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Efficacy of Laparoscopic Fundoplication for Gastroesophageal Reflux Disease in Neurologically Impaired Patients : Postoperative Quality of Life and Operative Outcomes

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SUMMARY

Background/Purpose : Fundoplication is often required for managing intractable gastroesophageal reflux disease (GERD) in neurologically impaired patients (NIPs). This study examines the efficacy of laparoscopic fundoplication for GERD in young and adult NIPs by interviewing caregivers and reviewing medical records to establish both patients and caregivers quality of life (QOL).

Patients and methods : Thirty-one NIPs who underwent laparoscopic fundoplication between April 2000 and December 2009 were enrolled in this study. Their symptoms, QOL, and satisfaction levels after the fundoplication were recorded by reviewing medical records and conducting a questionnaire survey. One pediatric surgeon conducted face-to-face or telephonic interviews with the caregivers.

Results : No patients died during the immediate postoperative period ; however, five (16.1%) of them died in the late postoperative period because of causes unrelated to the surgery. Of the surviving patients, five (16.1%) had complications, including GERD recurrence requiring further surgical intervention. Visick scores showed that gastrointestinal and respiratory symptoms had improved substantially after the fundoplication. Although body weights increased in 23 patients (92.0%), no statistically significant changes were observed in the z-score for body weights before and after surgery. 92.0% of the patients and 100% of the caregivers had QOL improved ; patient satisfaction level was at 88.0% and caregiver satisfaction level was at 76.0% .

Conclusions : Fundoplication is an effective method for controlling the symptoms of GERD in NIPs and improves the QOL of both NIPs and their caregivers.

Key Words : gastroesophageal reflux disease, neurological impairment, laparoscopic surgery, quality of life

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343-8555, Japan**INTRODUCTION**

Neurologically impaired patients (NIPs) may suffer from neuromuscular disease, metabolic diseases, brain injury, or a combination of these disorders. Many also

suffer from dysphagia and gastrointestinal motility disorders. In addition, hiatus hernia, scoliosis, respiratory dysfunction, and increased intra-abdominal pressure may cause gastroesophageal reflux disease (GERD). One of the first-line treatment for GERD is the administration of a proton-pump inhibitor, but patients with frequent vomiting or recurrent aspiration pneumonia may require surgical treatment, which includes fundoplication.

Nissen laparoscopic fundoplication is reportedly an effective treatment for childhood GERD¹⁻⁶. This technique has been demonstrated to ameliorate symptoms, decrease the frequency of hospital admission, and increase body weight in NIPs regardless of age⁶⁻¹². Several reports have documented the extent to which laparoscopic fundoplication can improve the quality of life (QOL) of NIPs and their caregivers¹³. The primary aim of the present study was to evaluate the outcomes of fundoplication for GERD in NIPs as well as the postoperative improvements in QOL for NIPs and their caregivers. Caregivers satisfaction with surgery was also evaluated.

METHODS

Patients

Thirty-five NIPs underwent laparoscopic fundoplication between April 2000 and December 2009 at Koshigaya Hospital, Japan. Among them, 31 patients with complete medical records were selected for inclusion in this study. The study was approved by the Research Ethics Committee of Dokkyo Medical University Koshigaya Hospital, and informed consent was obtained from all participants.

Symptoms and diagnosis of GERD

GERD was diagnosed based on one or more of upper gastrointestinal contrast studies, 24-h gastroesophageal pH monitoring using a DigitrapperTM pH system (Medtronic, Minneapolis, MN, USA), and gastroesophageal endoscopy. Diagnosis by pH monitoring was made according to the Japan Society of Pediatric Gastrointestinal Study guidelines¹⁴, which define gastroesophageal reflux (GER) as a reflux index (time at which pH<4) of $\geq 4\%$. If erosion, redness, or ulcers were observed on gastroesophageal endoscopy in the lower esophageal mucosa of a patient with GER, he/

she was diagnosed with reflux esophagitis.

