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Outcomes in Open Nissen Fundoplication Compared with Laparoscopic Nissen Fundoplication in Adults with Antireflux Surgery

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Abstract

Background: Laparoscopic Nissen fundoplication (LNF) is regarded as the surgical treatment of first choice for refractory gastroesophageal reflux disease. It has generally been assumed that patients undergoing laparoscopic fundoplication will have less pain and a faster recovery. Initially there has been some question about whether the laparoscopic fundoplication would be as effective as the open fundoplication in the treatment of gastroesophageal reflux disease, therefore randomized studies comparing the two have focused on several points. These include symptomatic relief, complications, post-operative side effects and durability of symptom relief.

Methods: A systematic search of the literature was conducted using Medline, Cochrane Database of Systematic Reviews (Evidence-based Medicine) and the Institute for Scientific Information Web of Science from January 2004 until February 2010 using terms: Gastroesophageal reflux and Nissen fundoplication or antireflux surgery or open Nissen fundoplication, randomized and outcomes. A manual search was performed using references from the articles retrieved and main review articles.

Results: Six randomized studies met the inclusion criteria. Of these, several involved the compilation of data from the same cohort of patients at different follow-up times. All data gathered from a particular cohort of patients was treated as a single trial event. Results revealed there was a reduction of 2.63 days in the duration of hospital stay for the LNF group when compared to the ONF group. The average duration of hospital stay was 4.03 days in the ONF group. The pooled sick leave days were shorter in the LNF compared to ONF (19.81 versus 31.4 days). On the other hand, operating times were greater in the LNF group compared to the ONF group (94.6 versus 66 minutes). The conversion rate to open surgery in the laparoscopic arm was 7.71% (27 cases). Dysphagia was seen 6 months postoperatively, however long term results did not show significant dysphagia.

Conclusion: Overall it was found that laparoscopic fundoplication reduced duration of postoperative hospital stay and decreased sick leave time and when compared to open group. The long term results confirmed that ONF and LNF are equally effective in controlling heartburn, regurgitation and dysphagia, with similar use of acid-suppressing drugs and patient satisfaction after surgery.

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**Outcomes in Open Nissen Fundoplication Compared with Laparoscopic
Nissen Fundoplication in Adults with Antireflux Surgery**

Supriya S Kaushik



A Clinical Graduate Project Submitted to the Faculty of the

School of Physician Assistant Studies

Pacific University

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Faculty Advisor: Randy Randolph PA-C, MPAS

Clinical Graduate Project Coordinators: Annjanette Sommers MS, PAC & Rob Rosenow
PharmD, OD

Biography

Supriya Kaushik moved to Portland, Oregon in 1996, after completing her graduate degree in Nutrition in India. Wanting to continue with her career in Dietetics, she moved to Corvallis and worked with Dr. Maret Traber at the Linus Pauling Institute focusing her graduate work and Master's thesis on Vitamin E content in milk. She completed her dietetic internship at OHSU and practiced as a critical care and ALS Dietitian prior to enrolling in PA school. Supriya would like to divide her time working part time in research and part time in clinical field. She loves to travel with her husband and son.

Abstract

Background: Laparoscopic Nissen fundoplication (LNF) is regarded as the surgical treatment of first choice for refractory gastroesophageal reflux disease. It has generally been assumed that patients undergoing laparoscopic fundoplication will have less pain and a faster recovery. Initially there has been some question about whether the laparoscopic fundoplication would be as effective as the open fundoplication in the treatment of gastroesophageal reflux disease, therefore randomized studies comparing the two have focused on several points. These include symptomatic relief, complications, post-operative side effects and durability of symptom relief.

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Conclusion: Overall it was found that laparoscopic fundoplication reduced duration of postoperative hospital stay and decreased sick leave time and when compared to open group. The long term results confirmed that ONF and LNF are equally effective in controlling heartburn, regurgitation and dysphagia, with similar use of acid-suppressing drugs and patient satisfaction after surgery.

Keywords: Open, Laparoscopic, Nissen fundoplication, Antireflux surgery, GERD.

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List of Abbreviations

GERD.....Gastroesophageal Reflux Disease
ONF.....Open Nissen fundoplication
LNF.....Laparoscopic Nissen fundoplication
FVC.....Forced Vital Capacity
FEV.....Forced Expiratory Volume
PPI.....Proton pump inhibitors

Outcomes in Open Nissen Fundoplication Compared with Laparoscopic Nissen Fundoplication in Adults with Antireflux Surgery

