Functional Outcome After Laparoscopic or Open Nissen Fundoplication

A Follow-up Study

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Objective: To compare the results of open and laparoscopic fundoplication.

Design: Nonrandomized controlled study with a 3-year follow-up.

Patients and Methods: Fifty-seven consecutive patients with erosive reflux esophagitis underwent laparoscopic (30 patients) or open (27 patients) fundoplication.

Interventions: Interview by an independent person. In addition, 52 patients (91%) underwent postoperative endoscopy, and 38 patients (67%) underwent esophageal 24-hour pH recording.

Results: Temporary dysphagia was reported by 20 patients (67%) after laparoscopic and by 11 (41%) after open fundoplication (P = .05). There were no differences between groups concerning incidence of persistent dysphagia (20% vs 18%, respectively) and mild to no reflux symptoms (97% vs 100%, respectively). In addition, bloating (50% vs 63%, respectively) and increased flatus (77% vs 78%, respectively) were equally common. Visual analog scale scores for dysphagia, bloating, and increased flatus were 0.6, 2.4, and 4.3, respectively, in the laparoscopic and 0.6, 3.5, and 3.4, respectively, in the open groups. Normal belching ability was reported by 12 patients (40%) after laparoscopic and by 20 (74%) after open fundoplication (P = .01). Visick grade 1 or 2 was reported by 21 patients (70%) after laparoscopic and by 24 (89%) after open fundoplication (P = .08). Defective fundic wrap was detected in 4 patients (13%) in the laparoscopic and in none in the open group. In addition, abnormal results of 24-hour pH recording were found in 4 patients (13%) in the laparoscopic and in 2 (10.5%) after open fundoplication.

Conclusion: From a functional point of view, both techniques were equally effective except concerning belching ability and temporary dysphagia.

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PATIENTS AND METHODS

The study group consisted of 57 consecutive patients who underwent primary laparoscopic or open Nissen fundoplication for severe symptomatic gastroesophageal reflux disease and fulfilled our inclusion criteria from January 1, 1993, to May 31, 1995. All operations were performed or directly supervised by two of us (laparoscopic fundoplication, I.H.K.; open fundoplication, J.A.S.) in Helsinki University Central Hospital, Helsinki, Finland. We excluded the first 12 patients to obtain adequate experience. All those surgeons who performed laparoscopic fundoplication in our study were otherwise experienced laparoscopic surgeons before starting to perform fundoplication.

In every case, long-term conservative treatment with histamine blockers or proton pump inhibitors had failed, or patients were dependent on these medicines and requested operative treatment. Inclusion criteria consisted of erosive esophagitis detected at preoperative endoscopy and pathological results of esophageal 24-hour pH recording. Those patients who underwent some other abdominal procedure simultaneously were excluded, as were also the patients with Barrett esophagus and esophageal stricture. In addition, we excluded all patients undergoing laparoscopy that had to be converted to an open procedure. There were no statistical differences between groups concerning the severity of gastroesophageal reflux disease, risk factors (severe concomitant diseases, previous laparotomy), and follow-up.

All interviews were performed by one of us (T.K.R.) who had not been involved previously in the patients’ care. All patients were interviewed according to standard formula, and incidence of heartburn, regurgitation, and dysphagia were recorded using the DeMeester-Johnson Reflux Scale. Postfundoplication increase of flatus and bloating was assessed by the patients as none, with some difficulties, or restored to preoperative ability. The Viscick grading system was used for estimation of patient satisfaction. Postfundoplication increase of flatus and bloating was assessed by the patients as none, mild, moderate, or severe. In addition, a Visual Analog Scale (VAS) was used to assess dysphagia, flatus, and bloating, where 0 indicates none and 10 very troublesome symptoms. Savary-Miller grading of the reflux esophagitis was used, and Barrett esophagus was defined when intestinal metaplasia in biopsy samples taken in tubular esophagus was detected. The state of fundic wrap was verified with retroflexed endoscope. Slipping was registered when there was a distinct gastric pouch above the narrowing caused by the folds of the wrap, and disruption implied no visible folds or only distorted, loose folds at the esophagogastric junction. Abnormal reflux was defined using previously presented criteria. During follow-up, repeated fundoplication had to be performed for 2 patients in the laparoscopic group.

STASTICAL ANALYSIS

The χ² 2-tailed test, Fisher exact 2-tailed test, and the Mann-Whitney U test were used for statistical comparisons. A probability of .05 was accepted as significant.

