

# Efficacy of laparoscopic Toupet fundoplication for non-erosive reflux disease assessed by combined multichannel intraluminal impedance–pH monitoring

Se Ryung Yamamoto · Fumiaki Yano ·  
Nobuo Omura · Kazuto Tsuboi · Masato Hoshino ·  
Hideyuki Kashiwagi · Katsuhiko Yanaga

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## Abstract

**Background** Non-erosive gastroesophageal reflux disease (NERD) is the most common form of gastroesophageal reflux disease (GERD). The aim of this study is to evaluate efficacy of laparoscopic Toupet fundoplication for NERD by combined multichannel intraluminal impedance–pH (MII–pH) monitoring.

**Methods** Twenty-eight patients who underwent laparoscopic Toupet fundoplication for NERD had MII–pH monitoring before surgery. Among them, 11 patients accepted to undergo MII–pH monitoring both before and after surgery. Their clinical data were collected in a prospective fashion and retrospectively reviewed. Patients' characteristics, the esophageal function of time pH below 4, DeMeester score, the numbers of acid and nonacid reflux episodes and symptom index (SI) were evaluated.

**Results** Pre- and postoperative time pH below 4 were  $5.8 \pm 7.1$  and  $0.7 \pm 1.3$ , respectively, and DeMeester score was  $19.7 \pm 23.3$  and  $2.8 \pm 3.8$ , respectively, both of which were significantly different ( $p = 0.022$  and  $0.019$ ). Pre- and postoperative numbers of all reflux episodes were  $84.3 \pm 52.5$  and  $36.2 \pm 22.8$ , respectively. Pre- and postoperative acid reflux episodes were  $39.5 \pm 35.2$  and  $9.9 \pm 19.2$ , respectively. There were significant differences in the number of both all and acid reflux episodes ( $p = 0.001$  and  $0.012$ ). Those of nonacid reflux episodes were  $44.8 \pm 37.4$  and  $26.3 \pm 13.9$ , respectively, which did

not achieve statistical significance ( $p = 0.068$ ). Six patients (54.5 %) had positive SI preoperatively, but no one had positive SI after surgery.

**Conclusion** Laparoscopic Toupet fundoplication can control gastroesophageal reflux events in patients with NERD.

**Keywords** Non-erosive gastroesophageal reflux disease · NERD · Antireflux surgery · Laparoscopic fundoplication · MII–pH

## Introduction

Gastroesophageal reflux disease (GERD) is a common condition which develops when the reflux of gastric contents causes troublesome symptoms and/or complications [1]. Non-erosive gastroesophageal reflux disease (NERD) is defined by the presence of troublesome reflux-associated symptoms and the absence of mucosal breaks at endoscopy [1]. It has been reported that 70 % of patients with GERD have no endoscopic evidence of erosive esophagitis [2, 3]. Patients with NERD have lower response to proton pump inhibitors (PPIs) than those with erosive GERD [4–7]. Recent studies documented the efficacy of antireflux surgery in patients with NERD [8–12].

In recent years, combined multichannel intraluminal impedance–pH (MII–pH) monitoring has been introduced as a new technique for monitoring gastroesophageal reflux (GER) [13, 14]. This technique detects all reflux episodes, not only liquid, gas and mixed reflux episodes, but also acid and nonacid reflux. The aim of this study is to evaluate the efficacy of laparoscopic antireflux surgery (LARS) for NERD using MII–pH monitoring.

S. R. Yamamoto (✉) · F. Yano · N. Omura · K. Tsuboi ·  
M. Hoshino · H. Kashiwagi · K. Yanaga  
Department of Surgery, The Jikei University School of Medicine,  
3-25-8 Nishishinbashi, Minato-Ku, Tokyo 105-8461, Japan  
e-mail: kimkim\_44@hotmail.com

