

Laparoscopic Nissen Fundoplication: Analysis of 162 Patients

Alpaslan Sari¹, Neset Nuri Gonullu², Cagri Tiriyaki³, Murat Burc Yazicioglu³, Ertugrul Kargi⁴, Emre Gonullu⁵, Ahmet Oktay Yirmibesoglu²

¹Department of General Surgery, Kocaeli Seka State Hospital, Kocaeli, Turkey

²Department of General Surgery, Kocaeli University, School of Medical, Kocaeli, Turkey

³Department of General Surgery, Kocaeli Derince Training and Research Hospital, Kocaeli, Turkey

⁴Department of General Surgery, Abant İzzet Baysal University, School of Medical, Bolu, Turkey

⁵Department of General Surgery, Eskisehir State Hospital, Eskisehir, Turkey

We aimed to evaluate the frequency of the need for proton pump inhibitor treatment following laparoscopic Nissen fundoplication (LNF) for gastroesophageal reflux disease (GERD). A total of 162 patients with GERD were treated surgically with LNF from October 2006 to March 2010 in our surgery department. Diagnoses were made by using upper gastrointestinal system (GIS) endoscopy and 24-hour pH monitoring, and all the patients underwent routine LNF surgery. The patients were questioned regarding complaints and proton pump inhibitor (PPI) usage during the postoperative period, and 40 patients who had postoperative GIS symptoms were included. Upper GIS endoscopy with antral biopsy for *Helicobacter pylori* (HP) identification and multichannel intraluminal impedance pH (MII-pH) monitoring were applied, and all the data were evaluated. The median postoperative follow-up time was 1.84 ± 0.850 (0.29–3.48) years. PPI treatment frequency was 37.5% (15 patients) in the 40 symptomatic patients, or 9.26% in all 162 patients who were operated on. The reason for PPI usage in 3 patients (7.5%) was regarded as recurrence. HP positivity was 67.5% in the symptomatic patients and 73.3% in the PPI treated group; 40% (6 patients) recovery was achieved in the HP (+) patients by using an HP eradication treatment protocol. The operated patients displayed statistically significant results in increased quality of life ($P = 0.001$) and lowered DeMeester scores ($P = 0.000$) during the postoperative period when compared with the

Corresponding author: Ertugrul Kargi, MD, Department of General Surgery, Abant İzzet Baysal University Medical School, 14280, Golkoy, Bolu, Turkey.

Tel: +90 374 2534656 3459; Fax: +90 374 253 45 15; E-mail: ertugrulkargi92@gmail.com

preoperative period. LNF treatment for GERD prevents pathologic reflux in the long term and maintains symptomatic control, which leads to increased and better quality of life. PPI treatment alone during the postoperative period does not indicate “recurrence.” One of the most important reasons for recurrence is antral gastritis secondary to HP infection; PPI usage diminishes remarkably with an HP eradication protocol. MII-pH monitoring is an effective method of determining recurrences due to reflux and their types in postoperative symptomatic patients.

Key words: Laparoscopic Nissen fundoplication – PPI treatment – Multichannel intraluminal impedance

Gastroesophageal reflux disease (GERD) is among the most common gastrointestinal problems worldwide, and accounts for 75% of cases of esophageal pathology. Risk factors associated with GERD include insufficiency of the lower oesophageal sphincter, relaxation of the lower oesophageal sphincter due to air swallowing, poor esophageal clearance, acid hypersecretion, delayed gastric emptying, and disorders of the mucosal defense mechanisms.^{1,2} The most important treatment choice is surgery, as it is the most effective option and is less expensive than medical treatment. Laparoscopic Nissen fundoplication (LNF) is the most common method of surgical treatment.³ However, after surgery, gastrointestinal side effects, such as bloating, diarrhea, burping, abdominal pain, and flatus may occur.⁴

The present study was performed to investigate the frequency and reasons for continuing proton pump inhibitor (PPI) use during the postoperative period in patients undergoing LNF.