LAPAROSCOPIC GROUP

Thirty patients underwent laparoscopic fundoplication. Fundic mobilization was performed in 24 patients (80%) and hiataloplasty in 28 (93%). Length of fundic wrap was 2 cm, and it was anchored to the esophagus in 8 patients (27%), gastric cardia in 2 (7%), and neither in 20 (67%). Nonabsorbable sutures were used in all patients, and patch where sutures were secured with Teflon pledgets was used in fundic wrap in 17 patients (57%). Nasogastric tubes (18F) and bougies (35F) were used with fundic wrap in all cases. Fundic mobilization and hiatal repair were not performed in every patient if it was otherwise possible to construct loose fundic wrap and if hiatal opening was not large. Preoperative clinical data are shown in Table 1.

All 30 patients consented to undergo at least postoperative endoscopy, but esophageal 24-hour pH recording was refused by 12 patients (40%). Manometry was performed in 4 patients. The mean follow-up time was 33 months (range, 12-44 months), and it was at least 24 months among those 28 patients who did not undergo reoperation.

OPEN GROUP

Standard technique was used in all 27 patients. It consisted of fundic mobilization, hiataloplasty, and 2-cm-long fundic wrap that was anchored to cardia in every case. In addition, patch where nonabsorbable suture was secured with Teflon pledgets was used in performing hiatal repair and in fundic wrap. Preoperative clinical data are shown in Table 1.

Postoperative endoscopy was refused by 5 patients (18%) and esophageal 24-hour pH recording by 7 (26%). In 1 patient, pH recording was technically unsuccessful. Postoperative endoscopy or successful esophageal 24-hour pH recording was performed in 23 patients (85%). Esophageal manometry was performed in 11 patients (41%). The mean follow-up time was 33 months (range, 24-45 months).

This study was approved by the Ethics Committee of the Department of Surgery, Helsinki University Central Hospital.

had moderate symptoms. Persistent dysphagia was reported by 6 patients (20%). Dysphagia decreased or disappeared postoperatively in 5 patients, was unchanged in 1 patient, and began postoperatively in 2 patients.

Fifteen patients (50%) had postoperative bloating. It was mild in 8 patients, moderate in 6 patients, and severe in 1 patient. Twenty-three patients (77%) reported increased postoperative flatus. It was mild in 7 patients, moderate in 12, and severe in 4. Preoperatively, 16 patients (53%) had had bloating and 19 (63%) had had in- creased flatus. Preoperative and postoperative VAS scores are shown in Table 2.

Postoperative ability to belch was assessed as none by 7 patients (23%), with some difficulties by 11 (37%), and restored to preoperative ability by 12 (40%). Eleven of those who could belch could not say the exact time when it first occurred; for the others, it happened on average 145 days after operation (range, 0-540 days).

Sixteen patients (53%) had no ability to vomit, whereas 7 (23%) had no need for vomiting postopera-
due to symptomatic paraesophageal herniation in 1. Doplication with recurrent esophagitis in 1 patient and formed during the observation period due to slipped fundoplication. Two reoperations (7%) have been performed. 2 had defective fundic wrap at endoscopy with reflux esophagitis in 1, intrathoracic fundic wrap in 1, and paraesophageal herniation in 1. Results of 4 (22%) of the 18 patients had defective fundic wrap or abnormal esophageal 24-hour pH recording (range, 0%-31.5%) and 1.0%, respectively. Defective fundic wrap was normal in every case, and no recurrent esophagitis was detected. Results of 2 (10%) of the 19 esophageal 24-hour pH recordings were pathological. One patient had pH of less than 4 in 6.1% and another in 9.1% at the registration time. However, both patients were asymptomatic, and the endoscopic findings were normal. The mean and median values when pH was below 4 were 5.5% and 2.0%, respectively. Only 5 patients (17%) could vomit normally, and 2 (7%) could with some difficulties.

Visick grade 1 was reported by 14 patients (47%), grade 2 by 7 patients (23%), grade 3 by 8 patients (27%), and grade 4 by 1 patient (3%).

Twenty-eight patients (93%) said that they would be willing to have the same operation again with the same symptoms. Postoperative functional results are shown in Table 3.