Fundoplication

The indications for laparoscopic fundoplication were : GERD with respiratory or gastrointestinal symptoms for which medical treatment failed and asymptomatic GER in patients requiring gastrostomy. Surgery was performed as per the conventional protocol for laparoscopic Nissen fundoplication using five trocars. Cardiopexy to the diaphragm was not performed routinely. To secure a route for enteral nutrition, most of the patients underwent gastrostomy tube insertion at the same time. The gastrostomy tube was placed at the site of the left subcostal trocar using Stamm-Kader's procedure. Pyloroplasty was also performed in 15 patients (48.4%) with delayed gastric emptying according to gastric scintigraphy.

Measurement of QOL after fundoplication

Postoperative QOL, satisfaction level, and the condition of the NIPs/caregivers were recorded through interviews with the patients and their caregivers. If the surgeon could not meet with the patients and caregivers in person during the study period, they were interviewed by phone. Caregivers of patients who died after surgery were not interviewed to avoid increasing their grief. The patients' clinical records were also reviewed to obtain demographic details, preoperative and postoperative symptoms, results of examinations, and postoperative complications.

QOL questionnaires pertaining to the views of the NIPs and their caregivers regarding the benefits and drawbacks of surgery after the surgery was performed. The questions included are shown in Table 1. Patients body weights were recorded preoperatively and at the time of the interview. Body weights at the two time points were plotted in growth curves and the deviations of the body weights from the mean values (z-score) were compared to evaluate postoperative weight gain. QOL, satisfaction level, and changes in body weight were each categorized into one of three grades and scored accordingly to the scheme shown in Table 2. Changes in symptoms (gastrointestinal and/or respiratory) were graded using a modified Visick score¹⁵ (Table 3) and were used along with the body weight to assess surgical outcome.

Table 1 Quality of life (QOL) questionnaire administered to caregivers

Q1) Is the patient alive?	Yes (go to Q2)		
	No (exclude)		
Q2) Has the patient had any symptoms such as vomiting or pneumonia since surgery?	Yes (go to Q3)		
	No (go to Q4)		
Q3) Specific symptoms and frequency after surgery	What is the symptom?	How often?	
Q4) Feeding methods	Gastrostomy		
	Oral		
	Both (gastrostomy and oral)		
Q5) Did body weight change after surgery?	Body weight (kg)	Increased	
		No change	
		Decreased	
Q6) Has the patient had any difficulties or complications related to surgery, nutrition or gastrostomy?	Yes (go to Q7)		
	No (go to Q8)		
Q7) What are (or were) the difficulties or complications?	Difficulties or complications		
Q8) Do you think the surgery decreased daily burden and/or suffering? (QOL)	For patient	Yes	Reason
		No	
		No opinion	
	For caregiver	Yes	Reason
		No	
		No opinion	
Q9) Do you think the surgery was beneficial to improve QOL? (satisfaction level)	For patient	Yes	Reason
		No	
		No opinion	
	For caregiver	Yes	Reason
		No	
		No opinion	

Statistical analysis

The z-scores for the preoperative body weight and those at the time of the interview were compared using the Student's t-test. Pearson's correlation coefficients were calculated to analyze the statistical associations between the changes in postoperative QOL and satisfaction level with the changes in body weight and Visick scores. Statistical analysis was performed with SPSS (Version 20.0.0.2 ; IBM, Armonk, NY, USA) and p-values less than 0.05 were defined as significant.

Table 2 Quality of life, body weight, and satisfaction level scoring system

Quality of life	Improved	No change/not clear	Worsened
	3	2	1
Body weight (z-score)	increase	no change	decrease
	3	2	1
Satisfaction level	Benefited	No opinion	Regretted
	3	2	1

Table 3 Visick scoring system for symptoms of gastroesophageal reflux disease

	Gastrointestinal symptoms	Respiratory symptoms
1	Complete absence of symptoms and infrequent episodes of vomiting	Clear subjective clinical benefit and absence of symptoms or decreased frequency of symptoms
2	Infrequent episodes of dysphagia, vomiting, pain, or other feeding problems	There was a clinical benefit but persistence of respiratory symptoms
3	Absence of postoperative symptom improvement	
4	No benefit and appearance of new symptoms requiring treatment	

