Late results after laparoscopic fundoplication denote durable symptomatic relief of gastroesophageal reflux disease

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**KEYWORDS:**
GERD; Gastroesophageal reflux disease; Laparoscopic fundoplication

Abstract

**BACKGROUND:** Late outcomes after laparoscopic Nissen fundoplication are only now becoming available. This study was undertaken to document late outcomes after laparoscopic Nissen fundoplication.

**METHODS:** Five hundred ten patients underwent laparoscopic Nissen fundoplication >10 years ago and were prospectively followed. Preoperatively and postoperatively, patients scored the frequency and severity of symptoms (from 0 = never/not bothersome to 10 = always/very bothersome). Symptom scores before and after fundoplication were compared. Median symptom scores are presented.

**RESULTS:** Early after fundoplication, significant improvements were noted in the frequency and severity of symptoms (e.g., for heartburn, from 8 to 0 and from 8 to 0, respectively, $P < 0.001$ for each). Late after fundoplication, significant improvements were maintained in the palliation of symptoms (e.g., frequency and severity for heartburn, 2, 1; respectively). At latest follow-up, 89\% of patients were pleased with their symptom resolution.

**CONCLUSIONS:** With long-term follow-up, laparoscopic Nissen fundoplication durably and significantly palliates symptoms of gastroesophageal reflux disease. This trial promotes the application of laparoscopic Nissen fundoplication.

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According to several population-based studies, the symptoms of gastroesophageal reflux disease (GERD) are experienced by 7\% to 20\% of Americans daily, and 15\% to 44\% of Americans experience GERD symptoms to some degree at least once a month.\textsuperscript{1–3} Patients who suffer from GERD report that they avoid eating and drinking particular foods and beverages. Some of the more common symptoms patients experience and consider bothersome include heartburn, dysphagia, regurgitation, chest pain, and a bitter taste in mouth.\textsuperscript{4}

Prolonged esophageal exposure to acid reflux can result in harmful outcomes, including Barrett’s esophagus, esophageal strictures, and ultimately adenocarcinoma. Operative treatment for GERD must be seriously considered. In 1965, Nissen and Rossetti described a technique for hiatal hernia repair that is considered the precursor for an “open” 360° fundoplication for GERD. In 1991, Dallamagne and
Geagea described a laparoscopic approach to fundoplication, which quickly gained favor at most surgical centers.\textsuperscript{5–8} Previous trials have determined surgical intervention to be superior to medical treatment.\textsuperscript{4,9} Generally, outcomes after laparoscopic fundoplication for the treatment of GERD are excellent. Most studies document that symptom relief and patient satisfaction are very high, but the vast majority of studies focus on short-term outcomes. The outstanding outcomes achieved with laparoscopic fundoplication suggest that it should replace lifelong medical therapy as an effective first-line therapy for patients with GERD requiring open-ended therapy.\textsuperscript{9}

We have published several articles establishing the efficacy of laparoscopic fundoplication by surveying patient satisfaction preoperatively and postoperatively.\textsuperscript{10–13} Despite these and numerous other studies, the safety, durability, and efficacy of fundoplication, and thus symptom relief, as well as patient satisfaction in late follow-up, are still topics of concern. This report is of a prospective trial of patients who underwent laparoscopic fundoplication, a large number of whom have follow-up at or beyond 10 years. The purpose of this trial was to analyze our long-term results (\(\geq 10\) years after fundoplication) and make meaningful conclusions regarding the safety, efficacy, and durability of laparoscopic fundoplication. In undertaking this study, we hypothesized that laparoscopic fundoplication can be applied safely and that symptom relief and patient satisfaction remains high in the long term.

**Methods**

Since 1992, with informed consent, 1,170 patients have undergone laparoscopic Nissen fundoplication and have been followed prospectively with institutional review board approval at the University of South Florida. Five hundred ten of the 1,170 patients had \(\geq 10\)-year follow-up. Before fundoplication, ambulatory esophageal pH monitoring was obtained to confirm the presence of excessive acid reflux. A stationary water perfusion esophageal manometry or esophagography in a \(15^\circ\) head-down position using barium-laden food bolus was used to document esophageal motility.\textsuperscript{14} All 510 patients included in this study had normal esophageal motility.

