

Laparoscopic Nissen Fundoplication for Gastroesophageal Reflux Disease: A Retrospective Study of 50 Consecutive Cases

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Abstract

Background: Laparoscopic anti-reflux surgery has been proven to be an effective treatment for gastroesophageal reflux disease (GERD) in Western countries. On the other hand, the concept of surgical treatment of GERD has not widely spread in Japan, and the number of operations performed remains extremely low.

Purpose: The aim of this study is to analyze our initial experience with laparoscopic Nissen fundoplication.

Patients and Methods: From August 2010 to November 2012, consecutive 50 adult patients diagnosed with GERD underwent laparoscopic Nissen fundoplication. There were 42 men and 8 women, with an average age of 45.6 ± 15.9 years. All patients were resistant to medical treatment for GERD. Pre-operative endoscopy showed hiatal hernias in 47 patients (94%), and Barrett's esophagus in 26 patients (52%). In regard to mucosal change of the lower esophagus, 38 patients (76%) were diagnosed as non-erosive gastroesophageal reflux disease (NERD) and the remaining 12 patients (24%) as reflux esophagitis (RE).

Results: Laparoscopic approach was successfully done in all patients without conversion. Mean operative time was 105.9 ± 22.7 min with mean blood loss of 6.5 ± 13.1 ml, and mean post-operative hospital stay was 2.0 ± 0.2 days. There was no intra-operative complication and no mortality. There were 4 post-operative complications in 4 patients (8%) during the mean follow-up period of 4.7 ± 5.5 months. The change in GERD symptoms was evaluated using FSSG (frequency scale for the symptoms of GERD) at each visit. The average total score was

24.0 ± 10.2 before surgery and significantly dropped to 8.4 ± 7.0 at 6 months after surgery ($p < 0.05$). PPIs were prescribed in 43 out of 50 patients (86%) before surgery and the percentage dropped to 8.7% (4 out of 46 patients) at the latest visit. Overall efficacy rate was 90%.

Conclusion: Laparoscopic Nissen fundoplication for medically uncontrolled GERD is safe and effective also in the Japanese population. Considering the recent rapid increase of obesity and westernized life style, the necessity of the treatment will be more and more important.

Keywords: Gastroesophageal Reflux Disease; Laparoscopic Fundoplication; GERD; NERD; Nissen; Japanese

Introduction

Gastroesophageal reflux disease (GERD) is a common condition, experienced by up to 20% of the population in Western countries [1] and although the data vary with the reports, up to 4.0-19.9% of the Japanese population [2-5]. Treatment of GERD includes a range of options and can be divided into three progressive steps. The first are changes to lifestyle, whereby overweight patients are advised to lose weight, reduce smoking/alcohol consumption, and to alter dietary and sleeping patterns. The second tier of treatment is the use of acid suppression therapy, using either histamine receptor antagonists (H2RA) or PPIs, followed by maintenance use of these acid suppression drugs. Surgery is currently considered the third tier of management and is usually confined to patients with severe symptoms which are not adequately controlled.

Surgical treatment of GERD has been shown to be effective by level I evidence (randomized controlled trials) compared to medical treatment, both in terms of symptom control and quality of life [6-12], and has been well established as one of the options in Western countries. According to data from the Nationwide Inpatient Sample in the United States, the annual number of anti-reflux procedures performed in the United States was 31,695 in 1999 and 23,998 in 2003 [13]. On the other hand, according to the most recent nationwide survey of endoscopic surgery in Japan, the number of laparoscopic anti-reflux surgery performed in 2011 was only 172 [14]. Thus, even allowing for the racial and cultural differences between Westerners and Japanese, the penetration of surgical treatment of GERD in Japan is very low. One possible reason would be that surgeons in Japan have limited experience of laparoscopic surgery for GERD. Another would be that many of the primary care physicians who usually take care of the condition, often do not know much about the effect of the surgical treatment, especially in the modern era of laparoscopic surgery. In this report, we show our initial experience of laparoscopic Nissen fundoplication for GERD among medically uncontrolled Japanese patients.