Materials and Methods

A total of 162 patients were enrolled in the study. All were hospitalized at the Department of General Surgery of University Faculty of Medicine between October 2006 and March 2010, and they underwent elective LNF for GERD. GERD was diagnosed by endoscopy and 24-hour pH monitoring. The surgery was performed by a single surgeon. There were no cases of perioperative complications, return to open procedure, or postoperative mortality. Postoperatively, all of the patients were discharged without any problems. They were recalled twice postoperatively for routine checks in the third month and after 1 year. Upper gastrointestinal endoscopy (based on antral biopsy) and multichannel intraluminal impedance pH (MII-pH) monitoring were performed in 40 of 162 patients (24.7%) who had gastrointes-

tinal complaints during the postoperative period and or had been continuing use of PPIs. MII-pH monitoring is a new technique designed to detect intraluminal bolus movement without the use of radiation, and is generally performed in combination with manometry, information on the functional (i.e., bolus transit) component of manometrically detected contractions, or pH testing that allows detection of gastroesophageal reflux independent of pH (i.e., both acid and nonacid reflux). Using these methods, the objective significance of the postoperative symptoms was investigated. The frequency and reason for sustained PPI use in the postoperative period were investigated, and the results were compared with data in the literature.

Statistical analysis

The median age of the patients and postoperative control times were calculated. Scores of preoperative and postoperative pH monitoring, DeMeester scores and GERD health-related quality of life (GERD-HRQL) scores were compared using the *t* test and Wilcoxon's test. Statistical calculations were performed using SPSS 13.0 for Windows (LEAD Technologies, Charlotte, North Carolina).

Results

A total of 40 patients, consisting of 21 (52.5%) men and 19 (47.5%) women with a mean age of 41.8 ± 10.688 (23–63) years, were included in the study. The mean duration of preoperative typical or atypical symptoms was 7.2 ± 6.97 (1–30) years. The median postoperative follow-up period was 1.84 ± 0.850 (0.29–3.48) years. During the postoperative follow-up period, recurrence was observed in 3 patients (7.5%). Gastroendoscopic examination revealed antral hyperemia in 33 of the 40 patients (82.5%), and the remaining 7 patients had normal

Table 1 The GERD-HRQL scale

Scale		
1. How bad is your heartburn?	1 2 3 4 5	0 = No symptoms
2. Do you have heartburn when lying down?	1 2 3 4 5	1 = Symptoms noticeable, but not bothersome
3. Do you have heartburn when standing up?	1 2 3 4 5	2 = Symptoms noticeable and bothersome, but not every day
4. Do you have heartburn after meals?	1 2 3 4 5	3 = Symptoms bothersome every day
5. Does heartburn change your diet?	1 2 3 4 5	4 = Symptoms that affect daily activities
6. Does heartburn wake you from sleep?	1 2 3 4 5	5 = Symptoms are incapacitating (unable to perform daily activities)
7. Do you have difficulty swallowing?	1 2 3 4 5	
8. Do you have pain with swallowing?	1 2 3 4 5	
9. Do you have gassy or bloating feelings?	1 2 3 4 5	
10. If you take medication, does it affect your daily life?	1 2 3 4 5	

gastroendoscopic findings. According to antral biopsies, which were taken for investigation of HP (*Helicobacter pylori*), 13 patients (32.5%) were HP (–), and different titres of HP (+) were found in 27 patients (67.5%). The median preoperative DeMeester score was 57.25 ± 85.16 (17.23–291.00), and the median postoperative DeMeester score was 2.61 ± 68.26 (0.2–279.0); improvements in these scores were seen in all but 3 of the 40 patients. The difference between the preoperative and postoperative DeMeester scores was statistically significant ($P = 0.00$).

The GERD-HRQL questionnaire was used to calculate the quality of life score (Table 1). The mean preoperative quality of life score was 32.34 ± 4.28 (22–38); postoperatively, the average value of this score decreased to 4.76 ± 0.92 (3–6). In the postoperative period, GERD-HRQL scores were significantly decreased compared to the preoperative period ($P = 0.001$). When questioned about their current status and benefit from the treatment, 17.5% of the patients reported that they were not satisfied; on the other hand, 82.5% reported that they were satisfied or very satisfied with the treatment (Table 2). The most frequent postoperative complaints were heartburn in 20 patients (50.0%), bloating in 17 patients (42.5%), dysphagia in 2 patients (5.0%)

and nausea in 1 patient (2.5%). One patient had heartburn and diarrhea at the same time. Fifteen of the operated patients (37.5%) reported that they continued to use the PPI during the postoperative period, although the persistence of dyspeptic symptoms and heartburn were reduced compared with the preoperative period. Twenty-five of the patients (62.5%) did not use the PPI during the postoperative period. Seventeen of the 27 HP (+) patients (62.96%) reported that their complaints disappeared after treatment, whereas 10 (37.04%) reported that they did not see any benefit from the treatment. Of the 15 patients using PPI, 11 (73.33%) were HP (+) and 4 (26.67%) were HP (–). The *Helicobacter pylori* eradication program was administered to the HP (+) patients. After treatment, improvement in symptoms was seen in 6 patients (40%), and the need for PPI use was eliminated. Five patients reported that they had no benefit from the eradication program and they continued to use PPI (Table 3). MII-pH results were analyzed with a medical measurement system (MMS) program, and acid fluid leakage (AL), slight acid leakage (SA), and nonacid leakage (NAL), as well as liquid, gas, and mixed leakage total amounts were calculated (Table 4).