Table 4 Demographic and clinical characteristics of patients

Sex	Male	21
	Female	10
Age : median (range)		13 years (7 months to 40 years)
Primary disease (more than one possible)	Cerebral palsy	17
	Epilepsy	13
	Congenital disease or anomaly	6
	Encephalopathy, encephalitis, or meningitis	3
	Hypoxic encephalopathy	3
	Perinatal asphyxia	3
Symptoms (more than one possible)	Respiratory symptoms (aspiration or recurrent pneumonia, wheezing, apnea, cyanosis, etc.)	25
	Gastrointestinal symptoms (vomiting, coffee-ground-like vomit, feeding difficulty, aspiration, etc.)	22
	Weight loss, failure to thrive	3
	Difficulty with nasogastric tube	4

RESULTS

The demographic and clinical characteristics of the NIPs included are shown in Table 4.

Diagnosis of GERD

According to the guidelines, GERD is diagnosed by combining fluoroscopy, endoscopy, manometry, ultrasonography and pH monitoring as appropriate. The combinations for the examinations were selected by the attending physicians. Of the 29 patients who underwent upper gastrointestinal contrast studies, 27 had features consistent with GERD, and 18 had hiatus hernia. All but one of the 31 NIPs underwent 24-h esophagogastric pH monitoring ; the median reflux index was 13.8% (range, 4.7%–43.7%). Diagnostic endoscopy was performed in 29 patients and reflux esophagitis was diagnosed in 23. The Los Angeles classification system for GERD¹⁶⁾ was used for 11 patients ; six were classified as Grade A, two as

Grade D, two as Grade M, and one as Grade B.

Outcomes after laparoscopic fundoplication

Thirty-two laparoscopic funduplications were performed for the 31 patients (one had to redo surgery for GERD recurrence) ; outcomes and complications are summarized in Table 5. The follow-up period ranged from 4 months to 10 years (median, 3 years and 3 months). During the follow-up period, five patients (16.1%) died. The causes of death were exacerbation of underlying disease in two patients, pneumonia in one, and unknown for two. It was judged that these deaths were not related to the surgical procedure.

Postoperative complications were classified as early (≤ 4 weeks after surgery) and late (> 4 weeks after surgery). Early complications included pneumonia and enteritis, and two NIPs with severe enteritis required surgical treatment ; one had necrotizing enterocolitis caused by *Klebsiella pneumoniae*, and the other devel-

Table 5 Surgical outcomes in 31 patients

1) Prognosis	Alive		26
	Months elapsed since surgery ; median (range)		43 (19–120)
	Died in postoperative period		5
	Months between surgery and death ; median (range)		28 (3–64)
2) Postoperative complications	≤4 weeks after surgery	Pneumonia	1
		Necrotizing enterocolitis (<i>Klebsiella pneumoniae</i>)	1
		Sepsis due to severe enteritis	1
		Dislodgement of gastrostomy tube	1
		Pyloric obstruction	1
		Failure to suture (gastrostomy site)	1
	>4 weeks after surgery	Granulation of gastrostomy site	6
		Dermatitis around gastrostomy site	5
		Recurrence of gastroesophageal reflux	2
		Ileus	2
		Dumping syndrome	1
		Gastric volvulus	1
		Gastric mucosal hemorrhage	1

