A Prospective Randomized Trial of Laparoscopic Nissen Fundoplication With Anterior vs Posterior Hiatal Repair

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Hypothesis: The technique used for repair of the esophageal hiatus during laparoscopic Nissen fundoplication can influence the likelihood of postoperative dysphagia.

Design: A prospective double-blind randomized control trial.

Setting: A university teaching hospital.

Participants: A total of 102 patients with proven gastroesophageal reflux disease, undergoing a laparoscopic Nissen fundoplication were randomized to undergo fundoplication with either anterior (47 patients) or posterior (55 patients) repair of the diaphragmatic hiatus. Patients were excluded for the following reasons: they had esophageal motility disorders, required a concurrent abdominal procedure, had undergone previous antireflux surgery, or had very large hiatus hernias.

Interventions: Laparoscopic Nissen fundoplication with anterior vs posterior hiatal repair.

Main Outcome Measures: Independent assessment of dysphagia, heartburn, patient satisfaction, and other symptoms 1, 3, and 6 months following surgery, using multiple standardized clinical grading systems. Objective measurement of lower esophageal sphincter pressure, esophageal emptying time, distal esophageal acid exposure, and endoscopic assessment of postoperative anatomy and esophageal mucosa.

Results: Symptoms of postoperative dysphagia, relief of heartburn, and overall satisfaction 6 months after surgery were not influenced by the hiatal repair technique. However, to achieve a similar incidence of dysphagia, more patients who initially underwent posterior hiatal repair required a second surgical procedure (6 vs 0 patients). The hiatal repair technique did not affect the likelihood of early postoperative paraesophageal herniation.

Conclusion: Anterior suturing of the hiatus appears to be at least as good in the short-term as posterior suturing as a method of narrowing the hiatus during laparoscopic Nissen fundoplication.

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Since the early 1990s, the status of laparoscopic antireflux surgery has moved from experimental to routine, with large experiences now reported by many centers. Furthermore, the outcome in the majority of patients undergoing such surgery is good, with relief of reflux symptoms and few adverse effects in about 90% of patients. However, some patients develop problems following fundoplication. Problems due to hiatal herniation after surgery are now less common because hiatal repair has become routine during laparoscopic Nissen fundoplication in most centers, but some patients still experience troublesome dysphagia following fundoplication. Recently reported randomized trials have suggested that the problem of dysphagia might be reduced following anterior partial fundoplication, while routine division of the short gastric vessels has not been demonstrated to be of benefit.

Previously, we have described the problem of postoperative hiatal stenosis. This causes dysphagia from narrowing of the diaphragmatic hiatus, due to excessive perihial scar tissue formation, which highlights the fact that in some patients postoperative dysphagia can be due to a problem at the hiatus, despite a technically correct total fundoplication. In addition, we have observed that postoperative barium swallow x-ray films usually demonstrate anterior displacement of the distal esophagus following Nissen fundoplication, and it is possible that this angulation could contribute to dysphagia fol-
PATIENTS AND METHODS
PARTICIPANT ASSIGNMENT
Patients undergoing laparoscopic Nissen fundoplication for gastroesophageal reflux disease were randomized to undergo fundoplication with either anterior or posterior repair of the diaphragmatic hiatus. Informed consent was obtained from all participants, and randomization occurred in the operating theater by opening 1 of 120 previously sealed envelopes after the commencement of general anesthesia. Preparation of the envelopes was undertaken before the study by an independent research officer, and envelopes were randomly selected by a departmental secretary at a surgeon’s request. No patients were withdrawn from the study following randomization.

PATIENT SELECTION AND PREOPERATIVE INVESTIGATION
Patients with proven gastroesophageal reflux disease, who presented to the University Department of Surgery at the Royal Adelaide Hospital, Adelaide, South Australia, for primary antireflux surgery by a laparoscopic technique were considered for entry. Patients were excluded from consideration if they had an esophageal motility disorder, which precluded a total fundoplication; they required a concurrent abdominal procedure at the same time as fundoplication; they had undergone previous antireflux surgery; or if they had a large hiatus hernia (ie, containing more than 50% of the stomach or >10 cm in length). All patients underwent preoperative investigation with esophageal manometry and endoscopy. Twenty-four-hour pH monitoring was only performed in patients who did not have unequivocal reflux disease demonstrated by preliminary endoscopy in association with typical reflux symptoms of retrosternal burning discomfort and/or acid regurgitation.

