Hypothesis: Laparoscopic Nissen fundoplication provides long-term relief of symptoms of gastroesophageal reflux disease.

Design: Prospectively evaluated case series.

Setting: University teaching hospital.

Patients: From September 1991 to December 1999, we performed more than 900 laparoscopic antireflux procedures. The outcome for patients who underwent surgery between September 1991 and June 1994 (178 cases) was determined. This included all patients having laparoscopic Nissen fundoplication, from the first procedure onward.

Interventions: Long-term follow-up for 5 or more years after laparoscopic Nissen fundoplication was obtained by an independent investigator who interviewed patients using a structured questionnaire.

Main Outcome Measures: Prospective evaluation of clinical symptoms using a structured questionnaire.

Results: Outcome data covering a period of 5 or more years after surgery was available for 176 patients (99%), with 2 patients lost to follow-up. Nine patients died (8 of unrelated causes) at some stage following surgery, and the outcome was difficult to determine in 1 patient with cerebral palsy. Hence, questionnaire data were available for 166 patients at a median follow-up of 6 years (range, 5-8 years). Three patients (1.7%) underwent revision surgery for recurrent reflux; 87% of the 176 patients remained free of significant reflux. Reoperation was required for dysphagia in 7 patients (3.9%), 2 for a tight wrap and 5 for a tight diaphragmatic hiatus. In addition, reoperation was necessary for a paraesophageal hiatus hernia in 13 patients (7.3%). Of the reoperations, 56% were performed within 12 months of the original procedure, and 22% during the second year of follow-up. Further surgery was uncommon after 2 years. The long-term outcome was considered “good or excellent” by 90% of patients.

Conclusions: The long-term outcome of laparoscopic Nissen fundoplication is similar to that following open fundoplication. Good results are obtained in most patients.

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PATIENTS AND METHODS

Follow-up data for a period of 5 or more years was sought for all patients undergoing a laparoscopic Nissen fundoplication between September 1991 and June 1994 at the University of Adelaide Department of Surgery at the Royal Adelaide Hospital in Adelaide, South Australia. This included every patient having the laparoscopic procedure since its inception in our institution in September 1991. During this period, all patients admitted for antireflux surgery were offered a laparoscopic approach, irrespective of any difficulties perceived by preoperative assessment such as obesity, large hiatal hernia, previous upper abdominal surgery, esophageal strictureing, or Barrett esophagus. Gastroesophageal reflux was initially diagnosed by the presence of endoscopic esophagitis in patients with typical reflux symptoms, and 24-hour pH monitoring was used to confirm the diagnosis of reflux in patients with atypical symptoms or who did not have endoscopic evidence of esophagitis.

Information about the preoperative assessment and management, surgical procedure, and postoperative outcome for each patient was collected prospectively and stored on a computerized database. Postoperative clinical follow-up was obtained through a standardized questionnaire administered by a nonclinical investigator both 3 months and 12 months following surgery and annually thereafter. This questionnaire was initially mailed to each patient. If it was not returned, the patient was located, and data were collected by telephone interview using the same structured questionnaire. A concerted effort was made to obtain follow-up information for every patient who had undergone surgery, in an attempt to complete follow-up at the 5-year interval.

The presence or absence of heartburn and liquid- and solid-food dysphagia, as well as patient satisfaction with the procedure, was graded from 0 to 10 (0= no symptoms; 10= severe symptoms) using visual analog scales. The presence or absence of gaseous bloating, the ability to belch, the ability to relieve abdominal distension, and the ability to eat a normal diet, and patients' opinions on whether they would undergo the same procedure again under similar circumstances, were also determined. Details of adverse outcomes such as hospital readmission, complications, or surgical revision were recorded. Esophageal manometry, pH monitoring, and endoscopy tended to be performed postoperatively in symptomatic patients with clinical indications, although manometry was sought in the early phase of this series as a method of objective follow-up. The results of this follow-up have been reported previously.

All data analysis was performed on an intention-to-treat basis, and patients whose laparoscopic operation was converted to an open procedure, as well as those requiring later surgical revision, remained in the overall patient group for data analysis.