At postoperative endoscopies, fundic wrap was normal in 26 patients (87%). In 4 patients, it was defective, including slipped fundoplication in 1 patient, disrupted fundic wrap in 1, intrathoracic fundic wrap in 1, and paraesophageal herniation in 1. Results of 4 (22%) of the 18 esophageal 24-hour pH recordings were abnormal. The mean and median values when pH was below 4 were 5.5% (range, 0%-31.5%) and 1.0%, respectively. Defective fundic wrap or abnormal esophageal 24-hour pH recording provided objective verification of recurrence of reflux in 6 patients (20%). Four of these had a pathological postoperative 24-hour pH measurement (<4 in 31.0%, 27.0%, 13.3%, and 10.0% of the registration time), and the other 2 had defective fundic wrap at endoscopy with reflux esophagitis. Two reoperations (7%) have been performed during the observation period due to slipped fundoplication with recurrent esophagitis in 1 patient and due to symptomatic paraesophageal herniation in 1.

### Table 1. Preoperative Clinical Data

<table>
<thead>
<tr>
<th>Operation Type</th>
<th>Laparoscopic (n = 30)</th>
<th>Open (n = 27)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age, y (range)</td>
<td>46 (29-66)</td>
<td>47 (22-67)</td>
</tr>
<tr>
<td>Sex, No. male-female</td>
<td>22.8</td>
<td>17.10</td>
</tr>
<tr>
<td>Mean body mass index, kg/m² (range)</td>
<td>26.9 (22.3-37.2)</td>
<td>26.5 (20.3-33.6)</td>
</tr>
<tr>
<td>Previous laparotomy, No. (%)</td>
<td>3 (10)</td>
<td>2 (7)</td>
</tr>
<tr>
<td>Esophagitis, No. (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grade 1</td>
<td>9 (30)</td>
<td>10 (37)</td>
</tr>
<tr>
<td>Grade 2</td>
<td>20 (67)</td>
<td>14 (52)</td>
</tr>
<tr>
<td>Grade 3</td>
<td>0 (0)</td>
<td>2 (7)</td>
</tr>
<tr>
<td>Grade 4</td>
<td>1 (3)</td>
<td>1 (4)</td>
</tr>
<tr>
<td>Mean total reflux time, % (range)</td>
<td>13.8 (4-51)</td>
<td>25.5 (2.2-92.5)</td>
</tr>
</tbody>
</table>

### Table 2. Preoperative and Postoperative VAS Scores*

<table>
<thead>
<tr>
<th>Operation Type</th>
<th>Laparoscopic</th>
<th>Open</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increased flatus</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preoperative</td>
<td>3.3</td>
<td>0.7</td>
</tr>
<tr>
<td>Postoperative</td>
<td>4.3</td>
<td>3.4</td>
</tr>
<tr>
<td>Bloating</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preoperative</td>
<td>2.4</td>
<td>2.1</td>
</tr>
<tr>
<td>Postoperative</td>
<td>2.4</td>
<td>3.5</td>
</tr>
<tr>
<td>Dysphagia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preoperative</td>
<td>1.5</td>
<td>1.1</td>
</tr>
<tr>
<td>Postoperative</td>
<td>0.6</td>
<td>0.6</td>
</tr>
</tbody>
</table>

* VAS indicates Visual Analog Scale. Scoring and the VAS are described in the “Patients and Methods” section of the text.

### Table 3. Functional Results and Patient Satisfaction After Laparoscopic and Open Fundoplication

<table>
<thead>
<tr>
<th>Operation Type, No. (%) of Patients</th>
<th>Laparoscopic</th>
<th>Open</th>
<th>P*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temporary dysphagia</td>
<td>20 (67)</td>
<td>11 (41)</td>
<td>.05</td>
</tr>
<tr>
<td>Persistent dysphagia</td>
<td>6 (20)</td>
<td>5 (18)</td>
<td>NS</td>
</tr>
<tr>
<td>Mild or no reflux symptoms</td>
<td>29 (97)</td>
<td>27 (100)</td>
<td>NS</td>
</tr>
<tr>
<td>Inability to belch</td>
<td>7 (23)</td>
<td>4 (15)</td>
<td>NS</td>
</tr>
<tr>
<td>Normal ability to belch</td>
<td>12 (40)</td>
<td>20 (74)</td>
<td>.01</td>
</tr>
<tr>
<td>Inability to vomit</td>
<td>16 (53)</td>
<td>9 (33)</td>
<td>NS†</td>
</tr>
<tr>
<td>No need for vomiting</td>
<td>7 (23)</td>
<td>12 (44)</td>
<td>NS†</td>
</tr>
<tr>
<td>Normal ability to vomit</td>
<td>5 (17)</td>
<td>4 (15)</td>
<td>NS†</td>
</tr>
<tr>
<td>Visick grade 1-2</td>
<td>21 (70)</td>
<td>24 (89)</td>
<td>.08</td>
</tr>
<tr>
<td>Willing to undergo surgery again</td>
<td>28 (93)</td>
<td>26 (96)</td>
<td>NS</td>
</tr>
</tbody>
</table>

* NS indicates not significant.
† Indicates whole scale of vomiting ability.