BACKGROUND

Gastroesophageal disease (GERD) is one of the most prevalent diseases in today's industrialized countries. In the United States alone, it is estimated that almost 40 percent of the adult population frequently complains of heartburn, one of the primary symptoms of GERD.¹ A current definition of GERD is a condition which develops when the reflux of stomach contents causes troublesome symptoms (i.e. at least two heartburn episodes per week) and/or complications.² Potential complications of untreated GERD include esophagitis, peptic strictures, Barrett's esophagus and adenocarcinoma. Several extra esophageal manifestations of the disease are well recognized, including laryngitis and cough (Figure 1). The primary pathophysiologic event in GERD is movement of acid, pepsin and other gastric refluxate from the stomach into the esophagus. This event also occurs as a part of normal physiologic response. Nevertheless, this can result in GERD when symptoms or esophageal mucosal injury occur. Esophageal mucosal injury is an effect of imbalance between mucosal defensive factors and a compromised antireflux barrier. This affects the esophageal acid clearance and leads to increased sensitivity of esophageal or supresophageal mucosa to the refluxate.³

Failure of the antireflux barrier is considered the most important factor in the pathogenesis of this disease. It is a mechanical disorder caused by a defective lower

esophageal sphincter (LES) and the crural diaphragm. The LES is the tonically contracted circular smooth muscle that generates a high pressure zone at the gastroesophageal junction and serves as a barrier between stomach and esophagus. The competence of the LES and its ability to establish a barrier to reflux, depends on several factors: adequate pressure and length, radial symmetry, and motility of the esophagus and stomach. A competent sphincter is at least two centimeter and carries a pressure between 6 and 26 mm Hg.⁴ At any given moment, LES pressure is affected by intra-abdominal pressure, gastric distention, peptides, hormones, various foods and many medications. All these anatomic and mechanical disruptions can result in reflux through the LES and are indicated in the development of this condition.

Diagnosis of Gastroesophageal Reflux Disease

The diagnosis of GERD relies on the demonstration of the presence of documented (photographic or histologic) esophageal mucosal injury (esophagitis) and excessive reflux during 24-h intra esophageal pH monitoring. Both pH monitoring and endoscopy are necessary for the objective documentation of the disease.^{5,6} With manometry other esophageal functional disorders, especially spastic disorders, which could potentially cause a postoperative failure can be excluded.^{6,7}

Treatment

Medical therapy is the first line of management for treatment. Proton pump inhibitors (PPIs) are an effective, though expensive means of controlling symptoms by the suppression of gastric acid secretion. Esophagitis will heal in approximately 90% of cases with intensive medical therapy. However, medical management does not address the condition's mechanical etiology; thus symptoms can recur in more than 80% of cases within one year of drug

withdrawal.⁸ Since this is a chronic condition, medical therapy involving acid suppression and/or promotility agents may be required for the rest of a patient's life. The expense and psychological burden of a lifetime of medication dependence, long term side effects and undesirable lifestyle changes make surgical treatment of GERD an appealing option. Antireflux surgery is the only modality of care that may prevent the need for long term medical therapy, while simultaneously correcting the pathophysiology leading to reflux. Two controlled trials which compared medical and surgical therapy of GERD favored surgical therapy.^{9,10} Longitudinal studies also record/state good to excellent long term results in 80–93% of surgically treated patients.¹¹⁻¹⁴

Rudolf Nissen performed the first Nissen fundoplication by wrapping the gastric fundus around the esophagus nearly half a century ago for treatment of GERD.¹⁵ This procedure, the open Nissen fundoplication, has become the standard against which all other antireflux operations are compared. Most variations of antireflux operations have some component of either a partial or total fundoplication.^{11,16-18} Until recently, the two main approaches have been the trans-abdominal approach, through some type of laparotomy, or a trans-thoracic approach, through a left posterior lateral thoracotomy. In 1991, a new era of antireflux surgery was ushered in with the first Nissen fundoplication performed through a laparoscopic approach.¹⁹⁻²¹

Although the laparoscopic fundoplication has rightfully taken its place as a standard of care for gastroesophageal reflux disease, the open approach is still a valuable alternative to the minimally invasive approach. The potential benefits of surgery must be weighed against potential deleterious effects. These include frequent need of revision, risk of dysphagia, increased flatulence, inability to belch and increased bowel symptoms such as diarrhea,

constipation and abdominal cramps.^{10,22,23} Reported rates of reoperation secondary to complication, are as high as seven percent with one to three years.²² Almost 60% of patients who have undergone such surgery continue to use medication for reflux symptoms 10-12 years postoperatively.²⁴

Critical elements to help assure a successful postoperative outcome include: a thorough preoperative evaluation, to determine the appropriateness of surgical intervention, accuracy of pre-operative diagnosis and the provider's surgical expertise. Presurgical factors associated with a successful outcome include the presence of typical symptoms (heartburn, regurgitation) good response to medical therapy, abnormal 24-hour pH monitoring and the absence of complicated disease.²⁵ According to the *SAGES* guidelines all patients must have Esophagogastroduodenoscopy (with biopsy, where appropriate) and Esophageal manometric evaluation prior to Nissen fundoplication. In selected cases, a 24-hour intraesophageal pH monitoring and Barium cineradiography may be indicated.²⁶

Purpose of the Study

Several studies have compared open Nissen fundoplication to laparoscopic Nissen fundoplication. To date, these studies have yielded inconsistent results in terms of short term and long term outcomes postoperatively. A systematic review of the literature was performed to determine whether a significant conclusion can be drawn as to whether antireflux surgery is associated with higher incidence of adverse postoperative outcomes and also if these outcomes vary with open versus laparoscopic Nissen fundoplication.