This surgical technique has previously been described in detail. Five trocars were sited in the upper abdominal wall. In the initial procedure, Veress needle insufflation at the left costal margin was used, and a single laparoscopic grasping instrument was used to retract the left lobe of the liver. Both pillars of the esophageal hiatus were dissected using electrocautery to expose the distal esophagus. Posterior hiatal repair was not performed routinely until 1994. Prior to this, it was performed only in patients with a moderate or larger hiatus hernia. In some patients, short gastric vessels were divided between clips as part of a randomized trial. In all patients, irrespective of whether these vessels were divided or not, a short, loose total fundoplication was constructed, calibrated over a 52F bougie within the lumen of the esophagus. Three interrupted polypropylene sutures were used to secure a total fundoplication of between 1.5 and 2 cm in length.

Long-term outcome data (beyond 5 years) was obtained for 176 patients (99%), with follow-up ranging from 5 to 8 years (median, 6 years). Two patients could not be contacted for follow-up purposes. One of these is an itinerant alcoholic of “no fixed abode” who was last seen in a beachside town on the coast of South Australia, and the other patient is hiding from his ex-wife, 3000 km away, somewhere in the Australian state of Queensland, and is said to be living in fear for his life. Since undergoing the operation, 9 patients have died; however, only 1 of these deaths was related to the laparoscopic procedure. This patient died following the development of thrombosis of the superior mesenteric and celiac arteries in the immediate postoperative period. Full details of this case have been reported. Four patients died of disseminated carcinoma (1 each of cancer of the prostate, colon, lung, and esophagus), 3 of ischemic heart disease, and 1 of “old age.” Another patient has severe cerebral palsy, and communication with her has been difficult, rendering symptomatic assessment unreliable. As far as could be determined, her results have been positive. However, she was excluded from data analysis because she could not be interviewed with the standardized questionnaire. Hence, standardized clinical follow-up data were collected from the remaining 172 patients.

RESULTS

From September 1991 to June 1994, 178 laparoscopic Nissen fundoplication procedures were performed by 6 different surgeons associated with the University of Adelaide Department of Surgery at the Royal Adelaide Hospital or by surgical trainees supervised by 1 of these surgeons. Hiatal repair was performed selectively for the first 153 procedures and routinely for the last 25, and although short gastric vessel division was not routinely performed, the last 30 patients were enrolled in a prospective randomized trial that compared division vs nondivision of these vessels.

This report includes our early learning experience, and 21 (12%) of these procedures required conversion from a laparoscopic to an open approach for the following reasons: intra-abdominal obesity restricting surgical access and obscuring anatomy (9 patients), inability to reduce a very large hiatal hernia (6 patients), dense upper abdominal adhesions (3 patients), and technical difficulties with esophageal dissection because of peri-esophagitis (3 patients).

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data at 5 or more years after surgery were available for 166 patients.

A further surgical procedure was required for 27 patients (15%) because of a problem that developed after the original fundoplication. Thirteen of these procedures were for the repair of a paraesophageal hiatus hernia, 7 were for dysphagia (5 because of a tight esophageal hiatus, 2 for conversion of the Nissen fundoplication to a posterior partial fundoplication procedure), 3 were for recurrent reflux (wrap undone), 3 were because of a technical error resulting in gastric obstruction (creation of an exaggerated bilobed stomach), and 1 patient underwent multiple laparotomies because of mesenteric thrombosis. Another patient (not included in the total) underwent an esophagectomy following the development of severe dysplasia in a segment of Barrett esophagus. Reoperation was performed within a year of the initial procedure in 15 (56%) of the patients, in the second postoperative year in 6 patients (22%), and beyond 2 years in the remaining 6 patients (22%). Thus, at 5 to 8 years’ follow-up, 78% of reoperations had been performed within 2 years of the original procedure. Early postoperative dysphagia sufficient to require endoscopic dilatation occurred in an additional 9 patients (5%). Eight patients were successfully managed with a single dilatation procedure, and 1 patient underwent several dilatations before adequate swallowing was achieved. None of these patients had preoperative endoscopic evidence of an esophageal stricture, although 2 patients did experience preoperative dysphagia of similar severity to what they experienced postoperatively.

In the 166 patients for whom clinical follow-up was obtained at 5 or more years after surgery, 100 patients (60%) had no heartburn, and 45 (27%) had occasional minor episodes of heartburn (heartburn score 1, 2, or 3). Fifteen patients (9%) reported a heartburn score of 4 to 6, and 6 patients (4%) graded their heartburn as 7 or higher (significant troublesome heartburn). Most patients reported a heartburn score of 7 or higher before surgery. Hence, 87% of patients were free of significant reflux symptoms at 5 or more years’ follow-up. Regular acid suppression medication for “reflux” symptoms is being taken by 18 patients (11%), who are included in the groups experiencing more severe symptoms described previously.