OPERATIVE TECHNIQUE
Laparoscopic Nissen fundoplication was performed using a previously described technique. This comprised dissection of the hiatal pillars, followed by full esophageal mobilization. The hepatic branch of the vagus nerve was always preserved, and the short gastric vessels were divided in only 5 patients. The hiatus was repaired in front (anterior) or behind the esophagus (posterior), according to the randomization. If assigned to posterior repair, the hiatus was repaired using interrupted 2-0 monofilament nonabsorbable sutures before constructing the fundoplication, and if assigned to anterior repair, the hiatus was repaired after the fundoplication was constructed. The different sequence of steps facilitated the technical performance of the surgery. With both hiatal repair techniques, the hiatus was closed so that the closure was adequate but not tight. This was determined by assessing the degree of narrowing while a 52F bougie was sited within the esophageal lumen. The repair was evaluated further by placing a closed laparoscopic grasping instrument between the repaired hiatal rim and the esophagus (which was distended by the bougie) to ensure that the repair was not too tight.

The anterior wall of the gastric fundus was pulled behind the esophagus and a 1.5- to 2.0-cm loose total fundoplication was constructed, while a 52F bougie was sited within the abdominal esophagus. Three nonabsorbable interrupted sutures were used to secure the wrap. If the laparoscopic procedure was converted to an open procedure due to intraoperative difficulties, the randomization schedule was still followed and the patient remained in the trial.

POSTOPERATIVE CARE
Nasogastric tubes were not used and patients were allowed oral fluids after the operation that evening and soft solid food the next day. Discharge from the hospital was encouraged after the second day after surgery. A barium meal examination was routinely obtained on the second day after surgery to detect any problems requiring early laparoscopic reintervention (eg, acute paraesophageal hernia, tight fundoplication, or hiatus). This is our usual clinical practice.

MASKING
Whether the hiatus was repaired in front or behind the esophagus was concealed from all patients, and all remained unaware of the exact procedure for the duration of follow-up fundoplication. This anatomical change could be due, at least in part, to posterior repair of the hiatus. Since anterior repair of the hiatus tends to push the esophagus posteriorly, thus keeping its axis straight, we hypothesized that anterior hiatal repair might be associated with less postoperative dysphagia. To test this hypothesis, we have undertaken a prospective double-blind randomized trial of anterior vs posterior hiatal repair during laparoscopic fundoplication.

RESULTS
From July 21, 1997, to October 29, 1999, 102 patients were entered into this trial. Forty-seven patients were randomized to undergo a total fundoplication with anterior hiatal repair, and 55 were randomized to undergo posterior repair. Fifty-two additional patients underwent a laparoscopic antireflux procedure during this same period. Of these patients, 27 were excluded from the trial because they had a very large hiatal hernia, 12 were excluded because of poor esophageal motility, 3 underwent a concurrent cholecystectomy, and 1 had undergone a previous antireflux procedure. Only 9 patients who were eligible for enrollment into the trial refused entry. Of these patients, 96 (94%) were able to be interviewed 1 month after surgery, 96 (94%) at 3 months, and 99 (97%) at 6 months. Although prospectively collected follow-up data were not available for a few patients at the specific follow-up intervals, no patient elected to withdraw from the study, and missing data were due to an inability to contact a small number of patients at the specific follow-up intervals. Only 1 patient could not be in-
of follow-up. While operating surgeons were aware of the procedure performed, follow-up was obtained by a scientific officer (T.E.) who was blinded to the randomization of each patient. Since she was not involved in the initial surgery, she remained unaware of the allocated group for each patient throughout follow-up.

CLINICAL FOLLOW-UP

Patients were interviewed before surgery and then 1, 3, and 6 months after surgery by the scientific officer, using a structured questionnaire. Longer-term follow-up is being sought at yearly intervals, but these data are not available in this article. The presence or absence of each of the following symptoms was determined: heartburn; epigastric pain; regurgitation; dysphagia for lumpy solids, soft solids, and liquids; odynophagia; early satiety; inability to belch; epigastric bloating; anorexia; nausea; vomiting; nocturnal coughing and wheezing; increased passage of flatus; and diarrhea. The ability to relieve bloating and whether a normal diet was being consumed were also determined. Heartburn was also scored using a visual analog scale (0 = no heartburn, 10 = severe heartburn).

