



Surgical results of laparoscopic Toupet fundoplication for gastroesophageal reflux disease with special reference to recurrence

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Abstract

Background Surgical results of GERD have mainly been reported from the Western countries, with a few reports found in Japan. We examined the surgical results of laparoscopic Toupet fundoplication and clarify the characteristics of recurrent cases.

Methods The subjects included 375 patients who underwent laparoscopic Toupet fundoplication from June 1997 to December 2016 as the initial surgery. Patient characteristics, pathophysiology, and surgical results were examined. In addition, we compared the patient characteristics and pathophysiology of recurrent cases in comparison with non-recurrent cases.

Results Age 59 (43–70) and male 211 (56.3%). The operation time was 141 min (113–180) and intraoperative complications were found to have onset in 13 subjects (3.5%). Dysphagia after surgery was found in 18 cases (4.8%). The A factor (the degree of hiatal hernia), P factor (the degree of esophagitis), and pH < 4 holding time significantly improved after surgery compared with prior to surgery ($p < 0.001$ for all), while the LES lengths and abdominal LES lengths were extended ($p < 0.001$ for each). Recurrence was found in 48 patients (15.1%) among the 318 patients for whom we could confirm the presence or absence of recurrence. The A factor, P factor, and pH < 4 holding time prior to surgery were, respectively, higher in the recurrence group ($p = 0.031$, $p < 0.001$, $p < 0.001$).

Conclusions Laparoscopic Toupet fundoplication for GERD could be performed safely, with a response rate as good as 85%. Compared with non-recurrent cases, preoperative clinical conditions such as esophageal hiatal hernia, reflux esophagitis, and acid reflux time were all advanced in recurrent cases.

Keywords GERD · Laparoscopic Toupet fundoplication · Surgical result · Recurrence

Introduction

The standard procedure for gastroesophageal reflux disease (GERD) is laparoscopic fundoplication [1]. Although surgical results have been reported from overseas, mainly from Europe and the United States [2–4], in Japan, the number of operations is much smaller than in Western countries, with a few reports including a large number of subjects. On the other hand, procedures widely used for fundoplication

around the world include the Nissen method (whole circumference) and the Toupet method (partial circumference). Both procedures do not differ in terms of the prevention effect of reflux. However, the occurrence of dysphagia in the early postoperative stages is less with the Toupet method, which is considered a more desirable operation from the viewpoint of QOL [5–7]. Since December 1994, our facility started laparoscopic fundoplication with the Nissen method at first, and then, from 1997, we aggressively introduced the Toupet method and it has now become the first-line choice procedure. We examined the surgical results of laparoscopic Toupet fundoplication (LTF) for GERD and attempted to extract the risk factors in the recurrence group.

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Patients

A total of 377 patients underwent laparoscopic Toupet fundoplication for GERD from June 1997 to December 2016 as the initial surgery. The subjects included 375 patients among these, excluding two who required laparotomies. Age 59 (43–70), male 211 (56.3%), BMI: 23.4 kg/m² (21.4–25.9), and duration of symptoms 35 months (11–84).

Methods

Parameters of patient characteristics consisted of age, sex, body mass index (BMI), and duration of symptoms. Regarding the pathology, the Anatomy–Function–Pathology classification (AFP classification) [8, 9] was used to evaluate esophageal hiatal hernia, duration of esophageal acid reflux, and reflux esophagitis. We carried out manometry to evaluate the function of the lower esophageal sphincter. Regarding the surgical results, we examined the operation time, intraoperative blood loss, intraoperative complications, presence or absence of blood transfusions, postoperative hospital stay, postoperative complications, and postoperative recurrence. Postoperative recurrence was defined as the occurrence of oesophagitis erosiva caused by endoscopy or the recurrence of esophageal hiatal hernia due to upper gastrointestinal series. All data were expressed as the median and interquartile range.

Patients were divided into a non-recurrent group and recurrent group, and the patient background, preoperative condition, and surgical results of both groups were compared to clarify the characteristics of the recurrence group.

