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ORIGINAL SCIENTIFIC REPORT

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Prophylactic anti-reflux procedure for children undergoing laparoscopic gastrostomy: Rethinking of the routine practice

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Abstract

Aim: Laparoscopic gastrostomy is a frequently performed procedure in children requiring long-term enteral nutrition. The role of prophylactic anti-reflux surgery during gastrostomy placements is controversial. The current study aims to evaluate the role of prophylactic anti-reflux procedures during gastrostomy placement.

Methods: A retrospective single-center analysis of all children without reflux receiving laparoscopic gastrostomy from January 2005 through December 2021 was performed. Demographics and clinical outcomes were compared between patients receiving gastrostomy placement alone and patients receiving gastrostomy with prophylactic anti-reflux surgery.

Results: A total of 79 patients had a confirmed absence of reflux by a 24-h pH/impedance study before operation. Thirty-six of these patients underwent prophylactic anti-reflux surgery (PAR) while 43 received gastrostomy (PG) alone. The operative time and conversion rate were significantly higher in the PAR group (140.5 $\pm$ 67.5 vs. 80.2 $\pm$ 66.8 min, $p = 0.0001$ and 8.3% vs. 0%, $p = 0.04$). There were no major complications in either group. De novo reflux was detected in five patients (11.6%) in the PG group. None of these patients progressed to require anti-reflux surgery.

Conclusion: The occurrence of de novo reflux after laparoscopic gastrostomy was low and could be managed without anti-reflux surgery. A routine pre-operative pH study is helpful for appropriate patient selection to avoid unnecessary anti-reflux surgery, which lengthens operative time and increases the conversion rate.

KEYWORDS

children, gastroesophageal reflux, gastrostomy, minimally invasive surgery

Adrian Chi Heng Fung and Yu Ning Ooi are contributed equally as co-first authors.

1 | INTRODUCTION

Gastrostomy tube insertion is a widely performed procedure in pediatric surgery, with rates of insertion increasing worldwide.[1–4] Gastrostomy tubes are commonly used in patients who require additional nutritional support via enteral feeding due to feeding difficulties.[3–6] Conditions that frequently indicate gastrostomy insertion include neurological impairment (NI),[2–7] cerebral palsy[3–6] and congenital malformation.[4,6] These patients often have complex medical requirements.[2,4] Impaired swallowing can lead to malnutrition and food aspiration, causing recurrent aspiration pneumonia; thus, an alternative long-term feeding arrangement is needed.[3–5] Gastrostomy has been shown to improve nutritional status and reduce lung complications,[3–5] with high rates of patient and family satisfaction.[5]

Previous studies have reported that gastrostomy insertion is associated with gastroesophageal reflux (GOR).[8–11] These studies often report a change in laxity of the lower esophageal sphincter,[8–10] leading to a reflux of stomach contents. Additionally, patients with NI have also been previously reported to have a higher risk of developing GOR.[6] Prophylactic anti-reflux surgery has been proposed as a concurrent procedure with gastrostomy tube insertion.[12] This procedure would involve undertaking fundoplication before continuing to gastrostomy tube insertion. However, several more recent studies using current techniques have disputed the relationship between gastrostomy insertion and GOR.[6,7,13] Furthermore, unnecessary surgical procedures should be avoided to decrease cost and harm to the patient.[14] Additional procedures increase the operative time, leading to longer recovery times and increased risk of complications such as bleeding, infection, and conversion to open surgery.[14,15] The usefulness of this additional procedure is debatable in the absence of preoperatively established GOR. Variations have been observed among pediatric surgeons on concurrent fundoplication during gastrostomy creations.[16,17]

This study aims to address the current gap in the literature surrounding the occurrence of GOR after gastronomy tube insertion in pediatric patients and evaluate the role of prophylactic anti-reflux surgery in gastrostomy tube insertion.

2 | METHODS

2.1 | Study design

We conducted a retrospective single-center analysis of all pediatric patients (<18 years of age) with preoperatively established absence of reflux via pH/impedance monitoring who were receiving laparoscopic gastrostomy. We reported the study according to Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines for observational studies where appropriate.[18]

2.2 | Workflow for gastrostomy

Patients who were indicated for gastrostomy underwent initial assessment for the presence of any clinical evidence of gastroesophageal reflux symptoms as defined in the joint updated guidelines of the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN) and the European Society for Pediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN) in 2018[19] Figure 1.

