



University of Groningen

Randomized clinical trial of standard laparoscopic versus robot-assisted laparoscopic Nissen fundoplication for gastro-oesophageal reflux disease

Draaisma, W.A.; Ruurda, J.P.; Scheffer, R.C.H.; Simmermacher, R.K.J.; Gooszen, H.G.; Rijnhart-de Jong, H.G.; Buskens, E.; Broeders, I.A.M.J.

Published in: British Journal of Surgery

IMPORTANT NOTE: You are advised to consult the publisher's version (publisher's PDF) if you wish to cite from it. Please check the document version below.

Document Version
Publisher's PDF, also known as Version of record

Publication date: 2006

Link to publication in University of Groningen/UMCG research database

Citation for published version (APA):

Draaisma, W. A., Ruurda, J. P., Scheffer, R. C. H., Simmermacher, R. K. J., Gooszen, H. G., Rijnhart-de Jong, H. G., Buskens, E., & Broeders, I. A. M. J. (2006). Randomized clinical trial of standard laparoscopic versus robot-assisted laparoscopic Nissen fundoplication for gastro-oesophageal reflux disease. *British Journal of Surgery*, *93*(11), 1351-1359.

Copyright

Other than for strictly personal use, it is not permitted to download or to forward/distribute the text or part of it without the consent of the author(s) and/or copyright holder(s), unless the work is under an open content license (like Creative Commons).

The publication may also be distributed here under the terms of Article 25fa of the Dutch Copyright Act, indicated by the "Taverne" license. More information can be found on the University of Groningen website: https://www.rug.nl/library/open-access/self-archiving-pure/taverne-amendment.

Take-down policy

If you believe that this document breaches copyright please contact us providing details, and we will remove access to the work immediately and investigate your claim.

Downloaded from the University of Groningen/UMCG research database (Pure): http://www.rug.nl/research/portal. For technical reasons the number of authors shown on this cover page is limited to 10 maximum.

Randomized clinical trial of standard laparoscopic *versus* robot-assisted laparoscopic Nissen fundoplication for gastro-oesophageal reflux disease

W. A. Draaisma¹, J. P. Ruurda¹, R. C. H. Scheffer¹, R. K. J. Simmermacher¹, H. G. Gooszen¹, H. G. Rijnhart-de Jong¹, E. Buskens² and I. A. M. J. Broeders¹

Departments of ¹Surgery and ²Health Sciences and Primary Care, University Medical Centre Utrecht, Utrecht, The Netherlands *Correspondence to:* Dr I. A. M. J. Broeders, Department of Surgery, H.P. G04-228, University Medical Centre Utrecht, PO Box 85500, 3508 GA, Utrecht, The Netherlands (e-mail: i.broeders@umcutrecht.nl)

Background: Robotic systems for minimally invasive surgery may be of added value during extensive dissection and suturing in confined spaces, such as laparoscopic Nissen fundoplication (LNF). The purpose of this trial was to compare standard LNF with robot-assisted Nissen fundoplication (RNF). Methods: Between 2003 and 2005, 50 patients with confirmed refractory gastro-oesophageal reflux disease were assigned to LNF (25) or RNF (25). Patients who had undergone previous antireflux surgery were excluded. Independent assessment of dysphagia, regurgitation, heartburn and general well-being was performed before and 6 months after surgery using questionnaires. Objective outcome was studied 6 months after surgery by oesophageal manometry, 24-h pH monitoring, barium oesophagram series and upper endoscopy.

Results: Operating time, blood loss, postoperative pain scores, hospital stay and complication rates did not differ significantly between the two groups. Reoperation rates were the same (one incisional hernia after LNF and one patient with repeat Nissen after RNF because of persistent dysphagia). Postoperative self-rated change in reflux symptoms and quality of life improved equally in both groups. The reduction in oesophageal acid exposure, increase in lower oesophageal sphincter tone and mucosal healing were comparable in both groups at follow-up.

Conclusion: RNF yielded similar subjective and objective results to LNF in this study. Therefore no additive value of robotic systems for this procedure was detected up to 6 months after surgery.

Paper accepted 27 September 2006 Published online in Wiley InterScience (www.bjs.co.uk). **DOI:** 10.1002/bjs.5535

Introduction

Laparoscopic Nissen fundoplication is the standard surgical treatment for refractory gastro-oesophageal reflux disease (GORD)^{1,2}. Reported short- and mid-term results are excellent in 85 to 90 per cent of patients which is at least similar to the outcome of conventional surgery, while postoperative pain is reduced and convalescence is shortened³⁻⁶.