Postoperative follow-up

Approximately 1 month after discharge, ambulatory examinations were carried out. Thereafter, patients made clinic visits at intervals of approximately 2 months. Approximately 1 year after surgery, if there were no particular problems, follow-up was carried out once a year. PH monitoring and manometry were performed approximately at 3 months after surgery, and an endoscopic examination was performed approximately 1 year after surgery in principle. Satisfaction was scored from 1 point (lowest rating) to 5 points (highest rating) by interview. For patients referred from a distant location, especially if there were no particular symptoms, we requested the referral source to conduct a follow-up.

Evaluation of esophageal hiatal hernia

Regarding the presence or absence of an esophageal hiatal hernia and the degree thereof, we carried out upper GI series and upper GI endoscopy, using the A factor of the AFP classification to evaluate the degree using four grades from 0 to 3. Specifically, A0: no esophageal hiatal hernia was found, A1: sliding esophageal hiatal hernia having a size of less than 3 cm, A2: sliding esophageal hiatal hernia having a size of 3 cm or more, and A3: mixed-type or paraesophageal hiatal hernia.

Evaluation of reflux esophagitis and looseness of the cardiac region

Regarding the degree of reflux esophagitis, we carried out an upper GI endoscopy and used the P factor of the AFP classification to evaluate the degree using three grades from P0 to P2. That is, P0: no esophagitis was found, P1: esophagitis of grade A or grade B according to the Los Angeles classification, and P2: esophagitis of grade C or grade D according to the Los Angeles classification. We also evaluated the looseness of the cardiac region using upper endoscopy and valve factor [10] using four grades from V0 to V3. We inflated the stomach with air during endoscopy, evaluating the open degree of the cardiac region. Specifically, V0: no esophageal hiatal hernia or dilatation of the cardiac region was found upon supplying air, V1: esophageal hiatal hernia was found but no dilatation due to supplying air, V2: no esophageal hiatal hernia but dilatation of the cardiac region due to supplying air, and V3: esophageal hiatal hernia was found along with dilatation of the cardiac region upon supplying air.

Measurement of the duration of intraesophageal acid reflux

24-h pH monitoring was used to measure the duration of intraesophageal acid reflux. Prior to examination, proton pump inhibitors or histamine H₂ receptor antagonists were discontinued for more than 1 week. At first, Digitrapper MK-II or MK-III (Medtronic Inc., Minneapolis, MN, USA) was used as the examination device, but thereafter changed to multichannel intraluminal impedance pH(MII-pH) (Sandhill Scientific, Highlands Ranch, CO, USA) from June 2008. The catheter was inserted under X-ray fluoroscopy, with an intraesophageal pH sensor placed 5 cm superior to the LES to carry out 24-h monitoring. During the examination, patients could only ingest hospital meals and water, with no snacks. Data were automatically analyzed using software to calculate the pH < 4 holding time (%).

Manometry

Esophageal manometry was initiated from June 2008 using the conventional methods, and then, high-resolution manometry (HRM) was introduced from October 2012. With HRM, Mano Scan (manufactured by Given Imaging) was used, inserting catheters nasally, confirming the distal end is inside the stomach and placing the catheter in a location where observation from the lower esophageal sphincter (LES) to the upper esophageal sphincter (UES) was performed. After a few minutes of rest, patients attempted to swallow 10 ml of water 10 times in the dorsal position and an evaluation was carried out. Mano View version 3.0 (Given Imaging) was used for data analysis, calculating the lower esophageal sphincter pressure (LESP), overall length of LES (OL), and length of abdominal esophagus(AL). We carried out manometry for 169 patients before operation and 103 patients after operation respectively.

Statistical analysis

The SPSS software program was used to perform the statistical analyses (SPSS Inc version 23.0, Chicago, IL, USA). All data were presented as the median and interquartile range (IQR). The Mann–Whitney test, Wilcoxon signed-rank test, and Chi-squared test were performed as appropriate. *p* value of <0.05 was considered to indicate a statistically significant difference.