Figure 1 and Figure 2 summarize the dysphagia scores for liquids and solids, respectively. More patients had severe dysphagia with liquids (score, 7-10) before surgery than after (P<.001, x² test), although a greater number of patients had milder degrees of dysphagia with liquids (scores, 1-3, 4-6) at long-term follow-up. The overall number of patients with dysphagia with liquids was similar before and after surgery. Although there was a significant reduction in the number of patients with severe dysphagia (scores 7-10) with solids following surgery (P<.001, x² test), fewer patients were totally free of dysphagia with solids, and a greater number reported mild dysphagia (scores, 1-3) at 5 years after surgery.

At 5 years’ follow-up, 72% of patients claimed that they were able to belch. Occasional epigastric bloating after eating was experienced by 66% of all patients, and 71% of this subgroup were able to relieve this symptom by belching. Certain foods were avoided by 11% of patients because of dysphagia or food intolerance. Overall patient satisfaction with the procedure produced a mean satisfaction score of 8.2 (of 10). In similar circumstances, 90% of patients said that they would repeat their operation.

Laparoscopic antireflux surgery is a relatively recent innovation, with most published series describing short-term follow-up,17-19 and relatively few series reporting medium-term outcomes with follow-up for 2 to 3 years after surgery.1,2 No previous studies have reported long-term (5-year) follow-up for a large group of patients who have...
undergone a laparoscopic antireflux procedure. However, the long-term outcome of this operation will ultimately determine its place in the treatment armamentarium for gastroesophageal reflux, and it is essential to demonstrate an acceptable long-term outcome rather than simply to assume that because short-term results are acceptable, long-term results will be equally good. This is of particular relevance to laparoscopic antireflux surgery because the introduction of this new technique was associated with unexpected complications, such as an increased incidence of paraesophageal hiatus herniation. Previous experience with open antireflux surgery had failed to predict many of these problems. Hence, we cannot be certain that long-term results can be extrapolated from short- to medium-term follow-up.

The long-term outcome for open Nissen fundoplication has been reported previously. Although widely quoted, the study of DeMeester et al, which demonstrated a positive outcome for 91% of patients undergoing open Nissen fundoplication, extrapolated a 10-year outcome through an actuarial analysis with a series that reported an average follow-up of 45 months. Long-term data is provided by various Scandinavian series. Lundell et al reported a 12% dysphagia rate and a 10% reflux rate for open Nissen fundoplication at 5 years’ follow-up within their randomized trial of Nissen vs posterior partial fundoplication. Johansson et al also reported a 21% dysphagia rate, 18% recurrent reflux rate, and 84% overall success rate for Nissen fundoplication at 5 years’ follow-up, whereas Luostarinen et al reported an overall success rate of 76% at 20 years’ follow-up. However, complete follow-up was not obtained for each of these series, with Lundell et al reporting a follow-up rate of 37% at 5 years; Johansson et al, 85% at 5 years; and Luostarinen et al, 87% at 20 years. No previous follow-up studies after antireflux surgery have achieved close to a 100% follow-up rate.

To achieve a minimum of 5 years’ follow-up for laparoscopic Nissen fundoplication, we attempted interviews with every patient who underwent this procedure between September 1991 and July 1994, generating a series of 178 laparoscopic Nissen fundoplications. We previously reported that there is a learning curve for this operation; the results of a surgeon inexperienced with this procedure are associated with a poorer outcome, a higher conversion rate, and a higher reoperation rate. Outcomes improve once surgeons have gained this learning experience. We opted to include this factor in our current study because those problems usually appeared at short-term follow-up, and the current study is primarily of long-term outcome. Hence, the 12% conversion rate to open surgery and the reoperation rate of 15% are both high, reflecting this initial learning experience. We now achieve a conversion rate of approximately 2% and a much lower reoperation rate. Although it could be argued that we should not have included “converted” cases in our follow-up analysis, we believe that it is better to include all patients who underwent an attempted laparoscopic procedure and to analyze the data on an intention-to-treat basis. Selectively omitting this group, who tended to be less satisfied with the outcome of their original procedure, could artificially enhance the quality of the overall outcome, and this should be avoided.