Dysphagia was scored by several methods. Visual analog scales (0 = no dysphagia, 10 = total dysphagia) were independently applied for solids and liquids, as well as a previously validated and described score6,13 (0 = no dysphagia, 45 = severe dysphagia), which combines information about difficulty swallowing 9 types of liquids and solids. Overall outcome was determined using 3 further scales. Patients ranked the outcome of surgery using a previously described modified Visick grading9 and were also asked to score the outcome as excellent, good, fair, or poor. An overall assessment of satisfaction with the operative outcome was scored by a visual analogue scale (0 = dissatisfied, 10 = satisfied).

OBJECTIVE FOLLOW-UP

Objective investigation with esophageal manometry, 24-hour pH monitoring, endoscopy, and a radionuclide esophageal emptying study were performed 3 to 4 months following surgery. Investigation sought to assess lower esophageal sphincter function, control of reflux, and postsurgical anatomy. The technique used for all studies has been described previously.2 The esophageal emptying study measured emptying of 3 swallows of a solid meal, with the emptying time deemed to be the average time taken for 95% of each bolus to clear from the esophagus (normal time, 7-93 seconds).

STATISTICAL ANALYSIS

The primary clinical outcome, which the trial was designed to evaluate, was postoperative dysphagia. Before commencement, it was determined that 84 patients (42 in each group) would be needed to demonstrate a 20% difference in this outcome measure, at a significance level of P < .05 and power of 90%. To ensure that this was achieved, it was intended that 100 patients would be recruited. All analyses were performed on an intention-to-treat basis, with all patients remaining in their initially allocated group for this analysis. Before commencing, it was intended to publish the initial outcomes and results of postoperative testing once all patients had been followed up for an initial 6-month period. This period should be adequate to allow for the assessment of any differences in the incidence of postoperative dysphagia between the 2 trial groups. Medium- to long-term outcomes will be reported once follow-up has matured.

All data were entered onto a computerized database (Filemaker Pro, version 4.0; Claris Corporation, Santa Clara, Calif) and analyzed using a commercially available statistical package (InStat, version 2.01; GraphPad Software, San Diego, Calif). The Fisher exact test was used to determine the significance of 22 × 2 contingency tables. A 2-tailed Mann-Whitney U test was used to assess the significance of continuous data sets. Statistical significance was accepted at P < .05. Unless otherwise stated, all data are reported as the percentage of the total patients in each group or as the mean (95% confidence interval [CI]).

ETHICAL APPROVAL

The protocol for this study was approved by the Royal Adelaide Hospital Human Research Ethics Committee, and the study was conducted in accordance with the World Medical Association declaration of Helsinki (revised 1989), and the National Health and Medical Research Council of Australia’s guidelines on human experimentation.
Preoperative esophageal manometry outcomes were similar. No significant differences were seen between the groups (Table 5). Twenty-four-hour ambulatory pH monitoring was performed in 20 of the patients who underwent anterior hiatal repair and 28 of those undergoing posterior repair. The mean percentage exposure time to an acid pH of less than 4 was 10.0% (6.8%-13.2%) for the anterior repair group and 8.7% (6.5%-10.8%) for the posterior repair group.

Surgery was performed by or under the direct supervision of 1 of 4 consultant surgeons (D.I.W., G.G.J., P.G.D., P.A.G.). Of the patients randomized to undergo anterior hiatal repair, 1 had the hiatus repaired posteriorly, as an adequate repair of the hiatal defect could not be achieved by the placement of anterior sutures alone. All patients randomized to posterior hiatal repair underwent this procedure. One patient in each group underwent an anterior 180° partial fundoplication rather than a Nissen fundoplication due to difficulty achieving a satisfactorily loose total fundoplication. In each instance, the surgeon elected to perform a partial fundoplication procedure rather than divide the short gastric vessels. All patients remained in their originally allocated groups for data analysis. In the anterior hiatal repair group, 1 suture was used to narrow the hiatus in 31 patients, 2 sutures in 14, and 4 sutures in 2 patients. In the posterior repair group, 1 suture was used in 38 patients, 2 sutures in 14, 3 sutures in 2, and 4 sutures in 1 patient.