Clinical Question

Do outcomes in open Nissen fundoplication compared with laparoscopic Nissen fundoplication in adults with antireflux surgery, differ? Most of the published studies on antireflux surgery focus on mortality, morbidity, decreased hospital stay, operating time and rates of reoccurrence. These, of course, are the most prominent outcome parameters, but the discrepancy between symptoms and acid reflux is well documented and surgery for refractory gastroesophageal reflux disease (GERD) is known to induce side effects. These side effects, such as dysphagia, bloating, regurgitation, heartburn and flatulence, are known to interfere with quality of life and should be part of the evaluation of the outcome of antireflux surgery.

METHODS

Search Strategy

A systematic search of the literature was conducted using Medline database, Cochrane Database of Systematic Reviews (Evidence-based Medicine) and the ISI Web of Science (science citation index, current contents) from January 2004 until February 2010 using the Medical Subject Headings of the National Library of Medicine (MESH). The terms researched were: Gastroesophageal reflux and Nissen fundoplication or antireflux surgery or open Nissen fundoplication, randomized and outcomes. A manual search was performed using references from the articles retrieved and main review articles.

Eligibility Criteria

Studies were judged suitable for systematic review and were eligible for inclusion only if they met all the following criteria: (1) prospective randomized trials (RCTs) of any size comparing open versus laparoscopic Nissen fundoplication for gastroesophageal reflux disease in the adult population, published in full peer-reviewed journal in English between 2004 and 2010 (2) well-defined outcomes including at least one of the following: (a) perioperative mortality and morbidity rates (b) details about the incidence of symptomatic adverse events (dysphagia, bloating, flatulence, esophagitis, heartburn).

Only results fully reported in journal articles were considered. The methodological quality of the selected studies was assessed using the Jadad scale ²⁷ with scores ranging from zero to five. The data extraction and critical appraisal focused on the following criteria: Jadad score > two and a description of the surgical treatment rendered (partial or total wrap). Six randomized studies met the inclusion criteria. Of these, several involved the compilation of data from same cohort of patients at different follow-up times. All data gathered from a particular cohort of patients was treated as a single trial event.

RESULTS

The outcomes of open versus laparoscopic Nissen fundoplication were investigated in six randomized control trials (RCTs) that included 702 antireflux surgeries. Table 1 lists the RCT with minor technical variations. All the RCTs were conducted between April 1992 and June 2000 and published between 1997 and 2010. The baseline characteristics of the patients in both groups were well matched for age, sex, weight (BMI) and previous use of PPI. All the studies used a subjective questionnaire with slight variations among the different studies, but

addressed determinants of GERD. The majority of the studies used upper endoscopy, 24 hour pH studies and esophageal manometry for preoperative and postoperative objective evaluation. There were three trials from Sweden, two from the Netherlands, one from Finland and one from the United Kingdom. The study quality was generally poor with a mean Jadad²⁷ score of three. Both laparoscopic Nissen fundoplication (LNF) and open Nissen fundoplication (ONF) were carried out using a loose 360 degree Nissen fundoplication technique in five of the six studies. Hakanson et al used partial posterior fundoplication in both groups.²⁸

Perioperative Outcomes

Nilsson et al (2000, 2002, 2004)

Nilsson et al reported a shorter postoperative hospital stay in the LNF group: three (2-6) versus three (2-10) days in the ONF group ($P < .021$). Postoperatively FVC and FEV were significantly higher in the laparoscopic group compared to the open surgery group ($P < .004$). There was no significant difference noted between the two groups with regards to analgesic use and median sick leave duration. Five patients in the laparoscopic group were converted to open surgery due to complications such as an enlarged liver, trocar damage to the liver, esophageal bleeding and pneumothorax. An analysis per protocol was carried out, i.e. excluding patients who were converted to open/laparotomy from the laparoscopic group.²⁹⁻³¹

Ackroyd et al (2004)

In a study by Ackroyd et al,³² the median operating time was 82 (40–197) minutes in the laparoscopic group and 46 (20–87) minutes in the open group ($P < .001$). Postoperative hospital stay (three *versus* five days) was longer in the open group ($P < .001$). Patients undergoing open fundoplication took longer to return to normal physical activity or work.

The median time to return to work was shorter in the laparoscopic group, four (0–13) *versus* seven (0–32) weeks ($P = .002$). There was less postoperative wound pain in the laparoscopic group than in the open group two of 52 *versus* 14 of 47 ($P < .001$). Moreover, the usage of analgesics was lower. The time from surgery to commencement of oral fluids was the same (both 1 (0–2) days; $P = .084$), but the time to commence solids was longer in the open group (2 (1–4) *versus* 2 (1–6) days; $P = .004$).

