Original Article

Complications in patients with neurological impairment after gastrostomy

Running head: Complications in patients with NI after gastrostomy

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Abstract

Background

Neurological impairment (NI) is responsible for most conditions that require a permanent gastrostomy tube. The present study assessed the occurrence of short- and long-term complications after video-assisted gastrostomy (VAG) in patients with NI.

Methods

The incidence rates of short- (<6 months) and long-term (over 2 years) complications of VAG were analyzed in a retrospective study. The differences between the incidence rates of the complications of VAG according to the age at surgery (≥16 vs. ≤15 years old) were also evaluated. The short- and long-term complications observed were granulation tissue formation, infection requiring antibiotic treatment, skin problems, perigastrostomy leakage, vomiting, accidental tube dislodgement, dumping syndrome, ileus, and peritonitis.

Results

Eighty-two patients were evaluated for short- and long-term complications. The long-term complication rate was significantly lower than the short-term complication rate (p=0.0026). Onodera's prognostic nutritional index before VAG in patients with long-term complications was significantly lower than in patients without such complications (p=0.046). The incidence

rates of long-term granulation tissue formation, infection, and vomiting were significantly lower than those of similar short-term complications. Long-term skin problems were associated with short-term skin problems (odds ratio: 18.95; 95% confidence interval: 4.53–92.98; $p<0.001$). The number of patients ≥16 years old with short- and long-term skin problems was significantly higher than in patients ≤15 years old ($p=0.0014$ and $p=0.0073$, respectively)

Conclusions

The incidence rate of granulation tissue formation and infection after VAG were lower in the long term than in the short term. However, patients ≥16 years old presented with persistent complications.

Key words: gastrostomy; neurological impairment; gastroesophageal reflux disease; complication; prognostic nutritional index

1. Introduction

Neurological impairment (NI) is responsible for most conditions that require tube feeding. Some patients require a nasogastric tube for enteral nutrition and oral pharmacotherapy. Trans nasal feeding tube placement is a simple and effective procedure. However, it has several disadvantages including constant irritation to the throat, risk of accidental dislodgement, and occasionally, difficulty during insertion. Therefore, a permanent gastrostomy tube is commonly used for patients with NI.

At present, percutaneous endoscopic gastrostomy (PEG) is the standard gastrostomy technique used in both adult and pediatric patients. However, it is associated with serious complications, including the risk of injury to other organs, bleeding, and dislodgement[1–4]. Video-assisted gastrostomy (VAG) is therefore used in patients with NI with anatomical problems that can cause difficulties during PEG. Several reports have described the short-term postoperative complications of VAG[5–8]. However, few studies have focused on the long-term postoperative complications of VAG in patients with NI[8].

The present study assessed the incidence rates of short- and long-term complications after VAG in patients with NI.

2. Methods

2.1 Study design

This study was a single-center, retrospective study. All patients who underwent VAG at Kurume University Hospital from July 2006 to June 2015 were included.

Complications that occurred within the first 6 months after surgery were considered short-term complications, and those that developed beyond two years after surgery were considered long-term complications. The short- and long-term complications observed were granulation tissue formation, infection requiring antibiotic treatment, skin problems (skin erosion, redness, and ulcer), perigastrostomy leakage, vomiting, accidental tube dislodgement, ileus, and peritonitis.

Preoperatively, all patients underwent 24-h multichannel intraluminal impedance pH measurements (MII-pH). If the patients were diagnosed with gastroesophageal reflux disease (GERD) based on their symptoms and MII-pH parameters, Nissen fundoplication was performed. In total, 44 patients underwent VAG alone, and 38 underwent VAG with Nissen fundoplication. Furthermore, one patient underwent additional tracheostomy, one underwent additional laryngotracheal separation, and one underwent additional laparoscopic cholecystectomy.

