ORIGINAL ARTICLE

Five-Year Follow-up of a Multicenter, Double-Blind Randomized Clinical Trial of Laparoscopic Nissen vs Anterior 90° Partial Fundoplication

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Hypothesis: Laparoscopic 90° anterior partial fundoplication for gastroesophageal reflux disease achieves equivalent results to laparoscopic Nissen fundoplication.

Design: A multicenter, prospective, double-blind randomized clinical trial with a minimum of 5 years' follow-up.

Setting: Nine university teaching hospitals in 6 major cities throughout Australia and New Zealand.

Participants: One hundred twelve patients undergoing primary antireflux surgery were randomized to undergo either laparoscopic Nissen fundoplication (52 patients) or anterior 90° partial fundoplication (60 patients).

Interventions: Laparoscopic Nissen fundoplication with division of the short gastric vessels or laparoscopic anterior 90° partial fundoplication.

Main Outcome Measures: Blinded assessment at 1 and 5 years' follow-up of clinical outcome for postoperative heartburn, dysphagia, gas-related symptoms, and satisfaction with the surgical outcome. Analog scales ranging from 0 to 10 were used to assess symptom severity.

Results: Ninety-seven patients underwent follow-up at 5 years. Three others died during follow-up, 4 refused follow-up, and 8 were lost to follow-up; 89% remained at 5-years' follow-up. At 5 years' follow-up, mean analog scores for heartburn were 2.2 for anterior fundoplication vs 0.9 for Nissen fundoplication ($P=.003$). There were no significant differences between the groups for dysphagia scores. The mean score for outcome satisfaction was 7.1 after anterior fundoplication vs 8.1 after Nissen fundoplication ($P=.18$). Eighty-eight percent reported a good or excellent outcome following Nissen fundoplication vs 77% following anterior fundoplication.

Conclusions: Laparoscopic Nissen and anterior 90° partial fundoplication achieve similar levels of patient satisfaction at 5 years' follow-up, with similar adverse effect profiles. However, at 5 years' follow-up, laparoscopic Nissen fundoplication achieves superior control of reflux symptoms.

Trial Registration: Australian New Zealand Clinical Trials Register Identifier: ACTRN12607000298415.

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LAPAROSCOPIC NISSEN FUNDOplication is generally considered to be the surgical procedure of choice for the treatment of gastroesophageal reflux disease. It provides durable control of reflux but at the expense of a small

See Invited Critique at end of article

but significant rate of dysphagia and gas-related adverse effects.[1] To minimize the risk of such adverse effects, partial fundoplications, anterior and posterior, have been adapted from the original Nissen fundoplication. In the recently reported long-term follow-up of a randomized trial comparing laparoscopic Nissen fundoplication with laparoscopic anterior 180° partial fundoplication, it has been shown that both procedures produce equivalent and durable control of reflux at up to 10 years' follow-up, with trends toward less dysphagia and better preservation of belching following anterior 180° partial fundoplication.[2]

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With the aim of developing an effective antireflux procedure, but with minimal adverse effects, we modified the anterior 180° fundoplication further to an anterior 90° partial fundoplication.[3,4] We first piloted this procedure in an experimental animal reflux model, and postfundoplication manometry in the model showed that the resting lower esophageal pressures and reflux were corrected similarly by the anterior 90° fundoplication when compared with a standard Nissen fundoplication.[3] This technique was then evaluated clinically against laparoscopic Nissen fundoplication in a multicenter, double-blind randomized control trial—this study.[5] We have previously reported 6 months' follow-up outcomes from this trial, and these early results suggested that patients were more likely to be able to belch and relieve gas bloat symptoms after anterior 90° partial fundoplication, offset by more heartburn-like symptoms, compared with patients who underwent laparoscopic Nissen fundoplication.[5] Overall satisfaction with the outcome of antireflux surgery was very high (98%) at 6 months following anterior 90° partial fundoplication, and the early data lent support to the hypothesis that anterior 90° fundoplication is an appropriate surgical procedure for the treatment for gastroesophageal reflux disease, although longer-term follow-up was needed to support this early outcome data. Five years have passed since the early outcomes were evaluated, and in this article, we are now able to report longer-term (5 years' follow-up) clinical outcomes from this randomized trial.

METHODS

The trial was undertaken in 9 university teaching hospitals in 6 major cities in Australia and New Zealand. Fifteen surgeons performed the surgical procedures, and all had significant experience with laparoscopic antireflux surgery before the trial commenced. The full details of the trial protocol have been described previously.[5] In brief, symptomatic patients with objective evidence of gastroesophageal reflux at upper gastrointestinal endoscopy or 24-hour pH monitoring were considered for entry. Patients were excluded if they had an esophageal motility disorder that was deemed to preclude performing a Nissen fundoplication or if they were undergoing a concurrent procedure or had undergone previous antireflux surgery.