Despite substantial advances in minimally invasive techniques, surgeons are still challenged by the limitations of standard laparoscopy. These include the lack of

The Editors have satisfied themselves that all authors have contributed significantly to this publication

depth perception from two-dimensional imaging and rigid instruments with a limited range of motion that is counter-intuitive with poor ergonomics for the surgical team. Consequently, the laparoscopic construction of a reproducible, standardized 'floppy' fundoplication may be impaired, as well as the learning curve associated with this procedure, which amounts to 20 procedures for surgeons experienced in minimally invasive surgery⁷.

The use of robotic technology in laparoscopic procedures has been shown to be a safe and effective alternative to standard laparoscopic surgery, particularly when dealing with complex pathology^{8,9}. Although the objective of using robot assistance in laparoscopic surgery is to improve patient outcomes, studies comparing standard

with robot-assisted approaches are scarce. In addition to two small series, Morino *et al.*¹⁰ recently published their results of a randomized trial on robot-assisted *versus* laparoscopic Nissen fundoplication (LNF), which found no advantage for patients who had robot-assisted surgery. However, this is the only adequate randomized study in a representative percentage of patients.

The purpose of the present study was to compare standard LNF with the robot-assisted laparoscopic approach (RNF) on subjective, anatomical and functional parameters to elucidate the value of robotic systems in LNF.

Patients and methods

The study, which was approved by the local ethics committee, was conducted at the University Medical Centre Utrecht. Patients older than 18 years who were diagnosed with GORD at the Department of Gastroenterology or Surgery were eligible. Medical history, barium oesophagram series, upper endoscopy, oesophageal manometry and 24-h pH monitoring were assessed to diagnose GORD. Surgical treatment was proposed for patients with GORD insufficiently reacting

to proton pump inhibitors, persisting oesophagitis and/or pathological oesophageal acid exposure. Patients unwilling to take lifelong medication to suppress their symptoms of GORD were also candidates for surgery. Patients with general contraindications for laparoscopy or previous abdominal surgery were excluded, as well as those with psychiatric diseases. All patients included in this study gave written informed consent.

Treatment allocation

All patients who were evaluated for surgical treatment of GORD were considered for entry into the trial (Fig. 1). Eligible patients were randomly assigned to undergo either LNF or RNF. If the patient was eligible for laparoscopic antireflux surgery, the institution's Trial Data Centre was contacted for checking and completing preoperative work-up. Of 62 consecutive patients considered for entry into the trial, 12 were excluded: eight refused to participate, one needed a concurrent laparoscopic cholecystectomy and three had had previous abdominal surgery. Patients who needed conversion to open surgery were kept in their original group according to the intention-to-treat principle. This trial was performed in accordance with the

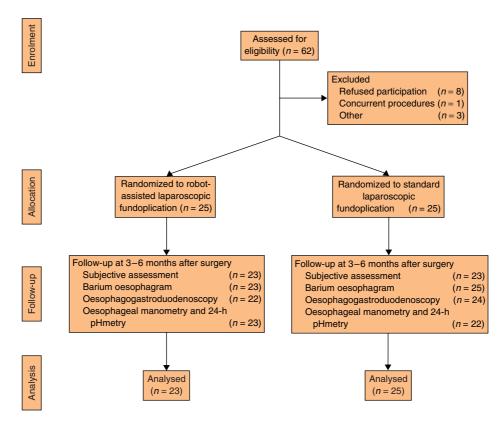


Fig. 1 Study flow diagram

World Medical Association declaration of Helsinki (revised 1989).

Preoperative work-up and postoperative evaluation

Clinical history was taken and a standardized questionnaire was filled out before, directly after and 6 months after surgery. Symptomatic outcome was determined using a general health questionnaire. The participant's global appraisal of general state of health was measured on a 10cm visual analogue scale. The change in quality of life was compared with baseline, measured on a four-point scale that ranged from 'resolved' to 'worsened' (Visick scale)¹¹. The self-rated change in reflux symptoms was compared with the preoperative state and satisfaction with overall outcome was determined.

Upper endoscopy, barium oesophagram series, oesophageal manometry and 24-h pH monitoring were performed before and 6 months after surgery. Barium oesophagram series were performed to determine the position of the gastro-oesophageal anatomy. During endoscopy, the presence of oesophagitis or diaphragmatic hernia was determined by experienced gastroenterologists. In all patients, the distance from the diaphragmatic oesophageal impression to the gastro-oesophageal junction (Z-line) was measured. Reflux oesophagitis was graded according the Los Angeles classification (*Table 1*) 12 .