Results

Preoperative pathophysiology

The degree of esophageal hiatal hernia as the A factor of the AFP classification was A1 (1–2), predominantly sliding hiatal hernias of less than 3 cm in size. Moreover, the

Table 2 Perioperative outcome

Operative time (min)	141 (113–180)
Estimated blood loss (mL)	≅ 0 (0–0)
Intraoperative complications (pts) ^a	30 (33 incidents)
Bleeding > 200 mL	8
Gastric wall injury	4
Esophageal wall injury	1
Small bowel injury	1
Pneumothorax	2
Others	17
Transfusion	None

^aOverlapping (+)

degree of reflux esophagitis as the P grade was P1 (0–2), predominantly grade A/B according to the Los Angeles classification. The valve factor showing the looseness of the cardia was 3 (3–3), indicating that looseness of the cardia was observed in the majority of subjects. The pH < 4 holding time was 3.8% (1–12.1), the longest duration of reflux was 7.7 min (7.7–21.6), the number of times of reflux more than 5 min was 1.1 per day (0–4.4), and the DeMeester score was 11.5 (3.3–28.05), indicating that the majority had relatively mild reflux. According to tests for esophageal motor function, OL 3 (2.4–3.9) cm, AL 1 (0–2.05) cm, LES pressure: 17.45 (10.425–24.7) mmHg, DCI 1250.4 mmHg-s-cm (666–2051.3), the number of times of normal esophageal peristalsis (number of times normal esophageal peristalsis was found in 10 measurements) was 10 (8–10) (Table 1).

Surgical results

Regarding the approach, while the conventional method with five ports was carried out in the majority of subjects, eight subjects (2%) underwent reduced port surgery including Single Incision Laparoscopic Surgery (SILS). In addition,

Table 1 Pathophysiology before and after operation

Parameter	Before operation	After operation	<i>p</i> value
A factor [#]	1 (1–2)	0 (0–0)	<0.001
F factor [#]	0 (0–2)	0 (0–0)	<0.001
P factor [#]	1 (0–2)	0 (0–0)	<0.001
V factor ^{##}	3 (3–3)	0 (0–0)	<0.001
pH < 4 (%)	3.8 (1.0–12.1)	0.1 (0–0.8)	<0.001
Longest reflux time (min)	7.9 (2.7–22.3)	0.2 (0–3.4)	<0.001
Reflux episodes over 5 time (number/day)	1.1 (0–4.4)	0	<0.001
Length of LES (cm)	3.0 (2.4–3.9)	3.3 (2.9–3.8)	<0.001
Abdominal length of LES (cm)	1.0 (0–2.1)	1.7 (1.3–2.4)	<0.001
LESP (mmHg)	17.5 (10.4–24.8)	17.0 (12.9–23.0)	0.933

[#]Anatomical factor, functional factor, and pathological factor based on AFP classification

^{##}Valve factor

mesh was used in 73 subjects (19.5%) as reinforcement after suturing of the hiatus. Since February 2011, we used mesh for patients with A2 or A3 hernia, severe reflux esophagitis, and over 75 years old. The operation time was 141 min (113–180), while the amount of bleeding was \approx 0 mL (0–0). Intraoperative complications were encountered in 13 subjects (3.5%). There were no blood transfusion cases or deaths (Table 2).

Postoperative course and satisfaction

The time patients started ingesting food was 2 days after surgery (2–2), while the length of hospitalization after surgery was 7 days (7–8). The incidence of postoperative complications was 7% of patients, among whom the number of patients with difficulty swallowing was the largest (approximately 70%). Other representative complications included delayed gastric excretion, postoperative bleeding, and dislocation with fundic wrap in the early postoperative stages (during hospitalization). On the other hand, satisfaction after surgery was good at 5 (4–5) (Table 3).

Postoperative pathology

Esophageal hiatus hernia, reflux esophagitis, and looseness of the cardiac region were significantly improved from prior to and after surgery (each $p < 0.001$). In addition, the pH < 4 holding time, longest duration of reflux, and number of times having reflux more than five minutes significantly decreased, respectively (each $p < 0.001$). Furthermore, the LES length and abdominal LES length also increased significantly (each $p < 0.001$), while the LESP did not change from prior to and after surgery (Table 1).

