

Influence of percutaneous endoscopic gastrostomy on gastro-oesophageal reflux evaluated by multiple intraluminal impedance in children with neurological impairment

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ABBREVIATIONS

GOR	Gastro-oesophageal reflux
GORD	Gastro-oesophageal reflux disease
MII/pH	Multiple intraluminal impedance
PEG	Percutaneous endoscopic gastrostomy

AIM The aim of the study was to estimate the influence of percutaneous endoscopic gastrostomy (PEG) placement on gastro-oesophageal reflux (GOR) by using multiple intraluminal impedance (MII/pH) measurements in children with neurological impairments.

METHOD Fifteen children with neurological impairments (cerebral palsy, $n=10$; cerebroido-lipofuscinosis, $n=2$; Aicardi syndrome, $n=1$; and secondary encephalopathy, $n=2$) were investigated (interquartile range [IQR] 6y 4mo–14y 8mo; median age 10y 2mo; eight male, seven female). Individuals with nutritional disorders that could not be corrected by physiological means or with swallowing disorders that either caused chronic respiratory symptoms or prevented food intake were included in the study. The exclusion criteria included previous major abdominal surgery and a lack of consent for PEG. Participants underwent MII/pH for a 24-hour period and had an oesophagogastroduodenoscopy before PEG placement, which was repeated 6 to 8 months later.

RESULTS At baseline, GOR was detected in 6 of the 15 participants, and the second MII/pH session revealed GOR in 2 of the 15 children. Differences between quantitative GOR indices obtained before and after PEG were not statistically significant, except for the proportion of the acidic/weakly acidic reflux events – among all participants in the first examination, 159 reflux episodes were acidic and 244 were weakly acidic, while in the follow-up recordings the proportion was inverted (244 acidic, 136 weakly acidic; $\chi^2=47.0$; $p<0.001$). Baseline endoscopy did not reveal any macroscopic changes in any of the examined individuals, but the follow-up examination revealed oesophagitis in two participants. The median body weight gain after 6 months as 22.0% (IQR 14.4–29.2%). All participants tolerated PEG feeding well, regardless of MII/pH results.

INTERPRETATION Identification of GOR based on MII/pH in children with neurological impairments does not exclude a good clinical response to PEG feeding.

Children with neurological impairments are often malnourished, which could have an impact on the progression of their primary disease. Enteral nutrition is an approach recommended for improving the nutritional status of individuals in this group;¹ however, individuals with neurological impairments are also believed to be at higher risk of developing gastro-oesophageal reflux (GOR) and its complications (gastro-oesophageal reflux disease [GORD]). A high frequency of GOR in neurologically impaired children (15–78%, depending on the source) has led some centres to endorse fundoplication and percutaneous endoscopic gastrostomy (PEG) as a routine treatment.^{2,3} However, because of the different methods of GOR evaluation and the bioethical constraints against carrying out randomized controlled studies on the GOR–PEG–fundoplication relationship, data published so

far are controversial and no commonly accepted evidence-based standards have been proposed.

Many different and centre-specific methods are used in diagnosing GOR (pH-metry, bilimetry, ultrasound, scintigraphy, radiology tests, endoscopy) in individuals with neurological impairments. Moreover, as emphasized in the latest (2009) guidelines for diagnosing and treating GOR/GORD, issued by the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition and the European Society for Paediatric Gastroenterology, Hepatology and Nutrition, both conditions should be precisely defined and differentiated. This is especially critical in establishing reflux in children.⁴

Multichannel intraluminal impedance (MII/pH) is currently recognized as the most precise diagnostic tool for evaluating GOR. In MII/pH, a specialized catheter is used to measure

the direction and composition of the intraluminal bolus movement (reflux/swallowed food), and simultaneously to measure the pH of the intraluminal content. There are no data available, based on MII/pH, prospectively analysing the impact of gastrostomy on GOR in children with neurological impairments. Therefore, the purpose of the present study was to evaluate the occurrence of GOR in this subgroup of children (using MII/pH) before and after PEG placement.

