

Prospective Study of Laparoscopic Nissen Fundoplication in a Community Hospital and Its Effect on Typical, Atypical, and Nonspecific Gastrointestinal Symptoms

Mark E. Ranson, MD, Amanda Danielson, MS, J. Gary Maxwell, MD, James A. Harris, MD

ABSTRACT

Background: Laparoscopic Nissen fundoplication (LNF) provides long-term improvement in the typical symptoms of gastroesophageal reflux disease. Few studies have prospectively addressed LNF in the community hospital or the effect of LNF on specific atypical symptoms, other related gastrointestinal symptoms, and weight change.

Methods: Data were collected prospectively on consecutive patients having LNF. Three typical, 6 atypical, and 3 other gastrointestinal symptoms were studied.

Results: Short-term data on 91 patients and long-term data on 84 patients were studied. Overall long-term improvement was 98%. Regarding typical symptoms, the greatest improvement occurred in heartburn and regurgitation. Regarding atypical symptoms, the greatest improvement occurred in cough and sore throat, but chest pain, hoarseness, and throat clearing also showed significant durable improvement. Bloating, nausea, and diarrhea showed no significant change from preoperative to postoperative surveys. Mild weight loss was common.

Conclusion: LNF can be safely performed in a community hospital with results equal to those of university hospitals. Improvement in typical symptoms was greater than improvement in atypical symptoms, but results for both were significant and durable. Nonspecific gastrointestinal symptoms, such as nausea, bloating, and diarrhea, may be unrelated to Nissen fundoplication.

Key Words: Laparoscopy, Nissen fundoplication, Community hospital.

Department of Surgery, University of North Carolina Chapel Hill, Chapel Hill, North Carolina, USA (Drs Maxwell, Harris).

Department of Surgery, New Hanover Regional Medical Center, Wilmington, North Carolina, USA (Drs Ranson, Maxwell, Harris).

Coastal Area Health Education Center, Wilmington, North Carolina, USA (all authors).

Address reprint requests to: Mark E. Ranson, MD, Department of Surgery, Coastal AHEC, PO Box 9025, 2131 S. 17th St., New Hanover Regional Medical Center, Wilmington, NC, 28402-9025, USA. Telephone: 910 762 9091, Fax: 910 763 4630, E-mail: ransonmark@hotmail.com

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INTRODUCTION

Laparoscopic Nissen fundoplication (LNF) was first introduced by Dallemagne et al in 1991 in Belgium.¹ Since its initial description, LNF has gained wide acceptance from surgeons and popularity with patients in the treatment of gastroesophageal reflux disease (GERD). Many short- and long-term studies have shown its effectiveness in the treatment of the classical symptoms of GERD, which include heartburn, regurgitation, and dysphagia. Results of prospective and retrospective studies with follow-up of 5 to 10 years confirm its utility.²⁻⁶ However, most studies have been based on patients treated in large university hospitals. Although retrospective studies have shown equivalent results, few of the prospective studies of LNF have been performed in a community setting.⁷ The response of atypical GERD symptoms, such as cough, hoarseness, throat clearing, chest pain, and asthma, to LNF performed in any setting remains controversial.⁸⁻¹⁰

We sought to answer the following 3 questions¹: Can LNF performed in a community hospital replicate the improvement in typical symptoms reported by university based series?² Can specific atypical symptoms be expected to improve after LNF?³ Are nonspecific GI symptoms improved or are they worsened as a result of the fundoplication procedure?

METHODS

Consecutive patients at New Hanover Regional Medical Center, a 690-bed community, nonuniversity teaching hospital, undergoing LNF by the same surgeon (JH) from October 2001 to August 2005 were studied. The institutional review board approved the study design. Patients with large, paraesophageal hernias, intrathoracic stomach, or those undergoing a nonelective repair were excluded. Additionally, those who underwent a Toupet type fundoplication or other partial wrap procedure were excluded. In order of frequency, patients were referred for surgical treatment by gastroenterologists, internal medicine specialists, family practitioners, otolaryngologists, other surgeons, and by self referral.