Reoperation for paraesophageal hiatus herniation was common initially, and we have discussed this in detail elsewhere. This was a technical problem caused by our failure to routinely narrow the esophageal hiatus (we had not regularly performed hiatal repair during open surgery). Since routinely narrowing the hiatus, the problem of postoperative herniation is now much less common. Similarly, the issue of a tight hiatus caused by fibrosis has become infrequent as we have made adjustments to our surgical technique. Approximately three quarters of all revision procedures were required within 2 years of the original operation, suggesting that many of the previous studies with shorter follow-up after laparoscopic antireflux procedures are reporting data that can reasonably be extrapolated to 5 years’ follow-up.

Postoperative dysphagia is often difficult to assess because the outcome reported depends on who asks about it (eg, surgeon vs independent investigator), how the questions are constructed, and the scoring system used. For this reason, it is better to consider data that compare the same patients at different time intervals (as we have done here) or comparative data from randomized trials. Within the current study, it is clear from Figure 1 that the incidence and severity of dysphagia with liquids was not influenced by laparoscopic Nissen fundoplication and that the number of patients with severe dysphagia with liquids at 5 years was less than the number reporting this problem before surgery. For dysphagia with solid food, there were also less patients with severe dysphagia 5 years after surgery than before surgery. However, more patients reported minor dysphagia with solids at 5 years follow-up than before surgery, and this was caused by an increase in the number of patients with mild dysphagia with solids. Although severe dysphagia was less common, there were more patients overall with dysphagia after surgery, even though it was not usually troublesome and did not require any dietary modification.

Of importance for the assessment of laparoscopic Nissen fundoplication is its ability to abolish reflux symptoms, particularly heartburn. This symptom was not experienced after surgery by 60% of patients. The 27% of patients with a score of 3 or less reported an occasional episode of mild heartburn that did not require medication. Moderate heartburn was reported by 9% of patients, and 4% reported severe heartburn. The outcomes are similar to those following open Nissen fundoplication, suggesting that the laparoscopic approach does not compromise reflux control. Of interest, overall patient satisfaction following surgery was high, with 90% of patients satisfied with their long-term outcome. However, our follow-up is clinical only, and objective follow-up using either pH or endoscopic studies was not sought. It is certainly possible that a few patients who claimed relief of reflux symptoms might demonstrate abnormalities if they underwent either pH monitoring or endoscopy. On the other hand, some of the patients who claimed to experience symptomatic reflux following surgery had no objective evidence of reflux when they underwent postoperative testing. For this reason,
in a clinical practice setting, the symptoms experienced by patients ultimately determine the success or failure of the operations we perform, not the outcome of follow-up tests or the surgeon’s opinion about technical success. Hence, we believe that laparoscopic Nissen fundoplication is an effective long-term treatment for gastroesophageal reflux disease, yielding similar results to open fundoplication but with the short-term advantages of quicker recovery and reduced wound-related morbidity.

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REFERENCES


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The Heart and Estrogen/Progestin Replacement Study Revisited: Hormone Replacement Therapy Produced Net Harm, Consistent With the Observational Data
John A. Blakely, BA, MD, FRCP

Lower coronary event rates in women receiving hormone replacement therapy (HRT) have led to a presumption of benefit. The Heart and Estrogen/Progestin Replacement Study, a large randomized trial, observed a 1.4% first year excess of coronary events, well beyond the plausible play of chance on the expected effect. Over the duration of the study, event rates were similar, but patients treated with HRT experienced them earlier, with a net loss of patient-months of event-free survival. The point at which the lower event rate in hormone-treated patients would fully repay the first year loss, with constant rates, is almost double the trial duration (of 4.1 years). Since patients in the trial were preselected for satisfactory adherence to therapy, the net benefit in practice is likely to be even less. Had the patients in the Heart and Estrogen/Progestin Replacement Study been recruited to an observational study at various intervals over the first 5 years after starting HRT, the apparent risk reduction over 5 years would have been between 21% and 34%. A previous meta-analysis of trials of HRT for other indications also shows net harm. Women with or at high risk of coronary heart disease should not start HRT. There is a risk that women without coronary heart disease might experience even greater net harm from HRT. The late benefit is necessarily limited, as it cannot exceed the event rate. The mechanism of the early loss is unknown; if it were reduced proportionately less than the late benefit, considerable net harm could result. (2000;160:2897-2900)

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