Oesophageal manometry was performed using a waterperfused system with a multiple-lumen catheter with an incorporated sleeve sensor (Dentsleeve, Adelaide, Australia). The manometric response to ten standardized wet swallows (5-ml water bolus) was recorded, during which both mean end-expiratory pressure and residual pressure during relaxation (nadir pressure) of the lower oesophageal sphincter were determined.

Antisecretory drugs were suspended for at least 3 days before 24-h pH monitoring was performed. At analysis, the percentages of total time with oesophageal pH < 4 and time in supine and upright positions with pH < 4 were determined. In addition, the symptom index and symptom association probability were calculated according to the total number of symptom episodes^{13,14}. These symptom indices were considered to indicate pathological

Table 1 Los Angeles classification of oesophagitis 12

Grade	
A B C D	Mucosal break \leq 5 mm in length Mucosal break $>$ 5 mm Mucosal break continuous between $>$ 2 mucosal folds Mucosal break \geq 75% of oesophageal circumference

reflux-related symptoms if greater than 50 and 95 per cent respectively. Abnormal reflux was defined as the percentage of time with pH < 4 greater than 5.78 for total time, 8.15for upright time and 3.45 for supine time¹⁵.

Surgical technique

All procedures were carried out by surgeons who had performed more than 30 laparoscopic Nissen fundoplications and more than 20 robot-assisted laparoscopic procedures, therefore after having completed the learning curves for both techniques⁷. In both approaches the patient was placed in a French, reverse Trendelenburg position and a nasogastric tube was inserted. The entire procedure was standardized according to the study protocol and performed similarly in all patients. Pneumoperitoneum was established using an open access technique in all patients.

For the LNF group, a 12-mm and 5-mm right subcostal, a 5-mm left subcostal, a 5-mm epigastric and a 10-mm supraumbilical camera port was used. After retraction of the left liver lobe, the hiatus and distal oesophagus were dissected and an intra-abdominal segment of the oesophagus was obtained measuring 3 cm. A posterior crural repair was performed in all patients with nonabsorbable sutures. The proximal short gastric vessels were ligated to mobilize the gastric fundus completely using ultrasonic dissection (UltraCision®; Ethicon Endo-Surgery, Amersfoort, The Netherlands). A floppy 360° Nissen fundoplication of 2.5-3.5 cm was constructed with three non-absorbable stitches.

RNF was carried out identically to the standard technique with the support of the da VinciTM robotic system (Intuitive Surgical, Goleta, California, USA). The camera port and both 5-mm subcostal ports, however, were now reserved for the 12-mm robotic camera port and both 8-mm da VinciTM instrument ports respectively. The camera and robotic instruments were controlled by the surgeon from behind the console. A tableside assistant was responsible for changing instruments, retraction, suction and passing sutures into the abdomen. A second tableside assistant retracted the left liver lobe anteriorly. The surgeon was able to use an electrocautery hook, a grasper and a needle driver while using a 30° angled scope. All robot-assisted procedures were carried out with 2:1 motion scaling. The short gastric vessels were also ligated using a robotic ultrasonic device (SonoSurg TM; Olympus, Hamburg, Germany). Hiatoplasty and construction of the Nissen fundoplication did not differ from the standard approach. All midline incisions of the fascia were closed.

Patients were allowed a normal diet on the first postoperative day, after removal of the nasogastric tube.

In both groups, patients were encouraged to ambulate on the same or the next postoperative day. Patients were discharged when in acceptable condition and when oral intake was well tolerated.

Outcome measures

Demographic data, body mass index, hospital stay and operative data were prospectively recorded. Operative data included operating time, intraoperative complications and estimated blood loss, and length of fundoplication. Operating time was defined as the time from first skin incision to the final closure of the last skin incision. Early and late (more than 30 days) complications and reoperations were also recorded.

The primary endpoints of this study were the anatomical results of the procedure as determined by barium oesophagram series. The functional result was measured by oesophageal manometry and 24-h pHmetry. A secondary endpoint was quality of life, measured with disease-specific questionnaires and a survey on general state of health. All subjective and objective results were gathered before and 6 months after surgery.

Statistical analysis

The main objective of this study was to find strong arguments to justify the use of expensive technology in laparoscopic Nissen fundoplication. Therefore, a 35 per cent difference in objective outcome parameters with a probability of a Type 1 error $\alpha < 0.05$ and a power of 80 per cent was sought. For this, 20 patients were necessary in each branch. Anticipating the possibility of incomplete pH studies, a total of 50 patients were included.