Franzen et al (2005)

Franzen and colleagues, reported significantly longer operating times, 155.6 minutes in the laparoscopic and 104.3 minutes in the open group, respectively ($P < .001$). Postoperative hospital stay was significantly shorter in the laparoscopic group when compared to the open group (3.61 *versus* 5.8 days; $P < .001$). Sick leaves were 20.7 days and 28.9 days, respectively. The difference was significant ($P < .05$).³³

Hakanson et al (2007)

Hakanson et al, showed median operating time of 95 minutes for the laparoscopic group and 80 minutes for the open surgery group ($P < .001$). The mean operative time did not change from the first to the second half of the study in the laparoscopic group: 105 and 103 minutes, respectively ($P = .85$). The length of hospital stay and sick leave were significantly shorter in the laparoscopic group as compared to the open group ($P < .001$). Five patients were converted from laparoscopic to open surgery. The time until first passage of flatus was longer in the open group compared to the laparoscopic group (two days *versus* one day, $P < .001$).²⁸

Laine et al (1997)

Laine et al, reported median operating time was 88 minutes in the laparoscopic group and 57 (20–87) minutes in the open group ($P < .001$). The postoperative hospital stay (six *versus* 3.2 days) was longer in the open group ($P < .001$). The median time to return to work was shorter in the laparoscopic group, 15 *versus* 37.2 days ($P = .002$). Five patients were converted to open/ laparotomy.³⁴

Postoperative Outcomes

Postoperative follow-up varied amongst different studies ranging from one month to 11 years. The long term studies at large, used a Visick score or a modified Visick score to monitor the subjective effect of surgery as it correlates to the most prominent symptom of GERD (heartburn). Visick grading comprised of the following: complete resolution (Visick I), improvement (Visick II), no effect of surgery (Visick III), or deterioration (Visick IV), always in comparison with patient's preoperative state. Short term and long term studies assessed presence of heartburn, regurgitation and dysphagia using a combined frequency and severity grading system resulting in a grade from zero (symptom absent) to three (symptom frequent and severe). Individual variations in outcomes were discussed under each cohort separately.

Short term follow-up

The majority of the studies showed improvement in frequency of heartburn, regurgitation and dysphagia postoperatively compared to the preoperative frequency of symptoms.

Nilsson et al (2000, 2002, 2004)

Nilsson et al reported no significant differences between the two groups in frequency or severity of heartburn or in regurgitation at six months after surgery and these results were consistent after five years. There was a tendency toward a higher frequency of mild dysphagia in the laparoscopic group after six months, but this was not statistically significant ($P = .051$). Difficulties with belching and increased flatulence were dominant side effects at five year follow-up without any significant differences between the two groups.²⁹⁻³¹

Ackroyd et al (2004)

Ackroyd and researchers, reported similar overall reflux symptom score for both groups ($P = .731$). No difference was noted in preoperative esophageal manometry or 24 hr ambulatory pH monitoring. There was a statistical clinical difference between the groups with regards to prevalence of hiatus hernia ($P = .030$). There was no significant difference in symptoms at discharge between the groups, other than a higher incidence of dysphagia in the laparoscopic group (to solids: 25 of 52 *versus* 13 of 47 patients; to liquids; four *versus* one; $P = .028$ for both comparisons). There were no differences between groups in the incidence of symptoms over the 12 months after surgery, with the exception of a higher incidence of postprandial fullness at 6 months in the laparoscopic group ($P = .036$) when compared to the open group. Outcomes were comparable at all follow-up intervals, according to the modified Visick scales.³²

Franzen et al (2005)

In a study by Franzen et al, eighteen percent (eight/45) of the patients in the laparoscopy group complained of dysphagia six months postoperatively. The corresponding

figure for open surgery was 2% (1/48). The difference was significant ($P < .05$). Six months after laparoscopy, four patients had disabling dysphagia. None of the patients had disabling dysphagia after the open surgery. Four patients had mild heartburn six months after laparoscopy, while two patients had mild heartburn after open surgery. Between 6 months follow-up and long term follow-up, six patients were reoperated on, in the laparoscopy group and two patients in the laparotomy group. After laparoscopy, at long term follow-up, 62% of the patients (28/45) were satisfied compared with 91% (41/45) after laparotomy ($P < .01$).³³

Hakanson et al (2007)

At six weeks postoperatively, Hakanson et al, reported a low frequency of dysphagia for solids, 1.1 % (1/91) in the open group versus 7.1 % (seven/98) in the laparoscopic group, ($P = .066$). At one year postoperatively, patient assessment of the overall successful results was 93.5% in the open procedure group and 88.8 % in the laparoscopic group ($P = .31$). At three years postoperatively, patient assessment of the overall success rate was 93.5% in the open procedure group and 90.8% in the laparoscopic group ($P = .59$). Total esophageal acid exposure time was not statistically different between groups ($P = .53$). There were four symptomatic recurrences in the open group (4.3%) and ten (10.1%) in the laparoscopic group occurring during the entire three year follow-up ($P = .17$).²⁸

Long term follow-up

Two studies have addressed long term issues with ONF and LNF. The long term data would provide critical information on reoperation rates and effectiveness of the surgeries and effective control, or lack thereof, in subjective outcomes.