Postoperative recurrence

Recurrence occurred in 48 patients (15.1%) among 318 patients in whom the presence or absence of recurrence

Table 3 Postoperative outcome

Diet started (day)	2 (2–2)
Hospital stay (day)	7 (7–8)
Postoperative complications (pts)	26 (6.9%)
Dysphagia	18
Gastric stasis	3
Postoperative bleeding	1
Dislocation with fundic wrap	1
Others	3
Follow-up (months)	59 (43–70)
Recurrence (pts)	48/315 (15.1%)
Satisfaction	5 (4–5)



Fig. 1 Typical recurrent case after operation. Dislocation of cardioplasty region with fundic wrap to mediastinum was seen

could be confirmed during the postoperative follow-up. We showed a picture of a typical recurrent case after surgery (Fig. 1). The recurrence form of 48 patients is shown in Table 4.

Comparison between the recurrence group and non-recurrence group

Regarding the patient background, there was no difference in age, gender, BMI, or preoperative duration of symptoms. As for the preoperative pathology, the A grade and P grade were

Table 4 Type of recurrence

A factor ^a before surgery	Type of recurrence	The number of the case
0	Dislocation with wrap	1
0	Mild RE without recurrent hernia	1
1	Dislocation with wrap	9
1	Mild RE without recurrent hernia	8
1	Mild hernia	2
2	Dislocation with wrap	8
2	Mild RE without recurrent hernia	4
2	Unknown in detail	3
3	Dislocation with wrap	12

RE reflux esophagitis

^aAnatomical factor based on ATP classification

Table 5 Comparisons of background and pathophysiology before operation between no recurrence group and recurrence group

	No recurrence (n = 270)	Recurrence (n = 48)	p value
Background			
Age (years)	58 (43–70)	61 (45–70)	0.431
Male:female	153:117	24:24	0.432
BMI (kg/m ²)	23.2 (21.4–25.9)	24.0 (22.2–26.7)	0.157
Duration of disease (months)	24 (11–84)	36 (8–78)	0.962
Pathophysiology			
A factor [#]	1 (1–2)	2(1–3)	0.031
V factor ^{##}	3 (3–3)	3 (3–3)	0.448
P factor [#]	0 (0–1)	2 (1–2)	<0.001
pH < 4 (%)	3.2 (0.8–11.0)	9.1 (4.2–24.2)	<0.001

[#]Anatomical factor and pathological factor based on AFP classification

^{##}Valve factor

significantly higher in the recurrence group (each $p = 0.031$, $p < 0.001$), while the degree of preoperative esophagus hiatal hernia and the degree of reflux esophagitis were advanced (Table 5). The acid reflux time was also significantly prolonged in the recurrence group ($p < 0.001$). On the other hand, there were no differences between the two groups in terms of surgical time, intraoperative bleeding volume, intraoperative complications, duration of postoperative hospital stay, and postoperative complications (Table 6). The postoperative follow-up period was significantly prolonged in the recurrence group ($p < 0.001$).

Discussion

The first report on laparoscopic surgery for GERD was reported by Dallemagne et al. in 1991 [11]. Thereafter, laparoscopic surgery spread quickly, currently having become

the standard approach in Japan, as well as in Europe and the United States. In Western countries, although there have been many reports on the surgical reports of laparoscopic surgery for GERD, reports from Japan are scarce [12, 13]. According to the 13th “Questionnaire survey on endoscopic surgical operation” by the Japan Society for Endoscopic Surgery, the number of operations in Japan is as small as 300 per year and the current situation is that it is very difficult for a single institution to report surgical results obtained from a large population. Since 1994, our institution has aggressively introduced laparoscopic surgery for GERD, accumulating treatment results for approximately 25 years. Now that we can conduct examinations among a relatively large population; we carried out a study on the surgical results.