Those with clinically significant reflux symptoms were offered concurrent anti-reflux procedures during

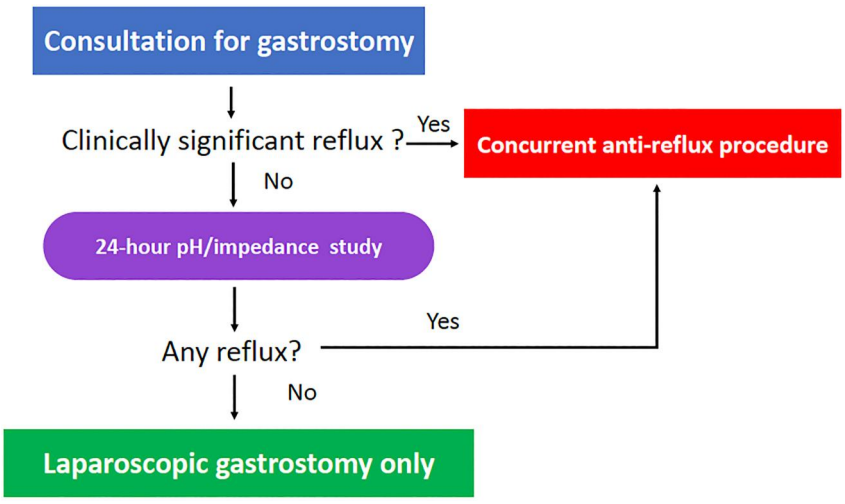

FIGURE 1 Flowchart showing logistics of gastrostomy arrangement. [Colour figure can be viewed at wileyonlinelibrary.com]

gastrostomy, while those without were provided with 24-h combined multichannel intraluminal impedance-pH monitoring (MII-pHM) and recording (Ohmega Ambulatory Impedance and pH Recorder; MMS). Impedance and pH data analysis were performed automatically by using MMS Investigation and Diagnostic Software®. All tracings were also manually reviewed by a dedicated specialist experienced in the interpretation of pH-impedance recording. Reflux index (RI, percentage of the entire record that the esophageal pH is < 4.0) greater than 4.2% for pHM and the number of refluxes for 24 h more than 50 for MII were accepted as positive test results.

Patients with a positive test result were offered concurrent anti-reflux procedures during gastrostomy, while those with negative test results were offered laparoscopic gastrostomy only. All the parents were counseled about surgical options by the same dedicated specialist who was also responsible for 24-h combined multichannel intraluminal impedance-pH monitoring (MII-pHM) and recording of their children. A final decision on proceeding to anti-reflux procedures or not depended on parental preferences after counseling.

2.3 | Surgical techniques

All gastrostomies were performed laparoscopically with the Seldinger Technique previously reported.[20] For patients without a concomitant anti-reflux procedure, two U-stitches were passed through both the abdominal wall and stomach anterior wall under laparoscopic guidance around the selected gastrostomy tube placement site. The stomach was then insufflated via a nasogastric tube, and a needle introducer was passed through the abdominal wall into the stomach between the two U-stitches. A guidewire was passed through the needle, and dilators were passed over the guidewire to dilate the tract serially using the Seldinger Technique. A French 12 gastrostomy tube was advanced over the guidewire into the stomach, and the balloon was then inflated.

Patients receiving concomitant anti-reflux procedures underwent fundoplication first before proceeding with gastrostomy. After the establishment of CO_2 pneumoperitoneum, the liver was retracted with a Nathanson retractor. The intra-abdominal esophagus was dissected free using hook cauterization. A floppy wrap was created by bringing the fundus through a retro-esophageal window in a Nissan fundoplication manner and sutured using 2/0 nonabsorbable sutures. Gastrostomy followed, as described above, after the completion of fundoplication.

