



## Does laparoscopy-aided gastrostomy placement improve or worsen gastroesophageal reflux in patients with neurological impairment? <sup>☆</sup>



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### ABSTRACT

**Background/purpose:** The purpose of this study was to retrospectively investigate whether laparoscopy-aided gastrostomy placement (LGP) improved or worsened gastroesophageal reflux (GER) in neurological impairment (NI) patients.

**Methods:** Subjects included 26 NI patients nourished via nasogastric tubes (age, 1–17 years; median, 6 years). They were divided into groups based on the percentage of time with an esophageal pH <4.0 (reflux index: RI) before LGP: Group I (GI, n = 13), RI <5.0%; Group II (GH, n = 13), RI ≥5.0%. Acid/nonacid reflux episodes (RE) were evaluated using combined pH-multichannel intraluminal impedance (pH-MII) monitoring, and gastric emptying was measured with the C breath test before and after LGP.

**Results:** RI and number of RE evaluated with pH analyses and number of total/acid distal and proximal bolus RE with pH-MH increased significantly in GI. RI and acid clearance time with pH analyses and number of total bolus RE with pH-MII decreased significantly in GH. Gastric emptying parameters did not change significantly in GI, whereas the half-gastric emptying time and gastric emptying coefficient improved significantly in GH.

**Conclusion:** LGP reduces GER in NI patients with pathological GER by improving gastric emptying, although it has a paradoxical influence on those without pathological GER.

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Gastrostomy feeding has been increasingly used as a method of nutritional support for patients with neurological impairment (NI) [1]. However, the development of gastroesophageal reflux (GER) after gastrostomy placement (GP) is still a matter of debate, and the influence of GP on esophagogastric motility has not yet been clarified [2–4]. Our previous data using 24-h esophageal pH monitoring have shown that esophageal acid exposure increased in patients without pathologic GER after GP, but decreased in those with pathologic GER [5]. Recently, combined esophageal pH-multichannel intraluminal impedance (MII) monitoring has been added to the repertoire of tests available for esophageal physiology [6–9]. Combined pH-MII monitoring has an advantage over traditional pH monitoring, which can detect both acid and nonacid GER. In addition, the <sup>13</sup>C-acetate breath test has been newly introduced for the evaluation of gastric emptying in pediatric patients [10,11]. We retrospectively investigated whether laparoscopy-aided gastrostomy placement (LGP) improved or worsened GER in patients with NI.

### 1. Methods

#### 1.1. Patients

Approval of the institutional review board was obtained from our hospital to conduct a retrospective review of the inpatient and outpatient medical charts of 26 patients with NI, who had undergone LGP and whose motor function of the upper gastrointestinal tract was evaluated with a 24-h combined esophageal pH-MII monitoring and the <sup>13</sup>C-acetate breath test. Both examinations had been performed routinely before and 6–13 days (median, 8 days) after LGP. The patients had been nourished via nasogastric tubes and were aged 1–17 years (median, 6 years). All patients had profound NI, such as cerebral palsy (n = 11), chromosomal anomaly (n = 4), West syndrome (n = 3), posttraumatic brain damage (n = 1), advanced mental retardation (n = 1), postherpes encephalitis (n = 1), Menkes disease (n = 1), holoprosencephaly (n = 1), metachromatic leukodystrophy (n = 1), myoclonic encephalopathy (n = 1), and mitochondrial disease (n = 1). Any respiratory and gastrointestinal conditions were controlled adequately with nasogastric tube feeding in the 26 patients. Five patients had undergone tracheostomy, of which three had undergone laryngotracheal separation before LGP. None of the 26 patients had an irreducible hiatal hernia on a preoperative upper GI study. The indication for LGP and the operative procedure of LGP have been described previously in detail [2,6]. No other surgery was conducted concomitantly with LGP.