Before and after fundoplication, all patients scored the frequency and severity of their symptoms, including symptoms of dysphagia and heartburn, using a Likert-type scale (from 0 = never/not bothersome to 10 = always/very bothersome; Table 1). Scores were noted early (3–6 months) and late (\(\geq 10\) years) after fundoplication. Patients were queried on their satisfaction at latest follow-up, with responses ranging from very unsatisfied to very satisfied. Patients also scored their outcomes as excellent (complete resolution of symptoms), good (symptoms less than once per month), fair (symptoms occurring less than once per week), or poor (symptoms similar to or worse than before fundoplication or the onset of new troubling symptoms).

**Table 1** Some of the symptoms queried before and after laparoscopic Nissen fundoplication

<table>
<thead>
<tr>
<th>How often do you experience</th>
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<tbody>
<tr>
<td>Food gets stuck</td>
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<tr>
<td>Postprandial chest pain</td>
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<tr>
<td>Forceful vomiting</td>
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<tr>
<td>Regurgitation</td>
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<tr>
<td>Choking</td>
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<tr>
<td>Coughing</td>
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<tr>
<td>Heartburn</td>
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<table>
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<tr>
<th>Severity of symptoms</th>
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<tbody>
<tr>
<td>Heartburn postprandial/while sleeping</td>
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<tr>
<td>Nausea/vomiting/regurgitation after meals</td>
</tr>
<tr>
<td>Food stuck in throat/chest</td>
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<tr>
<td>Difficulty swallowing</td>
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<tr>
<td>Bitter taste in mouth postprandial/while sleeping</td>
</tr>
<tr>
<td>Asthma/coughing</td>
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<tr>
<td>Gas/bloating</td>
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<tr>
<td>Have you had dietary changes for</td>
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<tr>
<td>Spicy foods</td>
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<tr>
<td>Bread</td>
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<tr>
<td>Meat</td>
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<tr>
<td>Coffee</td>
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<td>Alcohol</td>
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**Operative technique**

Our technique of laparoscopic Nissen fundoplication has been described previously.\textsuperscript{14} In brief, laparoscopic Nissen fundoplication was undertaken with the patient in the supine position using a 5-port technique. The gastrohepatic omentum was opened widely. Dissection was carried along the edge of the right crus, working to reduce any hiatal hernia and free an adequate length (6–8 cm) of intra-abdominal esophagus. The stomach was then rolled to the patient’s right, and the short gastric vessels were divided. Dissection was carried along the edge of the left crus and into the mediastinum such that any hiatal hernia was completely reduced and the sac excised. A generous window dorsal to the esophagus was established. A posterior cruroplasty was sutured with 0-gauge braided polyester sutures (Endostitch; Covidien, Norwalk, CT) to close the esophageal hiatal defect. The gastroesophageal fat pad was routinely removed. The posterior fundus was brought behind the esophagus with a 52-Fr to 60-Fr bougie placed per os into the stomach, and the fundoplication was constructed. The anterior fundus was secured twice to the esophagus and to the posterior fundus well above the gastroesophageal junction. A third suture brought the anterior fundus and the posterior fundus together at the gastroesophageal junction. Then, the dorsal-most portion of the posterior fundus behind the esophagus was sutured to the esophagus and then to the right crus to relieve tension, which might otherwise result in twisting of the lower esophagus or promoting “unwrapping” of the fundoplication. This final suture also augmented the angle between the stomach and esophagus.
accentuating the angle of His. All trocar sites were closed with monofilament absorbable sutures under laparoscopic visualization using the Endo Close device (Covidien). Patients were started on a liquid diet on the day of fundoplication and were discharged home <24 hours after their operations if possible. They were given instructions to advance to a soft mechanical diet over the next 2 weeks. After discharge, patients were seen in the outpatient clinic until well and followed annually thereafter. At the time of each contact, patients graded the frequency and severity of their symptoms.

