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Nissen fundoplication and gastrostomy in severely neurologically impaired children with gastroesophageal reflux

對神經嚴重受損的胃食道反流病童，進行尼森氏胃底成形術和胃造口術

Objectives. To study the effect of Nissen fundoplication and gastrostomy in severely neurologically impaired children.
Design. Prospective observational study.
Setting. Developmental Disabilities Unit of a regional medical centre in Hong Kong.
Patients. Children with severe neurological impairment and gastroesophageal reflux who were institutionalised between 1999 and 2004 inclusive.
Main outcome measures. Incidence of vomiting, gastro-intestinal bleeding, and pneumonia in the baseline year and consecutive years following surgery; 24-hour oesophageal pH monitoring; recurrence rate (determined by 24-hour oesophageal monitoring); body weight; complications of surgery; and mortality.
Results. Twenty children, with a mean age at surgery of 8.5 (standard deviation, 3.5) years, were recruited. Nissen fundoplication was performed in nine children and 11 children underwent laparoscopic fundoplication. Children were monitored for 1.3 to 5.7 years (median, 3.5 years) after surgery. The incidence of vomiting and gastro-intestinal bleeding was significantly decreased following surgery (P<0.001 and P=0.001, respectively; Friedman's test). There was no difference between the preoperative and postoperative incidence of pneumonia (P=0.973, Friedman's test). The median reflux index was reduced from 5.7% to 0.15% after surgery but six (30%) patients had recurrent gastroesophageal reflux. The mean body weight was 17.4 kg (standard deviation, 4.7 kg) at baseline and 22.8 kg (standard deviation, 4.4 kg) at the end of follow-up (P<0.05, Student's *t* test). One patient had mild dumping syndrome soon after fundoplication. One patient had one episode of intestinal obstruction. Four patients died 1.9 to 5.0 years following surgery due to respiratory disease.
Conclusion. Our results indicate that in severely neurologically impaired children with gastroesophageal reflux, vomiting, gastro-intestinal bleeding, and reflux indices based on 24-hour oesophageal pH monitoring were significantly reduced following fundoplication and gastrostomy. The incidence of pneumonia was unchanged. The recurrence rate of reflux was 30% and mortality rate was 20%.

目的：研究對神經嚴重受損的病童進行尼森氏胃底成形術和胃造口術的效果。
設計：前瞻性觀察研究。
安排：香港一間地區性醫療機構的發展障礙部。
患者：1999 至 2004 年期間，有神經嚴重受損和胃食道反流的住院兒童。
主要結果測量：嘔吐、胃腸出血和手術後及其後數年出現肺炎的情況；24 小時食道酸鹼值監察；復發比率（根據 24 小時食道監察資料）；體重；手術併發症，以及死亡率。
結果：這研究涉及 20 名兒童，手術時平均年齡為 8.5 歲（標準差 3.5 歲）。9 人接受了尼森氏胃底成形術，11人接受了腹腔鏡胃底成形術。手術後監察期介乎1.3年至 5.7 年不等（中位數 3.5 年）。手術後嘔吐和胃腸出血的情況大為減少（分別為 P<0.001 和 P=0.001；Friedman's test），但出現肺炎的情況則手術前後沒有明顯差別（P=0.973；Friedman's test）。手術後胃食道反流指數的中位數由 5.7% 減至 0.15%，但有 6 名病人（30%）出現復發性胃食道反流。病童手術前 1 年的體重平均為 17.4 公斤（標準差 4.7 公斤），到手術後監察期結束時的平均體重為 22.8 公斤

Key words:
Child;
Fundoplication;
Gastroesophageal reflux;
Mental retardation;
Recurrence

關鍵詞：
兒童；
胃底成形術；
胃食道反流；
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復發

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（標準差 4.4 公斤）（P<0.05；Student's *t* test）。有 1 名病童接受胃底成形術後出現輕微傾倒症候群，亦有 1 名病人出現腸梗塞。4 名病人先後於手術後 1.9 年至 5.0 年，因呼吸疾病死亡。

結論：研究結果顯示，對神經嚴重受損的胃食道反流病童進行尼森氏胃底成形術和胃造口術，能明顯減少病童嘔吐、胃腸出血和 24 小時食道酸鹼值監察到的反流情況。肺炎的情況則沒有改變。胃食道反流的復發率為 30% ，死亡率為 20% 。