Randomization was performed by opening a sealed envelope that specified the type of fundoplication to be performed. The envelopes were prepared independently and were only opened after the operation had commenced and it was determined that both operative approaches were feasible. The operative techniques have been described previously.[4,5] Common to both procedures was a laparoscopic approach and routine posterior hiatal repair. A loose 1- to 2-cm Nissen fundoplication was fashioned following division of the short gastric vessels and full mobilization of the gastric fundus. Key steps for the anterior 90° partial fundoplication included a posterior esophagopexy to the right hiatal pillar, fixation of a length of esophagus within the abdomen, recreation of the angle of His, and construction of a fundoplication that covered the left anterolateral intra-abdominal esophagus. A bougie was not used, and short gastric blood vessels were not divided. If a laparoscopic procedure was converted to an open approach, the selected fundoplication was still performed, and patients were still included in the data analysis on an intention-to-treat basis. Operative techniques were standardized by agreement between participating surgeons. Additional quality control was achieved by presentation and distribution of videotape demonstrations at meetings in December 1998 and December 2000.

The type of procedure performed was concealed from the patient as well as the research assistant performing subsequent clinical follow-up. Preoperative information was collected pro forma by the operating surgeon. Postoperatively, a research assistant collected information using a structured telephone interview at 1, 3, and 6 months and then annually thereafter. Details of the interview have been published previously.[5] Patients were asked about the presence or absence of certain symptoms and asked to grade heartburn and dysphagia (separately for liquids and solids) using analog scores from 0 to 10 (0=no symptoms, 10=severe symptoms). Dysphagia was also scored using a previously validated composite dysphagia score graded from 0 to 45.[6] Patients were also asked whether they were able to belch and eat a normal diet.

The overall outcome was graded using an analog score for overall satisfaction (0=unsatisfied, 10=totally satisfied) and a previously described 4-point outcome scale (excellent, good, fair, and poor).[7] Patients were considered to be satisfied if the outcome was rated as good or excellent. A further yes/no question asked whether patients thought they had made the correct decision to undergo antireflux surgery.

Data were analyzed on an intention-to-treat basis, with all patients remaining in their initially allocated groups. Data were stored in a database (Filemaker Pro version 8.5; Filemaker Corp, Santa Clara, California) and statistical analysis was performed with GraphPad Prism version 5a (GraphPad Software Inc, La Jolla, California). The human research ethics committee in each participating hospital approved the study protocol. The study was conducted in accordance with the guidance of the World Medical Association of Helsinki (revised 1989) and the National Health and Medical Research Council of Australia guidelines on human experimentation.

RESULTS

From February 11, 2000, to February 26, 2003, 112 patients were enrolled in this trial, and all underwent surgery. Sixty were randomized to undergo laparoscopic anterior 90° partial fundoplication and 52 to laparoscopic Nissen fundoplication. All patients underwent the specific fundoplication type that was allocated by the randomization process. There was 1 conversion to open operation during anterior 90° partial fundoplication. This was due to intra-abdominal adhesions. There were 2 conversions during Nissen fundoplication due to intra-abdominal obesity and bleeding.

Demographic, preoperative, and early postoperative (first 6 months) data for the 2 groups have been reported earlier.[5] There were no significant differences with respect to any preoperative variable except that a higher proportion of patients in the Nissen fundoplication group had undergone previous upper abdominal surgery.

At 1-year follow-up, data were collected from 105 patients (57 anterior, 48 Nissen; 94% follow-up). Three patients died between 1 and 5 years' follow-up from unrelated causes. At 5 years, follow-up data were not able to be obtained from a further 12 patients. Hence, a clinical outcome was available for 89% at 5 years. In the anterior fundoplication group, 5 patients were lost to follow-up, 1 refused follow-up, and 1 died, whereas in the Nissen fundoplication group, 3 were lost to follow-up, 3

Table 1. Clinical Outcomes at 12 Months for Heartburn, Dysphagia, and Other Adverse Effects

	No. (%)		
	Nissen Fundoplication (n=48)	Anterior Fundoplication (n=57)	*P* Value
Reflux symptoms			
Heartburn	5 (10)	15 (26)	.048[a]
Mean heartburn analog score	0.7	1.5	.04[b]
Consuming PPI medication	6 (12.5)	10 (17)	.59[a]
Dysphagia assessment			
Dysphagia for solids	25 (52)	12 (21)	.001[a]
Mean dysphagia analog score			
Liquids	0.9	0.4	.59[b]
Solids	1.7	1.6	.24[b]
Composite dysphagia score	7.2	3.5	.06[b]
Eats normal diet	41 (85)	55 (96)	.07[a]
Other adverse effects			
Abdominal bloating	18 (37)	25 (44)	.55[a]
Able to relieve bloating	29 (60)	45 (79)	.05[a]
Able to belch normally	30 (63)	52 (91)	.001[a]

Abbreviation: PPI, proton pump inhibitor.
[a] Fisher exact test.
[b] Mann-Whitney *U* test.