Only 1 procedure was converted to an open operation. This patient was randomized to undergo anterior hiatal repair. The patient's stomach was distended with air at the commencement of the procedure, and a concurrent hiatus hernia made placement of a nasogastric tube for decompression difficult, and it was, therefore, not possible to empty the stomach adequately to enable the planned laparoscopic procedure to proceed. Hence, the procedure was converted to an open operation.

Operating time varied from 20 to 120 minutes (mean [CI], 48.6 [42.6-54.6] minutes) when the hiatus was repaired anteriorly vs 25 to 110 minutes (mean [CI], 52.2 [46.7-57.6] minutes; P = .40) when the hiatus was repaired posteriorly. Operating surgeons were asked to rate the difficulty of the operative procedure using a scale from 1 to 10. The perceived difficulty was not influenced by the technique used (mean score, 4.5 for each group).

EARLY HOSPITAL OUTCOMES

The period between surgery and the commencement of oral intake of fluids and solids, as well as the length of hospital stay after surgery was not altered by the repair technique (mean, 0.9, 1.8, and 2.8 days, respectively). The incidence of postoperative complications within 30 days of surgery was also unaffected by the operative technique (11% in each group). In the anterior repair group, 3 patients underwent early endoscopic dilation for dysphagia, 1 experienced transient pulmonary edema (cause unknown), and 1 developed a left pneumothorax, which required no specific treatment. In the posterior repair group, 2 patients underwent early endoscopic dilatation for dysphagia and 4 patients underwent early reoperation (see below).
While reoperation within 6 months of surgery was not required for any patient randomized to undergo anterior hiatal repair, 8 (15%) patients randomized to undergo posterior repair underwent 9 further surgical procedures, 4 within 1 week of surgery, and 5 between 1 and 6 months following surgery. The decision to reoperate was made by the surgeon responsible for each patient’s clinical care. The early operations were for removal of hiatal repair sutures because of a tight hiatus (2 patients), repair of an acute paraesophageal hiatus hernia (1 patient), and conversion of the total to an anterior partial fundoplication because of significant dysphagia in the presence of a demonstrably loose hiatal repair (1 patient). The 3 procedures for dysphagia were carried out because the patients had significant dysphagia for liquids (2 had aphagia), whereas the later reoperations for dysphagia (see below) were carried out if patients found their level of dysphagia was intolerable.

Four of the late reoperative procedures were to widen a tight esophageal hiatus on days 35, 35, 105, and 180. The last of these patients had previously undergone removal of all hiatal repair sutures on the seventh day after surgery, and despite this developed a tight narrowing of the hiatus due to excessive scarring. While the other patients all had dense fibrosis of the hiatal ring, it is not possible to determine the exact cause of the narrowing, and it is possible that suture narrowing of the hiatal rim may have contributed, at least in part, to this problem. The fifth patient presented on day 100 following excessive consumption of carbonated liquids, resulting in acute distension of the stomach that caused the stomach to rupture. This required open repair of the perforation and reconstruction of the fundoplication. Full details have been reported elsewhere.14 Overall, there was a higher rate of revision for dysphagia in the group undergoing posterior hiatal repair (anterior hiatal repair group vs posterior hiatal repair group: 0 of 47 vs 6 of 55 patients; $P = .03$).

### POSTOPERATIVE SYMPTOM ASSESSMENT AT 1 TO 6 MONTHS

A detailed analysis of the outcome of the blinded standardized clinical assessment is summarized in Tables 1 through 4. No differences between the incidence of assessed symptoms in each group, or overall outcome, were seen at any stage of the initial 6-month follow-up period, with the exception of a higher incidence of epigastric bloating 3 months following surgery and early sati-
Table 5. Esophageal Manometry Results

<table>
<thead>
<tr>
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<th>Anterior Repair</th>
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*Data are given as percentage of total or mean (95% confidence interval). Swallowing was assessed from 10 wet swallows. LES indicates lower esophageal sphincter.