Values are presented as median (range) for continuous variables. SPSS® version 12.0.1 (SPSS, Chicago, Illinois, USA) was used for all analyses. Non-parametric data were analysed using the two-tailed Mann–Whitney U test, and the Student's t test was used if data were normally distributed. The two groups were compared with the χ^2 test for nominal variables. Differences in proportions with 95 per cent confidence intervals (c.i.) are presented. For continuous variables, the absolute differences were calculated with 95 per cent c.i. P < 0.050 was considered significant.

Results

Baseline characteristics

Operations on participating patients took place between January 2003 and October 2005; *Table 2* shows their

Table 2 Baseline patient characteristics

	RNF (n = 25)	LNF (n = 25)	Р
Age (years)* Sex ratio (M:F)	48·0 (20-74) 16:9	52·0 (27–71) 17:8	0.978
Body mass index (kg/m ²)*	25.6 (19.1-37.2)	28.7 (19.5-46.6)	0.690
Preoperative antisecretory medication	25	25	0.709
Operation indication			
Insufficient response to medical treatment	22	23	0.623
Unwilling to take lifelong medication	3	2	0.683

^{*}Values are median (range). RNF, robot-assisted laparoscopic Nissen fundoplication; LNF, standard laparoscopic Nissen fundoplication.

baseline characteristics. The two groups were similar in age, sex ratio and median body mass index. *Table 3* shows the results of preoperative work-up. No important differences between the groups were identified. In the RNF group, 16 patients (64 per cent) had a concomitant sliding hiatal hernia with a median size of 3·0 (range 0–7) cm. This was seen in 15 patients (60 per cent) in the LNF group with a median size of 3·0 (range 0–7) cm. All patients had been using antisecretory drugs, either proton pump inhibitors and/or histamine-2 receptor antagonists, for at least 6 months before surgery.

Operative data and perioperative follow-up

The median operating time was 120 (range 80–180) min for the RNF group and 95 (range 60–210) min for the LNF group (difference 25 (95 per cent c.i. – 6·0 to 32·0) min). Median set-up time of the robotic system was 10 (range 3–15) min. All robot-assisted procedures were completed by laparoscopy. Conversion to open surgery was necessary in two (8 per cent) patients during LNF, in both cases because of impaired view as a result of severe obesity and left lobe hepatomegaly. In one of these, a Belsey Mark IV procedure was performed; in the other, an open Nissen fundoplication.

The estimated blood loss did not significantly differ between the groups: 20 (range 0–200) ml after RNF and 45 (range 0–200) ml after the standard laparoscopic approach (difference 25 (95 per cent c.i. -58.2 to 8.9) ml). Minor intraoperative complications occurred in seven (28 per cent) patients after LNF: small liver capsule tears in four, small spleen capsule tears in two and a pneumothorax in one. Liver capsule tears occurred in two patients and minor bleeding occurred in another two patients after RNF. After surgery, two patients in the LNF group

Table 3 Preoperative diagnostic evaluation

	RNF (n = 25)	LNF (n = 25)	Р	95% c.i.
Oesophagitis at endoscopy				
No oesophagitis	6 (24)	8 (32)	0.612	
Grade A	6 (24)	5 (20)	0.543	
Grade B	7 (28)	6 (24)	0.552	
Grade C	3 (12)	0	0.103	
Grade D	2 (8)	1 (4)	0.112	
Unknown	1 (4)	5 (20)	0.104	
Oesophageal manometry (kPa)				
End-expiratory LOS pressure*	1.0 (0-3.5)	1.0 (0-5.0)	0.214	-0.6, 0.6
Nadir end-expiratory LOS pressure*	0.2 (0-1.0)	0.2 (0-2.0)	0.141	− 0.02, 0.1
Percentage of peristaltic contractions				
< 80%	1	2	0.312	
80-100%	24	23	0.422	
24-h pH monitoring				
Total oesophageal acid exposure time (percentage of	13.5 (5.2-29.5)	9.9 (1.3-24.8)	0.224	-0.1, 7.4
time with pH < 4.0)*				
> 5.78	24	21	0.386	
Symptom index*	65.5 (0-100)	71.4 (0-100)	0.162	– 18⋅3, 12⋅3
> 50	19	22	0.324	
Symptom association probability*	99-9 (0-100)	100 (0-100)	0.381	<i>−</i> 13·7, 11·8
> 95	21	21	0.811	

Values in parentheses are percentages unless otherwise indicated. *Values are median (range). RNF, robot-assisted laparoscopic Nissen fundoplication; LNF, standard laparoscopic Nissen fundoplication; LOS, lower oesophageal sphincter; c.i., confidence intervels.