2.4 | Patients and data collection

The chosen center was a tertiary pediatric surgical referral center providing specialist services for a network of hospitals across Hong Kong Island and Kowloon. We collected data for all pediatric patients referred to the center with the need for gastrostomy from January 1, 2005 to December 31, 2021. We extracted the data from medical records held on an electronic patient record (ePR) system and validated the operations received by reviewing each operative record. We included only pediatric patients who underwent 24-h combined multichannel intraluminal impedance-pH monitoring (MII-pHM) and recording and laparoscopic gastrostomy. We excluded patients with clinically significant reflux symptoms, positive preoperative MII-pHM recording, receiving concurrent operations for other conditions, and having other underlying congenital anomalies with increased risk of reflux: malrotation, esophageal atresia, and tracheoesophageal fistula, or congenital diaphragmatic hernia. The data we analyzed included patient demographics and details of operations, operative outcomes, complications, and hospitalization.

2.5 | Outcome measures

The primary outcome of this study was the occurrence of de novo reflux defined as the occurrence of GOR symptoms (defined by NASPGHAN & ESPGHAN 2018 guidelines[19]) after operation in patients proven to be reflux negative with 24-h MII-pHM before gastrostomy. Secondary outcomes included 30-day complications, operative time, conversion rates, length of hospital stay, time to full enteral feeding, and need for reoperation.

2.6 | Statistical methods

We analyzed and compared all the data statistically using the Statistical Package for the Social Sciences® version 26 (IBM). Descriptive statistics are given as the number of units (n) and the percentage (%). The data are expressed as medians with interquartile ranges. We analyzed the continuous variables using the Student's t-test and analysis of variance (ANOVA) as appropriate. We analyzed the ordinal variables using the Mann–Whitney U test and the categorical variables using the chi-squared test. We considered a p-value of < 0.05 statistically significant.

3 | RESULTS

A total of 149 children underwent laparoscopic gastrostomy during the study period. All patients underwent a 24-h MII-pHM study as a preoperative workup. A total of 70 patients were excluded as they were proven to have GOR before operation, and 79 were confirmed as having no reflux before operation and were included for analysis. Table 1 shows the clinical characteristics of the patients included in the study. Among the patients

included, 36 received prophylactic anti-reflux (PAR), while the remaining ($n = 43$) did not. Majority of patients were male (58.2%, $n = 46$) with a median body weight of 8.4 (5.7–13) kg and a median age of 6 (3–9) months at operation. Most of the patients were referred for gastrostomy because of underlying neurological impairment (64.6%, $n = 51$). The demographic features of the two operative groups were comparable. The patients received follow-up at a median duration of 68 (34–99) months.

Clinical outcomes were compared between the two operative groups (Table 2). The operative time was significantly longer in the PAR group (134 [92.5–155] vs. 51 [45–80] mins, $p = 0.0001$). Patients in the PAR group also had a significantly higher conversion rate than the PG group (9% vs. 0%, $p = 0.04$). On the other hand, the duration of hospital stay was comparable between the PAR group and PG group, with a median stay of 2 (1–9) and 2 (1–7.8) days, respectively ($p = 0.431$). There was also no significant difference in the time to full enteral feeding between the two groups (6 [2–9.3] vs. 4[2–7] days, $p = 0.286$). There were no major complications (e.g., perforation, bleeding, injury to major organs, leakage etc.) in either group. Minor complications (e.g., tube dislodgement and blockage, gastrostomy granuloma, wound infections etc.) occurred similarly in both groups (PAR group: 60% vs. PG group: 64%, $p = 0.749$).

De novo reflux was detected in five patients (10.4%) in the PG group, among which two of them were confirmed with a 24-h MII-pHM recording and three were diagnosed solely based on clinical symptoms as

TABLE 1 Clinical characteristics of included patients.