2.2 Operative procedure

VAG is a laparoscopically assisted gastrostomy procedure. In this study, VAG was performed as follows: preoperative antibiotic prophylaxis was administered after which a 5-mm trocar was safely inserted into the abdomen through a lower umbilical skin incision using OptiView^{TM}. Pneumoperitoneum was established with CO_2 insufflation and the stomach was identified using a 5-mm 30° laparoscope. A 5-mm trocar was inserted at the right flank region into the abdominal cavity under visual control with a laparoscope. The anterior stomach wall on the opposite side of the gastric angle was grasped through this port by using an instrument and was elevated to the abdominal wall to establish a gastrostomy site. A 12-mm trocar was inserted at this point through the rectus muscle and into the abdominal cavity under visual control with a laparoscope. The gastrostomy in the stomach wall was grasped through this port with clear margins from the pylorus and exteriorized when the grasper and trocar were pulled back. The stomach was then sutured to the rectus muscle fascia at four points, and a purse string suture was performed around the gastrostomy opening in the stomach wall. The gastrostomy tube was then inserted into the cavity of the stomach through a small incision in the stomach wall.

In cases of fundoplication, three 5-mm trocars were inserted at the lower umbilicus

using a laparoscope and at the right and left flank regions. A 12-mm trocar was inserted at the left flank region and a liver retractor was inserted at the epigastric region. After fundoplication was completed and the gastrostomy site on the gastric body was established, mini laparotomy was performed at the skin region of the gastrostomy site and the stomach wall was exteriorized through the site.

2.3 Data collection and follow-up

The participants were prospectively followed up, and postoperative data concerning the short- and long-term complications were collected retrospectively.

Data, including the age, gender, body mass index (BMI) (calculated as the weight [kg] divided by the height [m] squared [kg/m^2]) before VAG, Onodera's prognostic nutritional index (PNI) before VAG[9], underlying disease, type of complication, death, and relocation from the study area, were collected. The PNI is a useful tool for predicting the short- and long-term postoperative outcomes in patients[9]. It is calculated based on the serum albumin concentration and peripheral blood lymphocyte count (10×serum albumin concentration [g/dL] + 0.005 × total peripheral lymphocyte count [per mm^3]). The PNI allows for the automatic daily assessment of the nutritional status of all inpatients that undergo a routine analysis[9,10].

In addition, long- and short-term complications, such as granulation tissue formation, infection, skin problems, perigastrostomy leakage, vomiting, accidental tube removal, ileus, and peritonitis, were recorded.

2.4 Statistical analyses

All statistical analyses were performed using the JMP software package (SAS, Cary, NC, USA). Data were presented as the mean ± standard deviation, median, and range. Wilcoxon's signed-rank test was used to analyze the categorical values for the short- and long-term complications. The complications were compared using the Mann–Whitney U test and chi-square test. The relationship between short- and long-term complications was then assessed based on the odds ratios (ORs) and 95% confidence intervals (CIs) obtained via a univariate logistic regression analysis. Fisher's exact test was used to evaluate the differences between the incidence rates of the complications of VAG according to the age at surgery (≤15 vs. ≥16 years old). A p value < 0.05 was considered statistically significant.

2.5 Informed consent

This study was performed after informed consent was obtained from the parents and caregivers

of the patients. This study was approved by the ethics committee for clinical research of Kurume University School of Medicine (approval no. 14213).

3. Results

A total of 89 patients with NI underwent VAG during the study period and these patients were included in the follow-up over 2 years. Two patients died as a result of an underlying disease within 2 years after surgery. However, there were no deaths due to VAG or aspiration secondary to vomiting. Five patients had incomplete data owing to missed follow-up sessions caused by moving away or transferring to other hospitals. Thus, 82 patients (42 men and 40 women) were evaluated for their short- and long-term complications.

The median age at the time of surgery was 11.5 years (interquartile range: 4–25.3 years). Short-term complications were defined as those that occurred within the first 6 months, and long-term complications were defined as those that developed beyond 2 years after surgery (median: 1770 days[interquartile range: 1088–1979 days]). Regarding the causal disorders of NI, 62 patients presented with cerebral damage in the neonatal period or infancy, 10 presented with genetic or chromosomal aberrations, 4 presented with metabolic disorders, 5 presented with adrenoleukodystrophy, and 1 presented with mitochondrial disease. Table 1 shows the characteristics of patients with cerebral damage.