Table 4 Subjective evaluation before and after surgery

	RNF (n = 25)		LNF (n = 25)			
	Before	After	Before	After	P	95% c.i.
General quality of life (VAS score 0-100)*	22.5 (12-99)	72.0 (21–98)	32.5 (0-96)	76-0 (26-100)	0.284	– 18·1, 9·2†
Self-rated change in reflux symptoms compared with						
preoperative state						
Resolved		14		15	0.514	
Improved		9		9	0.971	
Unchanged		1		0	0.381	
Worsened		1		1	0.672	
Self-rated change in general quality of life compared with						
preoperative state						
Improved		22		20	0.583	
Unchanged		0		3	0.093	
Worsened		3		2	0.181	
Satisfied with outcome (%)		92		88	0.103	-0.13, 0.21

*Values are median (range). †LNF *versus* RNF 6 months after surgery. RNF, robot-assisted laparoscopic Nissen fundoplication; LNF, standard laparoscopic Nissen fundoplication; VAS, visual analogue scale; c.i., confidence intervels.

developed pneumonia and one suffered from a urinary tract infection compared with none after RNF. In both groups, median hospital stay was 3 days, with ranges 2-6 days after RNF and 1-13 days after LNF.

Symptomatic outcome

Table 4 summarizes the subjective outcome results. Neither visual analogue scale scores nor symptom assessments

showed differences in quality of life. Satisfaction with the outcome of surgery was reported in 92 per cent of patients after RNF and 88 per cent after LNF (difference 4 (95 per cent c.i. -0.13 to 0.21) per cent). A total of 23 patients scored their reflux symptoms as cured or improved after RNF (92 per cent) and 24 patients after LNF (96 per cent). All patients after LNF and all but one after RNF would have chosen surgery again in retrospect.

Objective follow-up

A total of 46 (92 per cent) patients had a postoperative endoscopic examination at 3–6 months, 22 in the RNF group and 24 in the LNF group. Forty-five (90 per cent) had 24-h pH monitoring and oesophageal manometry, 23 and 22 in the RNF and LNF groups respectively. Barium oesophagram series were performed in 48 patients (96 per cent), 23 after the robot-assisted procedure and all 25 after LNF. The remaining patients refused one or more postoperative investigations.

Endoscopic examination revealed residual oesophagitis in three patients in both groups. This was a significant decrease in incidence of oesophagitis compared with preoperative evaluation (P < 0.001 and P = 0.009 for RNF and LNF respectively). After both RNF and LNF, grade A oesophagitis was demonstrated in one and grade B in two patients. One patient after RNF appeared to have a recurrent sliding hiatal hernia of 3 cm. After LNF, three patients had recurrent hiatal hernias of 4, 3 and 3 cm (P = 0.317), which were also recognized on barium oesophagram series.

Table 5 shows the results of oesophageal manometry and 24-h monitoring. Oesophageal body motility variables were similar in both groups before and after surgery. Three patients after both RNF and LNF had peristaltic oesophageal contractions up to 80 per cent, comparable to preoperative manometric evaluation (P = 0.300 and P = 0.951 respectively). Median lower oesophageal sphincter pressure increased after RNF (difference 0.8 (95 per cent c.i. 0.4 to 1.5) kPa) and after LNF (difference 0.8 (95 per cent c.i. -1.4 to 0.05) kPa). Furthermore, nadir lower oesophageal sphincter pressures increased significantly after both techniques. Both groups also had similar outcomes for 24-h pH monitoring. Oesophageal acid exposure in the RNF group decreased significantly

for upright, supine and total oesophageal acid exposure time after surgery (difference 16·3 (95 per cent c.i. 11·9 to 19·1) per cent for upright, 7·7 (95 per cent c.i. 3·2 to 13·5) per cent for supine and 12·8 (95 per cent c.i. 9·9 to 14·8) per cent for total oesophageal acid exposure time). Similar results were obtained in the standard LNF group (differences 12·5 (95 per cent c.i. 8·8 to 14·3) per cent, 4·7 (95 per cent c.i. 1·7 to 9·7) per cent and 9·6 (95 per cent c.i. 6·5 to 10·9) per cent respectively compared