METHOD

Study group

In this prospective study, 15 permanently neurologically disabled children (eight males; seven females) aged 4 to 16.7 years (median age 122mo; interquartile range [IQR] 77–178mo) who were hospitalized in the Allergology, Gastroenterology and Nutrition Clinic of the Medical University in Lodz and receiving home enteral nutrition from the Outpatient Department for Enteral Nutrition were evaluated. All the children subjected to the study were non-ambulatory, and 13 of 15 were on scheduled anticonvulsant therapy owing to epilepsy. The inclusion criteria for PEG were (1) nutritional disorders that cannot be corrected through physiological means; (2) swallowing disorders that prevent adequate intake of food in a physiological way; and (3) swallowing disorders that cause chronic/recurrent respiratory symptoms. The exclusion criteria included previous major abdominal surgery and lack of consent for the PEG procedure.

The study was approved by the Bioethics Committee of the Medical University of Lodz and informed consent was obtained from the individuals' parents in all cases. The clinical data of the study group are presented in Table I.

Multichannel intraluminal impedance

All individuals underwent a 24-hour MII/pH (SLEUTH Sandhill Scientific, Denver, CO, USA) evaluation before the PEG procedure and 6 to 8 months afterwards. During the baseline impedance monitoring, 10 children were fed orally and five by nasogastric tube. In all participants the same protocol for the 24-hour MII/pH measurements was used: the indi-

What this paper adds

- The first prospective evaluation of gastro-oesophageal reflux (GOR) by means of multiple intraluminal impedance (MII/pH) monitoring in neurologically impaired children undergoing PEG.
- Based on MII/pH, the overall number of reflux episodes and quantitative GOR indices did not tend to increase after PEG formation.
- The identification of GOR based on MII/pH procedure in children with neurological impairments does not exclude a good clinical response to enteral nutrition through PEG.

viduals had an empty stomach for 6 hours before the test; ZAI S61C04E catheters with the lower oesophageal sphincter location option (Air Flow Sphincter Locator; Sandhill Scientific, Denver, CO, USA) were used in individuals more than 12 years of age and/or more than 150cm in height – in the individuals 12 years old or less and/or with a height between 75 and 150cm, ZPN S61C01E catheters; Sandhill Scientific, Denver, CO, USA (following the manufacturer's recommended radiographic control of catheter-tip position) were used – and before each test the catheters underwent a calibration procedure; a 22-hour period was the minimum recording time of the MII/pH; the traces were analysed using BioView 5.3.4 software (Sandhill Scientific Inc. Denver, CO, USA), and all the recordings were verified manually.

Interpretation of the MII/pH data was based on the *Porto Consensus on Detection and Definitions of GOR*, with modifications published by Zerbib et al.^{5,6} Acid reflux was defined as a reduction of the starting value of pH >4 to pH <4 during the presence of the acid bolus/refluxate in the oesophagus. Reflux events with intraluminal pH in the range of 4 to 6.5 were classified as weakly acidic reflux events. Reflux events with an intraluminal pH >6.5 were considered as weakly alkaline reflux events. The acid reflux index (total oesophageal acid exposure) was defined as the percentage of the recording time with pH <4 (the normal values are up to 12% in the first year of life and up to 6% thereafter, as accepted by the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition guidelines).⁷

An MII/pH result was considered to be positive if the number of reflux events per 24-hour monitoring period was ≥75 and/or the number of acidic events was ≥50 and/or the number of the weakly acidic reflux events was ≥33, and/or the number of weakly alkaline events was ≥15.^{5,6}

The symptom index was defined as the percentage of reflux events accompanied by clinical symptoms such as choking, regurgitation, and vomiting in relation to the total number of reflux events (based on records and diary completed by the caregiver/nursing staff) – a value ≥50% was considered as a positive.⁵

Oesophagogastroduodenoscopy

All individuals also underwent oesophagogastroduodenoscopy to evaluate gross mucosa appearance (Hetzl–Dent scale). The first procedure was carried out simultaneously with PEG placement and the second one after 6 to 8 months of PEG enteral nutrition (usually the day after the MII/pH assessment, according to the study protocol). In every case, the endoscopic examinations were performed under general anaesthesia.