Introduction

Gastroesophageal reflux (GOR) is common in neurologically impaired (NI) children.[1,2] Fundoplication and gastrostomy has previously been indicated in NI children with GOR who have not responded to medical treatment. In neurologically normal (NN) children surgical treatment is successful in 90% of patients, but in NI children the failure rate is reported to be rather high.[3,4] In a large United States retrospective study of fundoplication in 7467 children (56% NN, 44% NI),[5] 95% of NN children achieved a good-to-excellent outcome as did 84% of NI children. In an earlier study,[6] 71% of NI children reported recurrence of GOR symptoms within a mean follow-up of 3.5 years after surgery although this was only confirmed by investigation in 25%. Other studies have recorded recurrence of GOR in 29% of children with psychomotor retardation received fundoplication,[7] and in 16 of 70 NI children who underwent fundoplication.[8] Most studies did not include 24-hour oesophageal pH monitoring. We conducted a prospective study to determine whether fundoplication and gastrostomy resulted in improved GOR in a group of severely NI children with GOR. Symptoms of GOR (ie vomiting, gastro-intestinal bleeding [GIB], and pneumonia) and results of 24-hour oesophageal pH studies before and after surgery were compared.

Patients and methods

This was a prospective cohort study of severely NI children with GOR who underwent Nissen fundoplication and gastrostomy between June 1999 and December 2004 inclusive. All children were resident at the Developmental Disabilities Unit of Caritas Medical Centre, which is a residential and rehabilitation centre for non-ambulatory children with severe neurological impairment. Open surgery was performed in nine children and 11 underwent laparoscopic surgery. All children had been fed via a nasogastric tube for a minimum of 1 year prior to surgery, had persistent GOR symptoms for more than 3 months, and had been prescribed prokinetics, histamine-2-receptor antagonists (H_2 blocker), or proton pump inhibitors (PPIs). The total number of episodes of vomiting, GIB, and pneumonia per month while undergoing medical treatment were recorded. Information related to vomiting episodes was obtained from the vomiting chart, completed daily by health care assistants (blinded to both patient medication and type of surgery). Daily activities including oral or enteral intake (eg water, milk, or diet), vomiting, bowel opening, seizures, and concurrent illness were also recorded. Symptom charts are commonly used in the Unit. Vomiting charts are used for all patients with frequent vomiting to record the details of every vomiting episode (such as amount and nature of the vomitus, the feeding rate, posture of the patients, and any concurrent illness). Information about episodes of pneumonia and GIB was retrieved from the daily patient record. A diagnosis of pneumonia was based on a clinical examination supported by chest X-ray, blood test, and sputum culture. Gastro-intestinal bleeding was defined as coffee-ground/fresh blood aspirate or haematemesis. Occult GIB was not studied. Both events have been used as outcome measures in previous studies of antireflux treatment.[9,10]

Diagnosis of GOR was based on: (1) reflux index (RI) of higher than 5% in 24-hour oesophageal pH studies (13 patients), (2) endoscopic evidence of oesophagitis (five patients), or (3) GOR shown on barium meal (two patients). Details of 24-hour oesophageal pH measurements have been published previously.[9] Two patients had recurrent vomiting and coffee-ground aspirates with respective RIs of 4.4% and 4.6%, longest reflux durations of 17 and 22 minutes, and three and two reflux episodes longer than 5 minutes. In view of these abnormal findings and the GOR symptoms, pathological GOR was diagnosed.

Nissen fundoplication was initially an open procedure but later it was performed laparoscopically. Open surgery involved a 6 to 8 cm upper transverse incision, followed by division of the gastrohepatic and phrenoesophageal ligaments and exposure of the right diaphragmatic crus and oesophagus. If present, any hiatus hernia was reduced and the hiatus closed by approximating the right and left crura with two to four 3/0 prolene sutures. The fundus of the stomach was mobilised by division of the short gastric vessels. The fundus was grasped and passed behind the oesophagus from left to right to produce a 360-degree fundal wrap around the lower end of the oesophagus: the two flaps of the fundus were sutured together with 3/0 prolene. The muscular wall of the oesophagus was incorporated in the fundoplication to prevent migration of the wrap. A standard percutaneous gastrostomy was then performed using the pull method for enteral feeding. In the laparoscopic approach, a 4-port technique was used with 5-mm ports: an epigastric port for the camera, a right subcostal port for lifting the left lobe of the liver and two working ports, one each in the right upper and left upper quadrant. The technique was similar to the open method but the short gastric vessels were not divided. The fundal wrap was performed using 2/0 vicryl on a ski needle. The gastrostomy was inserted at one of the port sites.