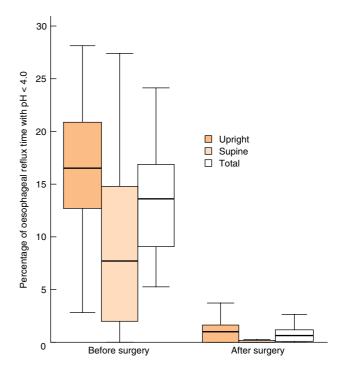


Fig. 2 Oesophageal acid exposures before and after robot-assisted laparoscopic Nissen fundoplication. Data are shown as median (horizontal line), interquartile range (box) and 5th to 95th percentiles (vertical line)

Table 5 Oesophageal manometry and 24-h pH monitoring 6 months after surgery

	RNF (n = 25)	LNF (n = 25)	Р	95% c.i.
Oesophageal manometry (kPa)				
End-expiratory LOS pressure*	1.8 (0.7-3.9)	1.8 (0.6-4.0)	0.233	−0.6, 0.6
Nadir end-expiratory LOS pressure*	0.7 (0.2-2.0)	1.0 (0.0-1.6)	0.119	-0.3, 0.3
24-h pH monitoring				
Total oesophageal acid exposure time (percentage of	0.7 (0-6.6)	0.3 (0-11.5)	0.088	−2.5, 1.8
time with pH < 4.0)*				
> 5.78	3	3	0.551	
Symptom index*	0.0 (0.0-16.7)	0.0 (0.0-0.0)	0.441	-6.9, 2.7
> 50%	0	0	0.338	
Symptom association probability*	0.0 (0.0-64.2)	0.0 (0.0-0.0)	0.625	−2.8, 15.4
> 95%	0	0	0.527	

^{*}Values are median (range). RNF, robot-assisted laparoscopic Nissen fundoplication; LNF, standard laparoscopic Nissen fundoplication; LOS, lower oesophageal sphincter; c.i., confidence intervel.

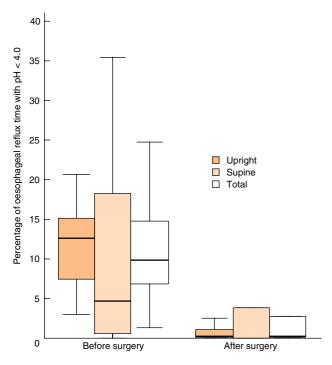


Fig. 3 Oesophageal acid exposures before and after standard laparoscopic Nissen fundoplication. Data are shown as median (horizontal line), interquartile range (box) and 5th to 95th percentiles (vertical line)

with preoperative evaluation (Figs 2 and 3). Pathological oesophageal acid exposure was encountered in three patients after both RNF and LNF. Symptom indices, however, were 0 per cent in all six patients. Antisecretory drugs were used by two of the patients after RNF and one after LNF; these three were the only patients who had resumed their antisecretory medication. Median symptom index and symptom association probability decreased significantly after RNF and LNF during 24-h pH monitoring (Table 5).

Reinterventions

At 6 months' follow-up, a total of four patients underwent reintervention after an initially successful Nissen fundoplication (8 per cent), two after RNF and two after LNF. One patient experienced troublesome dysphagia with significant weight loss following RNF. A repeat Nissen fundoplication had to be performed, during which a wrap that was too tight was found. Another patient had an incisional hernia at the umbilicus 3 months after RNF that required surgery. After LNF, one patient had severe dysphagia that necessitated reoperation. The Nissen fundoplication was converted to a Toupet fundoplication in this patient with no anatomical abnormalities detected during surgery. Another patient experienced troublesome dysphagia as well, which could be managed by Savary dilatation of the distal oesophagus. In retrospect, one of the patients with dysphagia following RNF was found to have had hypertensive lower oesophageal sphincter pressure with incomplete relaxation. Pathological oesophageal acid exposure or upper endoscopic abnormalities were not encountered in any of the patients who needed reintervention.

Discussion

Robot-assisted surgery is one of the latest developments in the evolution of endoscopic surgery. Numerous reports have addressed the feasibility and safety of using these systems in several surgical procedures, although it is still unclear whether a robotic system improves anatomical and functional outcome in gastrointestinal surgery^{9,16-18}. The present study was a randomized controlled trial comparing robot-assisted and standard laparoscopic Nissen fundoplication in patients with refractory GORD to assess whether robotic assistance in this procedure enhances surgical precision resulting in a more favourable subjective and objective outcome.