Salminen et al (2007)

In a study by Salminen et al, Forty-nine patients in the laparoscopic group and 37 patients in the open group were available for evaluation of late subjective results, including postoperative symptoms and evaluation of the surgical result. These were similar in both groups. In the whole study group, sixty patients (73.2%) had mild upper abdominal symptoms, including heartburn or regurgitation. Eight (9.8%) of the patients had moderate symptoms and fourteen patients (17.0%) of them suffered from difficult upper abdominal symptoms. Only three patients (3.6%) had difficult or severe dysphagia. Bloating and the presence of increased passage of flatus were the most common postoperative complaint. Thirty seven (45.1%) of the patients reported the severity of this symptom to be clearly disturbing. In this study, no statistically significant differences were found between the laparoscopic and open group with regards to long term subjective outcomes such as heartburn, regurgitation, dysphagia, bloating and increased flatulence. The patient satisfaction and preference to surgical treatment did not differ significantly between the two groups. There were ten incisional hernias in the open group compared with none in the laparoscopic group ($P < .001$). In the laparoscopic group, there were five (13.2%) partially or totally disrupted plications compared with the 14 (40.0%) disrupted plications in the open group ($P = .0152$). A total of 39.5% ($n = 15$) of the patients in the open group and 40.9% ($n = 18$) of the patients in the laparoscopic group had started taking acid suppression medications postoperatively ($P = 1.0000$). Overall, 73.7% of the patients in the open group and 81.8% in the laparoscopic group would again choose surgical treatment ($P = .30$).³⁵

Broeders et al (2009)

Seventy nine patient in LNF and sixty nine patients in ONF, participated in a 10-year follow-up study by Broeders et al. The percentage of patients with no or mild heartburn was (94.9% vs. 91.1%) and dysphagia (92.4% vs. 85.1%) was similar in LNF and ONF. Severity of heartburn and dysphagia were similar, but slightly more patients had relief of regurgitation after LNF (98.7% vs. 91.0%; $P = .030$). The percentage of patients using PPIs slowly increased with time in both groups to 26.6% for LNF and 22.4% in ONF. At ten years (LNF 10, ONF 10) patients were dependent on daily PPIs. Twice as many patients underwent reoperation after ONF compared with LNF (12 vs. 24; $P = .006$), including a higher number of incisional hernia corrections (two vs. nine; $P = .015$). The percentage of patients who would have opted for surgery again was similar as well (78.5% vs. 72.7%).³⁶

DISCUSSION

Based on pooled estimates of the six RCTs there was a reduction of 2.63 days in the duration of hospital stay for the LNF group when compared to the ONF group. The average duration of hospital stay was 4.03 days in the ONF group. The pooled sick leave days were shorter in LNF compared to ONF (19.81 versus 31.4 days). On the other hand, operating times were greater in the LNF group compared to the ONF group (94.6 versus 66 minutes). The conversion rate to open surgery in the laparoscopic arm was 7.71% (27 cases). Table 2 shows postoperative outcomes in the selected RCTs. Overall it was found that laparoscopic fundoplication reduced duration of postoperative hospital stay and decreased sick leave time and when compared to open group. Other randomized comparisons of laparoscopic and

open fundoplication have been performed. Heikkinen et al^{28,37} showed at intermediate follow-up of two years, in laparoscopic (22 patients) and open (20) surgery seemed to be equally effective treatments. Larger studies have been reported by Chrysos et al²² and Bais et al³⁸ with 106 and 103 patients entered respectively. All of these studies reported short term outcome between 3 and 12 months. The hospital stay was shortened, with a more rapid return to work in the laparoscopic groups, at the expense of increased operating time.

Only the duration of the operation seemed to be prolonged in the laparoscopic arm. Laparoscopic surgery was still in its infancy in early 1990s and use of 2 dimensional techniques versus laparotomy/open surgery might have played a role in longer operating time. Studies have demonstrated that the laparoscopic technique requires greater concentration and places greater mental stress on surgeons than does open surgery.⁴² More experience with laparoscopy may decrease this effect.³⁹ In the early, 1990s surgeons were not required to have a minimum number of surgeries to categorize them as an expert surgeon. Some surgeons may have been novice at this technique which could explain the longer operating times.

The conversion rate to open surgery in the laparoscopic arm was 7.71% (27 cases). An intent- to- treat analysis was not carried out. The correct way to analyze a randomized study is generally to perform an intention-to-treat analysis, so that all patients are taken into account in the analysis. Furthermore, as the rate of conversions in smaller studies was high, such analysis might have made the results difficult to generalize; an additional per-protocol analysis was therefore done.