Patients and Methods

From August 2010 to November 2012, consecutive 50 adult patients diagnosed with GERD underwent laparoscopic Nissen

fundoplication. Indications for surgery were set according to the SAGES guidelines in 2010, which are those who: (1) have failed medical management (inadequate symptom control, severe regurgitation not controlled with acid suppression, or medication side effects); (2) opt for surgery despite successful medical management (due to quality of life considerations, lifelong need for medication intake, expense of medications, etc.); (3) have complications of GERD (e.g. Barrett's esophagus, peptic stricture); (4) have extra-esophageal manifestations (asthma, hoarseness, cough, chest pain, aspiration) [15]. Pre-operative evaluations consisted of detailed interview/questionnaire regarding the presence or absence of subjective symptoms; endoscopic findings of the esophagus; and barium investigations of the esophagus. Ambulatory 24-hour pH monitoring was also performed arbitrarily.

Patients were placed in a supine position under general anesthesia, and two 12-mm ports and three 5-mm ports were inserted. The surgical procedure involved resecting the short gastric vessels, mobilization of the gastric fundus, division of the phrenoesophageal ligament, and dissecting tissue around the esophagus to obtain at least 3cm of abdominal esophagus. Anterior and posterior branches of vagus nerve were visualized and preserved. Calibration at crural repair was done using a 45-F bougie inserted into the esophagus, according to the floppy Nissen fundoplication. After a "shoeshine" maneuver was done to prevent undue tension, 360 degree wrapping of the gastric fundus was done with three stitches and a width of 1.5-2cm. A naso-gastric tube was not placed. Oral intake started from the first postoperative day, after confirming the passage of the plicated esophagogastric junction by swallowing contrast medium.

Patients' demographics, symptoms, results of preoperative studies, operative data, postoperative complications, and surgical outcomes were collected from medical records. Data were analyzed using SPSS software (Chicago, IL, USA). For comparison, the Wilcoxon signed-rank test was used, and P values of less than 0.05 were considered significant. Results were expressed as mean ± SD.

Results

There were 42 males and 8 females with an average age of 45.6 ± 15.9 years (range: 19-76 years). Mean time of duration of symptoms was 6.2 ± 6.9 years (range: 6 months-20 years). All patients were resistant to conventional medical treatment for GERD, including 43 patients (86%) taking proton pump inhibitors (PPIs). Pre-operative studies showed hiatal hernias in 47 patients (94%). Barrett's esophagus was present in 26 (52%), and reflux esophagitis in 12 (24%) (Table 1).

Laparoscopic Nissen fundoplication without open conversion was successfully done in all patients. One patient underwent concomitant laparoscopic cholecystectomy. Mean skin to skin operative time was 105.9 ± 22.7 min, with mean blood loss of 6.5 ± 13.1 ml, and mean post-operative hospital stay of 2.0 ± 0.2 days. Transition of the skin to skin operative time and intra-operative blood loss in our series are shown in Figure 1. Both

Table 1: Pre-operative endoscopic findings of the 50 patients.

Modified Los Angels classification	
Grade 0 (normal appearance)	8 (16%)
Grade M (minimal change)	30 (60%)
Grade A	8 (16%)
Grade B	2 (4%)
Grade C	2 (4%)
Grade D	0 (0%)
Hiatal hernia	
No	3 (6%)
mild	25 (50%)
Moderate	17 (34%)
severe	4 (8%)
Barrett's Esophagus	
No	24 (48%)
SSBE	25 (50%)
LSBE	1 (2%)

intra-operative complication and mortality were nil. There were 4 post-operative complications that occurred in 4 patients (8%) during the mean follow-up period of 4.7 ± 5.5 months (range: 2 days to 25 months, follow-up rate: 92%). They included one gastroesophageal junction obstruction caused by residue on POD 14 which required endoscopic removal; one prolonged gas-bloating which occurred immediately after the operation and has still existed even after 4 months despite the continuous administration of antiflatulents; one mild recurrence which was controlled by PPI on demand; and one wrap herniation into the mediastinum revealed 20 months after the operation and subsequently fixed laparoscopically (Figure. 2).