For evaluating symptoms, we considered the Visick grading system, but wished to utilize a more simple system to

maximize the completion rate.¹¹ We used a modified version of the previously validated Allen scoring system.¹² Twelve distinct GI symptoms were graded individually by the patient as none, mild, moderate, or severe, and converted to a numeric score from 0 (none) to 3 (severe). Preoperative, postoperative, and long-term surveys all used the same scoring system. The 3 typical symptoms were defined as heartburn, regurgitation, and difficulty swallowing. Atypical symptoms investigated were chest pain, cough, hoarseness, sore throat, throat clearing, and asthma. Nonspecific GI symptoms studied consisted of nausea, bloating, and diarrhea.

All patients had been previously treated or were currently under treatment with proton pump inhibitor (PPI) therapy. Patients with typical GERD symptoms who had an appropriate response to PPI therapy and return of symptoms when medications were stopped were considered to have classical reflux and did not undergo an esophageal pH probe, although in some patients this had been performed before referral. All patients with atypical symptoms or a poor response to PPI therapy underwent a preoperative esophageal pH study. All patients underwent preoperative esophagogastroduodenoscopy (EGD), either before referral or by the operating surgeon, and esophageal manometry.

At the laparoscopic repair, the gastroesophageal junction was circumferentially mobilized, the short-gastric vessels were divided routinely, and the gastric fundus was completely mobilized. Two sutures were routinely placed to close the crus posterior to the esophagus. Three gastrogastric sutures, incorporating the esophagus, were then placed over a 54- to 60-French bougie to construct a 2-cm floppy Nissen wrap.

Patients were seen in follow-up in the office at 1 to 2 weeks and then at 6 weeks postoperatively. Questionnaires were completed at the preoperative and each of the postoperative office visits to assess the 12 GI symptoms described, and information regarding weight loss, early satiety, increased flatus, and response to surgery were recorded. The long-term survey was identical to the short-term survey and was conducted by one of the authors (MR, AB) by phone between August and October of 2005. Exhaustive attempts were made to locate and contact every patient.

Patient weights were recorded at all visits. Early satiety and increased flatus, compared with that preoperatively, was scored as either present or absent. Patients scored their overall response to surgery as marked improvement,² some improvement,¹ no change (0), somewhat

worse (-1), and much worse (-2). As data were collected, they were entered into a database.

Mean category scores were calculated, and paired *t* tests were conducted to compare preoperative scores with those of long-term follow-up. To assess changes in individual symptoms, paired *t* tests were conducted for each symptom; however, to control for the number of individual *t* tests, the significance level was adjusted to 0.01.

RESULTS

The study comprised 35 men (38%) and 56 women (62%). The mean age was 46.8 ± 12.70 years (range, 18 to 74). No perioperative or postoperative deaths occurred, although 2 patients died 1 year later; 1 after complications of gastric bypass surgery performed at an outside institution, and 1 from an apparent suicide. Conversion to an open procedure was not required. The average length of stay was 1.1 ± 0.43 days (range, 7 hours to 2 days). Three patients required a second operation: 1 for a port-site hernia repair, 1 for laparoscopic conversion to a Toupet for postoperative dysphagia, and 1 for a laparoscopic repair of a herniated wrap after a fall. One patient required 2 operations: laparoscopic repair of a slipped wrap initially followed by a second recurrence with conversion to a Collis-Nissen gastroplasty to correct esophageal shortening.

Preoperative pH study of the esophagus was completed in 36 patients, (40%) with an average preoperative DeMeester score of 53.97 (range, 7.70 to 363.00). Manometry was done on 73 patients (80%), and the average lower esophageal sphincter pressure was 20.54 mm Hg (range, 0 to 56). EGD was completed on 91 (100%) patients. Esophagitis was present in 36 patients (40%), but in more than half the condition was considered mild. Eight patients had a Schatzki ring, and in 3 there was significant stricture formation.

Of the 91 patients who underwent LNF during the study period, 94% of preoperative and short-term surveys were completed. Long-term data were collected on 85% of the 84 patients who were more than 6 months postoperative. Mean time from surgery to long-term survey was 24.6 ± 11.41 months (range, 6 to 46.5). Only individuals who completed all surveys were used in the final symptom comparative analysis (n=69).