The early postoperative results were in favor of the laparoscopic procedure. The finding of fewer general complications, shorter length of stay and recovery, similar need for

reoperations, and comparable 3-year outcomes, makes the laparoscopic approach the primary choice when considering surgical options for the treatment of gastroesophageal reflux disease (GERD).

Dysphagia is a common sequelae of Nissen fundoplication that occurs in 20% of cases after the open procedure¹⁷ and according to some studies^{21,22} is even higher after the laparoscopic approach. However, other studies have yielded conflicting findings, reporting a similar incidence of postoperative dysphagia with both approaches. The high rate of dysphagia sometimes associated with laparoscopic Nissen procedure has been attributed to inexperience at the early stages of the learning curve, resulting in inadequate mobilization of the esophagogastric region and creation of an overly tight wrap; thus, as technical experience is gained with laparoscopic Nissen fundoplication and the learning curve is surpassed, the incidence of dysphagia decreases.⁴⁰ In this systematic review, dysphagia was seen 6 months postoperatively, however long term results did not show significant dysphagia.

Recent, long term RCTs showed comparable results between ONF and LNF and confirmed that ONF and LNF are equally effective in controlling heartburn, regurgitation and dysphagia, requiring use of acid-suppressing drugs and resulting in equal patient satisfaction after surgery. A reduced incidence of incisional hernias was recommended as a major long term benefit of laparoscopic surgery compared with open surgery.

Limitations of the Study

Different patient selection criteria, operative details, surgical experience and variations in postoperative assessment methodology are all confounding factors. An overall Jadad score of 3 was indicative of the generally poor quality of the studies. The level of

blinding the patients was not consistent and the description of withdrawal or dropouts not specified. Also, an intent-to-treat analysis was not conducted in the majority of the studies.

The follow-up time frame varied from study to study making comparisons difficult in terms of outcomes at different timelines resulting in little consistency. Some studies used Visick scoring for symptom reporting which is a validated scoring system while others used modified Visick criteria or a severity grading system. Postoperative follow-up criteria varied widely amongst the different studies.

CONCLUSION

The early postoperative results were in favor of the laparoscopic procedure. Although median operating time was longer than in open surgery, recovery was substantially faster. The finding of fewer general complications, shorter length of stay and recovery, makes the laparoscopic approach the primary choice for surgery when considering surgical options for the treatment of gastroesophageal reflux disease (GERD). The long term results confirmed that ONF and LNF are equally effective in controlling heartburn, regurgitation and dysphagia, with similar use of acid-suppressing drugs and patient satisfaction after surgery.

REFERENCES

1. Locke GR,3rd, Talley NJ, Fett SL, Zinsmeister AR, Melton LJ,3rd. Prevalence and clinical spectrum of gastroesophageal reflux: a population-based study in Olmsted County, Minnesota. *Gastroenterology*. 1997;112(5):1448-1456.
2. Vakil N, van Zanten SV, Kahrilas P, Dent J, Jones R, Global Consensus G. The Montreal definition and classification of gastroesophageal reflux disease: a global evidence-based consensus. *Am J Gastroenterol*. 2006;101(8):1900-1920.
3. Pandolfino JE, Kwiatek MA, Kahrilas PJ. The pathophysiologic basis for epidemiologic trends in gastroesophageal reflux disease. *Gastroenterol Clin North Am*. 2008;37(4):827-843.
4. Townsend C.M., Beauchamp R. D., Evers B. E., Mattox . L. E. ., Sabiston Textbook of Surgery:The Biological Basis of Modern Surgical Practice. In ; 2008.
5. Costantini M, Crookes PF, Bremner RM, et al. Value of physiologic assessment of foregut symptoms in a surgical practice. *Surgery*. 1993;114(4):780-786.
6. Fuchs KH, Feussner H, Bonavina L, Collard JM, Coosemans W. Current status and trends in laparoscopic antireflux surgery: results of a consensus meeting. The European Study Group for Antireflux Surgery (ESGARS). *Endoscopy*. 1997;29(4):298-308.
7. Peters JH, DeMeester TR, Crookes P, et al. The treatment of gastroesophageal reflux disease with laparoscopic Nissen fundoplication: prospective evaluation of 100 patients with "typical" symptoms. *Ann Surg*. 1998;228(1):40-50.
8. Klingman RR, Stein HJ, DeMeester TR. The current management of gastroesophageal reflux. *Adv Surg*. 1991;24:259-291.
9. Spechler SJ. Comparison of medical and surgical therapy for complicated gastroesophageal reflux disease in veterans. The Department of Veterans Affairs Gastroesophageal Reflux Disease Study Group. *N Engl J Med*. 1992;326(12):786-792.
10. Lundell L, Miettinen P, Myrvold HE, et al. Seven-year follow-up of a randomized clinical trial comparing proton-pump inhibition with surgical therapy for reflux oesophagitis. *Br J Surg*. 2007;94(2):198-203.
11. Donahue PE, Samelson S, Nyhus LM, Bombeck CT. The floppy Nissen fundoplication. Effective long-term control of pathologic reflux. *Archives of Surgery*. 1985;120(6):663-668.
12. Grande L, Toledo-Pimentel V, Manterola C, et al. Value of Nissen fundoplication in patients with gastro-oesophageal reflux judged by long term symptom control. *Br J Surg*. 1994;81(4):548-550.