Table I: Characteristics of individuals who qualified for enteral nutrition and PEG

Median age 122mo (IQR 77–178mo)
Eight males, seven females
Clinical diagnosis
Cerebral palsy (<i>n</i> =10)
Ceroidlipofuscinosis (<i>n</i> =2)
Encephalopathy following brain tumour surgery (<i>n</i> =1)
Encephalopathy following congenital toxoplasmosis (<i>n</i> =1)
Aicardi syndrome (<i>n</i> =1)
Indications for enteral nutrition
Disorders of nutritional status
Severe undernutrition (BMI for age z-score <−3; <i>n</i> =8)
Undernutrition (BMI for age z-score <−2 <−3; <i>n</i> =7)
Dysphagia
Inadequate oral intake (<i>n</i> =13)
Respiratory tract complications (<i>n</i> =2)

PEG, percutaneous endoscopic gastrostomy; BMI, body mass index.

All individuals received home enteral nutrition. The general condition (including general appearance, feeding tolerance – volume of formula, stool frequency and consistency, regurgitations/ emesis, respiratory tract infections – physical evaluation including the appearance of the skin in the PEG region) and nutritional status (weight and height measurements) of each participant were evaluated every 4 weeks during the period of enteral nutrition, and daily caloric intake and gain in body weight after 6 months were calculated. The incidence of ambulatory-treated respiratory tract infections was estimated based on data provided by parents/caregivers.

In a single participant with positive impedance results, a proton pump inhibitor (omeprazole) was prescribed (the therapy was stopped 7d before the MII/pH recording so that all the MII/pH measurements were performed with a 7d washout period for proton pump inhibitors). An anticonvulsant treatment regimen was sustained during the impedance monitoring.

Statistical analysis

Continuous data are presented as median and interquartile range (25–75%) and nominal data are given as *n* and percentage. Comparisons of continuous variables were performed using the Wilcoxon's matched-pairs signed-rank test. Nominal variables were compared using the McNemar χ^2 test for paired observations and the Pearson χ^2 test for unpaired observations. A *p* value of 0.05 was considered as the threshold of statistical significance.

RESULTS

The average time between PEG placement and the follow-up tests (MII/pH and gastroscopy) was 7.35 months (SD 0.71). There was no statistically significant difference between the median duration of MII/pH monitoring recorded before and after PEG (22h 21min [IQR 22h 06min–24h 37min] vs 23h 50min [IQR 23h 20min–24h 55min]; $z=1.04$; $p=0.300$). GOR (as determined by MII/pH) was present in 6 of 15 (40.0%) participants before placing the PEG. After PEG placement, MII/pH was positive in two of the six individuals (13.3%) and negative in four individuals (26.7%; $\chi^2=2.25$; $p=0.134$). Acid reflux was present in 2 (13.3%) of the 15 children before PEG placement but was not found in any after PEG formation. Weakly acidic reflux was found in 4 (26.7%) of the 15 children before PEG placement; after PEG placement, weakly acidic

reflux was noted in two different individuals, but was absent in all four individuals with reflux at baseline ($\chi^2=0.17$; $p=0.683$).

Quantitative assessment by MII/pH showed that (1) overall, in the examined group of individuals, 406 reflux events were recorded before forming the PEG (316 in orally fed and 90 in nasogastric tube-fed children) compared with 369 in the follow-up investigation; and (2) overall, the average numbers of all reflux events (acidic, weakly acidic, and weakly alkaline) before and after PEG placement were similar (Table II). Individual median percentage of acidic reflux events did not differ between baseline and follow-up (50.5% [IQR 7.1–87.5%] vs 65.9% [IQR 42.9–90.1%]; $z=0.66$; $p=0.510$). Similarly, the individual percentage of weakly acidic reflux episodes did not show statistically significant differences between the baseline (44.1% [IQR 12.5–92.9%]) and follow-up examinations (30.0% [IQR 2.9–51.4%]; $z=0.60$; $p=0.551$). The individual variability of the number and type of reflux episodes is depicted in Figure 1.

In the independent comparison of the number of acidic and weakly acidic reflux episodes, the difference between baseline and follow-up frequency was statistically significant in each case. In the first examination, 159 reflux episodes were acidic and 244 were weakly acidic, while in the follow-up examination the proportion was inverted, with 244 episodes being acidic and 136 weakly acidic ($\chi^2=47.0$; $p<0.001$). In one participant, a positive symptom index was obtained both before and after PEG.

Endoscopic evaluation of the oesophageal mucosa during assessment of qualification for enteral nutrition did not reveal any macroscopic changes in any of the examined individuals; however, in three individuals histopathological features of mild chronic oesophagitis were found, including mild diffuse lymphocytic infiltration of the lamina propria.