When we initially introduced laparoscopic surgery, the Nissen method was widely used in Europe and the United States and, therefore, introduced it first at our facility. With the Nissen method, under bougienage of the esophagus (56–60 Fr), wrapping was carried out while performing esophageal calibration. However, many patients suffered from relatively prolonged dysphagia during the period of approximately 3 months after surgery. Therefore, the QOL in the early postoperative period was determined to be low, so we adopted the Toupet method from 1997, and in 2000 made it the first-choice operation. Several meta-analysis have been reported overseas with regard to comparing the surgical results of the Nissen method and Toupet method including postoperative complications. Tian et al. [7] conducted a meta-analysis of the randomized controlled trials (RCT) previously performed, and compared the treatment results of laparoscopic Nissen fundoplication (LNF) and laparoscopic Toupet fundoplication (LTF). As a result of comparing 814 LNF subjects and 750 LTF subjects, the occurrence rate of dysphagia, gas-bloat syndrome, and the inability to belch were reported to be higher in the LNF group. In addition, also based on the results of meta-analysis, Broeders et al. [6] showed that LTF resulted in less postoperative dysphagia and dilatation for dysphagia compared to LNF and that reflux control is equal, leading them to recommend LTF as

Table 6 Comparisons of perioperative and postoperative outcome between no recurrence group and recurrence group

	No recurrence (n = 270)	Recurrence (n = 48)	p value
Operative time (min)	139 (111–178)	145 (116–186)	0.21
Estimated blood loss (mL)	0	0	0.523
Intraoperative complications (pts)	25	5	0.790
Blood loss > 200 mL	8	2	0.651
Others	18	3	1
Hospital stay (day)	7 (7–8)	7 (7–8)	0.464
Postoperative complications (pts)	16	3	1
Dysphagia	14	1	0.71
Others	2	2	0.11
Follow-up period (months)	23 (8–45)	45 (28–113)	<0.001

the first choice for GERD surgery. In addition, against dysphagia and gas bloating syndrome after Nissen fundoplication, remarkable relief was reported by converting to Toupet fundoplication [14]. Therefore, it can be assumed that the risk of postoperative dysphagia is lower in LTF than LNF. In our results, as well, the occurrence of dysphagia after LTF was only 5%, among which only six cases (33%) required endoscopic dilatation, which was as small as 1.6% of the total. No subjects complained of gas-bloat syndrome symptoms over the long term. From the viewpoint of postoperative complications, the Toupet method is considered to be superior.

Long-term results regarding symptom control have been reported. A review article by Frazzoni et al. [15] stated that “Laparoscopic fundoplication is the standard surgical treatment for GERD. It is highly effective in curing GERD, with a 80% success rate upon 20-year follow-up.” On the other hand, Koch et al. [5] reported that both LNF and LTF improved the symptoms of GERD and quality of life, and that the therapeutic effect was equivalent. In addition, the results of meta-analysis conducted by Ten et al. [7] showed that there is no difference in the operative time, perioperative complications, postoperative satisfaction, recurrence, etc. More reports state that there is no difference between LNF and LTF in terms of response rate as well as the anti-reflux effect. However, Simorov et al. [16] reported that the overall recurrence rate was 33.9% in radiographic studies for subjects undergoing follow-up for more than 3 years, 84% of which were asymptomatic, indicating that the asymptomatic recurrence rate was high. In other words, even if the symptoms improved, recurrence may be found upon imaging diagnosis. Therefore, in the current study, the symptoms were examined according to the satisfaction level, while recurrence was objectively evaluated by upper endoscopy and/or upper gastrointestinal series. First, the A, F, and P factors according to the AFP classification and V factor were significantly improved after surgery. In addition, the postoperative length of the LES and the abdominal length of the LES were also significantly extended (Table 1). In the previous studies, we have already reported that “the back-flow prevention mechanism of LTF is considered to improve the overall LES function without elevating LESP” [17], and there was no difference in LESP between prior to and after surgery in the current study, as well. The objectively evaluated recurrence rate was good at approximately 15%. The median satisfaction level was also high at 5, so we believe that the treatment outcome of LTF was good.

