15 (26)

Values in parentheses are percentages. * $P < 0.001$ versus preoperative values; † $P = 0.018$ versus Nissen (Fisher's exact test).

Table 4 Preoperative symptoms in effective and ineffective oesophageal motility groups

	Effective (n = 75)				Ineffective (n = 52)			
	Total	Mild	Moderate	Severe	Total	Mild	Moderate	Severe
Heartburn	71 (95)	5 (7)	16 (21)	50 (67)	50 (96)	3 (6)	9 (17)	38 (73)
Regurgitation	65 (87)	17 (23)	29 (39)	19 (25)	49 (94)	5 (10)	19 (37)	25 (48)*
Dysphagia	30 (40)	17 (23)	13 (17)	0 (0)	22 (42)	16 (31)	6 (12)	0 (0)

Values in parentheses are percentages. * $P = 0.014$ versus effective motility (χ^2 test).

(40.2 per cent) had no dysphagia before or after surgery, and in 38 (32.5 per cent) the surgery either improved or abolished preoperative dysphagia. Although new-onset dysphagia or a postoperative worsening of dysphagia occurred in a greater proportion of all patients having total compared with partial fundoplication (14 of 59 versus nine of 58; $P = 0.376$) and in the subgroup with effective motility (ten of 35 versus six of 34; $P = 0.430$), these differences were not significant.

There were no differences in the incidence of new-onset or worsened postoperative dysphagia between the effective and ineffective motility groups when viewed overall (16 of 69 versus seven of 48; $P = 0.360$) or in their operative subgroups. In particular, there were no significant differences in dysphagia rates between patients in the effective and ineffective motility subgroups who had total fundoplication (ten of 35 versus four of 24; $P = 0.361$). Three patients (two Nissen, one Toupet; 2.4 per cent overall) complained of severe postoperative dysphagia. All responded to a single endoscopic balloon dilatation, and there have been no reoperations for dysphagia.

Visick scores

Patient satisfaction with the outcome of surgery, expressed by Visick scores, was similar in the Nissen and Toupet groups, with 92 and 91 per cent of patients respectively reporting Visick grade 1 or 2 at 1 year after surgery. At 1 year there were no significant differences in scores between effective and ineffective motility groups (91 versus 92 per cent Visick grades 1 and 2).

Manometry

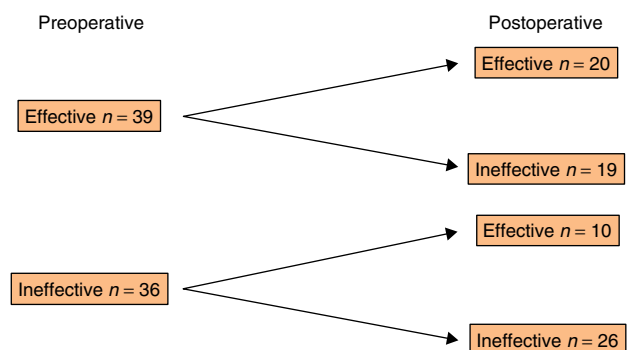
Seventy-five patients (59.1 per cent) had postoperative oesophageal manometry studies. Preoperative manometric characteristics were similar between the Nissen and Toupet groups (Table 1). Postoperative LOS pressure characteristics were not significantly different from those before surgery in any group (Nissen 12.3 versus 9.9 mmHg; Toupet 10.5 versus 10.0 mmHg; effective motility 12.1

versus 11.0 mmHg), except the ineffective motility group in which the postoperative LOS pressure was significantly higher (10.5 versus 7.0 mmHg; $P < 0.001$).

Fig. 2 shows the changes in oesophageal body motility after surgery. There was no clear pattern of transition from normal preoperative motility to ineffective postoperative motility, or the other way around.

pH studies

Seventy-six patients (59.8 per cent) had postoperative pH studies. All groups showed significant postoperative improvements in overall acid exposure times. Overall acid exposure times were lower in the Nissen than in the Toupet group (median 0.1 versus 0.4 per cent; $P = 0.036$), although the median value was well within normal parameters in both. There were eight surgical failures on pH criteria, three in the Nissen group (one with effective and two with ineffective motility before surgery) and five in the Toupet group (two with effective and three with ineffective motility before operation). Of these eight failures, three had normal overall acid exposure times but abnormal nocturnal times. Acid exposure times were reduced after surgery in six of the eight patients, but did not reach normality. There was no clear relationship between an abnormal postoperative pH study and symptoms; only two patients experienced significant symptoms requiring redo fundoplication.

**Fig. 2** Changes in oesophageal body manometric characteristics with surgery

Discussion

This study found no significant differences in reflux-related symptoms up to 1 year after surgery between treatment groups, although dysphagia of any degree and chest pain on eating were more prevalent at 1 year in the Nissen group. Similarly, there were no significant differences in postoperative symptoms between the effective and ineffective oesophageal motility groups, other than an increased severity score for flatus in the effective motility group 6 months after surgery.

The present study is only the second reported two-way randomization between differing fundoplication techniques and differing degrees of oesophageal body motility, and had a longer clinical follow-up than the trial reported by Fibbe and colleagues⁸ (12 *versus* 4 months), although with broadly similar findings.

In spite of the groups being well matched and randomly allocated, dysphagia that was classified as moderate by the patient was significantly more common before surgery in patients having Nissen fundoplication. Bearing this in mind, the study demonstrated a higher prevalence of dysphagia 12 months after Nissen rather than Toupet fundoplication, although there was no significant difference in the prevalence of new-onset or worsened dysphagia after surgery. The presence of preoperative dysmotility does not seem to affect the risk of postoperative dysphagia. In fact, the overall prevalence of new or worsened dysphagia was lower in the ineffective motility group than in the effective motility group (15 *versus* 23 per cent). In addition, the clinical outcome of surgery as measured by modified Visick scores showed no differences between any of the four subgroups. This clearly goes against the expectations of those who would propose tailoring antireflux procedures to the results of preoperative oesophageal manometry tests^{3–5}, but is in agreement with an increasing body of evidence that suggests such a policy is unnecessary^{14–18}.

It is important to appreciate that dysphagia is not an entirely postsurgical phenomenon. The significant incidence of preoperative, non-obstructive dysphagia (40.9 per cent in the present study) is often overlooked by those assessing the results of antireflux surgery, as is the fact that many more patients are rendered symptom free or have their symptoms improved than develop new-onset or worsened dysphagia after surgery.

The present study provides no clear conclusions regarding the efficacy and durability of Nissen compared with Toupet fundoplication in controlling the reflux symptoms of heartburn and regurgitation. Although there were greater postoperative acid exposure times and more pH failures in the Toupet group, not all patients had postoperative pH studies, and in those who did there was a

poor correlation between symptoms and pH parameters. A number of reports have suggested a higher recurrent reflux rate with a partial fundoplication^{9,19,20}. It may be relevant that two of the three pH failures in the Nissen group had normal overall acid exposure times and only their nocturnal acid exposure was greater than normal, compared with only one of the five pH failures in the Toupet group.

Tailoring the surgical antireflux procedure to the results of preoperative oesophageal body motility studies cannot be supported and should be abandoned.

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