Postoperatively, 24-hour oesophageal pH studies were performed if patients had symptoms suggestive of GOR or

Table 1. Diagnosis, co-morbidities, and outcome of 20 patients undergoing Nissen operations (fundoplication and gastrostomy)

Patient No.	Age at surgery (years)	Nissen operation (open/laparoscopic)	Cause of mental retardation	Grade of mental retardation
1	10.7	Open	Birth asphyxia	Severe
2	3.9	Open	Birth asphyxia	Severe
3	6.1	Open	Dandy-Walker syndrome, arthrogryposis multiplex	Profound
4	6.5	Open	Robinow syndrome	Profound
5	7.9	Open	Congenital cytomegalovirus infection	Profound
6	3.6	Open	Birth asphyxia	Profound
7	7.4	Open	Birth asphyxia	Severe
8	4.8	Open	Unknown	Profound
9	6.5	Open	Unknown	Profound
10	9.9	Laparoscopic	Birth asphyxia	Profound
11	5.7	Laparoscopic	Congenital myopathy	Profound
12	13.5	Laparoscopic	Birth asphyxia	Profound
13	8.5	Laparoscopic	Convulsion	Profound
14	11.3	Laparoscopic	Arthrogryposis multiplex congenita	Severe
15	13.9	Laparoscopic	Familial	Profound
16	10.2	Laparoscopic	Hypoxic ischaemic encephalopathy	Profound
17	7.2	Laparoscopic	Birth asphyxia	Profound
18	13.2	Laparoscopic	Lissencephaly	Profound
19	14.4	Laparoscopic	Tuberculosis meningitis	Profound
20	4.3	Laparoscopic	Birth asphyxia	Profound

* H_2 blocker denotes histamine-2-receptor antagonists, PPI proton pump inhibitors
† GOR denotes gastroesophageal reflux

routinely 1 year after the surgery. Recurrence was defined as presence of GOR symptoms and an RI of higher than 5% or presence of oesophagitis following fundoplication. Oesophagogastroduodenoscopy was routinely performed in all patients with GIB.

All patients were followed prospectively for GOR symptoms (vomiting, GIB, and pneumonia) and postoperative complications after fundoplication. The incidence of GOR symptoms in the year prior to fundoplication served as the baseline. The incidence of GOR symptoms after surgery was recorded every 3 months. The results were presented as corresponding vomiting, GIB, and pneumonia indices. Vomiting index was defined as the number of vomiting episodes per patient per duration of observation. For example, if a patient had 50 episodes of vomiting during the first postoperative year, the vomiting index for that patient 1 year after surgery was 50. The GIB and pneumonia indices were calculated in the same way. These data were compared with the preoperative and postoperative symptom indices of a subgroup of patients prescribed PPIs preoperatively. Body weight was recorded each month following surgery and the gastrostomies were reviewed monthly for the presence of inflammation, erosion, and granuloma. The use of feeding aids (Foley catheter, gastrostomy tube, or gastrostomy button) was also recorded. All data, including symptom indices, recurrence rate, body weight, surgical complications, and number of deaths were censored in December 2004.

Statistical analysis

The preoperative and postoperative RI based on 24-hour oesophageal pH monitoring were compared using the Wilcoxon's signed rank test. The body weight at baseline and at the end of the follow-up was compared using Student's *t* test. The preoperative and postoperative GOR symptoms were compared by Friedman's test. The preoperative and postoperative GOR symptoms in the subgroup prescribed PPIs preoperatively were analysed by Wilcoxon's signed rank test. Survival analysis was performed to determine the time to relapse of GOR. Log-rank test was used to examine the difference in recurrence rate between patients who underwent open versus laparoscopic surgery.

Results

A total of 20 children with a mean age of 8.5 years (standard deviation [SD], 3.5 years; range, 3.6-14.4 years) at surgery were recruited. The median duration of postoperative observation was 3.5 years (range, 1.3-5.7 years). Demographic data including the aetiology of mental retardation, type of cerebral palsy, preoperative antireflux treatment, and outcome are shown in Table 1.