Among the 82 patients, 59 had short-term complications of granulation tissue formation (n = 49 [59.8%]), perigastrostomy leakage (n = 9, [11.0%]), skin problems (n = 12, [14.6%]),

infection (such as perigastrostomy and the formation of abscess at the gastrostomy site; n = 10, [12.2%]), tube dislodgement (n = 2, [2.4%]), vomiting (n = 10, [12.2%]), ileus (n = 1, [1.4%]), and peritonitis (n = 1, [1.4%]) (Table 2). In total, 40 patients had long-term complications of granulation tissue formation (n = 15, [18.3%]), perigastrostomy leakage (n = 16, [19.5%]), skin problems (n = 13, [15.9%]), tube dislodgement (n = 8, [9.8%]), and vomiting (n = 2, [2.4%]). None of the patients developed long-term complications of infection, ileus, or peritonitis. The incidence rate of long-term complications was significantly lower than that of short-term complications ($p = 0.0026$). In particular, the incidence of granulation tissue formation, infection, and vomiting, were significantly lower than those of short-term complications (Table 2).

In terms of age, gender, operative time, BMI before VAG, and postoperative Nissen fundoplication, there were no significant differences between patients with short- and long-term complications. The PNI before VAG of patients with long-term complications was significantly lower than that of patients without complications ($p = 0.046$). The follow-up duration of patients with long-term complications was significantly longer than that of patients without complications ($p = 0.03$). Furthermore, the incidence rate of short-term complications among patients with long-term complications was significantly higher than that among patients

without long-term complications ($p = 0.014$) (Table 3).

Among the 10 patients who presented with vomiting, 4 patients recovered due to prokinetics, 3 patients recovered due to half-solidifying agents for enteral nutrition, and 1 patients recovered due to stomach decompression, respectively. Two patients experienced vomiting after two years and were diagnosed with GERD. Patients without the short-term complication of vomiting had no vomiting in the long term.

Table 4 shows the risk of long-term complications in patients with short-term complications. Long-term skin problems were associated with short-term skin problem (OR: 18.95; 95% CI: 4.53–92.98; $p < 0.001$). The risk of other long-term complications was not significant. The number of adult patients with NI with short- and long-term skin problems was significantly higher than the number of pediatric patients with NI ($p = 0.0014$ and 0.0073, respectively). No other significant differences were noted (Table 5).

4. Discussion

The occurrence of postoperative complications after VAG in our patients decreased with time. Indeed, the incidence rates of infection and granulation tissue formation were higher during the short-term follow-up than the long-term follow-up. The formation of granulation tissue is caused by the body's attempt to fix the skin disrupted by the tube, and it usually occurs as part of the wound healing process. Granulation tissue can be treated appropriately while caring for the tube and its stoma without causing chronic wound infection. In this way, the occurrence of granulation tissue formation and infection was able to be reduced.

In a previous study of short-term complications, approximately 13% of patients presented with wound infection, and 5%–20% of patients presented with perigastrostomy leakage around the gastrostomy site[5,6]. In the current study, long-term perigastrostomy leakage occurred in 19.5% of patients, and long-term skin problems were observed in 15.9% of patients with NI. Our long-term findings could not be compared with data from previous studies because no study has assessed the complications that occur beyond 2 years after VAG.

Two studies have assessed the occurrence of leakage over 3 months after VAG[7,8]. In the study of Franken et al.[7], postoperative complications occurred three months after VAG in children. Approximately 6 of 50 patients (12%) experienced leakage after VAG. Salo et al.[8]