According to the results of impedance in the 15 patients using PPI, recurrence was detected in 3 patients who also had pathologic DeMeester scores and acid leakage; among the 12 with normal DeMeester scores, acid leakage was detected in 3 patients (25%), mild acid leakage was detected in 6 patients (50%), and nonacid leakage was detected in 3 patients (25%).

Table 2 Postoperative patient satisfaction levels

Satisfaction	Number of patients	Percentage (%)	Cumulative percentage (%)
Very satisfied	17	42.5	42.5
Satisfied	16	40	82.5
Not satisfied	7	17.5	
Total	40	100.0	

Table 3 Frequency of HP eradication of the patient group using PPI

Presence of HP	Number of patients	Percentage (%)	Improvement in symptoms	No improvement in symptoms
HP(+)	11	73.33	6 (%40.0)	5 (%33.33)
HP(-)	4	26.67		
Total	15	100.0		

Discussion

Laparoscopic hiatal hernia repair was first performed by Dallemagne in 1991, and it was widely adopted once the safety of the laparoscopic approach and the advantages to the patient had been demonstrated. LNF with a less than 1% mortality and morbidity rate has become the gold standard treatment for GERD.⁵

The goals of GERD treatment are to reduce symptoms, treat esophagitis, and prevent complications. However, there is no consensus between surgeons and gastroenterologists regarding the selection of treatment, and there is still debate about whether medical or surgical treatment is best. With the development of laparoscopic antireflux surgery, reductions have been achieved in morbidity, mortality and even in the rate of recurrence of surgical treatment.⁶ Moreover, although successful results of laparoscopic antireflux surgery have been reported, the limited number of studies comparing surgical and medical treatment has prevented resolution of this debate. Given the prognosis of the disease, the incidence of complications is also increasing with the severity of disease. For example, mechanical disorders in the sphincter mechanism have been shown to have negative effects on the prognosis of GERD.⁷

Although PPI is an effective treatment for alleviating GERD symptoms, the undesirable effects of these drugs and lifelong use make these patients candidates for surgical antireflux procedure as a permanent solution. Laparoscopic antireflux surgery completely ameliorates the symptoms and reduces the need for medical treatment in a large number of patients. Although the main drug used to

treat GERD is PPI, Tamhankar *et al*⁸ reported that PPI did not reduce reflux, but only resulted in a change in the character of the leakage in a study using MII-pH. The fact that medical treatment has to be continued for life complicates compliance with treatment and increases the cost of treatment, especially in young patients with a long life expectancy. If surgical complications and failed surgical procedures are disregarded, antireflux surgery is a more appropriate and cost-effective treatment choice for GERD compared with medical treatment in the long term.^{9,10}

Although LNF is a very successful method of controlling GERD symptoms, some patients continue to use PPI postoperatively. Different frequency rates of postoperative PPI use have been reported in the literature. Ciovica *et al*¹¹ found a significant reduction in GERD symptoms after LNF, with only 4.2% of patients still needing medical treatment. Other publications have reported postoperative PPI use rates of 43% and 10%.^{12,13} A high-volume study in the literature about this subject also came to our attention; 844 patients were included, and the average postoperative follow-up period was 5.9 years. Postoperative follow-up showed that 312 patients used one or more drugs: 82% used PPIs, 9% used an H2 blocker, and 34% used antacid therapy. A total of 52 patients (17%) continued to use drugs postoperatively, and 260 (83%) began to use drugs after an average of 2.5 years. The drugs were used for the same symptoms by 31% of the patients, and for the onset of other symptoms by 49%. In addition, 20% of the patients continued to use drugs without any reason.¹⁴

Of the 40 symptomatic patients included in our study, 15 (37.5%) continued using PPI during the

Table 4 Results of MII-pH analysis

	AL	SA	NAL	Liquid	Gas	Mixed
Mean	34.30	39.53	12.45	32.39	49.18	53.49
Median	10.90	28.40	2.30	17.90	10.50	33.45
SD	80.88	41.35	24.86	46.40	110.60	80.54
Minimum	0.0	0.0	0.0	0.0	0.0	0.0
Maximum	498.3	161.0	132.40	251.9	585.3	490.9