24-Hour oesophageal monitoring

The preoperative median RI of patients was 5.7% (range, 0-22.6%), median longest reflux was 12.1 (range, 0-90.6) minutes, and median episodes of reflux longer than 5 minutes was 4 (range, 0-35). Postoperatively the median RI was 0.15% (range, 0-13.6%), the median longest duration of reflux was 1.15 (range, 0-48.2) minutes, and the median number of reflux episodes longer than 5 minutes was 0.5 (range 0-8). The median RI was significantly reduced after surgery (Wilcoxon's signed rank test, P=0.009).

Type of cerebral palsy	Epilepsy	Scoliosis	Preoperative antireflux medication (duration [days])*	Morbidity	Mortality
Mixed	No	No	Sucralfate (549)	Nil	Death
Mixed	No	No	H_2 blocker (59)	Dumping syndrome	Survival
Spastic	Yes	Yes	PPI (72)	Recurrence of GOR†	Death
Spastic	Yes	No	H_2 blocker (214)	Nil	Survival
Spastic	No	No	PPI (136)	Nil	Survival
Spastic	No	Yes	H_2 blocker (371)	Recurrence of GOR	Survival
Mixed	No	Yes	Prokinetics (864)	Intestinal obstruction	Survival
Spastic	Yes	No	Prokinetics (488)	Nil	Survival
Spastic	Yes	Yes	PPI (522)	Nil	Survival
Mixed	Yes	Yes	PPI (351)	Nil	Survival
Hypotonic	Yes	Yes	H_2 blocker (499)	Nil	Survival
Spastic	Yes	Yes	PPI (71)	Recurrence of GOR	Survival
Spastic	Yes	No	H_2 blocker (398)	Nil	Survival
Spastic	Yes	No	PPI (289)	Recurrence of GOR	Survival
Dystonic	Yes	Yes	PPI (51)	Nil	Death
Spastic	Yes	No	PPI (272)	Recurrence of GOR	Death
Mixed	Yes	No	H_2 blocker (363)	Nil	Survival
Spastic	Yes	Yes	H_2 blocker (282)	Nil	Survival
Spastic	Yes	No	H_2 blocker (375)	Nil	Survival
Spastic	Yes	No	PPI (399)	Recurrence of GOR	Survival

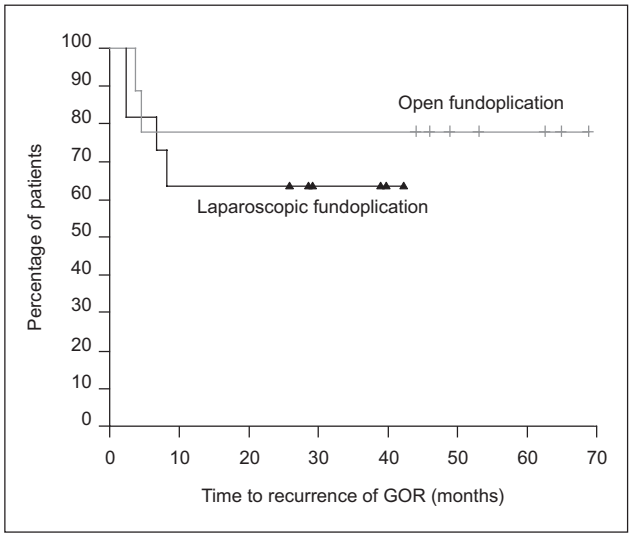

Fig. Time to recurrence of gastroesophageal reflux (GOR) after open and closed Nissen operations

Recurrence of gastroesophageal reflux

Six patients had recurrent GOR postoperatively—two underwent open Nissen fundoplication and four laparoscopic fundoplication. For the two patients who underwent open Nissen fundoplication, GOR symptoms recurred at 3 and 4 months (Fig)—one patient had recurrent vomiting and 24-hour oesophageal pH study confirmed acid reflux relieved by H_2 blocker; the second patient developed recurrent vomiting and GIB after fundoplication; endoscopy showed oesophagitis and she was prescribed a PPI. Vomiting continued but there were no further episodes of GIB. For the four patients who underwent laparoscopic fundoplication, two had recurrent vomiting at 2 months and one at 8 months after surgery. One patient had persistent respiratory symptoms. In the latter, postoperative 24-hour oesophageal pH monitoring revealed excessive acid reflux. All four patients responded to acid suppression using H_2 blocker or PPI.

The overall recurrence rate was 30% (6/20). All recurrence of GOR was noted within the first year after the operation. The recurrence rate was 22% and 36% following open Nissen fundoplication and laparoscopic fundoplication, respectively, which was a non-significant difference (P=0.52, log-rank test).