reported the occurrence of postoperative complications in children who underwent VAG. Granulation tissue formation and perigastrostomy leakage were observed in 7% and 3% of patients, respectively. Although both these studies were based on data obtained in the most recent month, approximately 2%–20% patients did not have NI[7,8]. Leakage, which is a long-term complication, was observed at the gastrostomy site. In addition, most patients in those studies with NI were undernourished and had a high intra-abdominal pressure due to hypertonia, which increases the risk of skin problems and perigastrostomy leakage around the gastrostomy tubes. The complications were affected by malnutrition. In the present study, the PNI before VAG in patients with long-term complications was significantly lower than in patients without complications. The mechanisms underlying delayed gastric emptying (GE) in patients with NI might have caused aggravated perigastrostomy leakage, which is affected by issues with gastric motility, such as the abnormal modulation of extrinsic innervations due to damage of the central nervous system or hypoxic–ischemic damage to the enteric nerves[11]. Furthermore, a combination of several factors, such as scoliosis, horizontal position, and long-term anticonvulsant use, may delay GE. Several reports have shown that severe NI in children is associated with a high risk of delayed GE[7,12,13]. Based on the findings of the ^{13}C-octanoic acid gastric emptying breath test, Franken et al.[7] found that most patients (≥75%) with leakage

and/or feeding intolerance after gastrostomy had delayed GE. Postoperative delay in gastric GE was observed in most patients with postoperative leakage and feeding intolerance.

Long-term skin problems were found to be associated with short-term skin problems in the present study, and the proportion of NI adult patients with short- and long-term skin problems was significantly higher than that of NI pediatric patients. The causes of skin problems are reportedly a decreased collagen production in patients with chronologically aged skin[14] and poor physical activity and malnutrition in patients with NI[15].

Vomiting can be attributed to other underlying problems or physiologic gastroesophageal reflux. Backman et al.[6] reported that vomiting occurred after surgery in 28% of NI children. Furthermore, the incidence rate reached 22% at 6 months after VAG surgery. Franken et al.[7] showed that 8 of 50 patients (16%) presented with signs of feeding intolerance, including vomiting, after VAG. Salo et al.[8] revealed that vomiting was observed in 2.0% of patients. In the present study, long-term vomiting was only noted in 2.4% of patients. Previously, based on MII-pH measurements, we reported that VAG and Nissen fundoplication mainly reduced the volume of acid reflux and might improve mucosal integrity up to the middle of the esophagus in children with NI[16]. This result supported the notion that MII-pH measurements and Nissen fundoplication are associated with a reduced risk of long-term

vomiting.

No patients showed dumping syndrome after VAG in the present study. The risk factors of dumping syndrome after gastrostomy construction were an inappropriate position of gastrostomy and inappropriate tube position. In VAG, the position of the gastrostomy is observed and determined laparoscopically, so it is possible to construct a gastrostomy at the anterior stomach wall on the opposite side of the gastric angle as an appropriate position. In addition, in our department, button-type devices are used that can prevent the tube from migrating into an inappropriate position.

In our study, the follow-up duration of patients with long-term complications was significantly longer than that of patients without complications ($p = 0.03$). Granulation, leakage, and tube dislodgement occurred regardless of the presence of short-term complications and the postoperative duration.

Several limitations associated with the present study warrant mention. First, a small number of patients with a wide age distribution were enrolled. Second, information from the patients' medical charts was prospectively collected but retrospectively compiled. The complication rates might have been influenced by this approach because attending physicians may have had different evaluation findings and methods of documentation. Furthermore,

complications, such as intermittent infections and perigastrostomy leakage, might not have been recorded in the medical charts; as a result, they were not included in the evaluations. Third, the use of medications and devices and the size of the feeding tubes were not assessed. Finally, there were no data from 6 months to 2 years. Given these limitations, prospective studies providing more accurate results that are less strongly affected by bias must be conducted.

Conclusion

In conclusion, the incidence rate of granulation tissue formation and infection after VAG were lower in the long term than in the short term. However, patients ≥16 years old presented with persistent complications, such as perigastrostomy leakage and skin problems. These results may be suitable for consideration when deciding whether VAG should be performed.

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Disclosure

There were no conflicts of interest.

Author contribution

S.S. and N.H. performed the data collection and analysis and prepared the manuscript. Y.T. and M.Y. supervised the execution of the study and reviewed the manuscript. All other authors contributed to the data collection and interpretation and reviewed the manuscript. All authors read and approved the final manuscript.