AL, acid fluid leakage; NAL, nonacid leakage; SA, slight acid leakage.

postoperative period and 25 (62.5%) did not. To investigate the reasons for PPI use, MII-pH and endoscopies were performed in the patients. Endoscopic antral biopsies revealed the presence of HP in 67.5% of all patients ($n = 40$) and in 73.3% of the group using PPI ($n = 15$). HP eradication protocols were administered to the HP (+) patients, after which 40% ($n = 6$) improved and no longer needed PPI. In three patients (7.5%), recurrence was identified with endoscopy, and pathologic DeMeester scores and acid fluid leakage were shown by MII-pH. Normal DeMeester scores were found in the other 12 patients. Nonpathologic acid leakage was identified in 3 (25%) of the 12 patients with normal DeMeester scores; 6 (50%) had mild acid leakage, and nonacid leaks were detected in 3 patients (25%). In the present study, the preoperative and postoperative median DeMeester scores were 57.25 ± 85.16 (17.23–291.00) and 2.61 ± 68.26 (0.2–279.0), respectively; the difference was statistically significant ($P = 0.000$). When asked about current status and benefit of the treatment, 17.5% of the patients reported that they were not satisfied with the treatment, whereas 82.5% reported that they were satisfied or very satisfied. The preoperative mean quality of life score was 32.34 ± 4.28 (22–38), which decreased to 4.76 ± 0.92 (3–6) postoperatively. GERD-HRQL scores in the postoperative period were significantly lower than the preoperative values ($P = 0.001$).

In Kornmo's 10-year prospective study on patients treated with LNF, patient satisfaction (satisfied/very satisfied) after 6 years was 93%, and increased to 97% in the 10th year.¹⁵ In a similar study, the postoperative GERD-HRQL score was 5.71 ± 7.99 (0–45), and 71% of the patients were satisfied with the surgical treatment over the long term.¹² Madan *et al*¹⁶ reported that 90% of 100 patients were satisfied with antireflux surgery, and 80% reported that they would agree to undergo the operation again if the need arose. More than two-thirds of the patients (67%) described a significant reduction in the severity of their symptoms, and no patient's symptoms worsened postoperatively.

Although antireflux surgery for GERD is successful in the control of both esophageal and extraesophageal symptoms, similar or different symptoms may occur in some patients during the postoperative period.¹⁷ These symptoms are heartburn, flatulence, diarrhea, and regurgitation. In the present study, the most common complaint was heartburn in 20 patients (50.0%); we also observed bloating in 17 patients (42.5%), dysphagia in 2

patients (5.0%), and nausea in 1 patient (2.5%). One patient who complained of heartburn had been suffering from diarrhea at the same time. In a 2-year follow-up, Papasavas *et al*¹³ found a significant decrease in mean symptom scores: for example, heartburn decreased from 84% to 1.7%, regurgitation from 7.2% to 0.7%, and dysphagia from 3.7% to 1.0%. Previous reports have indicated that bloating and excessive gas discharge decrease over the years, but can continue. A 10-year follow-up study found that suffering from excessive gas and bloating decreased to 52% in 6 years and to 39% in 10 years.¹⁵ In another study, a follow-up evaluation of 118 patients who underwent antireflux surgery showed that heartburn, regurgitation, and need for PPI use decreased from 43% to 19%, 19% to 3%, and 74% to 19%, respectively.¹⁷

Conclusions

LNF is an effective method for the treatment of GERD—it has a low recurrence rate, is more cost-effective than medical treatment, and is very effective for the management of symptoms. Different levels of PPI use during the postoperative period have been reported in various studies. We found that average postoperative PPI use in symptomatic and all operated patients (162 patients) was 37.5% and 9.26%, respectively. Postoperative PPI use was not a definitive indicator of recurrence. Some symptoms may be due to recurrence, but a significant portion correlated with HP (+). When an HP eradication protocol is applied, a significant reduction in symptoms and PPI use is recorded. Most symptoms that occur during the postoperative period can be controlled either spontaneously over time or with suitable medication. MII-pH is a useful examination for determining pathologic reflux and the nature of existing leakage in symptomatic patients during the postoperative period. Our study showed a significant difference in the health-related quality of life (HRQL) of patients who underwent surgery for GERD. In addition, there was a significant difference between the preoperative and postoperative levels of patient satisfaction.

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