Thereafter, we compared 270 non-recurrence cases with 48 recurrence cases to examine the characteristics of the recurrence cases. As a result, there was no difference in age, sex, BMI, and duration of symptoms between the two groups. Regarding BMI, some reports from Europe and the United States have stated that obesity is a risk factor

of postoperative recurrence [18]. However, we previously reported that a BMI of $\geq 25 \text{ kg/m}^2$, the obesity criteria in Japan, is not a risk factor of recurrence in studies using propensity score-matched analysis [19], and the same results could be obtained in the current study. Regarding the clinical conditions, A factor and P factor were significantly higher in the recurrence group, the acid reflux time in the esophagus was also prolonged, and the preoperative pathology was advanced in the recurrence group. There was no difference in operation time, intraoperative blood loss, postoperative hospital days, and postoperative complications.

Morgenthal et al. [20] reported that clinical conditions for which successful outcomes can be expected include: responsiveness to preoperative acid reducing medications; having typical GERD symptoms; and BMI $< 35 \text{ kg/m}^2$, while they suggest sex, age, esophageal hiatal hernia, reflux esophagitis, and acid reflux time do not have any influence. However, their definition of failure was reoperation, lack of satisfaction, and severe symptoms at follow-up, but not recurrence of endoscopic reflux esophagitis or recurrence of esophageal hiatal hernia. Although Staehelin et al. [21] also conducted a similar study and reported that male sex and the presence of a hiatus hernia are associated with a better clinical outcome after surgery, it was a study focusing on the improvement of symptoms. In contrast, Power et al. [22] pointed out the existence of a large hernia of 3 cm or more as a risk factor, with failure defined from the viewpoint of symptoms. Paraesophageal hernia involves higher difficulty of surgery and a higher recurrence rate compared to sliding hiatal hernia, with many studies using mesh to prevent recurrence having been carried out. Therefore, paraesophageal hiatal hernia corresponding to A3 or less according to the AFP classification is considered to have a high risk of recurrence. When evaluating the therapeutic effect of surgery against GERD, it is certainly important to focus on the improvement of symptoms. However, if an analysis is conducted from the viewpoint of reflux esophagitis or recurrence of esophageal hiatal hernia, this study revealed that the degree of esophageal hiatal hernia, the degree of reflux esophagitis, and acid reflux time are more advanced in recurrent cases compared with non-recurrence cases.

There were several limitations in the current study. The first being that it is a retrospective analysis with an examination period of approximately 20 years. However, the surgeons and assistants involved in the surgery were almost unchanged, the staff were specialized in esophageal surgery, and the treatment method (Toupet method) itself did not change significantly. Therefore, we do not believe that the treatment outcome was greatly affected by above problems. The second point is that the follow-up period following surgery in the non-recurrence group was shorter than the recurrence group. Recurrent patients are more likely to undergo periodic postoperative outpatient observation, because they

require medication, while non-recurrent patients often have no postoperative symptoms and outpatient observation is often discontinued due to non-compliance of the patient. This point is not specific to our facility and is a common problem for postoperative observation of esophageal benign diseases. The third point being that we have not been able to identify specific clinical conditions with regard to the degree of esophageal hiatus hernia and the degree of reflux esophagitis, which is a risk factor for recurrence. As for this limitation, further examination is required in a large series.

Conclusion

In summary, LTF for GERD can be performed safely, obtaining good postoperative results. On the other hand, as compared with non-recurrent cases, esophageal hiatal hernia, reflux esophagitis, and acid reflux time were all advanced in recurrent cases. Therefore, surgical indications for GERD should be considered at an earlier stage before the development of advanced clinical conditions.

Author contributions NO analyzed data and wrote the manuscript. FY, KT, MH, S-RY, SA, TM, and HK collected data. KY critically revised the manuscript.

Compliance with ethical standards

Ethical statement The protocol of this study has been approved by the Jikei University School of Medicine Institutional Review Board (#28–047). All informed consent was obtained from the subjects and guardians.

Conflict of interest Drs. Omura, Yano, Tsuboi, Hoshino, Yamamoto, Akimoto, Masuda, Kashiwagi, and Yanaga have no conflicts of interest or financial ties to disclose.

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