Table 6 Surgical outcomes of the 25 surviving patients

1) Symptoms	Gastrointestinal symptoms (n=20)	Visick 1	17 (85.0%)	
		Visick 2	1 (5%)	
		Visick 3	2 (10%)	
		Visick 4	0 (0%)	
	Respiratory symptoms (n=19)	Visick 1	6 (31.6%)	
		Visick 2	11 (57.9%)	
		Visick 3	1 (5.3%)	
		Visick 4	1 (5.3%)	
		2) Body weight	Increased	23 (92.0%)
			Decreased	2 (8.0%)
Change in weight (z-score)	Increased		16 (64.0%)	
	No change		2 (8.0%)	
	Decreased	7 (28.0%)		

oped sepsis and peritonitis. In addition, one patient had a dislodged gastrostomy button that required emergency laparotomy. Infected granulation tissue and dermatitis at/around the gastrostomy site were the most common late complications. Postoperative ileus was observed in two patients, but neither required surgical treatment. Gastropexy was required for one patient who had developed postoperative gastric volvulus. GER recurred in two patients (6.5%) during the follow-up period ; one underwent a second fundoplication, while the other underwent esophago-gastric dissociation¹⁷.

Postoperative symptoms

One of the 26 surviving NIPs was excluded from the analysis after undergoing esophago-gastric dissociation for recurrent GER. Ultimately, symptoms and QOL were assessed in 25 patients (Table 6). Seventeen out of 20 patients (85.0%) with preoperative gastrointestinal symptoms, such as frequent and/or coffee-ground-like vomiting, experienced complete resolution of symptoms following surgery. Moreover, preoperative aspiration and/or recurrent pneumonia symptoms improved in 17 out of 19 NIPs (89.5%), although only six (31.6%) were Visick Grade 1.