## Patients

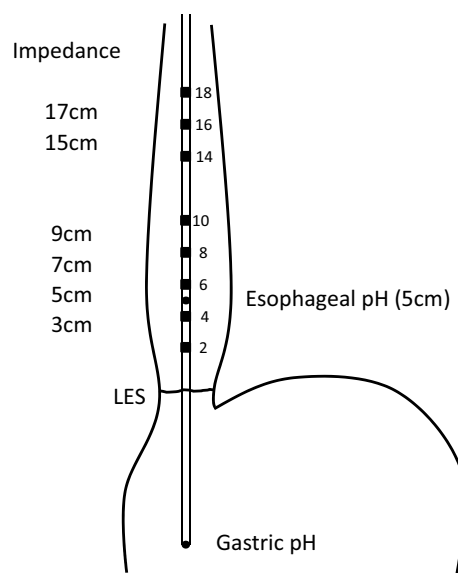
The database of GERD at our department was investigated to identify patients who underwent LARS and MII–pH monitoring between May 2008 and August 2012. Office charts were retrospectively reviewed to exclude patients who had a history of administration PPI before the first esophagogastroduodenoscopy (EGD). Patients who underwent prior thoracic, esophageal or gastric surgery and/or esophageal motility disorders (e.g., achalasia, scleroderma) were also excluded. There were 28 patients with NERD, 14 men and 14 women with a mean age of  $48.8 \pm 16.4$  (range, 15–81) years. Among them, we identified 11 patients who had combined MII–pH monitoring before and after surgery.

## Surgical technique

All patients underwent laparoscopic Toupet fundoplication. Five ports are used for the operation. A 1–2 cm incision is made above the umbilicus in the midline, through which a camera port is introduced. A 10-mm port is placed on the left subcostal area, and 5-mm ports are placed on the right subcostal and left lateral areas, and a liver retractor is introduced from upper midline. The procedure is begun with dissection of the hiatal pillars followed by esophageal mobilization. The peritoneum and the phrenoesophageal membrane above the esophagus are transected and the anterior vagus nerve is identified. The right crus is separated from the right side of the esophagus, identifying the posterior vagus nerve. The esophagus is retracted upward to create a window between the gastric fundus, esophagus, and diaphragmatic crura, and the window is created by blunt and sharp dissection under the esophagus. A penrose drain is passed around the esophagus which is mobilized for some distance into the chest to obtain esophageal length. Short gastric vessels are divided and the diaphragmatic crura are closed before fundoplication. A 210–240° wrap is created by fixing the fundus for 4 cm to the esophagus on both sides.

## MII–pH monitoring

MII–pH monitoring was performed using a six-impedance, two-pH catheter (ZAN-BG-44; Sandhill Scientific Inc. Highlands Ranch, CO, USA). The design of the catheter allows recording impedance data at 3, 5, 7, 9, 15, and 17 cm above the lower esophageal sphincter (LES). In addition, pH was recorded at 5 cm above the LES and 10 cm below the LES (Fig. 1). The six impedance and two pH signals were recorded at 50 Hz on a 128 MB



**Fig. 1** A combined multichannel intraluminal impedance–pH (MII–pH) catheter with six impedance segments and pH sensor 5 cm above and 10 cm below the LES [15]

compact Flash. Acid antisecretory agents such as PPI were discontinued at least 7 days before MII–pH monitoring. The recording was performed in the hospital. The patients arrived at the laboratory after an overnight fasting were encouraged not to lie down during daytime and had regular diet during recording. They were also instructed to push event button when they perceived reflux-related symptoms. Before data acquisition, the pH probe was calibrated in buffers of pH 4.0 and 7.0. The catheter was transnasally inserted into the esophagus and stomach, and the pH electrode was positioned 5 cm above the LES under X-ray. At the end of the 24-h recording period, data were transferred and autoscanned using a dedicated software program (Bioview Analysis; Sandhill Scientific Inc. Highlands Ranch, CO, USA).

## Definitions of reflux episodes

Liquid reflux was defined as a retrograde 50 % drop in impedance starting distally (at the level of the LES) and propagating to at least the next two more proximal impedance-measuring segments. Gas reflux was defined as a simultaneous increase in impedance  $>3,000$  Ohms in any two consecutive impedance sites with one site having an absolute value  $>5,000$  Ohms in the absence of swallowing. Mixed liquid–gas reflux was defined as gas reflux occurring immediately before or during a liquid reflux. Simultaneously recorded pH data were used to classify reflux episodes as acid or nonacid: (a) acid reflux:

impedance-detected reflux episodes with a nadir pH less than 4, (b) nonacid reflux: impedance-detected reflux episodes with a nadir pH 4 or more [15].