Table 2. Clinical Outcomes at 5 Years for Heartburn, Dysphagia, and Other Adverse Effects

	No. (%)		
	Nissen Fundoplication (n=44)	Anterior Fundoplication (n=53)	*P* Value
Reflux symptoms			
Heartburn	12 (27)	21 (44)	.28[a]
Mean heartburn analog score	0.9	2.2	.003[b]
Consuming PPI medication	2 (4.5)	13 (24)	.01[a]
Dysphagia assessment			
Dysphagia for solids	18 (41)	17 (32)	.40[a]
Mean dysphagia analog score			
Liquids	0.5	0.5	.29[b]
Solids	2.1	1.5	.16[b]
Composite dysphagia score	6.7	5.5	.62[b]
Eats normal diet	37 (84)	48 (91)	.37[a]
Other adverse effects			
Abdominal bloating	26 (59)	31 (58)	>.99[a]
Able to relieve bloating	25 (57)	36 (68)	.29[a]
Able to belch normally	28 (68)	50 (94)	.001[a]

Abbreviation: PPI, proton pump inhibitor.
[a] Fisher exact test.
[b] Mann-Whitney *U* test.

refused follow-up, and 2 died. No revision operations were undertaken in either group during the 6 months' to 5 years' postoperative follow-up period.

Clinical follow-up data at 12 months and 5 years are summarized in **Tables 1**, **2**, **3**, and **4**. When patients were asked using a yes/no question whether they had heartburn at 12 months' follow-up, significantly more reported heartburn after anterior 90° partial fundoplication (Table 1), although at 5 years there was no statistically significant difference (Table 2). However, when heartburn was assessed using the 0-10 analog score, patients reported significantly more heartburn after anterior 90° partial fundoplication at both 12 months' and 5 years' follow-up (Table 1 and Table 2).

Table 3. Assessment of Overall Outcome at 12 Months

	No. (%)		
	Total Fundoplication (n=48)	Anterior Fundoplication (n=57)	*P* Value
Satisfied with outcome	44 (92)	45 (79)	.10[a]
Mean analog score of satisfaction	8.4	8.2	.99[b]
Would choose operation again	43 (90)	50 (87)	.77[a]

[a] Fisher exact test.
[b] Mann-Whitney *U* test.

At 12 months after surgery, patients were less likely to report dysphagia for solids following anterior 90° partial fundoplication, although there were no significant differences between the 2 groups for the dysphagia scores for both liquids and solids at 1 year (Table 1), and at 5 years' follow-up, the incidence and severity of dysphagia were not significantly different for the 2 groups for all measures of dysphagia. The ability to belch was better preserved 1 and 5 years after anterior fundoplication (Table 1 and Table 2). At 12 months' and 5 years' follow-up, there were no significant differences for any measures of satisfaction with the overall outcome (Table 3 and Table 4).

COMMENT

Antireflux surgery has an important role in the treatment of patients with refractory gastroesophageal reflux disease and in patients who do not wish to continue taking lifelong antisecretory medication. Traditionally, the Nissen 360° fundoplication has been widely applied, and it provides good control of reflux for most patients, with success rates approaching 90% at 10 years' follow-up.[8,9] However, in some patients, achieving excellent reflux control can be followed by significant long-term adverse effects, most commonly dysphagia, inability to belch, gas bloat, and flatulence. To minimize the risk of adverse effects, many surgeons construct a partial fundoplication.[2,4,10] This strategy is reported to reduce the risk of dysphagia and wind-related adverse effects, although there has been concern that the control of gastroesophageal reflux may not be adequate following a partial fundoplication.[11]

When constructing a partial fundoplication, there are 2 broad approaches to consider: anterior vs posterior. Posterior fundoplications have been more widely performed, particularly in North America and Europe, and studies of case series generally report good outcomes. This type of partial fundoplication has been compared with Nissen fundoplication in randomized controlled trials.[10,12,13] In general, the results from these trials demonstrate similar outcomes for reflux control and dysphagia, but with less wind-related adverse effects following posterior partial fundoplication. To our knowledge, only 1 randomized trial has demonstrated less dysphagia following posterior partial fundoplication, and this was only

at 4 months' follow-up.[13] Hence, we have hypothesized that anterior partial fundoplication may be associated with fewer adverse effects but still achieve adequate reflux control.