13. Luostarinen M. Nissen fundoplication for reflux esophagitis. Long term clinical and endoscopic results in 109 of 127 consecutive patients. *Ann Surg.* 1993;217(4):329-337.
14. Luostarinen M, Isolauri J, Laitinen J, et al. Fate of Nissen fundoplication after 20 years. A clinical, endoscopic, and functional analysis. *Gut.* 1993;34(8):1015-1020.
15. Nissen R, Rossetti M. Surgery of hiatus hernia. *Medical World.* 1959;91:20-26.
16. Rossetti M, Hell K. Fundoplication for the treatment of gastroesophageal reflux in hiatal hernia. *World J Surg.* 1977;1(4):439-443.
17. DeMeester TR, Bonavina L, Albertucci M. Nissen fundoplication for gastroesophageal reflux disease. Evaluation of primary repair in 100 consecutive patients. *Ann Surg.* 1986;204(1):9-20.
18. Watson A, Jenkinson LR, Ball CS, Barlow AP, Norris TL. A more physiological alternative to total fundoplication for the surgical correction of resistant gastro-oesophageal reflux. *Br J Surg.* 1991;78(9):1088-1094.
19. Dallemagne B, Weerts JM, Jehaes C, Markiewicz S, Lombard R. Laparoscopic Nissen fundoplication: preliminary report. *Surg Laparosc Endosc.* 1991;1(3):138-143.
20. Geagea T. Laparoscopic Nissen's fundoplication: preliminary report on ten cases. *Surg Endosc.* 1991;5(4):170-173.
21. Watson DI, Jamieson GG. Antireflux surgery in the laparoscopic era. *Br J Surg.* 1998;85(9):1173-1184.
22. Bais JE, Bartelsman JF, Bonjer HJ, et al. Laparoscopic or conventional Nissen fundoplication for gastro-oesophageal reflux disease: randomised clinical trial. The Netherlands Antireflux Surgery Study Group. *Lancet.* 2000;355(9199):170-174.
23. Kahrilas PJ, Shaheen NJ, Vaezi MF, American Gastroenterological Association I, Clinical Practice and Quality Management, Committee. American Gastroenterological Association Institute technical review on the management of gastroesophageal reflux disease. *Gastroenterology.* 1413;135(4):1392-1413.
24. Spechler SJ, Lee E, Ahnen D, et al. Long term outcome of medical and surgical therapies for gastroesophageal reflux disease: follow-up of a randomized controlled trial. *JAMA.* 2001;285(18):2331-2338.
25. Oelschlager BK, Quiroga E, Parra JD, Cahill M, Polissar N, Pellegrini CA. Long term outcomes after laparoscopic antireflux surgery. *Am J Gastroenterol.* 2008;103(2):280-287.
26. Guidelines for surgical treatment of gastroesophageal reflux disease (GERD). Society of American Gastrointestinal Endoscopic Surgeons (SAGES). *Surg Endosc.* 1998;12(2):186-188.