Symptom association

The symptom index (SI) was calculated as the percentage of symptoms preceded by a reflux event detected by MII or a drop in esophageal pH below 4 within a 5-min time frame divided by the total number of symptoms. A positive SI was defined as 50 % or more (i.e., at least half of the events were preceded by reflux) [16].

Statistical analysis

For statistical testing of normality, the chi-square test was used. The differences between the 2 groups were compared using the paired *t* test, Wilcoxon signed-ranks test or Mann–Whitney’s *U* test. The differences were considered

statistically significant for *p* < 0.05. Unless otherwise specified, the data were presented as mean ± standard deviation.

Results

Patients’ characteristics and the results of combined MII–pH monitoring are shown in Table 1. Twenty-five patients (89 %) had a hiatal hernia (A0: 3 patients, A1: 21 patients, A2: 3 patients, A3: 1 patients) [17]. The mean esophageal function of time pH below 4 was 2.6 ± 4.8 %, and 6 patients (21 %) had an abnormal acid exposure. The mean number of all reflux was 69.1 ± 39.4 and those of acid and nonacid reflux were 25.7 ± 27.3 and 43.4 ± 27.7, respectively. The mean number of total liquid reflux and total gas reflux was 57.6 ± 38.3 and 11.6 ± 9.0, respectively. Thirteen patients (46 %) had positive SI. All of the patients were administered PPI before surgery.

All patients underwent laparoscopic Toupet fundoplication. None of the patients required conversion to open surgery. The mean operative time was 121.7 ± 38.1 min. Vagus nerve injuries were identified perioperatively in 1 patient. All cases started oral intake on postoperative day 1. The median length of hospital stay was 7 days (range, 5–158). There was no perioperative motility. Postoperative complications occurred in 3 patients. Two patients showed difficulty with swallowing. One patient had had intestinal malrotation and showed duodenal obstruction after primary surgery. This patient needed reoperation and adhesiotomy and partial small bowel resection were performed. Six patients had H2 blocker or PPI after surgery.

A comparison of the pre- and postoperative MII–pH monitoring results is shown in Table 2. Pre- and postoperative esophageal function of time pH below 4 was 5.8 ± 7.1 and 0.7 ± 1.3, respectively, while DeMeester score was 19.7 ± 23.3 and 2.8 ± 3.8, respectively. Both parameters decreased significantly after surgery