The follow-up endoscopy revealed macroscopic signs of oesophagitis in two individuals (grade 4 in one and grade 2 in one, based on the Hetzel–Dent scale), although both of them had negative MII/pH results. In one endoscopy-positive child presenting with high-grade oesophagitis, the route of feeding was changed from PEG to the percutaneous endoscopic gastrojejunostomy. In the 13 children the macroscopic appearance of the oesophageal mucosa was normal. However, in five of these 13 individuals, histological features of mild oesophagitis were observed while the results of MII/pH monitoring were negative. Two individuals with positive MII/pH results

Table II: GOR parameters determined by MII/pH before and after PEG placement

Indices of MII/pH	Before PEG placement, median (range)	After PEG placement, median (range)	Wilcoxon's test (z-score; <i>p</i> value)
<i>N</i> of reflux events	20 (3–51)	20 (7–35)	0.25; 0.807
<i>N</i> of acidic events	2 (1–8)	13 (5–29)	1.14; 0.256
<i>N</i> of weakly acidic events	2 (1–33)	4 (1–15)	0.42; 0.675
<i>N</i> of weakly alkaline events	0 (0–0)	0 (0–1)	1.53; 0.128
Total reflux per cent time bolus exposure	1.4 (0.9–3.0)	1.1 (0.3–1.6)	1.73; 0.084
Acid reflux index	0.10 (0.0–7.7)	5.0 (1.1–6.4)	0.94; 0.346

GOR, gastro-oesophageal reflux; MII/pH, multiple intraluminal impedance; PEG, percutaneous endoscopic gastrostomy.

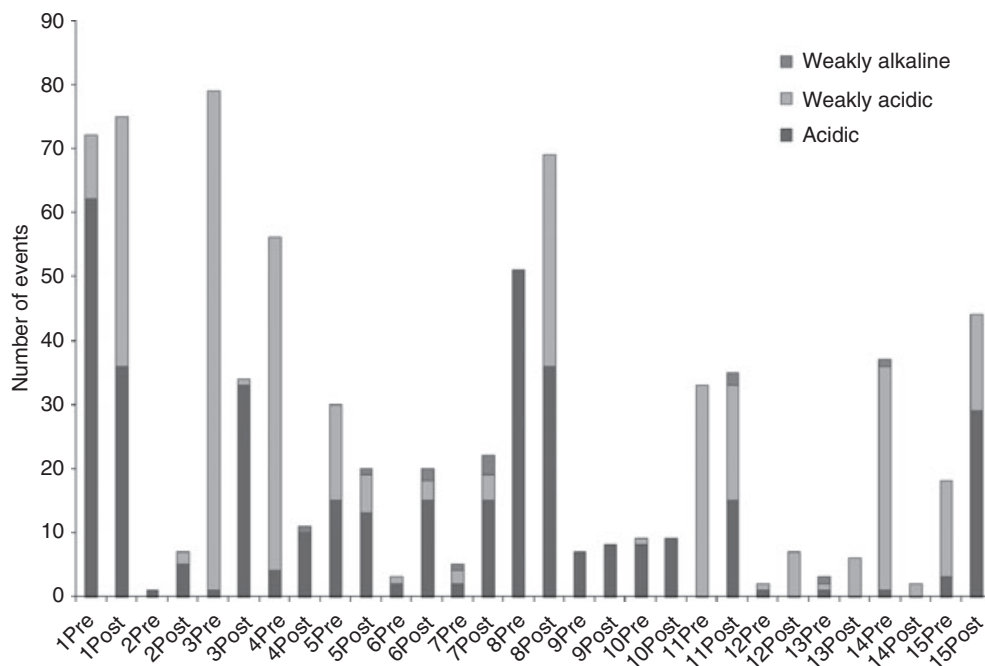


Figure 1: Individual variability of the number and type of reflux episodes determined by multiple intraluminal impedance.

(weakly acidic reflux events) showed neither macroscopic nor microscopic abnormalities of the oesophageal mucosa. All individuals tolerated enteral nutrition through the PEG well (feeding tolerance assessment was based on data reported by parents/caregivers and physical examination performed on office visits, as described in the Method section), although the impedance results were positive in some of them.