References

1. Lantz M, Hultin Larsson H, Arnbjörnsson E. Literature review comparing laparoscopic and percutaneous endoscopic gastrostomies in a pediatric population. Int J Pediatr 2010;507616.

2. Larson DE, Burton DD, Schroeder KW, DiMagno EP. Percutaneous endoscopic gastrostomy. Indications, success, complications, and mortality in 314 consecutive patients. Gastroenterology 1987;93:48-52.

3. Merli L, De Marco EA, Fedele C et al. Gastrostomy placement in children: percutaneous endoscopic gastrostomy or laparoscopic gastrostomy? Surg Laparosc Endosc Percutan Tech 2016;26:381-384.

4. Suksamanapun N, Mauritz FA, Franken J, van der Zee DC, van Herwaarden-Lindeboom MY. Laparoscopic versus percutaneous endoscopic gastrostomy placement in children: results of a systematic review and meta-analysis. J Minim Access Surg 2017;13:81-88.

5. Grant JP. Comparison of percutaneous endoscopic gastrostomy with Stamm gastrostomy. Ann Surg 1988;207:598-603.

6. Backman T, Sjövie H, Mellberg M et al. Pre- and postoperative vomiting in children undergoing video-assisted gastrostomy tube placement. Surg Res Pract 2014;871325.

7. Franken J, Mauritz FA, Stellato RK, Van der Zee DC, Van Herwaarden-Lindeboom MYA. The effect of gastrostomy placement on gastric function in children: a prospective cohort study. J Gastrointest Surg 2017;21:1105-1111.

8. Salö M, Santimano A, Helmroth S, Stenström P, Arnbjornsson E. Long-term outcomes of children undergoing video-assisted gastrostomy. Pediatr Surg Int 2017;33:85-90.

9. Onodera T, Goseki N, Kosaki G. [Prognostic nutritional index in gastrointestinal surgery of malnourished cancer patients]. Nihon Geka Gakkai Zasshi. 1984;85:1001-1005. Japanese.

10. Adachi Y, Akino K, Nojima M et al. Prognostic nutritional index and early mortality with percutaneous endoscopic gastrostomy. *QJM*. 2018;111:635-641.

11. Zangen T, Ciarla C, Zangen S et al.Gastrointestinal motility and sensory abnormalities may contribute to food refusal in medically fragile toddlers. J Pediatr Gastroenterol Nutr 2003;37:287-293.

12. Gatti C, di Abriola FF, Dall'Oglio L, Villa M, Franchini F, Amarri S. Is the 13C-acetate breath test a valid procedure to analyse gastric emptying in children? J Pediatr Surg 2000;35:62-65.

13. Ishii S, Fukahori S, Asagiri K et al. Severe delayed gastric emptying induces non-acid

reflux up to proximal esophagus in neurologically impaired patients. J Neurogastroenterol Motil. 2017;23:533-540.

14. Varani J, Dame MK, Rittie L et al. Decreased collagen production in chronologically aged skin: roles of age-dependent alteration in fibroblast function and defective mechanical stimulation. Am J Pathol 2006;168:1861-1868.

15. Yoshida M, Asagiri K, Fukahori S et al. The utility of a phase angle analysis in patients with severe motor and intellectual disabilities. Brain Dev 2017;39:557-563.

16. Fukahori S, Yagi M, Ishii S et al. Laparoscopic Nissen fundoplication mainly reduces the volume of acid reflux and potentially improves mucosal integrity up to the middle esophagus in neurologically impaired children detected by esophageal combined pH-multichannel intraluminal impedance measurements. J Pediatr Surg 2016;51:1283-1287.