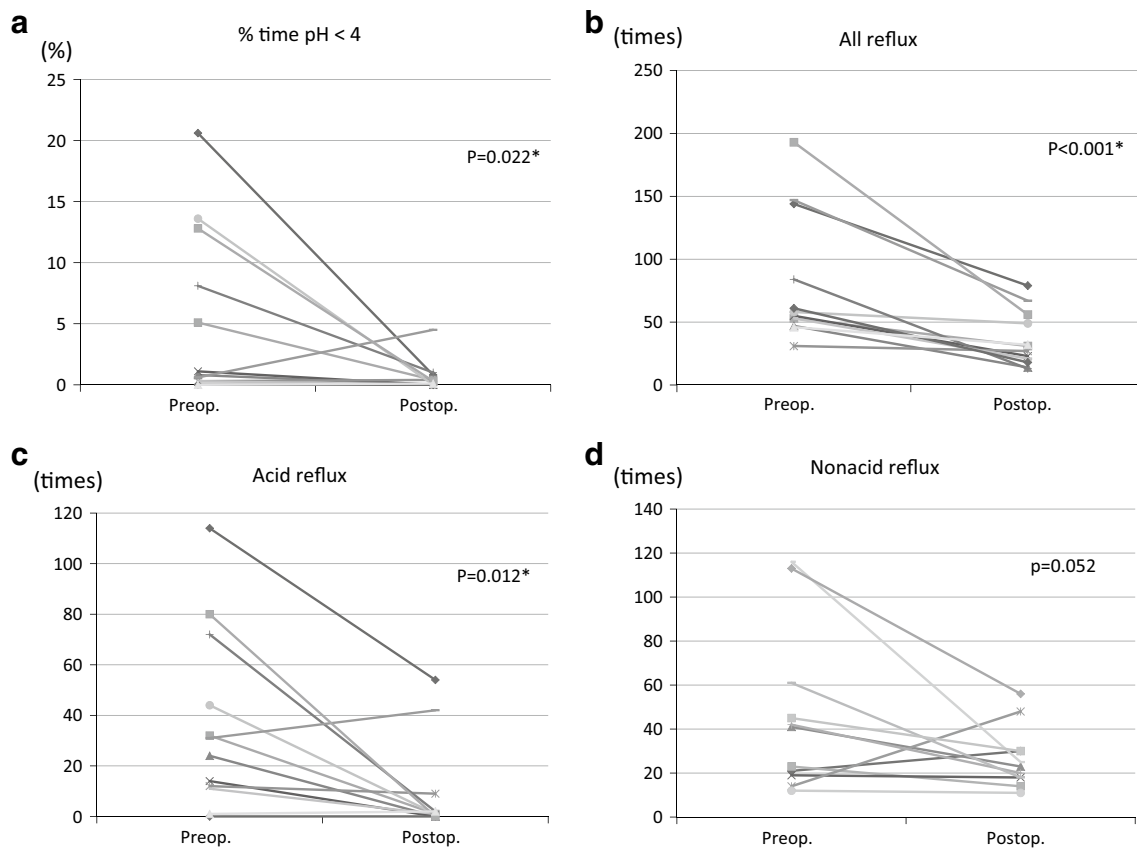
**Table 1** Patient characteristics

Male: female	14:14
Age (years)	48.8 ± 16.4 (15–81)
Hiatal hernia (yes:no)	26:2
A0:A1:A2:A3	3:21:3:1
% time pH < 4	2.6 ± 4.8 (0.0–20.6)
DeMeester score	9.0 ± 15.7 (0.8–70.5)
The number of Acid reflux	25.7 ± 27.3 (1–114)
The number of nonacid reflux	43.4 ± 27.7 (12–116)
The number of all reflux	69.1 ± 39.4 (17–193)
The number of liquid acid reflux	23.5 ± 26.0 (0–107)
The number of liquid nonacid reflux	34.1 ± 25.7 (3–105)
The number of total liquid reflux	57.6 ± 38.3 (11–174)
The number of gas acid reflux	2.2 ± 6.1 (0–32)
The number of gas nonacid reflux	9.4 ± 6.6 (0–33)
The number of total gas reflux	11.6 ± 9.0 (1–41)

**Table 2** Preoperative and postoperative detailed findings at 24-h multichannel intraluminal impedance–pH monitoring

	PRE-FP	POST-FP	<i>p</i> value
% time pH < 4	5.8 ± 7.1 (0.0–20.6)	0.7 ± 1.3 (0.0–4.5)	0.022*
DeMeester score	19.7 ± 23.3 (0.8–70.5)	2.8 ± 3.8 (0.8–13.9)	0.019*
Acid reflux	39.5 ± 35.2 (1–114)	9.9 ± 19.2 (0–54)	0.012*
Nonacid reflux	44.8 ± 37.4 (12–116)	26.3 ± 13.9 (11–56)	0.052
All reflux	84.3 ± 52.5 (31–193)	36.2 ± 22.8 (13–79)	0.001*
Liquid acid reflux	35.0 ± 17.4 (0–107)	8.8 ± 17.4 (0–49)	0.006*
Liquid nonacid reflux	34.3 ± 35.2 (3–105)	18.1 ± 11.4 (7–43)	0.069
Total liquid reflux	69.3 ± 54.1 (13–174)	26.9 ± 21.2 (8–66)	0.005*
Gas acid reflux	4.5 ± 9.5 (0–32)	1.1 ± 1.7 (0–4)	0.141
Gas nonacid reflux	10.5 ± 8.4 (0–31)	8.2 ± 6.1 (2–23)	0.203
Total gas reflux	15.0 ± 12.1 (1–41)	9.3 ± 5.9 (3–23)	0.084