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The patients were divided into two groups on the basis of the range of the percentage of total preoperative time for which the esophageal pH was less than 4.0 (reflux index, RI) which was determined using the 24-h combined esophageal pH-MII monitoring. The goal was to separately analyze the esophagogastric motility data in those with and without pathologic GER: Group I ( $n = 13$ ) with an RI  $< 5.0\%$  and a median age of 6 years (range, 2–17 years) and Group II ( $n = 13$ ) with an RI  $\geq 5.0\%$  and a median age of 5 years (range, 1–14 years). The postoperative follow-up period ranged from 10 months to 5 years and 6 months (median, 46 months).

### 1.2. 24-h combined esophageal pH-MII monitoring

Any antireflux medications, such as prokinetic agents, histamine-2 receptor antagonists, and proton-pump inhibitors, were discontinued at least 72 h before the 24-h combined esophageal pH-MII monitoring. We used a combined pH-MII flexible probe (outer diameter, 2.1 mm; Sandhill Scientific, Highlands Ranch, CO, USA) that was equipped with 7 or 8 impedance rings for the 6 esophageal impedance channels and 2 antimony pH sensors for the distal esophageal and gastric pH. The pH-MII probe for each patient was chosen from 3 probes types, according to the patient's height. The impedance channels were located 3, 5, 7, 9, 11, 13, and 15 cm from the distal tip of the probe (ZPN-S62C21E) in patients  $< 75$  cm in height, at 11, 13, 15, 17, 19, 21, and 23 cm (ZPN-S62C07E) in patients 75–130 cm in height, and at 12, 14, 16, 18, 20, 24, 26, and 28 cm (ZAN-BG-44) for those  $> 130$  cm in height, respectively. The gastric pH sensor was located at the distal end of the probe, and the distal esophageal pH sensor was located at 6, 12, or 15 cm from the distal tip of the 3 probes, respectively. Before the pH measurements were made, the probe was calibrated using pH 4.0 and 7.0 buffer solution as specified by the manufacturer. The pH-MII probe was inserted nasally under fluoroscopic observation, and the distal esophageal pH sensor was placed at the level of a vertebral body length above the line between the bilateral cranial peak points of the diaphragmatic dome. The probe was connected to a data logger (Sleuth System; Sandhill Scientific) that stored data from the probe. The pH-MII data obtained in each study were downloaded onto a personal computer and analyzed with the Bioview Analysis software, version 5.5.8.0 (Sandhill Scientific).

The impedance and pH data were automatically analyzed with the AutoSCAN software. This identified pH drops in the distal esophagus, which indicated traditional chemical reflux episodes (RE), and also identified impedance drops by liquid in the proximal channels, which indicated bolus RE irrespective of pH changes. One of the authors then manually analyzed the 3 min tracings. A bolus (impedance) RE was defined as a retrograde impedance drop  $> 50\%$  (in Ohms), and  $> 2$  s from the pre-episode baseline mean in at least two consecutive channels of the four distal channels. The end of the bolus RE was defined as the time the impedance level returned to 50% of the pre-episode impedance baseline for  $> 5$  s.

The bolus RE were divided into two categories on the basis of a nadir pH value during RE and were either labeled either acid or nonacid. An acid RE was defined as RE during which the esophageal pH was lower than 4.0 or that occurred when the distal esophageal pH was already below 4.0. A nonacid RE was defined as RE in which the distal esophageal pH reduced by at least 1 unit and the nadir esophageal pH did not drop below 4.0. An RE that reached the channel two was defined as a proximal extent bolus RE.

The clearance dynamics were quantified by both acid and bolus clearance. Acid clearance referred to the chemical neutralization of the remaining hydrogen ions as measured by the pH sensor at the clearance level. The acid clearance time was the elapsed time between the acid entry and acid clearance in a pH channel located in the distal esophagus. If the pH decreased to less than 4.0, the points in time when the pH was 4.0 and when it recovered to above 4.0 were marked, and the resulting acid clearance times were calculated. Bolus clearance referred to the

physical clearance of the bolus as measured by the impedance at the clearance level. A bolus clearance time was defined as the elapsed time between the bolus entry and bolus clearance as measured by the impedance. The mean acid clearance time and median bolus clearance time were calculated in each patient using the Bioview Analysis software.