Quantitative measurement of gastroesophageal reflux symptoms

The median preoperative vomiting index of the patients was 63 (range, 5-127) per year while the median postoperative vomiting indices at the first, second, third, and fourth years were 7.5 (0-40), 5.5 (0-128), 0 (0-106), and 0 (0-41), respectively. The median preoperative GIB index was 1 (0-59) per year, and the corresponding indices for the first, second, third, and fourth year were 0.0 (0-4), 0 (0-1), 0 (0-2), and 0 (0-1), respectively. The median preoperative pneumonia index was 1 (1-3) per year, and postoperatively for the first, second, third, and fourth year the respective indices were 0.5 (0-3), 0 (0-4), 0 (0-3), and 0 (0-3). Friedman's test showed there were significant differences in vomiting index (P<0.001) and GIB index (P=0.001) at baseline and after surgery and the effects were sustained over 4 years post-surgery. Surgery did not significantly affect the pneumonia index (P=0.973).

Table 2. Vomiting, gastro-intestinal bleeding (GIB), and pneumonia indices in nine patients who received a proton pump inhibitor (PPI) before surgery and the first year after fundoplication*

	Median duration (days)	Median vomiting index (No. of episodes/day)	Median GIB index (No. of episodes/day)	Median pneumonia index (No. of episodes/day)
During PPI treatment	183 (51-399)	0.21 (0-0.43)	0.05 (0-0.1)	0 (0.01)
After surgery	365	0.04 (0-0.1)	0 (0-0.01)	0 (0-0.005)
P value†	-	0.008	0.05	0.176

* Range is shown in brackets
† Wilcoxon's signed rank test

Table 3. Morbidity and mortality following Nissen operations (fundoplication and gastrostomy)

	Open surgery (No. of patients with the event/Total No. of patients having the procedure)	Laparoscopic surgery (No. of patients with the event/Total No. of patients having the procedure)
Recurrence of gastroesophageal reflux	2/9	4/11
Mortality (years after surgery)	2/9 (4.4, 4.5)	2/11 (1.9, 5.0)
Intestinal obstruction	1/9	0/11
Dumping syndrome	1/9	0/9

Comparison of gastroesophageal reflux symptoms in patients prescribed proton pump inhibitors and the year after surgery

Nine patients were prescribed PPIs with a median period of 183 days (range, 51-399 days) before fundoplication. The median vomiting index, GIB index, and pneumonia index per day during PPI treatment and 1 year after surgery are shown in Table 2. There were significant reductions in the vomiting (P=0.008) and GIB (P=0.05) indices after surgery but not in the pneumonia index (P=0.176; Wilcoxon's signed rank test) [Table 2].

Body weight

The mean body weight was 17.4 (SD, 4.7) kg before fundoplication and 22.8 (SD, 4.4) kg (P=0.0005, Student's *t* test) at the median follow-up of 3.5 years.

Postoperative complications

Early complications (within 1 week of fundoplication)

In one patient, a pneumothorax was diagnosed after laparoscopic fundoplication and resolved following insertion of a chest drain. Stoma ulcers occurred in six patients in the first week following laparoscopic fundoplication. Early stoma complications were less common in patients who underwent open Nissen fundoplication; two developed stoma ulcers and infection 7 days postoperatively and one had cellulitis over the stoma.

Late complications (more than 1 week following fundoplication)

Air bloating and diarrhoea for 2 months following open Nissen fundoplication were reported by one patient. Symptoms were attributed to dumping syndrome and resolved after introduction of a fibre-containing formula. One patient developed intestinal obstruction 10 months following open Nissen fundoplication that resolved with conservative management. Neither dumping syndrome nor intestinal obstruction was noted in patients who underwent laparoscopic fundoplication.

Mortality

Two patients in each group died (Table 3). In the Nissen group, one had a known history of bronchiectasis with frequent pneumonia, though postoperative 24-hour oesophageal monitoring revealed no acid reflux but eventually that patient died of respiratory failure. Another had recurrent vomiting post-surgery and postoperative 24-hour oesophageal pH study showed an RI of 6%. Her reflux symptoms resolved after addition of an H_2 blocker. She died of a chest infection and severe obstructive sleep apnoea. Among patients who underwent laparoscopic fundoplication, one died 1.9 years after surgery. She had a history of recurrent severe asthma and pneumonia requiring intensive care treatment 2 to 6 times per year. Her GOR symptoms (recurrent vomiting and GIB) responded to surgical treatment and her postoperative 24-hour oesophageal pH study was normal. Her asthma remained unchanged postoperatively, but eventually died from pneumonia and status asthmaticus. The other patient with bronchiectasis was free of GOR symptoms and postoperative 24-hour oesophageal pH study was normal but died 5.0 years after fundoplication due to pneumonia and respiratory failure.