Typical symptoms were more common than atypical symptoms at presentation with 93% of patients complaining of significant typical symptoms (moderate or severe, score of 2 or 3), while 74% complained of significant atypical symptoms. While 71% had mixed significant typ-

ical and atypical symptoms, only 19% presented with only significant typical symptoms, 7% had only atypical symptoms. Fifty-two percent of patients reported at least one significant nonspecific GI symptom. No patient underwent antireflux surgery for nonspecific GI symptoms without at least one significant typical or atypical symptom.

The mean scores for each of the 12 GI symptoms from preoperative through long-term follow-up are summarized in **Table 1**. Prevalence of preoperative typical symptoms was heartburn in 95%, regurgitation in 98%, and dysphagia in 72%. Heartburn and regurgitation had the greatest overall improvements of typical symptoms, while cough and sore throat had the greatest improvements of atypical symptoms. Prevalence of preoperative atypical symptoms was throat clearing in 86%, cough in 75%, chest pain in 75%, hoarseness in 63%, sore throat in 53%, and asthma in 34%. Of the atypical symptoms, chest pain, cough, hoarseness, sore throat, and throat clearing all showed statistically significant improvement. Asthma did not show significant improvement. Typical symptoms showed greater improvement than atypical symptoms did, but both were statistically significant (**Table 2**).

Although atypical symptoms were prevalent in our study, their severity was less than that of typical ones (mean score: 1.9±0.61 typical, 1.1±0.68 atypical). **Table 3** sum-

marizes those symptoms present at any time during the study and their change by individual patient over time.

Early satiety and increased flatus were both common after surgery. At short-term follow-up, 96% of patients reported early satiety. This dropped to 78% at long-term follow-up. Increased flatus was stable throughout the postoperative period with 79% and 78% reporting it at short- and long-term surveys.

Mean objective short-term weight loss was 6.6±5.56 pounds (range, 7 lb gain to 43 lb loss). Mean subjective long-term weight loss was 7.0±13.32 lbs.

Overall subjective patient improvement was high. At the short-term evaluation, 100% of patients felt they were better: 87% reported marked improvement, and 13% some improvement. This improvement was durable with 98% remaining improved at long-term follow-up: 86% reported marked improvement, 12% some improvement, 1% no change, and 1% worse.

DISCUSSION

Many published studies address the impact of LNF on the typical symptoms of GERD, with patient satisfaction of 86% to 93% at 5 years and 10 years after surgery reported

Table 1.
Symptom Responses* After Laparoscopic Nissen Fundoplication

Symptom	Pre-op	Short-term	Long-term	% Decrease	P Value
Typical					
Heartburn	2.3 ± 0.81	0.1 ± 0.32	0.6 ± 0.98	74%	< 0.01
Regurgitation	2.1 ± 0.76	0.1 ± 0.38	0.3 ± 0.72	86%	< 0.01
Dysphagia	1.3 ± 1.09	0.7 ± 0.72	0.6 ± 0.98	54%	< 0.01
Atypical					
Chest Pain	1.4 ± 1.05	0.5 ± 0.66	0.7 ± 0.94	50%	< 0.01
Cough	1.2 ± 0.97	0.4 ± 0.63	0.5 ± 0.76	58%	< 0.01
Hoarseness	1.2 ± 1.05	0.4 ± 0.66	0.6 ± 0.84	50%	< 0.01
Sore Throat	0.9 ± 0.98	0.2 ± 0.44	0.4 ± 0.89	56%	< 0.01
Throat Clearing	1.5 ± 0.97	0.6 ± 0.66	0.8 ± 0.95	47%	< 0.01
Asthma	0.5 ± 0.85	0.2 ± 0.48	0.4 ± 0.82	20%	ns
Nonspecific GI					
Nausea	0.8 ± 0.96	0.2 ± 0.79	0.4 ± 0.80	50%	ns
Bloating	1.2 ± 1.16	0.7 ± 0.73	1.0 ± 1.13	31%	ns
Diarrhea	0.8 ± 0.96	0.45 ± 0.71	0.5 ± 0.85	50%	ns

*Modified Allen scores

Table 2.
Summary of Responses of Symptoms* After Surgery

Category	Preop	Short-term	Long-term	% Decrease	P Value
Typical	1.9 ± 0.61	0.3 ± 0.32	0.5 ± 0.57	74%	< 0.01
Atypical	1.1 ± 0.68	0.4 ± 0.34	0.5 ± 0.55	55%	< 0.01
Non-specific GI	1.0 ± 0.87	0.4 ± 0.49	0.6 ± 0.68	40%	ns

*Modified Allen scores.