Four randomized trials, including our current trial, have compared an anterior partial fundoplication variant with Nissen fundoplication.[2,5,14,15] Two of these evaluated an anterior 180° partial fundoplication.[2,14] Outcomes at 6 months and 5 years from the trial undertaken in Adelaide, Australia, demonstrated similar reflux control, but less dysphagia and other adverse effects, following anterior 180° partial fundoplication.[16,17] However, at the 10-year follow-up, the outcome following anterior 180° partial fundoplication was not significantly different from that of Nissen fundoplication.[2] The second trial from Baigrie et al[14] also demonstrated fewer adverse effects offset by more heartburn symptoms at 2 years' follow-up following anterior 180° partial vs Nissen fundoplication. In both of these trials, high rates of patient-reported satisfaction were observed following anterior 180° partial fundoplication at up to 10 years' follow-up. Anterior 90° partial fundoplication has also been compared with Nissen fundoplication (without division of the short gastric blood vessels) in a further trial from Adelaide.[15] The 6 months' follow-up outcomes were similar to the early outcomes from our current trial, ie, fewer adverse effects following anterior 90° partial fundoplication, good reflux control, and high rates of satisfaction.[15] The only trial to report a poor result following an anterior partial fundoplication variant was reported by Hagedorn et al.[11] They compared anterior 120° partial fundoplication with posterior fundoplication. In their trial, there was a high rate of recurrent reflux following anterior partial fundoplication at early follow-up, and this was confirmed by pH monitoring. However, these outcomes were very different from those reported in the other trials. A possible explanation for this is that the construction of the anterior 120° partial fundoplication applied in the trial reported by Hagedorn et al was different from that tested in other trials, with fewer sutures used to attach the gastric fundus to the right hiatal pillar and therefore less anchorage of the esophagus and fundoplication within the abdomen.

In our current trial, the initial 6-month follow-up outcomes were excellent following anterior 90° partial fundoplication.[5] Reflux control, as measured by symptom scores and pH monitoring, was very good, adverse effects were less frequent, and 98% of patients were highly satisfied with the overall outcome following anterior 90° partial fundoplication. However, when treating reflux surgically, long-term outcomes are very important, and the 5-year follow-up reported in the current article suggests patients were more likely to experience reflux symptoms at later follow-up following anterior 90° partial fundoplication. Furthermore, the previously reported advantages of better satisfaction and fewer adverse effects were not seen at 5 years' follow-up. However, while there were no statistically significant differences between the dysphagia scores for the 2 study groups, there was a trend toward less dysphagia following anterior 90° partial fundoplication, and this trend is consistent with the results of other trials.

Table 4. Assessment of Overall Outcome at 5 Years

	No. (%)		
	Total Fundoplication (n=44)	Anterior Fundoplication (n=53)	*P* Value
Satisfied with outcome	39 (88)	41 (77)	.10[a]
Mean analog score of satisfaction	8.1	7.1	.18[b]
Would choose operation again	40 (91)	45 (84)	.37[a]

[a] Fisher exact test.
[b] Mann-Whitney *U* test.

In considering heartburn and other clinical indicators of recurrent reflux, we use 3 clinical questions. While it is unlikely that any one of these correlates perfectly with reflux, it is likely that they do provide an overall indication of the relative risk of further reflux following each operation. For instance, heartburn was assessed with a yes/no question and an analog score. Affirmative answers to these questions do not always indicate reflux, as other symptoms could be confused with actual reflux. Similarly, not all individuals who consume proton pump inhibitors following fundoplication have reflux.[18] For these reasons, it is unlikely that 27% and 44% of patients had recurrent reflux after Nissen and anterior fundoplication, respectively, particularly because at 5 years' follow-up satisfaction with surgery was approximately 90% following both procedures. Nevertheless, the reported clinical outcomes are likely to be informative, to the extent that they suggest reflux is a greater problem at 5 years' follow-up following anterior 90° partial fundoplication compared with the Nissen procedure.