A standard caloric diet (1kcal/mL) was used in 12 individuals (Nutrini in two children and Nutrison Standard in 10 individuals; N.V. Nutricia, Zoetemeer, the Netherlands); a high-calorie formula was given to 2 (Nutrison Energy, 1.5kcal/mL); and one individual, who presented with constipation, was given a fibre-enriched formula (Nutrison Multifibre) in addition to pharmacological treatment. Median caloric intake in the examined group amounted to 62.5 (IQR 52.9–76.1) kcal/kg/day (range 32–112kcal/kg/d). Median body weight gain after 6 months was 22.0% (IQR 14.4–29.2%). According to the statements of parents/caregivers, the post-PEG rate of ambulatory-treated respiratory tract infections was decreased or constant in all investigated children compared with the preceding 6 months. Numerical analysis of the incidence of respiratory tract infections was not performed.

DISCUSSION

The first evidence-based recommendations in Europe for helping to assess whether individuals qualified for enteral nutrition were published in 2006 by the European Society for Clinical Nutrition and Metabolism.¹ In our study, the main indication for enteral nutrition in children with neurological impairments was a swallowing disorder complicated by severe undernutrition. It should be stressed that, in individuals with

neurological impairments, dysphagia results mainly from disorders of the pharyngeal phase of swallowing; furthermore, delayed gastric emptying, posture during feeding, organoaxial gastric volvulus, and use of medications influencing gastrointestinal motility may be relevant.^{8–11} It is thought that formation of the PEG changes in some way the mechanical functioning of the gastrointestinal tract and contributes to the failure of the gastro-oesophageal junction, and that fundoplication surgery counteracts this effect. However, the number of antireflux surgical procedures performed recently among the general population worldwide has decreased (especially in adults),⁴ which is probably a consequence of unsatisfactory outcomes. A multicentre trial conducted by Spechler et al.¹² showed that, 7 years after antireflux surgery, 62% of individuals were taking proton pump inhibitor medication regularly owing to persistent GOR symptoms. Wijnhoven et al.¹³ reported that 37% of their participants needed one or more antisecretory drugs after antireflux surgery (5y follow-up), including 83% who restarted medication 2 years 6 months after the surgery. Similar conclusions, indicating only partially successful surgical GORD treatment, were reported by Broeders et al.¹⁴ Finally, the 2010 European Society for Paediatric Gastroenterology, Hepatology and Nutrition Committee on Nutrition comment *Practical Approach to Paediatric Enteral Nutrition* emphasizes the difficulties in determining optimal handling of individuals with neurological impairments who require enteral nutrition in terms of the decision on fundoplication.¹⁵

There is wide variation in GOR frequency in children with neurological impairments (15–78%) reported by particular centres, which stems from the use of different inclusion

criteria, variability of assessment methods (pH-metry, radiology tests, endoscopy, scintigraphy), and also interpretation of the data provided by the above-mentioned procedures.^{3,7}

Studies evaluating the impact of PEG on GOR occurrence in children are rather scarce and based solely on the results of pH-metry. In the study of Razeghi et al.,¹⁶ the percentage of individuals with positive pH-metry results did not significantly differ before and after PEG placement (22.1% vs 25%). The need for future trials directly addressing the GOR-PEG interplay in individuals with neurological impairments was recently highlighted by Fortunato et al.¹⁷ following the retrospective analysis of preoperative clinical factors and PEG outcome in 760 children and young adults (322 individuals with neurological impairments).

Our results are based on research that prospectively monitored GOR features using MII/pH and clinically evaluated the children with neurological impairments under conditions resembling their real-life situations (diet, medications). Overall, in the examined group of individuals, the number of reflux events recorded before and after PEG was similar (406 vs 369). Moreover, pathological MII/pH results were found initially in 40% of the individuals and decreased to 13.3% ($p=0.134$) after PEG, which does not support the hypothesis that gastrostomy contributes to the augmentation of GOR.