In this study, 20 severely NI children with GOR symptoms underwent fundoplication and gastrostomy between 1999 and 2004. Postoperatively, GOR symptoms and 24-hour oesophageal pH findings improved and the patients gained weight. In the nine patients prescribed PPIs preoperatively, a significant improvement in postoperative vomiting and GIB was observed. Fundoplication and gastrostomy appeared to have no effect on the incidence of pneumonia. Six patients had recurrent GOR within 1 year

of fundoplication, and all responded to medical treatment. Four patients died 1.9 to 5.0 years after the surgery. All deaths were attributed to underlying lung disease and not related to the surgery. Mild stoma complications were common in all patients.

Discussion

This is the first report of the results of fundoplication and gastrostomy in Chinese children with severe neurological impairment and GOR. The recurrence rate in our study was 30%. This compares favourably with the study by Martinez et al[6] since we defined recurrence of GOR objectively and excessive acid reflux had to be confirmed by 24-hour oesophageal pH study. In Martinez et al's study,[6] subjective symptoms (pain and irritability) in addition to pneumonia and vomiting were regarded as indicative of GOR. In the present study, pain and irritability were not considered symptoms of GOR. This may explain why 71% of patients in Martinez et al's study[6] reported recurrent GOR though only 25% could be documented by objective investigations. In the report by van der Zee et al,[7] of 28 children with psychomotor retardation who underwent laparoscopic Thal fundoplication, the results were comparable to ours. Twenty-three patients were free of symptoms after fundoplication and seven had pathological reflux (according to pH studies). One patient had oesophagitis but the pH studies were normal. The recurrence rate was 28.5%.

The prevalence of co-morbidities, such as spasticity, epilepsy, and scoliosis was high in our patients (Table 1). These factors may explain why they were prone to recurrent GOR after fundoplication.[11] The antireflux effect of Nissen fundoplication was initially related to the structural alteration that increases the tone of the lower oesophageal sphincter (LOS), lengthens the intra-abdominal oesophagus, and tightens the crura.[12] It was proposed that fundoplication could result in decreased transient LOS relaxation by decreasing the fundic volume and causing fundal denervation.[12] Kawahara et al[13] studied the mechanism of operative failure in NI children. Wrap herniation, wrap slippage down to the stomach, and partial wrap disruption were identified. Manometry studies revealed that transient relaxation of LOS was the predominant mechanism of recurrent GOR.[13] The cause of operative failure was not sought in our patients. Five of six patients who had recurrence had been prescribed PPIs before fundoplication and had persistent GOR symptoms that warranted fundoplication. Both the recurrent GOR symptoms and RI reduced further after treatment with PPI. The incidence of chest infection in our group of patients did not decrease after fundoplication. Most patients in our study already had irreversible chronic respiratory disease due to lung injury secondary to aspiration pneumonia. Moreover, they were older than those reported by others,[5,14] most of whose patients were less than a year old.

The efficacy of fundoplication in severely NI children has been doubted.[11,12] Morbidity, mortality, and recurrence rates are higher than those reported in NN children. Long-term use of PPIs has been advocated.[11,15] In our experience, PPI use improved GOR in the short term.[9] Our pilot study[9] suggested that they might effectively reduce GOR in severely NI children. The study was then extended to 15 children with positive GOR symptoms, all of whom received PPIs for 1 year. Eight experienced a 50% reduction in GOR symptoms but the overall results did not attain statistical significance (unpublished data). A subgroup of patients in our study was prescribed PPIs preoperatively and experienced significantly less vomiting and GIBs after fundoplication.

The 5-year 75% survival in our unit (unpublished data) did not appear to be prolonged by fundoplication and gastrostomy. As the mean age of our patients was 8.5 years, most already had bronchiectasis and continued to have had frequent episodes of postoperative pneumonia and mortality therefore remained high. Nonetheless quality of life was significantly improved as a result of less vomiting and fewer episodes of GIB.

In this study on children with severe NI children and GOR unresponsive to medical treatment, the Nissen operation (open or closed fundoplication and gastrostomy) reduced vomiting and GIB, but not pneumonia.

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