Improvement of post-operative symptoms was evaluated using FSSG (frequency scale for the symptoms of GERD) at each visit. The FSSG consists of 12 simple questionnaires to evaluate the subjective symptoms of GERD and has been well validated in the literature, especially in Japanese patients [15-17]. The average total score (higher FSSG score indicating more likely to be GERD) before surgery was 24.0 ± 10.2. Immediately after surgery the score dropped significantly, to: 11.1 ± 7.0 at 1 week; 11.3 ± 7.2 at 1 month; 8.9 ± 6.7 at 3 months; and 8.4 ± 7.0 at 6 months (p<0.05) (Figure. 3). Before surgery various kinds and doses of PPIs were prescribed in 43 out of 50 patients (86%), and their symptoms were not fully controlled. After surgery at the latest visit only 4 out of 46 (excluding 4 patients lost to follow-up) (8.7%) needed either continuous, or on demand, PPI administration. In 5 out of 50 patients (10%) their subjective GERD symptoms were not ameliorated after surgery, which accounted for the overall efficacy rate of 90%.

Discussion

Gastroesophageal reflux disease (GERD) is a common

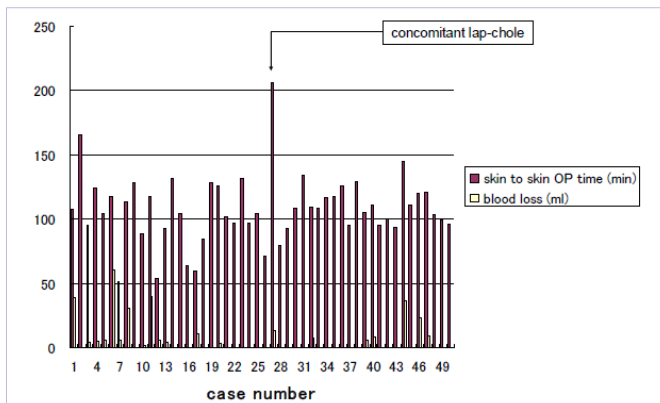


Figure 1: Learning curve of laparoscopic Nissen fundoplication in our series.

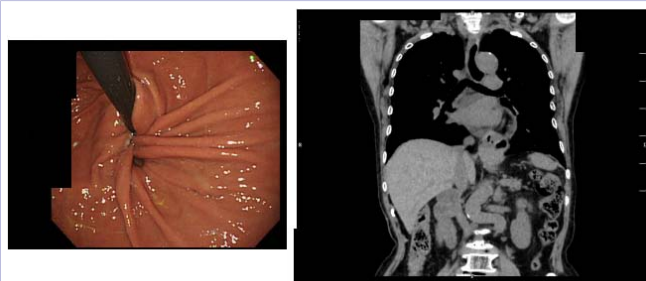


Figure 2: Wrap herniation into mediastinum which revealed 20 months after the primary lap-Nissen in a 74-year-old female. Her main complaint was dysphagia. Laparoscopic redo was successfully performed and the condition normalized.

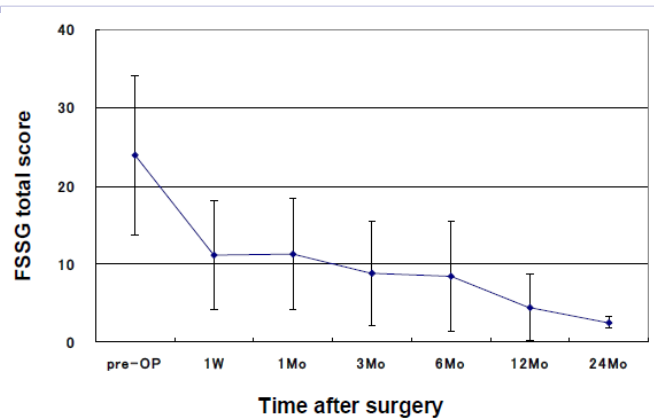


Figure 3: Change in subjective symptoms score.

condition affecting up to 20% of the population in Western countries (1). Although life style modification such as change in dietary and sleeping patterns is considered to be the first thing to do, there has been little evidence showing its clinical effectiveness [18]. Thus, realistically, the main actor in the treatment of GERD is acid suppression therapy such as histamine receptor antagonists (H2RA) and proton-pump inhibitors (PPIs). The pharmacological therapy, especially PPIs, is actually very effective with an 84%

efficacy rate for healing the endoscopic esophagitis, and 77% for symptom control (heartburn relief) [19]. However, there are still about 10-20% of patients estimated to be resistant to the above mentioned medical therapy, which is huge considering the high prevalence of the disease. Also, the situation is even worse in patients with non-erosive gastroesophageal reflux disease (NERD) which has been shown to be more resistant than those with reflux esophagitis (RE) [20, 21]. Therefore surgery becomes an important decision branch for those who are resistant to medical therapy.