	Overall ($n = 79$)	With prophylactic anti-reflux ($n = 36$)	Without prophylactic anti-reflux ($n = 43$)	p
Gender				0.0986
Female	33 (41.8%)	15 (41.7%)	18 (41.9%)	
Male	46 (58.2%)	21 (58.3%)	25 (58.1%)	
Indications of gastrostomy				0.267
Failure to thrive				
Cardiopulmonary diseases	3 (3.8%)	1 (2.8%)	2 (4.6%)	
Metabolic diseases	8 (10.1%)	5 (13.8%)	3 (6.9%)	
Others	3 (3.8%)	2 (5.6%)	1 (2.3%)	
Feeding difficulties/aspiration risk				
Neurological impairment	51 (64.6%)	20 (55.6%)	31 (72.1%)	
Oropharyngeal abnormalities	14 (17.7%)	8 (22.2%)	6 (14.0%)	
Body weight at operation (kg)	8.4 (5.7–13)	6.9 (5.4–12)	9.8 (6.0–15)	0.259
Age at operation (months)	6 (3–9)	6 (3–9)	5 (3–9)	0.620
Follow-up duration (months)	68 (34–99)	75.5 (52.3–101)	60 (29–96)	0.249

Note: Continuous data were expressed as median (interquartile range).

TABLE 2 Clinical outcomes of included patients.

	With prophylactic anti-reflux ($n = 36$)	Without prophylactic anti-reflux ($n = 43$)	p
Operative time (min)	134 (92.5–155)	51 (45–80)	0.0001*
Conversion to open	3 (8.3%)	0 (0%)	0.04*
Complications			0.749
Major	0 (0%)	0 (0%)	
Minor	22 (60%)	27 (64%)	
Length of hospital stay (days)	2 (1–9)	2 (1–7.8)	0.431
Time to full enteral feeding (days)	6 (2–9.3)	4 (2–7)	0.286
De novo reflux	/	5 (11.6%)	/

Note: Continuous data were expressed as median (interquartile range).

defined by NASPGHAN and ESPGHAN 2018 guidelines.[19] Three of the de novo reflux patients needed proton pump inhibitors more than 1 year after operation for symptom relief. However, none of them required subsequent anti-reflux surgery.

Subgroup analysis was performed for patients with neurological impairment, which revealed no statistically significant differences in the risk of de novo reflux (13% vs. 8.3%, $p = 0.413$) and minor complication rate (67% vs. 58%, $p = 0.609$) between patients with or without underlying neurological impairment (Table 3).

4 | DISCUSSION

Gastrostomy tubes are effective alternative routes for long-term enteral nutrition in patients with feeding difficulties.[21] Insertion of a gastrostomy tube is a common surgical procedure in children and infants, first described via an open surgical approach by Stamm in 1894.[22] Traditional laparotomy was the method of choice until the introduction of percutaneous endoscopic gastrostomy (PEG) in 1980.[23] In the last couple of decades, the laparoscopic approach has gained popularity and was identified as a method comparable to PEG, if not potentially superior to it due to reduced rates of complications.[21,24]

De novo reflux post-gastrostomy insertion is a topic debated in the literature. Early studies, using Stamm gastrostomy, proposed post-gastrostomy GOR to be due to the relaxation of the lower esophageal sphincter.[9] In 1998, Sulaeman et al. identified reflux as a common finding post-PEG.[25] These findings, however, have been challenged by studies published in the current decades. A systematic review carried out by Noble et al. in 2012 reported that the literature did not demonstrate a causal effect of PEG on GOR.[13] Similarly, in 2020, Franken et al. carried out a prospective study of 50 patients, which showed no association between laparoscopic gastrostomy insertion and change in acid exposure on pH monitoring or GOR symptoms.[6] An additional factor to consider is the presence of NI in these patients. NI has been associated with GOR independent of gastrostomy insertion in several studies, and pediatric patients receiving gastrostomy tubes are predominantly affected by NI.[7,12] Following reports of post-gastrostomy GOR, a prophylactic procedure against this complication was proposed, especially in patients with NI, given the higher prevalence of GOR in these patients.[7,12]

PAR involves concurrent fundoplication and gastrostomy insertion during the same procedure. The necessity of undertaking PAR is debatable in the literature, demonstrated by highly variable rates of PAR with gastrostomy insertion across centers. An observational study in 2018 in the United States showed a significant variation in practice among 54 hospitals.[17] Another national study in 2021, also in the United States, reported similar findings, with rates of PAR ranging from 4.2% to 75.2%.[16] Fundoplication has been shown in earlier studies to effectively treat GOR in children and infants, especially in patients with neurological deficits.[15,20] However, conflicting evidence subsequently created skepticism toward its role in patients receiving gastrostomy.[7,26–28] Thus, more work is therefore necessary to fill this research gap.