Statistical analysis

Data are maintained in a file-based registry (Excel; Microsoft Corporation, Redmond, WA) and were analyzed using Wilcoxon’s matched-pairs test or the Mann-Whitney U test, using GraphPad InStat version 3.06 (GraphPad Software, Inc, San Diego, CA). For each patient, symptom scores before fundoplication and early and late after fundoplication were compared using Wilcoxon’s matched-pairs test. Significance was accepted with 95% probability. As appropriate, data are presented as median (mean ± SD).

Results

Since 1992, 510 patients with a median age of 54 years, a median body mass index of 27 kg/m², and normal esophageal motility underwent laparoscopic Nissen fundoplication for the treatment of GERD, with postoperative follow-up of ≥10 years. Of these patients, 44% were men. Seventy-three patients (14%) had undergone previous fundoplication and underwent “redo” fundoplication because of recurrent symptoms of GERD; 64 of these patients (88%) had their primary fundoplication at an outside facility.

The median preoperative DeMeester scores was 39 (mean, 57 ± 56.7), and the median preoperative duration of symptoms was 8 years (mean, 11 ± 9.9 years). Before laparoscopic fundoplication, patients reported the frequency and severity of their symptoms to be both frequent and severe, respectively (Fig. 1). Heartburn was a particularly frequent and severe symptom.

The median length of hospital stay for patients undergoing Nissen fundoplication was 1 day (mean, 3 ± 5.2 days). Intraoperative inadvertent events or complications occurred in 22 patients (4%), of whom 6 had capnothorax and 16 were converted from laparoscopic Nissen fundoplication to an “open” operation via a midline abdominal incision; 8 patients underwent intraoperative repair of a gastrostomy or esophagotomy, 1 patient had hemorrhage from gastric varices, 1 patient had a splenic tear, and 6 conversions to open operations were undertaken in patients with previously failed Nissen fundoplication because of extensive adhesions. Postoperative complications occurred in 25 patients (5%) and were generally minor in consequence and not specific to laparoscopic Nissen fundoplication. However, 1 patient aged 76 years died 19 days postoperatively because of myocardial infarction.

Of the 510 patients who underwent laparoscopic Nissen fundoplication, 317 (62%) are currently followed via questionnaires delivered to them in the clinic, at home, or by phone. Of the 193 patients who were lost to follow-up, 90 patients are dead and 103 have discontinued follow-up because of failure to notify us of an address change or repeated failures to reply to the questionnaire. For patients dying during long-term follow-up, their median age at laparoscopic fundoplication was 67 years (mean, 67 ± 12.5 years), and their median age at death was 75 years (mean, 74 ± 12.4 years).

Palliation of symptoms was dramatic in the months after fundoplication for all symptoms queried (Fig. 1). After the most recent survey of patients with ≥10 years of follow-up, patients continue to report widespread and dramatic palliation of symptoms compared with preoperative symptoms (Fig. 1). Despite the slight increase in scores of frequency of dysphagia and severity of heartburn between the early (3–6 months) and late (≥10 years) periods after fundoplication, the scores were not significantly different, and overall, the scores were low. Symptom relief in the early postoperative period compared with the late postoperative period showed no significant change in the palliation of reflux symptoms with prolonged follow-up.

Early after laparoscopic Nissen fundoplication, 76% of patients reported a good or excellent overall experience. Seventy-six percent of patients reported that they were satisfied or very satisfied with their symptom resolution, and 91% said that they would undergo the operation again knowing what they know now. Eighty-four percent reported that they would undergo the operation again knowing what they know now. Eleven percent of patients scored outcomes as poor.