### 1.3. $^{13}\text{C}$ -acetate breath test

The method of  $^{13}\text{C}$ -acetate breath has been previously reported in detail [12]. This test measured changes in the  $^{13}\text{CO}_2/^{12}\text{CO}_2$  isotope ratio in the patient's exhaled breath, which resulted from the absorption and metabolism of a  $^{13}\text{C}$ -labeled test meal marker as it exited in the stomach. Specifically, after a baseline collection of the patient's breath, 100 mg of  $^{13}\text{C}$ -labeled sodium acetate dissolved in a liquid meal was administered. The liquid formulas given to patients via a nasogastric tube before LGP and via a gastrostomy tube after LGP were pediatric elemental diet formula (Elental P<sup>TM</sup>,  $n = 1$ ), low residual formula, including Racol<sup>TM</sup> ( $n = 10$ ), Ensure<sup>TM</sup> ( $n = 9$ ), and Twinline-NF<sup>TM</sup> ( $n = 3$ ), and a hypoallergic formula (New MA-1<sup>TM</sup>,  $n = 3$ ). The volume of the liquid meal was calculated at 300 mL per  $1.73 \text{ m}^2$  of body surface area. Patients were tested for four hours in the supine position after more than six hours of fasting. The gastric emptying was evaluated via a continuous breath test in real time using the BreathID<sup>TM</sup> system (Oridion BreathID Ltd., Jerusalem, Israel). Patients were connected to the device via a cannula, which was attached to the nose for 21 patients or via a tracheostomy tube for five patients. The test meal was processed and emptied by the stomach, and after absorption and metabolism,  $^{13}\text{C}$  was produced and exhaled in the breath as  $\text{CO}_2$ . The device continuously measured the ratio of  $^{13}\text{C}$  and  $^{12}\text{C}$  in the exhaled  $\text{CO}_2$  using molecular correlation spectroscopy, which absorbed the radiation emitted by the radioisotope. The BreathID<sup>TM</sup> device measured the ratio of C isotopes, which was normalized for patient weight, height, and  $^{13}\text{C}$  substrate and dose, and provided a percentage-dose recovery and cumulative percentage-dose recovery. The excretion of  $^{13}\text{CO}_2$  in the breath was mathematically analyzed using two nonlinear regression equations to find the best fitting curve through the measured data points with the affiliated computer software (Oridion Research Software<sup>TM</sup>). The data from the breath test were used to calculate three common parameters for gastric emptying, using formulas based on the analysis described by Ghos et al. [12]. The first parameter was the half emptying time (T1/2), which was the time required for half of the gastric contents to be emptied. The second parameter was the lag time (Tlag), which was the time that corresponded to the point of inflection of the curve after mathematical integration (i.e., the time of maximal  $^{13}\text{CO}_2$  excretion based on the fitted curve). The third parameter was the gastric emptying coefficient (GEC), which was an index of the global gastric emptying rate. In the current study, delayed gastric emptying was defined as a T1/2 value  $> 100$  min according to data shown by Lysy et al. [13], who reported using the same technique that the normal T1/2 value was 50–94 min in adult patients.

All data are expressed as medians and ranges. The Wilcoxon signed-rank test was used to compare data before and after LGP. Statistical significance was accepted at  $p < .05$ .

## 2. Results

The data of each pH and impedance parameter before and after LGP are detailed in Table 1. No parameters in the overall 26 patients showed any significant changes.

In the analyses of the pH alone, RI ( $p = 0.01$ ) and the numbers of RE ( $p = 0.01$ ) increased significantly in Group I. In the analyses of combined impedance and pH, the numbers of acid ( $p = 0.02$ )/total ( $p = 0.01$ ) bolus RE and acid ( $p = 0.04$ )/total ( $p = 0.03$ ) proximal extent bolus RE increased significantly, although an increase in the percent time of acid bolus RE did not reach significance ( $p = 0.12$ ). Bolus clearance time decreased significantly ( $p = 0.03$ ).

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