Laparoscopic surgery for the correction of gastroesophageal reflux has become common throughout the Western world, partly because of better patient acceptance due to a perception that surgical procedures are now less invasive and also because of an apparently increasing incidence of reflux presenting as a clinical problem. The Nissen (total) fundoplication in its various forms remains the most commonly performed procedure, and its long-term efficacy was well established in the era of open surgery. Furthermore, this is the procedure against which all other antireflux operations should be compared. Unfortunately, however, it is not a perfect operation, as it can be followed by a variety of adverse effects, and a few patients will require further surgery following their original procedure, either for recurrent reflux or to correct a postoperative problem.

Dysphagia is perhaps the adverse outcome that attracts most attention following Nissen fundoplication. To some extent this is unfair, as many patients, including more than 40% of those entering the trial, have dysphagia to some extent before they even undergo surgery, and many of the patients with preoperative dysphagia, this problem improves following surgery. However, a few patients will develop new dysphagia following laparoscopic Nissen fundoplication, and it is this adverse outcome in these patients that draws attention to the issue of troublesome dysphagia following surgery. Postoperative dysphagia can be due to the technical error of constructing a tight fundoplication. This is probably not related to the issue of whether short gastric vessels are divided or not, although this is not accepted by all surgeons. Dysphagia can also be caused by a tight diaphragmatic esophageal hiatus. This problem can be due to either overtightening of the hiatal opening at the time of surgery or excessive fibrosis of the hiatus after surgery, which can occur even when sutures have not been placed to reduce the hiatus. In our overall experience with dysphagia after laparoscopic antireflux surgery, reoperation for hiatal problems has been more prevalent (2%) than problems with the fundoplication (<1%).

While it is possible that posterior hiatal repair could be responsible for some specific instances of dysphagia requiring revision, we believe that hiatal repair is an important step in a laparoscopic fundoplication. We, and others, have shown previously that failure to routinely repair the hiatus, even in patients without a hiatus hernia, can lead to a higher incidence of postoperative paraesophageal hiatus herniation. However, it is possible that posterior hiatal repair, by lifting the esophagus forward and changing the axis of the distal esophagus, could contribute to dysphagia following Nissen fundoplication. Anterior hiatal repair was not associated with any instances of hiatal herniation during the early follow-up period, and it was not associated with any in-

**COMMENT**

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stances of reoperation for hiatal narrowing. The dysphagia symptom scores at 6 months were similar in the 2 groups, and hence the overall results do not support our original hypothesis. However, this was only achieved by operating again on 5 of the patients who underwent posterior repair and in whom hiatal sutures needed to be removed (2 patients) or the hiatus was tight due to excessive fibrosis (3 patients). It is not surprising that the dysphagia scores at each time point were similar, as the patients with more severe dysphagia usually underwent reintervention before the relevant clinical assessments were performed by the scientific officer.

One interpretation of our study is that anterior hiatal repair is better than posterior repair. However, another interpretation needs to be discussed. The 9% incidence of reoperation for hiatal narrowing in the posterior repair group is much larger than the incidence we have found outside this trial, and in fact, in our most closely observed patients, those involved in 2 other prospective randomized trials,

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It should also be recognized that our management protocol for laparoscopic antireflux surgery encourages a low threshold for early laparoscopic reexploration should a patient’s initial postoperative progress be unsatisfactory. The rationale for this, which has been reported previously,

reintervention before the relevant clinical assessments were performed by the scientific officer.

Nevertheless, we can draw some conclusions from the outcome of this trial. First, a priori, we had thought that an anterior repair was a less satisfactory repair than a posterior repair, since it somehow seems less “anatomical,” it involves suturing under greater tension to oppose the margins of the hiatus, and it tends to make the hiatus a “slit” rather than a “hole.” This study at least allows confidence that an anterior repair can be undertaken with, at least, equal efficacy to a posterior repair, in the short term. It provides an adequate barrier to hiatal herniation, and it does not appear to be responsible for new dysphagia following laparoscopic Nissen fundoplication. Second, the trial demonstrates that dysphagia following antireflux surgery is often due to hiatal problems alone. This has implications for surgical strategies when reoperating for the correction of postfundoplication dysphagia. In these circumstances, the hiatus and the fundoplication should be carefully assessed at surgical reexploration, and if the fundoplication is demonstrably loose and the hiatus is tight, then the hiatus alone should be widened, and the fundoplication can be left intact.

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