Unlike other randomized trials that have evaluated antireflux procedures within a single unit, our current trial is a multicenter study from 9 sites spread across Australia and New Zealand. While all the surgeons involved in the trial work in university teaching hospitals, they also work in both teaching hospital and private practice environments, and approximately 50% of the patients in this trial were managed in the private sector. Furthermore, the majority of laparoscopic antireflux surgery in our countries is performed by specialist upper gastrointestinal surgeons who work in these settings, and this reflects the range of patients recruited into the trial. For these reasons, we believe that the results better reflect the outcomes for this type of surgery across Australia and New Zealand than previously reported studies from single centers.

The follow-up rate of approximately 90% at 5 years in our trial was not as high as the 96% to 99% follow-up rates reported in other randomized controlled trials from Adelaide.[2,7,15,17] This was because the multicenter recruitment process increased the difficulties associated with tracking patients across multiple Australian states and New Zealand. Nevertheless, we were still able to obtain a high rate of follow-up, and few other randomized trials have been able to obtain this level of long-term follow-up. The outcomes reported in this trial were clinical symptom scores. Even though at late follow-up we did not un-

dertake further investigation with studies such as pH monitoring, we are confident that the symptom scores reflect the clinical situation and provide reliable information about the surgical outcome. Esophageal manometry, pH monitoring, and endoscopy were undertaken at early follow-up, but in our community, it is not possible to obtain adequate compliance with pH studies and other investigations at multiple points during clinical trials. When patients undergo surgery for gastroesophageal reflux, arguably the most important outcome is a patient who is satisfied with the overall result following surgery. When patients consider this outcome, they balance reflux control against new postsurgical adverse effects. Some patients with excellent postsurgical reflux control are unsatisfied with the results of antireflux surgery because they developed unwanted adverse effects. There were no statistically significant differences between the satisfaction outcomes at 1 or 5 years in this trial.

Given the outcome at 5 years, how have the results of our trial influenced the practice of antireflux surgery in our hospitals? Following completion of the enrolment phase, the majority of participating surgeons reverted to their standard clinical practice. For most surgeons, this meant undertaking a Nissen fundoplication, although some surgeons adopted posterior or anterior 180° partial fundoplication procedures, with 1 surgeon continuing to apply the anterior 90° partial fundoplication for selected patients undergoing surgery for reflux. In general, however, the participants chose to await the longer-term outcomes from the trial before considering routine clinical application of the anterior 90° partial fundoplication procedure.

In conclusion, at 5 years' follow-up, patients who underwent a laparoscopic Nissen fundoplication were less likely to report heartburn-type symptoms compared with those undergoing anterior 90° partial fundoplication. For the other outcomes (adverse effects and satisfaction), the results were not significantly different at 5 years' follow-up. This suggests a better overall outcome at 5 years following laparoscopic Nissen fundoplication compared with anterior 90° partial fundoplication.

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INVITED CRITIQUE

Better Is the Enemy of Good

This pearl is usually imparted to a trainee attempting to add perfection to an adequate operation. Trying to create perfection has plagued antireflux surgery more than most operations, ever since Harrington[1] published the first series of diaphragmatic hernia repairs (28 patients) in the *Archives* in 1928. Allison reported his anatomical repair in 1945, then Nissen experimented with several techniques over 25 years, initially favoring Allison's technique, then gastropexy, before settling on fundoplication in the 1960s. Belsey, Hill, Rosetti, and Toupet all tried to make a good operation better, while Angelchik tried to invent a new one. However, the biggest redefinition of outcome resulted from the introduction of laparoscopy.

This group, led by Jamieson and Watson, has unarguably made the greatest contribution to the evidence surrounding laparoscopic fundoplication, publishing a series of well-constructed randomized trials on many aspects, including division vs no division of short gastric vessels and partial vs total fundoplication. The first modification studied by them was the anterior 180° wrap, and their recently published 10-year outcome[2] confirmed their early success with this operation, which sustained good reflux control while reducing adverse effects. This success encouraged their investigation of the minimalist 90° wrap.

This article reports the 5-year outcome of their multicenter trial comparing the 90° wrap with Nissen fundoplication, and the results suggest that there is a limit to minimalism. Recurrent heartburn was reported by 44% of the patients who underwent the 90° procedure and there was no benefit for dysphagia after 1 year. While not quite reaching statistical significance, the trends to both poorer Visick and satisfaction scores in the 90° group are highly suggestive. They correctly conclude that laparoscopic Nissen has a better overall outcome at 5 years compared with the 90° version. Tellingly, they concede that 14 of the 15 participating trial surgeons have abandoned this operation altogether, while 1 uses it selectively.

Nijjar et al are to be congratulated on their honest and conclusive study, which should result in the 90° wrap being bracketed with current endoscopic techniques as a disappointing procedure that has failed to make better an already good (if imperfect) therapy.

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