In our cohort of 79 pediatric patients undergoing laparoscopic gastrostomy with confirmed absence of reflux in a 24-h MII-pHM study, 36 received concurrent PAR (PAR group) based on surgeon and parent preference, despite having no clinical or investigational evidence of reflux, while the rest of 43 patients did not (PG group). De novo reflux was detected in five PG group patients (11.6%), concurring with published data of 11%–15% occurrence.[27,29] Three were diagnosed solely based on clinical symptoms, while two were confirmed on postoperative 24-h MII-pHM given their equivocal symptoms. Yet, all five patients were medically using proton pump inhibitors, and none required further anti-reflux surgery. This finding is comparable to

TABLE 3 Subgroup analysis for neurologically impaired patients.

$N = 43$	Neurologically impaired ($n = 31$)	Non-neurologically impaired ($n = 12$)	p
Complications			0.609
Major	0 (0%)	0 (0%)	
Minor	21 (67%)	7 (58%)	
Tube dislodgement	5	1	
Tube blockage	3	1	
Granuloma	11	4	
Wound infection	2	1	
De novo reflux	4 (16%)	1 (8.3%)	0.413

other studies that similarly found low rates of further anti-reflux surgery in PG patients.[6,11,27,29] Although none of the PAR group had reflux after the operation, a majority of PG patients (88.4%) also remained GOR-free. On the other hand, the PAR group had a longer operative time and higher conversion rate. Therefore, it beckons the question of whether many of the PAR group patients underwent an unnecessary additional procedure that lengthened the operation and increased the need for conversion just because of the myth of de novo reflux and surgeon preferences. Surprisingly, even in our subgroup analysis, patients with neurological impairment were not associated with an increased risk of de novo reflux and complications. This brought up the need of rethinking whether anti-reflux procedure should be routinely utilized in children without the evidence of reflux on the basis of neurological impairment alone.

A shortcoming of the current study is the small sample size, which may have weakened the statistical power of the analysis, in particular with the subgroup analysis for neurological impaired patients. However, including 79 patients over a 15-year review period provided a sample size comparable to those of the published studies.[6,7,30] Furthermore, the retrospective nature of our study made it somewhat difficult to analyze the actual effects of the two treatment options in an unbiased manner. Since patients were offered PAR procedures based on surgeon preferences rather than objective evidence or standardized protocol, selection bias was inevitably incurred. A well-designed prospective randomized controlled trial with standardized group allocation and a follow-up protocol would be valuable for defining the best surgical approaches. A collaborative multicenter study could be considered to broaden the scale of the study.

In conclusion, the occurrence of de novo reflux after the procedure was low and could be managed without anti-reflux surgery. Neurologically impaired patients did not carry an increased risk of de novo reflux. The surgeon should reconsider the necessity of routine prophylactic anti-reflux procedure during gastrostomy tube insertion. A routine preoperative pH study is helpful for appropriate patient selection to avoid unnecessary anti-reflux surgery, which lengthens operative time and increases the conversion rate.

AUTHOR CONTRIBUTIONS

Adrian Chi Heng Fung: Conceptualization; data curation; formal analysis; methodology; writing—original draft; writing—review and editing. **Yu Ning Ooi**: Data curation; writing—original draft. **Ho Ming Hui**: Conceptualization; data curation; formal analysis. **Michelle Kam Yan Mok**: Conceptualization; data curation; formal analysis. **Kenneth Kak Yuen Wong**: Supervision; writing—review and editing.

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CONFLICT OF INTEREST STATEMENT

Adrian Chi Heng Fung, Yu Ning Ooi, Ho Ming Hui, Michelle Kam Yan Mok, Patrick Ho Yu Chung, and Kenneth Kak Yuen Wong have no conflicts of interest or financial ties to disclose.

ETHICS STATEMENT

Institutional review was waived since the study did not include any interaction or intervention with human subjects or any access to identifiable private information.

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