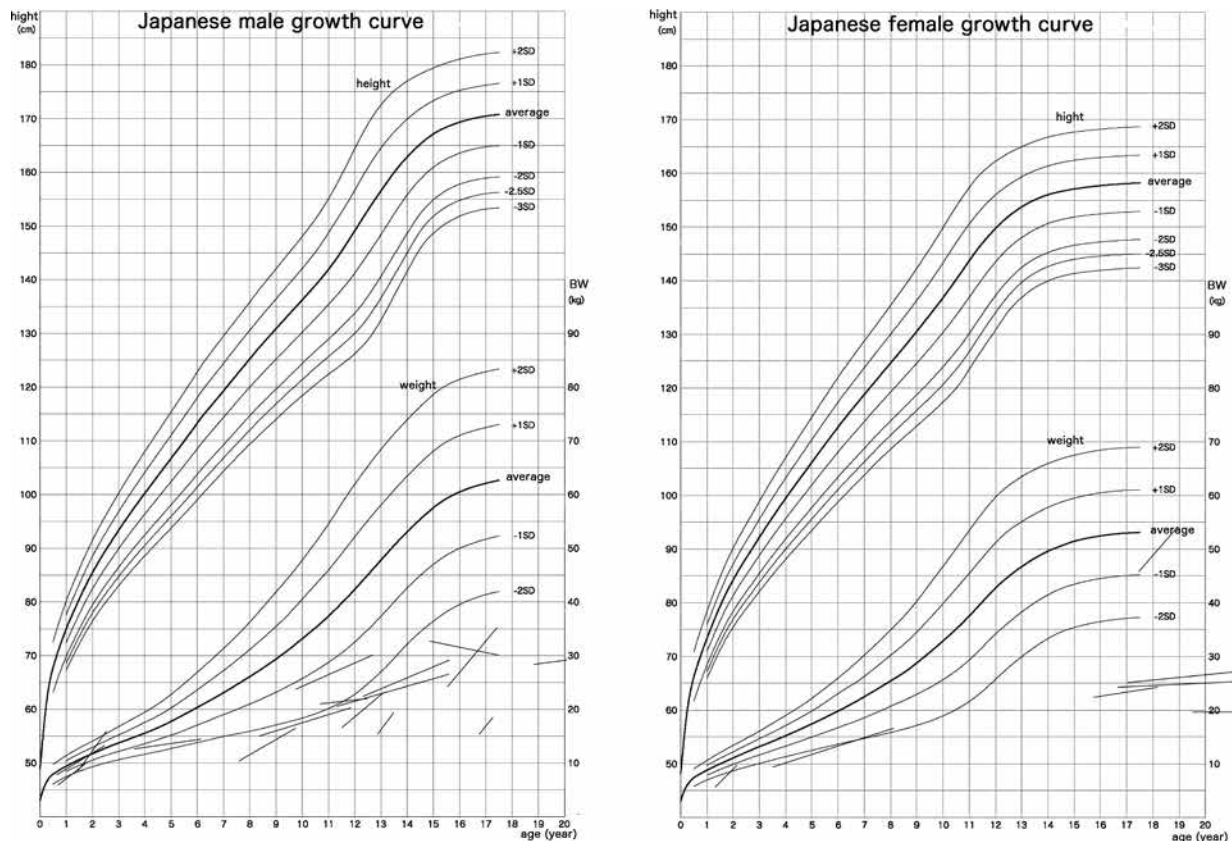


Fig. 1 Changes in body weights during the follow-up period.

Three patients required tracheostomies (one before and one after fundoplication), and one required laryngo-tracheal separation more than a year later.

Body weight

Body weight was measured preoperatively and at the time of the interview. The period between the two measurements ranged from 5 months to 105 months (median 29 months). Body weight increased in 23 NIPs (92.0%), and decreased in two (8.0%). The patients' body weights were plotted on a growth curve (Fig. 1). The z-score for body weight increased in 16 (64.0%) patients, and decreased in 7 (28.0%) patients (Table 6). The mean z-score for preoperative body weights in 25 patients was -2.7 and at the time of the interview was -2.3 . The difference was not statistically significant ($p=0.21$).

QOL

Twenty-three caregivers (92.0%) stated that their child's QOL had improved after surgery as the symptoms and general conditions improved (Table 7). All

25 caregivers interviewed stated that their own QOL had improved. Seventeen (68.0%) stated this was largely as a result of the change in the feeding route, shorter food administration time, removal of the nasogastric tube, and the ease of gastrostomy use. The second most common reason given by 10 caregivers (40.0%) was the improvement in patient symptoms or condition.

Among the 25 caregivers interviewed, 22 (88.0%) were satisfied with the outcomes of the surgery and three gave no opinion; in other words, no caregiver regretted agreeing to the surgery (Table 8). The NIPs cared for by the three caregivers who gave no opinion experienced serious complications or remained symptomatic. Nineteen caregivers (76.0%) reported they had personally benefited from the surgery on the NIPs and six gave no opinion; thus, no caregiver regretted agreeing to the surgery. NIPs cared for by the caregivers who gave no opinion reported problems with the gastrostomy (including an inability to eat by mouth or attend a day-care center without a medical staff on duty at all times, fewer meal choices,

Table 7 Postoperative quality of life for the 25 surviving patients

1) Patients	Improved		23 (92.0%)
	Reasons (multiple answers)	Decreased frequency of pneumonia of admission	6
		Decreased wheezing and secretions	4
		Decreased frequency of vomiting	4
		Improved nutrition or body weight gain	4
		No requirement for nasogastric tube	4
		Looks better or more comfortable	3
		No fever or immediate resolution of fever	3
		No choking	2
		Enabled oral feeding	1
	No change, do not know		2 (8.0%)
2) Caregivers	Improved		25 (100%)
	Reasons (multiple answers)	Ease of feeding via gastrostomy	7
		Decreased feeding time	6
		Nasogastric tube no longer needed	5
		Decreased need for oral and nasal suction	4
		Decreased frequency of pneumonia or admission	3
		Decreased frequency of vomiting	2
		Decreased distress	2
		Decreased care burden	1

Table 8 Satisfaction with surgery among the 25 surviving patients

1) For patients	Benefited	22 (88.0%)
	No opinion	3 (12.0%)
2) For caregivers	Benefited	19 (76.0%)
	No opinion	6 (24.0%)
3) Reasons for dissatisfaction (multiple answers)	Bothered by gastrostomy	2
	Difficulty in swallowing	2
	Difficulty in attending day-care center with gastrostomy	1
	Less variety of food with gastrostomy	1
	Increased feeding time due to dumping syndrome	1
	No improvement in symptoms	1
	Postoperative course was more complicated than expected	1

and equipment being troublesome), lack of improvement of patient symptoms, and/or serious postoperative complications experienced by the patient.