At present, only three randomized controlled trials on robot-assisted procedures have been published, all on laparoscopic Nissen fundoplication 10,19,20. Although no routine postoperative objective evaluation was applied in two of these three studies, no differences in intra- and postoperative complications, hospital stay and symptomatic outcome were detected. Furthermore, operating times were frequently found to be longer than in standard laparoscopic procedures and, in addition, using robotic assistance increased costs considerably, up to €1630 per procedure¹⁰. The largest randomized study focusing on the potential benefit of robotic surgery in Nissen fundoplication, by Morino et al. 10, also failed to show a distinct advantage for the use of robotic systems. Therefore the primary emphasis in the present randomized trial was short-term outcome to elucidate the value of robotic assistance. All currently available high-level studies, including the present one, were conducted in relatively small patient series and therefore suffer from a lack of adequate power. Nevertheless, no clinically relevant differences between standard and robot-assisted laparoscopic Nissen fundoplication, or in perioperative data, or in symptomatic and objective postoperative evaluation, were detected in this study. Overall, symptomatic outcome, patient satisfaction, reoperation rate and medication use after surgery were comparable to those reported in the literature. Although the surgeons

experienced a clear improvement in visualization of the operative field, superior instrumental capacities and better ergonomics, the results of this study do not support the use of robot assistance with the da Vinci[™] system in laparoscopic Nissen fundoplication for refractory GORD. Results appear to be similar, but operations take longer and cost considerably more. A cost-effectiveness study on standard LNF recently performed by the authors revealed that total hospital costs including work and follow-up averaged €7807²¹. When using dedicated robotic instruments, these costs are expected to increase by approximately €1000. In addition, substantial hardware, maintenance and upgrade costs should be taken into account.

An outcome difference of 35 per cent is high for comparing the two surgical techniques in this study. However, the goal was to detect arguments supporting a multicentre randomized trial comparing two techniques in Nissen fundoplication with different costs. An adequate equivalence trial based on a more realistic difference, for example 10 per cent, should include 600 patients in both arms. With financial implications in mind, there should at least be evidence of a substantial outcome difference before starting such a large trial. Although this study may be underpowered and a large patient series might reveal symptomatic or functional differences in the short or long term, the results of both techniques are reasonable and appear to be comparable. As the differences in both this and the other published studies appear to be very small, the scientific or clinical value from large multicentre trials on robot assistance in Nissen fundoplication with the current technology cannot be substantial. A meta-analysis on the four available randomized studies may, however, be of interest to reduce the uncertainty of relevant differences (Type 2 errors) which may now be underexposed owing to the small patient numbers, although no uniform endpoints were used to determine possible differences between the robot-assisted and standard laparoscopic approach in the studies. Nevertheless, a meta-analysis is now in progress to investigate parallels between the four trials.

Robotic systems are designed to enhance endoscopic manoeuvrability (careful dissection and suturing) in relatively small confined spaces, so these systems are used for demanding procedures such as Heller myotomy, large hiatal hernia repair, thoracoscopic oesophageal dissection and redo antireflux surgery. Nissen fundoplication may continue to be an attractive procedure to gain experience with robot-assisted surgery for those who perform complex endoscopic surgery frequently. Surgeons who are bound to start to use these systems can perform several cholecystectomies and Nissen fundoplications to learn the basic concepts of the system, and to practice the dissection

and suturing capacities before progressing to more complex endoscopic procedures.

No differences were demonstrated between patients who had laparoscopic Nissen fundoplication aided by the da VinciTM robotic system and patients who had the standard laparoscopic procedure with respect to perioperative results or postoperative symptomatic or objective outcome. The present authors no longer routinely use robotic systems in laparoscopic Nissen fundoplication as costs are substantially higher but quality of care does not seem to improve in the short term.