Table 3.
Specific Symptoms Responses* After Laparoscopic Nissen Fundoplication

Symptoms by Individual	Prevalence† (n) %	Resolved (n) %	Improved† (n) %	No change (n) %	Worsened (n) %
Typical					
Heartburn	(67) 97%	(44) 66%	(61) 91%	(4) 6%	(2) 3%
Regurgitation	(67) 97%	(53) 79%	(58) 87%	(4) 6%	(5) 7%
Dysphagia	(55) 80%	(28) 51%	(37) 67%	(10) 18%	(8) 15%
Atypical					
Chest Pain	(55) 80%	(27) 49%	(38) 69%	(9) 16%	(8) 15%
Cough	(55) 80%	(35) 64%	(42) 76%	(6) 16%	(7) 13%
Hoarseness	(47) 68%	(22) 47%	(33) 70%	(6) 13%	(8) 17%
Sore Throat	(41) 59%	(25) 61%	(31) 76%	(2) 5%	(8) 20%
Throat Clearing	(60) 87%	(26) 43%	(40) 67%	(12) 20%	(8) 13%
Asthma	(24) 35%	(10) 42%	(12) 50%	(6) 25%	(6) 25%
Non-specific GI					
Nausea	(32) 46%	(16) 50%	(19) 59%	(6) 19%	(7) 22%
Bloating	(54) 78%	(15) 28%	(25) 46%	(10) 19%	(19) 35%
Diarrhea	(40) 58%	(18) 45%	(24) 60%	(8) 20%	(8) 20%
All Typical	(189) 91%	(125) 66%	(156) 83%	(18) 9%	(15) 8%
All Atypical	(282) 68%	(145) 51%	(196) 70%	(41) 15%	(45) 16%
Non-specific GI	(126) 61%	(49) 39%	(68) 54%	(24) 19%	(34) 27%

*Modified Allen scores.

†“Prevalence” is symptom at either preoperative or postoperative evaluation. “Improved” includes those patients whose symptoms resolved.

from large university studies,^{2,3,5,6,12,13} We were able to demonstrate a similar community hospital response with 98% of patients stating they were improved (86% markedly improved) at a mean of 2 years following surgery. Although our follow-up duration was shorter compared with that of some studies, patient satisfaction remains durable across time.⁶

The most impressive response of LNF is on relief of heartburn and regurgitation. In our patients, improvement of

heartburn was achieved in 91% with complete resolution 66%. Regurgitation improved in 87% with complete resolution in 79%. These results compare favorably with results reported in the literature.^{2,4,7}

Response to dysphagia is difficult to predict, with lack of improvement varying from 1% to 37% in reported studies.^{6,7,14-16} The mechanism of dysphagia before surgery may be completely different than that taking place after surgery. Preoperative difficulty swallowing from GERD is

secondary to the pathologic acid exposure to the esophagus, with or without stricture formation from chronic inflammation. Postoperative dysphagia may be a sign of continued reflux pathology or may result from the wrap itself. The broad range in prevalence among the reports cited is due, at least partly, to the different definitions by the authors. We chose a very loose definition and simply asked the patient whether they had any difficulty swallowing solids or liquids. The preoperative prevalence of dysphagia in this study was 80%; 67% improved (51% resolved), but 15% worsened in their symptom score. While this result is within the reported range, we feel our less stringent definition may provide a more realistic expectation of patients postoperatively.