Comments

The large number of Americans who require relief from their symptoms of GERD confirms the need for effective long-term treatment. Aside from medical therapy, the long-term problems of which are well documented, several endoscopic treatments have also been studied. These treatments can be grouped into those that pleat or plicate the upper stomach, deliver thermal energy into the lower esophageal sphincter, or inject or implant biopolymers into the gastroesophageal junction. However, although these treatments have shown to improve symptoms in the short term, none has proved to have long-term durability, and there are safety concerns with some of these treatments. Therefore, in looking to declare laparoscopic Nissen
Fundoplication as definitive therapy, it is imperative to document and assess long-term symptom relief after this operation. With our long-term follow-up, we have confirmed the long-term efficacy and durability of laparoscopic Nissen fundoplication for symptomatic control of GERD. Of the 510 patients who underwent laparoscopic Nissen fundoplication for treatment of GERD with follow-up ≥ 10 years, most were of middle age, with a relatively equal distribution of men and women. Preoperatively, patients reported having symptoms of GERD for approximately 10 years, with high preoperative DeMeester scores. Early after laparoscopic fundoplication, patient relief from symptoms was dramatic. Short-term results were maintained >10 years later, as patients had no significant change in palliation of their reflux symptoms. Nearly 80% reported good or excellent overall experience and were satisfied or very satisfied after undergoing their operations. This is very rigorous in our evaluation of laparoscopic fundoplication, because to achieve a “good outcome,” symptoms must occur only once per month or less.

Fewer than 2 of 10 patients would not elect to undergo laparoscopic fundoplication again, knowing what they know now. It seems that there is no single reason why these patients would not undergo fundoplication again. However, included in their list of reasons to forgo the initial fundoplication are recurrence of symptoms, appearance of new symptoms, cost, pain, inconvenience of travel, and time off work.

Postoperative complications occurred in a small number of patients, most of little consequences. Notably, a relatively large number, 14%, of patients were undergoing revisional operations for their reflux. The great majority of these patients had their previous fundoplication at other institutions. Of the patients in this prospective study, nearly 1 in 5 died during follow-up. These patients were generally elderly at the time of their fundoplication, and 10-year follow-up would have given a median age of nearly 80 years. Of patients believed to be alive, three quarters are being followed at ≥ 10 years. Some patients were lost to follow-up despite aggressive attempts to find and follow them.

In this study, there is a lack of objective evidence that documents resolution of GERD. Postoperative Bravo pH studies were not undertaken by protocol to objectively evaluate patients’ resolution of reflux, though patients subjectively reported long-term satisfaction and symptom resolution after their operations. In our experience, patients will not routinely undergo Bravo pH probe placement and study, and all that entails, because of cost, inconvenience, time, discomfort, and considerations that such study is superfluous.

Other authors have shown similar results to ours with considerably fewer patients. Broeders et al\textsuperscript{16} randomized
148 patients to undergo either open Nissen fundoplication or laparoscopic Nissen fundoplication and found after 10 years of follow-up that GERD symptoms were relieved in 92% versus 91% after laparoscopic versus open Nissen fundoplication. Slightly more patients had relief of regurgitation after laparoscopic as opposed to open fundoplication. The authors found that there was a higher risk for operative reinterventions with open Nissen fundoplication because of incisional hernia repairs. The 10-year effectiveness of laparoscopic and open fundoplication was similar with regard to control of GERD symptoms, proton pump inhibitor use, and quality of life. The percentage of patients who would have opted to undergo fundoplication again was 79%. Another trial by Salminen et al had found that 89% of 394 patients that had undergone laparoscopic Nissen fundoplication between 1996 and 2001 regarded their operative results as excellent, good, or satisfactory at 51 months; 83% would choose surgical intervention again, and 87% of the patients had no significant reflux symptoms.

GERD is not likely to disappear in the immediate years to come. Rather, with ever worsening obesity and other factors promoting GERD in the United States, GERD will become an even larger public and personal health issue than it is today. Efficacious and durable relief of GERD must be recognized and applied.

This prospective trial of patients undergoing laparoscopic Nissen fundoplication denotes dramatic short-term palliation of symptoms of GERD, which proves to be durable and efficacious with follow-up at a decade or more. Thereby, this trial promotes continued application of laparoscopic Nissen fundoplication.

References