References

- 1 Catarci M, Gentileschi P, Papi C, Carrara A, Marrese R, Gaspari AL et al. Evidence-based appraisal of antireflux fundoplication. Ann Surg 2004; 239: 325–337.
- 2 Spechler SJ, Lee E, Ahnen D, Goyal RK, Hirano I, Ramirez F *et al.* Long-term outcome of medical and surgical therapies for gastroesophageal reflux disease: follow-up of a randomized controlled trial. *JAMA* 2001; **285**: 2331–2338.
- 3 Ackroyd R, Watson DI, Majeed AW, Troy G, Treacy PJ, Stoddard CJ. Randomized clinical trial of laparoscopic *versus* open fundoplication for gastro-oesophageal reflux disease. *Br* 7 Surg 2004; 91: 975–982.
- 4 Chrysos E, Tsiaoussis J, Athanasakis E, Zoras O, Vassilakis JS, Xynos E. Laparoscopic *vs* open approach for Nissen fundoplication. A comparative study. *Surg Endosc* 2002; **16**: 1679–1684.
- 5 Laine S, Rantala A, Gullichsen R, Ovaska J. Laparoscopic vs conventional Nissen fundoplication. A prospective randomized study. Surg Endosc 1997; 11: 441–444.
- 6 Nilsson G, Wenner J, Larsson S, Johnsson F. Randomized clinical trial of laparoscopic *versus* open fundoplication for gastro-oesophageal reflux. *Br J Surg* 2004; **91**: 552–559.
- 7 Watson DI, Baigrie RJ, Jamieson GG. A learning curve for laparoscopic fundoplication. Definable, avoidable, or a waste of time? *Ann Surg* 1996; **224**: 198–203.
- 8 Hazey JW, Melvin WS. Robot-assisted general surgery. Semin Laparosc Surg 2004; 11: 107–112.
- 9 Ruurda JP, Draaisma WA, van Hillegersberg R, Borel Rinkes IH, Gooszen HG, Janssen LW *et al.* Robot-assisted endoscopic surgery: a four-year single-center experience. *Dig Surg* 2005; **22**: 313–320.
- 10 Morino M, Pellegrino L, Giaccone C, Garrone C, Rebecchi F. Randomized clinical trial of robot-assisted *versus* laparoscopic Nissen fundoplication. *Br J Surg* 2006; 93: 553–558.
- 11 Velanovich V. Comparison of symptomatic and quality of life outcomes of laparoscopic *versus* open antireflux surgery. *Surgery* 1999; 126: 782–788.
- 12 Lundell LR, Dent J, Bennett JR, Blum AL, Armstrong D, Galmiche JP et al. Endoscopic assessment of oesophagitis: clinical and functional correlates and further validation of the Los Angeles classification. Gut 1999; 45: 172–180.

- 13 Weusten BL, Roelofs JM, Akkermans LM, Van Berge Henegouwen GP, Smout AJ. The symptom-association probability: an improved method for symptom analysis of 24-hour esophageal pH data. *Gastroenterology* 1994; **107**: 1741–1745.
- 14 Wiener GJ, Richter JE, Copper JB, Wu WC, Castell DO. The symptom index: a clinically important parameter of ambulatory 24-hour esophageal pH monitoring. Am J Gastroenterol 1988; 83: 358–361.
- 15 Richter JE, Bradley LA, DeMeester TR, Wu WC. Normal 24-hr ambulatory esophageal pH values. Influence of study center, pH electrode, age, and gender. *Dig Dis Sci* 1992; 37: 849–856.
- 16 Horgan S, Vanuno D. Robots in laparoscopic surgery. J Laparoendosc Adv Surg Tech A 2001; 11: 415–419.
- 17 Satava RM. Robotic surgery: from past to future a personal

- journey. Surg Clin North Am 2003; 83: 1491-1500.
- 18 Weber PA, Merola S, Wasielewski A, Ballantyne GH. Telerobotic-assisted laparoscopic right and sigmoid colectomies for benign disease. *Dis Colon Rectum* 2002; **45**: 1689–1694.
- 19 Cadiere GB, Himpens J, Vertruyen M, Bruyns J, Germay O, Leman G et al. Evaluation of telesurgical (robotic) NISSEN fundoplication. Surg Endosc 2001; 15: 918–923.
- 20 Melvin WS, Needleman BJ, Krause KR, Schneider C, Ellison EC. Computer-enhanced vs. standard laparoscopic antireflux surgery. *J Gastrointest Surg* 2002; **6**: 11–15.
- 21 Draaisma WA, Buskens E, Bais JE, Simmermacher RKJ, Rijnhart-de Jong HG, Broeders IAMJ *et al.* Randomized clinical trial and follow-up study of cost-effectiveness of laparoscopic *versus* conventional Nissen fundoplication. *Br J Surg* 2006; **93**: 690–697.

If you wish to comment on this, or any other article published in the *BJS*, please visit the on-line correspondence section of the website (www.bjs.co.uk). Electronic communications will be reviewed by the Correspondence Editor and a selection will appear in the correspondence section of the Journal. Time taken to produce a thoughtful and well written letter will improve the chances of publication in the Journal.