Table 1: Characteristics of the participants (n＝82)

Cerebral damage in the neonatal period or infancy	**62**
Hypoxic ischemic encephalopathy	10
West syndrome	4
Cerebral hemorrhage	4
Lissencephaly	3
Rett syndrome	3
Epilepsy	3
Congenital cytomegalovirus infection	2
Holoprosencephaly	2
Lennox-Gastaut syndrome	2
Encephalopathy	1
Anencephaly	1
Aicardi syndrome	1
Kernicterus	1
Encephalomalacia	1
Meningitis	1
Unknown	23
Genetic or chromosomal anomalie	**10**
Metabolic disorder	**4**
Adrenoleukodystrophy	**5**
Mitochondrial disease	**1**

Table 2: Proportion of patients with short- and long-term complications (n=82)

Complication	Short term n=82	Long term n=82	*p* value※
All	59 (72.0)	40 (48.9)	0.003
glanuation tissue	49 (59.8)	15 (18.3)	<0.001
leakage	9 (11.0)	16 (19.5)	0.090
skin trouble	12 (14.6)	13 (15.9)	0.530
infection	10 (12.2)	0	0.001
tube dislodgement	2 (2.4)	8 (9.8)	0.057
vomitting	10 (12.2)	2 (2.4)	0.004
ileus	1 (1.4)	0	-
peritonitis	1 (1.4)	0	-

Data are listed as number (%) of complications; a single patient can have more than 1 complication

※ : Wilcoxon rank sum test

Table 3: Characteristics of patients with short- and long-term complications (n=82)

Short-term	Complication (+) n=59	Complication (-) n=23	*p* value
Age (year)	17.6±17.5	16.0±11.7	0.770
Gender (M/F), n	29/30	13/10	0.550
Body Mass index before VAG	14.4±3.5	13.6±3.6	0.577
Prognostic Nutritional Index before VAG	51.8±9.4	52.7±9.1	0.635
Operation time (min)	179.8±93.2	185.6±106.9	0.900
Nissen funduplication, n	28	10	0.809
Long-term	**Complication (+) n=40**	**Complication (-) n=42**	***p* value**
Age(year)	18.6±16.5	16.1±15.7	0.460
Gender (M/F), n	18/22	24/18	0.270
Body Mass index before VAG	14.6±3.3	13.7±3.7	0.184
Prognostic Nutritional Index before VAG	50.1±8.7	53.9±9.5	0.046
Follow-up length (days)	1991.2±1008.2	1560.1±781.1	0.030
Operation time (min)	173.6±91.5	189.1±102.1	0.680
Short-term Complication (+), %	34 (85.0)	25 (59.5)	0.014
Nissen funduplication, n	16	22	0.278

VAG, video-assisted gastrostomy

Data are listed as mean ± SD

Table 4: Risk of long-term complications in patients with short-term complications(n=5

Long-term complication	Odds ratio	95%CI lower	95%CI upper	*p* value
Glanuation tissue	2.10	0.644	8.19	0.225
leakage	4.07	0.895	17.68	0.068
Skin trouble	18.95	4.53	92.98	<0.001
tube dislodgement	0	-	-	0.519
vomitting	0	-	0.194	0.003

Table 5: Differences in complications rates after VAG according to age at surgery (n=82)

Complication	Age at 16>= n=47	Age at 15<= n=35	P- value※
Short-term			
All	36 (76.6)	23 (65.7)	0.325
Glanuation tissue	30 (63.8)	19 (54.3)	0.495
Leakage	6 (12.8)	3 (8.6)	0.726
Skin trouble	2 (4.3)	11 (31.4)	0.001
Infection	4 (8.5)	6 (17.1)	0.312
Tube dislodgement	1 (2.1)	1 (2.9)	1.000
Vomitting	7 (14.9)	3 (8.6)	0.504
Ileus	1 (2.1)	0	-
Peritonitis	1 (2.1)	0	-
Dumping syndrome	1 (2.1)	0	-
Long-term			
All	22 (46.8)	18 (51.4)	0.824
Glanuation tissue	11 (23.4)	4 (11.4)	0.249
Leakage	6 (12.8)	10 (28.6)	0.094
Skin trouble	2 (4.3)	9 (25.7)	0.007
Infection	0	0	-
Tube dislodgement	5 (10.6)	3 (8.6)	1.000
Vomitting	2 (4.3)	0	0.505

Data are listed as number (%) of complications; a single patient can have more than 1 complication

※Fisher exact test. VAG,video-assisted gastrostomy