Values are mean ± SD  
FP fundoplication



**Fig. 2** Changes of %time pH < 4 (a), all reflux (b), acid reflux (c) and nonacid reflux (d) in 11 patients

( $p = 0.022$  and  $0.019$ ). Pre- and postoperative number of all reflux episodes was  $84.3 \pm 52.5$  and  $36.2 \pm 22.8$ , respectively. Pre- and postoperative acid reflux episodes were  $39.5 \pm 35.2$  and  $9.9 \pm 19.2$ , respectively, while those of nonacid reflux episodes were  $44.8 \pm 37.4$  and  $26.3 \pm 13.9$ , respectively. The number of both all and acid reflux episodes was significantly different ( $p = 0.001$  and  $0.012$ ). Although the number of nonacid reflux episodes tended to decrease, there was no significant difference ( $p = 0.068$ ). The number of both total liquid and liquid acid reflux episodes decreased significantly ( $p = 0.005$  and  $0.006$ ). The number of nonacid liquid reflux tended to decrease, but there was no significant difference ( $p = 0.069$ ). Each number of gas reflux episodes did not decrease significantly. The preoperative SI was positive in 6 of 11 patients (55 %), but none of the patients had positive SI postoperatively.

Changes of esophageal function of time pH below 4 (%time pH < 4), all reflux, acid reflux and nonacid reflux in 11 patients are shown in Fig. 2. Among them, 6 patients had abnormal acid exposure before surgery and all patients showed no abnormal acid exposure except 1 patient after surgery. The number of all reflux reduced in all patients after surgery (Fig. 2b). The number of acid reflux reduced

in all but 1 patient (Fig. 2c). The number of nonacid reflux reduced in 9 patients and that of acid reflux increased in 2 patients after surgery (Fig. 2d).

## Discussion

NERD and erosive GERD are the two main types of GERD. Pathogenesis of GERD is acid reflux, which has a strong correlation with severity of esophageal mucosal damage. On the other hand, pathogenesis of NERD is thought to be multifactorial. Martinez et al. [18] reported that only 45.1 % of NERD patients had an abnormal pH test compared with 75 % of patients with erosive GERD. In our study, only 6 of 28 patients (21 %) had an abnormal pH test, so the incidence was almost half of their study.

Data from this study showed by pH monitoring that laparoscopic Toupet fundoplication was effective in controlling % time pH < 4, DeMeester score, acid reflux and all reflux. According to the MII, liquid reflux and total liquid reflux were well controlled. On the other hand, the number of nonacid reflux was likely to reduce, but there was no significant difference. This result is consistent with previous studies [19, 20]. They reported that this preferential

**Table 3** Pathophysiology of NERD

1	Abnormal acid exposure
2	Hypersensitivity to reflux events (pH < 4) within the normal range
3	Hypersensitivity to minute pH changes (pH > 4)
4	Nonacid-related intraesophageal stimuli
5	Psychological factors

decrease in acid reflux episodes after LARS may be the result of inhibition of transient LES spontaneous relaxations which is associated with acid reflux episodes. But LARS does not control immediate postprandial reflux episodes, the majority of which are nonacid when the stomach is most distended allowing nonacid liquid and gas content to be vent. However, none of the patients had a positive SI postoperatively and therefore, Toupet fundoplication may be sufficient to treat patients with NERD.