Retrospective and prospective studies have looked at change in atypical symptoms of GERD after laparoscopic antireflux procedures.^{8-10,13,16,17} Most of these studies do not separate the outcomes based on the surgical technique utilized and include a variety of different procedures: Nissen, Collis-Belsey, Belsey, Toupet, and Hill. Only one study looked solely at LNF, was done prospectively, and was a symptom-based study.¹³ Given the continued controversy over outcomes based on the procedure performed, it is difficult to know whether the outcome of atypical symptoms is influenced by the type of repair and, if so, what kind of results the surgeon and patient can expect for atypical symptoms for any given approach.⁶ We chose to examine a single approach, LNF, to avoid confounding factors. Confusion is added from the varying definition of atypical symptoms. Few authors report the response to specific symptoms but rather lump all atypical symptoms together or into classes: laryngeal, chest/epigastric pain, and/or pulmonary symptoms.^{8-10,18} Included in the definition of atypical symptoms by different authors are the following: asthma, chest pain, epigastric pain, odynophagia, cough, hoarseness, globus, halitosis, enamel loss, sore throat, vocal cord polyps, indigestion, vomiting, choking, belching, wheezing, and aspiration.^{8-10,15,17-19}

A large variation also exists in the reported response to atypical symptoms. Improvement in atypical symptoms ranges from 41% to 93% and resolution from 13% to 48%.^{8,9,13,18} This broad range in results is secondary to the huge variation in study types, included symptoms, and definition of "improved" and "resolved." We chose a strict definition of "resolved" for our data; even mild symptoms were not considered resolved. With this strict definition, our findings of overall resolution in 51% and improvement in 70% of patients for a wide range of atypical symptoms compares very favorably with results of other studies.

Our data show that the prevalence of atypical symptoms varies from 35% to 80%, depending on the symptom. We also found the majority of patients present with a mixed typical and atypical symptom combination. Our results also varied significantly by symptom. The greatest improvements were seen in cough and sore throat, while the worst was seen in asthma. Had we lumped asthma and cough together as "all pulmonary," we would have missed the improved potential to help patients with cough rather than asthma as a symptom.

The presence of nonspecific GI symptoms (nausea, bloating, and diarrhea) encountered by patients who undergo laparoscopic antireflux procedures is well documented.^{3,4,5,8,15,16} Rates of postoperative bloating, 20% to 66%, and diarrhea, 12% to 25%, have been previously reported.^{3,4,5,15} These symptoms are frequently reported postoperatively without a preoperative comparison and erroneously attributed to the fundoplication.¹⁵ Because we found these symptoms to be less severe than the reflux symptoms for which the patient is referred, the patient may indeed have recall bias in many of these reports as they focus more on their relatively more severe reflux symptoms and only notice the milder GI symptoms once their reflux is relieved postoperatively. Our preoperative survey of these nonspecific gastrointestinal symptoms shows that they are relatively common and actually improve more often than they worsen. We found no statistically significant change in these symptoms from preoperative to long-term follow-up evaluation. This finding demonstrates that their presence postoperatively may be unrelated to the fundoplication itself.

Our high rates of early satiety and increased flatus are higher than those in other reports. Weight loss has not been previously reported after laparoscopic antireflux procedures. Our high rate of early satiety (96%) may explain the modest weight loss of 6.6lbs for the cohort. We found satiety to improve over the long-term but did not find the same for improvement in the increased flatus. Seventy-eight percent of patients experienced this at an average of 2 years of follow-up; this rate is higher than that in other published data.^{2,15,16} Booth et al² followed this symptom for up to 8 years and found it to decrease from 55% at 2 to 5 years postoperatively to 38% at 5 to 8 years. The high rate of early satiety among our patients may be due to routine complete mobilization of the distal esophagus and the utilization of the fundus in the wrap, thus affecting its receptive-relaxation function.

Several weaknesses can be described in our study. Our mean long-term follow-up of 24.6 months is considered

only intermediate in length compared with follow-up in some series. Our reported long-term data are subjective in nature and based on symptoms rather than objective, quantitative data. However, other studies have already documented the short-term and very long-term results of LNF, and our community data compare favorably.²⁻⁶ Anvari and Allen³ demonstrated in a large prospective study that pH probe and manometry are poor predictors of perceived severity as well as response to fundoplication. Additionally, as fundoplication is typically done to control symptoms, patient perception of the control of the symptoms for which they underwent surgery is the best determinant of success.

CONCLUSION

LNF can safely be performed in a community setting with results similar to those reported in large university based practices. Typical symptoms show a greater response to LNF than atypical symptoms. Most of the atypical symptoms show significant and durable responses. Increased flatus, early satiety, and mild weight loss are common after LNF. When seen postoperatively, nausea, bloating, and diarrhea are not necessarily a side effect of the fundoplication.

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