There were no significant correlations between the changes in QOL and satisfaction level and the changes in body weight and Visick scores (Table 9).

DISCUSSION

In 1948, Visick classified the postoperative symptoms of gastrectomy into five grades¹⁸. Since then, Washer *et al.* applied this grading system to patients

with reflux esophagitis to compare the postoperative outcomes of Roux-en-Y duodenal diversion and fundoplication, and modified it for use in studies regarding the effectiveness of different surgical interventions for GERD¹⁹. However, few studies have applied the Visick scoring system to NIPs with GERD. In the present study, modified Visick scores¹⁵ and body weight were used to assess changes in NIP symptoms following laparoscopic fundoplication. Overall, symptoms improved in most patients postoperatively, and the z-score for body weight increased in 16 (64%)

Table 9 Correlation coefficients between the changes in quality of life (QOL), satisfaction level and symptoms/patient status

Changes in symptoms/ patient status	Changes in QOL and satisfaction level		
	QOL	Satisfaction level	
	Patient	Patient	Caregiver
Body weight (z-score)	-0.046	0.150	0.333
Visick respiratory	-0.355	-0.231	0.023
Visick gastrointestinal	-0.349	0.319	0.508

Correlation coefficient for caregiver QOL was not calculated because QOL improved for all caregivers and comparisons were not possible. No statistically significant correlations were found.

patients. Although there were no significant correlations between QOL, satisfaction level, and symptoms, gastrointestinal and respiratory symptoms were improved in the majority of patients.

To measure improvements in nutritional status, the preoperative body weight and body weight at the time of interview (postoperative) were examined. Finally, we did not compare the actual weight gain before and after the surgery, and instead used the z-score for body weight to eliminate the influence of growth. Body weight increased in 92% NIPs who underwent surgery and the z-score increased in 64%, implying that malnutrition was improved in more than half of the patients. Thus, fundoplication was effective in improving the nutritional status of NIPs. However, 7 (28%) patients remained or became malnourished following the surgery. Surgeons and pediatricians should regard the postoperative nutrition status of NIPs as an important parameter because improving nutritional status can effectively prevent some of the postoperative complications, including infection and dermatitis.

The proportion of caregivers satisfied with the fundoplication was not as high as expected considering the reported improvements in patient and caregiver QOL. Although no caregiver reported regret in agreeing to the surgery, three were uncertain regarding the efficacy of the surgery. These included one case where the patient's symptoms did not improve, one where serious complications were encountered, and one where GERD recurred. Dissatisfaction with this surgical procedure is to be expected for patients with

poor postoperative outcomes and lack of QOL improvements.

The current study had some limitations. First, only the caregivers of patients who survived were asked to complete the questionnaire, to avoid adding to the distress of the caregivers of patients who had died. This may have led to a bias in the results, even though these deaths were not directly related to the surgery. Second, the amount of time between surgery and the study interview differed for each patient; caregiver impressions of the surgery may have changed over time^{20,21} Third, we did not use previously established questionnaires for NIPs with GERD. Although using a different questionnaire may make some or all of the present findings difficult to compare with others, our questionnaire had the advantage of illuminating the reasons for the improvement of QOL and satisfaction.

Our results demonstrated that laparoscopic fundoplication for GERD in NIPs is not only effective for symptom control in patients but also improves QOL for most patients and caregivers. Postoperative weight gain (z-score) was observed in 64% of the included patients. Interestingly, the change in the nutritional route of NIPs following surgery improved caregiver QOL more frequently than patient symptoms. Although none of the caregivers regretted their decision to consent to the surgery, satisfaction levels were a little lower than expected considering the improvements in QOL reported. Satisfaction level was influenced by the postoperative course and occurrence of

complications. Clinicians should focus on preoperative optimization of the condition of NIPs requiring fundoplication to ensure the best possible outcomes. Further research would be greatly assisted by the development of a validated means of measuring QOL in NIPs with GERD.

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