**OPEN GROUP**

Temporary postoperative dysphagia was reported by 11 patients (41%), and it lasted on average 96 days (range, 7-360 days).

Twenty-three patients (85%) had no and 4 (15%) had mild reflux symptoms on follow-up. Persistent dysphagia was reported by 5 patients (18%). Dysphagia decreased or disappeared postoperatively in 8 patients, was unchanged in 2, and began in 2. Seventeen patients (63%) had postoperative bloating, which was mild in 7, moderate in 7, and severe in 3. Increased flatus was reported by 21 patients (78%), which was mild in 8, moderate in 11, and severe in 2. Preoperatively, 13 patients (48%) had had bloating and 12 (44%) had had increased flatus. Preoperative and postoperative VAS scores are shown in Table 2.

Postoperative ability to belch was assessed as none by 4 patients (15%), with some difficulties by 3 (11%), and restored to preoperative ability by 20 (74%). Two patients could not say the exact time when they could belch the first time; to the others, it happened on average 79 days after operation (range, 0-360 days).

Nine patients (33%) had no ability to vomit, whereas 12 (44%) had no need for vomiting postoperatively. Only 4 patients (15%) had normal ability to vomit, and 2 (7%) could do it with some difficulties.

Visick grade 1 was reported by 16 patients (59%), grade 2 by 8 (30%), and grade 3 by 3 (11%).

Twenty-six patients (96%) expressed willingness to have the same operation again with the same symptoms. Postoperative functional results are shown in Table 3.

No reoperation was performed during the observation period in this group. At postoperative endoscopies, fundic wrap was normal in every case, and no recurrent esophagitis was detected. Results of 2 (10%) of the 19 esophageal 24-hour pH recordings were pathological. One patient had pH of less than 4 in 6.1% and another in 9.1% at the registration time. However, both patients were asymptomatic, and the endoscopic findings were normal. The mean and median values when pH was below 4 were 2.1% (range, 0%-9.1%) and 1.1%, respectively.
In this group, 2 postoperative incisional hernias (7%) have been found. The patient with the symptomatic hernia has undergone operation.

**COMMENT**

According to Ollyo et al., 23% of patients with reflux esophagitis receiving nonsurgical therapy progressed steadily to more severe forms of esophagitis. It is well-known that the results of antireflux surgery among patients with end-stage disease are no better than those in patients with milder forms of reflux disease. Therefore, those patients with gastroesophageal reflux disease who are thought to have a risk for progressive disease should be offered surgical treatment as soon as this possibility has been noticed. Guidelines for the increased risk for progressive disease are low pressure of the lower esophageal sphincter and massive acid reflux detected in esophageal 24-hour pH recording. When Nissen fundoplication is performed at this time, success rates have been reported to be 80% to 90%.16,18

Our success rates concerning reflux control in both groups are comparable with those presented earlier, 97% and 100% of the patients having no or mild reflux symptoms. In addition, our incidence of persistent dysphagia (20% and 18%) compares favorably with other reports and is equally common in both groups. Instead, we found a higher incidence of postoperative increased flatus (77% and 78%) and bloating (50% and 63%) than in most of the studies, as can be seen from the VAS scores. In addition, many of our patients had these symptoms preoperatively. Luostarinen et al19 and Blomqvist et al8 found that many of their patients had these symptoms preoperatively. However, their patients were satisfied with the postoperative situation of not having reflux symptoms any more, even if they quite often had bloating and increased flatus. This was also the case among our patients.

Herniation of the stomach into the chest may be the cause of unsatisfactory long-term results.20 This complication was present in 2 patients (7%) in the laparoscopic group, whereas none in the open group had the same complication.