27. Jadad AR, Moore RA, Carroll D, et al. Assessing the quality of reports of randomized clinical trials: is blinding necessary?. *Control Clin Trials*. 1996;17(1):1-12.
28. Hakanson BS, Thor KB, Thorell A, Ljungqvist O. Open vs laparoscopic partial posterior fundoplication. A prospective randomized trial. *Surg Endosc*. 2007;21(2):289-298.
29. Nilsson G, Larsson S, Johnsson F. Randomized clinical trial of laparoscopic versus open fundoplication: blind evaluation of recovery and discharge period. *Br J Surg*. 2000;87(7):873-878.
30. Nilsson G, Larsson S, Johnsson F. Randomized clinical trial of laparoscopic versus open fundoplication: evaluation of psychological well-being and changes in everyday life from a patient perspective. *Scand J Gastroenterol*. 2002;37(4):385-391.
31. Nilsson G, Wenner J, Larsson S, Johnsson F. Randomized clinical trial of laparoscopic versus open fundoplication for gastro-oesophageal reflux. *Br J Surg*. 2004;91(5):552-559.
32. Ackroyd R, Watson DI, Majeed AW, Troy G, Treacy PJ, Stoddard CJ. Randomized clinical trial of laparoscopic versus open fundoplication for gastro-oesophageal reflux disease. *Br J Surg*. 2004;91(8):975-982.
33. Franzen T, Anderberg B, Wiren M, Johansson KE. Long term outcome is worse after laparoscopic than after conventional Nissen fundoplication. *Scand J Gastroenterol*. 2005;40(11):1261-1268.
34. Laine S, Rantala A, Gullichsen R, Ovaska J. Laparoscopic vs conventional Nissen fundoplication. A prospective randomized study. *Surg Endosc*. 1997;11(5):441-444.
35. Salminen PT, Hiekkanen HI, Rantala AP, Ovaska JT. Comparison of long term outcome of laparoscopic and conventional nissen fundoplication: a prospective randomized study with an 11-year follow-up. *Ann Surg*. 2007;246(2):201-206.
36. Broeders JA, Rijnhart-de Jong HG, Draaisma WA, Bredenoord AJ, Smout AJ, Gooszen HG. Ten-year outcome of laparoscopic and conventional nissen fundoplication: randomized clinical trial. *Ann Surg*. 2009;250(5):698-706.
37. Heikkinen TJ, Haukipuro K, Bringman S, Ramel S, Sorasto A, Hulkko A. Comparison of laparoscopic and open Nissen fundoplication 2 years after operation. A prospective randomized trial. *Surg Endosc*. 2000;14(11):1019-1023.
38. Chrysos E, Tsiaoussis J, Athanasakis E, Zoras O, Vassilakis JS, Xynos E. Laparoscopic vs open approach for Nissen fundoplication. A comparative study. *Surg Endosc*. 2002;16(12):1679-1684.
39. Berguer R, Smith WD, Chung YH. Performing laparoscopic surgery is significantly more stressful for the surgeon than open surgery. *Surg Endosc*. 2001;15(10):1204-1207.

40. Eshraghi N, Farahmand M, Soot SJ, Rand-Luby L, Deveney CW, Sheppard BC. Comparison of outcomes of open versus laparoscopic Nissen fundoplication performed in a single practice. *Am J Surg.* 1998;175(5):371-374.
41. Franzen T, Anderberg B, Wiren M, Johansson KE. Long term outcome is worse after laparoscopic than after conventional Nissen fundoplication. *Scand J Gastroenterol.* 2005;40(11):1261-1268.
42. Zheng B, Cassera MA, Martinec DV, Spaun GO, Swanström LL Measuring mental workload during the performance of advanced laparoscopic tasks. *Surg Endosc.* 2010 Jan; 24(1):45-50.

TABLE 1. MATRIX OF REVIEWED LITERATURE

Author/ Title/ Journal	Year Published /Country	Patients/ Population	Intervention	Comparison	Outcome(s)	Study	Validity (Jadad Score)
			ONF *	LNF^			
Nilsson et al ²⁹⁻³¹	2004/Sweden	Adults with GERD	30	30	Perioperative course, postoperative complication, symptomatic relief, recurrence rate	RCT	4
Ackroyd et al ³²	2004/ United Kingdom	Adults with GERD	47	52	Reflux symptom and objective findings	RCT	3
Franzen et al ⁴¹	2005/Sweden	Adults with GERD	48	45	Reflux symptom and side effects of antireflux surgery	RCT	2
Hakanson et al ⁴²	2007/ Sweden	Adults with GERD	93	99	Perioperative course, postoperative complication, symptomatic relief, recurrence rate	RCT	3
Laine & Salminen et al ^{34, 35}	2007/ Finland	Adults with GERD	55	55	Reflux symptom	RCT	3
Broeders et al ³⁶	2006 & 2009/The Netherland	Adults with GERD	69	79	Reflux symptom, general health, PPI use	RCT	3

*ONF: Open Nissen Fundoplication

^ LNF: Laparoscopic Nissen Fundoplication

TABLE 2. Perioperative Outcomes in Open versus Laparoscopic Antireflux Surgery

Author	Groups and Patients		Conversion		Average Length (minutes)	Average Hospital Stay (days)	Average Sick Leave (days)
			No.	%			
Nilsson et al ²⁹⁻³¹	ONF	30			109	3	32
	LNF	30	5	16.6%	148	3	27
Ackroyd et al ³²	ONF	47			46	4	49
	LNF	52	5	9.6%	82	3	28
Franzen et al ⁴¹	ONF	48			104	5.8	28.3
	LNF	45	1	2.2%	155.5	3.6	20.7
Hakanson et al ⁴⁷	ONF	93			80	5	42
	LNF	99	5	5.5%	95	3	28
Laine Salminen et al ^{34,35}	ONF	55			57	6.4	37.2
	LNF	55	5	9%	88	3.2	15.2
Draaisma/Broeders et al ³⁶	ONF	69			-	-	-
	LNF	79	6	8%	-	-	-
Pooled	ONF	352	-		66	4.03	31.41
	LNF	350	27	7.71%	94.6	2.63	19.81

FIGURE 1. The Montreal definition of GERD.² The overarching definition mandates that troublesome symptoms and/or complications are present regardless of syndrome(s) present and that those syndromes are caused by reflux.