Surgical treatment for GERD has been shown to be effective by level I evidence (randomized controlled trials) even compared to medical treatment, both in terms of symptom control and quality of life [6-12], and has been well established as one of the options in Western countries. In Japan, according to the most recent nationwide survey in 2011, the number of (laparoscopic) anti-reflux operations performed was only 172 a year [14]. Considering that the reported prevalence of GERD in Japanese adults is 4.0-19.9% [2-5], and that there is no obvious evidence so far that the efficacy rate of PPIs differs between Westerners and Japanese, the penetration of surgical treatment of GERD in Japan has to be considered as extremely low. In other words, there may be potentially a large number of patients whose GERD is inadequately treated. One possible reason would be that surgeons in Japan have limited experience of laparoscopic surgery for GERD. Another would be that many of the primary care physicians who usually take care of the condition do not know much about the concept, and the effect, of surgical treatment in the modern era of laparoscopic surgery.

There are already several reports showing the effects of surgical treatment of GERD in Japanese patients. Takeyama et al., reported their experience of 23 patients who underwent laparoscopic Nissen fundoplication. They examined the changes in GERD-related symptoms, endoscopic findings, gastroesophagogram findings and the results of intraesophageal 24-h pH monitoring, and concluded that the effectiveness of the operation was 89.5%, with acceptable complication rates [22]. Omura et al., reported their experience of 22 NERD patients undergoing laparoscopic fundoplication (Nissen in 10 patients and Toupet in 12 patients). This is a very important study because more than half of GERD patients in Japan are in the state of NERD [23] and, as mentioned above, NERD patients are more likely to be resistant to medical therapy [20,21]. 91% of their patients had a sliding hernia and 95% had a loose cardiac orifice detected in pre-operative endoscopy. They established their own surgical indications for NERD as follows: positive acid reflux on pH monitoring (pH < 4 time fraction: 4% or more); positive bilirubin reflux detected by Bilitec2000 (abs > 0.14: 4% or more); improvement of symptoms by 50% or more with the administration of a PPI, but with a desire not to continue long-term administration; symptoms of esophageal hiatal hernia and reflux other than heartburn, including regurgitation, belching, and epigastric discomfort. Under these indications they reported an overall efficacy rate of 95%, and 21 out of the 22 patients achieved discontinuation of PPIs [24].

In our series, 76% of the patients (38 out of the 50) were diagnosed as NERD and 94% of them had hiatal hernias in various degrees. Before surgery PPIs were prescribed in 86% of the patients and the percentage dropped to 8.7% at the latest visit. Our overall symptom-based efficacy rate was 90%, which is similar to the previous reports for Japanese patients.

The learning curve for laparoscopic anti-reflux surgery has been well documented in the literature with reports of increased failure rates [25], complications [26], re-operations [26], operative time [27], hospital days [27], and conversions to open surgery [26,27] by less experienced surgeons. The learning phase for laparoscopic anti-reflux surgery is reported to be 15-20 cases and studies have suggested that surgeons seek experienced supervision during their learning period to minimize adverse outcome [26]. Also, good results have been reported by young surgeons after appropriate training in laparoscopy [28,29]. In our series, we experienced neither open conversion nor surgical mortality. The post-operative complication rate (including minor ones) of 8% is thought to be acceptable [30]. We did not see any specific learning effect regarding the operative time and the blood loss throughout the series as shown in figure 1. Probably this is because we introduced the operation after extensive experience of general MIS including bariatric surgery.

A limitation of the study is that the number of patients is small, and the follow-up period is relatively short. Also, we basically made the decision of efficacy of the treatment by a symptom scale, which is well-validated in the literature but subjective none the less. In conclusion, laparoscopic Nissen fundoplication is effective in controlling symptoms of GERD in Japanese patients. Since our experience is still limited, a study of larger scale could define more clearly the efficacy of this treatment modality.

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