However, there were also significant differences between open and laparoscopic fundoplication in our study. Temporary dysphagia was more common (P = .05) and normal ability to belch was less frequent (P = .01) after laparoscopic technique. Similar findings have been reported previously.8,21-23 Reasons for these differences remain unknown. In 1 report, esophageal clearance was slower after laparoscopic than after open fundoplication.24 This might be 1 reason for higher incidence of temporary dysphagia after laparoscopic technique, occurring in all patients in the study of Anvari and Allen.24 The causes of temporary dysphagia after open Nissen fundoplication were thought to be esophageal stretching25 and local edema.20 Maybe there is more esophageal stretching after laparoscopic technique. This speculation is supported by Peters et al,17 who thought that there might be less fundic mobilization in laparoscopic than in open fundoplication and that this causes more lateral stretching in the fundic region. In open fundoplication, it has been proposed to make a large posterior hiatal window.10,20 The posterior hiatal window might be smaller in laparoscopic than in open surgery, because video can cause misrepresentation when evaluating size, and the created window can seem bigger than it is. This also can be 1 reason for the higher incidence of temporary dysphagia seen in laparoscopic antireflux surgery. In open fundoplication, 60F bougie, shortening of fundic wrap, and fundic mobilization have been shown to lessen temporary dysphagia.16 A 60F bougie should be used also in laparoscopic fundoplication; in our patients, it might have diminished the occurrence of postoperative dysphagia. Instead, concerning laparoscopic operation, there have been conflicting reports about the effect of fundic mobilization on temporary dysphagia. In 1 report, fundic mobilization caused less temporary dysphagia,26 in the other report,27 it had no effect on it. Also, the incidence of subjectively normal belching ability was more common after open fundoplication (74% vs 40%; P = .01) in our study. The subjective evaluation of belching ability has many sources of errors, including difficulties in distinguishing gastric and esophageal belching. However, we think that patients can say reliably if changes have occurred in their ability to belch postoperatively. Thus, subjective evaluation can be used to indicate postoperative changes in belching ability. Also, Blomqvist et al8 found that inability to belch was more frequent after the laparoscopic procedure. However, some of their open procedures were partial Toupet fundoplications. Reasons for the difference in normal ability to belch after laparoscopic and open fundoplication remain unknown. In 1 study,1 lower esophageal sphincter pressure was higher and lower esophageal sphincter relaxation occurred less frequently after laparoscopic fundoplication. After open Nissen fundoplication, the subjective ability to belch has been somehow better after floppy fundoplications.19,28,29 Instead, after laparoscopic operations, inability to belch was more common after fundic mobilization in 1 study.27 In our study, fundic mobilization was used in every patient in the open group and in 80% in the laparoscopic group.

According to previously presented studies, there were no differences between open and laparoscopic techniques concerning patient satisfaction,4 or it was better after open fundoplication.18 In our study, there were no differences in willingness to have surgery again (93% vs 96%). Instead, there were more patients in the laparoscopic group who had Visick grade 3 or 4, even if the difference did not reach statistical significance (P = .08). Larger incision had no effect on patient satisfaction, but the final result of surgery is the most important thing to a patient.

Some reports indicated that there would be more early reoperations after laparoscopic surgery.30 In our study, 4 patients undergoing laparoscopy had defective wrap at follow-up endoscopy, whereas the wrap was intact after open fundoplication in all patients. The reasons may be obscure, but 1 explanation may be that all sutures of the wrap were secured with Teflon pledgets in open fundoplication, whereas the pledgets were used only in 17 patients (57%) in the laparoscopic group. The second explanation may be the more demanding laparoscopic technique. In our study, there have been 2 reoperations (7%) in the laparoscopic group and none in the open group. According to Watson et al,31 reopera-
tions were more common when a single surgeon had performed fewer than 5 operations or the overall group in the same institute had performed fewer than 20 operations. Surgeon experience had no effect on functional outcome and patient satisfaction in our study; we found no recurrences among patients who underwent operation under these circumstances.

Contrary to many other reports where postoperative interviews have been performed by operating surgeons, which may have influenced the results, the same surgeon who had not participated in the patients' care performed our interviews. In addition, we had adequate follow-ups in both groups of at least 2 years (average, 33 months). The longest follow-up after laparoscopic fundoplication that we found was in the study of Anvari and Allen. In their study, 260 (68.2%) of the 381 patients undergoing operation underwent 6-month follow-up studies, and 108 (28.3%) underwent 2-year follow-up studies. Results were good concerning reflux symptoms, persistent dysphagia, and recurrences. However, functional outcomes were not mentioned.

Our study shows that open and laparoscopic Nissen fundoplication were effective in reflux control after almost 3 years of follow-up. However, temporary dysphagia and more disturbed belching ability may lessen advantages of laparoscopic technique.

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REFERENCES