Pathophysiology of NERD was advocated by Fass and is listed in Table 3 [21]. In this study, there were no patients who had abnormal acid exposure after surgery in those who had abnormal acid exposure before surgery (Fig. 2a). In these patients, the majority of reflux episodes before surgery were acid reflux, which could cause their symptoms. Although one patient's number of nonacid reflux increased after surgery, total number of reflux reduced after surgery. Therefore, main causative factor was abnormal acid exposure. Of the 6 patients who had no abnormal acid exposure before surgery, 2 patients had abnormal gastroesophageal reflux in which the majority of reflux was nonacid reflux. The number of nonacid reflux reduced significantly in both patients after surgery, which could lead to improvement of symptoms. Interestingly, one of the patients had an abnormal acid exposure after surgery, though this patient's symptom improved greatly after surgery. In these patients, the main causative factor was clearly nonacid-related intraesophageal stimuli. The remaining 4 patients had normal gastroesophageal reflux and their symptoms may be more strongly correlated with hypersensitivity.

NERD patients have less acid exposure compared with erosive GERD and it is more important for NERD patients to prevent nonacid reflux besides acid reflux. PPIs have antisecretory action of acid, but have no control of gastroesophageal reflux. Therefore, PPIs are not expected to improve symptoms which are correlated with nonacid-related intraesophageal stimuli. On the other hand, antireflux surgery aims to protect the esophageal mucosa from gastric contents and is expected to improve symptoms of any patients correlated with not only acid reflux but also nonacid reflux. In addition, antireflux surgery can be effective for symptoms caused by hypersensitivity. Our study confirmed that symptoms of patients with NERD had stronger correlation with nonacid-related intraesophageal

**Table 4** Surgical indications in each patient

Patient no.	Surgical indications
1	1, 2, 3
2	1
3	3, 4
4	3, 4
5	4
6	1, 4
7	1, 2, 3, 4
8	4
9	2, 3
10	1, 4
11	1, 2, 3, 4

Criteria for surgical indications: 1 abnormal acid exposure detected by pH monitoring (% time pH < 4: 4.2 % or more), 2 abnormal gastroesophageal reflux by MII (the number of total reflux >73), 3 positive symptom index; 4 esophageal hiatal hernia

stimuli or hypersensitivity as compared to those of erosive GERD and that antireflux surgery could lead to improvement of symptoms.

The surgical indications for NERD in our department are abnormal acid exposure by pH monitoring (% time pH < 4: 4.2 % or more), abnormal gastroesophageal reflux by impedance MII (the number of total reflux >73), and positive SI or esophageal hiatal hernia. Table 4 shows the indications for surgery in the 11 patients. The surgical indication for NERD is not yet well standardized. Patients without abnormal acid reflux are sometimes considered as functional heartburn and those patients were not indicated for surgery in a previous study [12]. However, there was another study which included patients without abnormal acid reflux for surgical treatment [22]. We believe that considering all of patients without abnormal acid reflux as functional heartburn sometimes leads to misdiagnosis and MII-pH monitoring should be performed.

Regarding surgical results, Broeders et al. [12] documented that Nissen fundoplication in patients with PPI-refractory NERD was equally effective in patients with PPI-refractory erosive GERD. We have also previously reported that Toupet fundoplication is effective in patients with NERD without abnormal acid exposure [11]. Results of this study were consistent with these reports. Previous meta-analysis reported that there was no significant difference in reflux control between Nissen and Toupet fundoplication [23]. More recent study reported that Laparoscopic Nissen and partial fundoplications proved to be durable and achieved good long-term outcomes [24]. Both Nissen and partial fundoplication can be good option for NERD patients.

There were some limitations in this study. Foremost is that it is a retrospective review, although all data were

collected prospectively. Additionally, MII–pH monitoring after surgery was performed for only patients who agree to undergo MII–pH monitoring after surgery and MII–pH monitoring was not performed in more than half of patients after surgery.

In conclusion, laparoscopic Toupet fundoplication can control gastroesophageal reflux events, which is expected to be effective in patients with NERD.

**Ethical Statement** This study conformed to the guidelines set forth in the Helsinki Declaration of 1975 as revised in 2000 and 2008, concerning human or animal rights and we followed out policy concerning Informed Consent as shown on Springer.com.

**Conflict of interest** Drs. Se Ryung Yamamoto, Fumiaki Yano, Nobuo Omura, Kazuto Hoshino, Masato Hoshino, Hideyuki Kashiwagi and Katsuhiko Yanaga have no conflict of interest or financial ties to disclose.

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