The interpretation of the MII/pH results includes numerical analysis of the acidic, weakly acidic, and alkaline/weakly alkaline reflux events. We found that, although the overall number of reflux episodes did not tend to increase after PEG formation, there was a shift in the reflux composition – the proportion of acid reflux events to the total number of refluxes was statistically higher in the post-PEG MII/pH recordings than in the baseline ones (244 vs 159 acidic reflux; $\chi^2=47.0$; $p<0.001$), whereas the weakly acidic reflux events were less frequent ($p<0.001$; Table II). These observations, originating from our research, deserve further exploration and raise the question of whether the higher proportion of acid refluxes, even if the MII/pH numerical results remain within the ‘normal’ range, may be potentially harmful to the oesophageal mucosa in individuals who had undergone the PEG procedure. One can hypothesize that the shift in the pH of retrograde bolus from weakly acid towards acid might be explained by the improved nutritional status of children with neurological impairments, resulting in more adequate gastric secretion. The associations between severe undernutrition and decreased maximal gastric acid output and improvement following nutritional support were demonstrated in both experimental and clinical studies.^{18,19} Alternatively, some authors postulate the presence of the unbuffered highly acidic gastric zone above the ingested food, called an *acid pocket*, as the possible cause of GOR symptoms in PEG-fed individuals.²⁰

In our research, endoscopic features of oesophagitis were found in two of the 15 individuals (and the histological features of mild oesophagitis were described in five of the 15 participants) within 6 to 8 months of PEG/percutaneous endoscopic gastrojejunostomy feeding, but only one of them demonstrated occasional clinical symptoms such as vomiting. Thus, the incidence of oesophagitis was not higher with PEG

than with the normal route of feeding. Moreover, the results of the impedance analysis (which were negative) did not contribute to establishing a diagnosis of GORD. Although in our series of individuals the incidence of reflux oesophagitis was rare, it is important to emphasize that GORD in individuals with neurological impairments often remains silent, even in the presence of severe oesophageal lesions; thus, endoscopy-based follow-up should be considered as reasonable and ethically justified. On the other hand, one should note that, according to the above-mentioned European Society for Paediatric Gastroenterology, Hepatology and Nutrition guidelines,⁴ histopathological changes in the oesophageal mucosa are not synonymous with a diagnosis of reflux oesophagitis. Similar changes may be present in a number of different oesophageal diseases (e.g. Crohn disease, eosinophilic oesophagitis, fungal infections, and viral infections such as herpes simplex virus and cytomegalovirus); therefore, careful differential diagnosis should always be performed (the above-mentioned pathologies were ruled out in our two individuals with endoscopic signs of oesophagitis).

To our knowledge, our study is the first prospective evaluation of GOR by means of intraoesophageal MII/pH monitoring in children with neurological disabilities undergoing PEG.

However, authors from the Boston Medical School²¹ recently reported results of a retrospective analysis of 34 individuals (aged 2mo–22y) who underwent a fundoplication procedure and had impedance measurements taken before the surgery (the average time from the MII/pH to fundoplication was 4.9mo [SD 3.9]). The goal of that research was to determine the prognosis of the fundoplication surgery by using MII/pH parameters (e.g. the number of acid reflux events, non-acid reflux events, symptom index). The study showed that no single impedance parameter predicts the effectiveness of fundoplication, which relieved the clinical symptoms of GORD in 65% of participants. Data focusing on MII/pH GOR exponents in children with neurological disabilities were also published by Del Buono et al.²² This study consisted of 16 participants (median age 23mo; no previous PEG and/or fundoplication procedure) in whom MII/pH results were analysed with respect to mode of feeding – by mouth or nasogastrically. The authors reported a trend towards more GOR events ($p=0.628$) in individuals receiving tube feeding, which was not confirmed by our findings (316 reflux episodes recorded in 10 orally fed children compared with 90 in five individuals on tube feeding); however, the sample size was too small to draw final conclusions. Interestingly, the same study reported that the number of GOR events (acid/non-acid) at baseline was nearly double that in our study (425 GOR events in 16 children, 12h MII/pH monitoring period vs 406 refluxes in 15 individuals and 23h monitoring), although the proportion of acid reflux events was similar (186/425 vs 159/406).

Our study has at least two limitations. The 6-month period of follow-up in our study may be too short to define the influence of PEG on GOR; therefore, more research is warranted. Next, the size of the sample was relatively small ($n=15$), which might influence the statistical significance of the results obtained.

Clearly, however, the fact that the children with neurological impairments tolerated the enteral nutrition well (as evidenced by weight gain, general condition, and reduced frequency of infections) through the PEG or PEG/percutaneous endoscopic gastrojejunostomy without the need to perform the fundoplication procedure is an important argument for careful assessment of qualification for surgery of the gastro-oesophageal junction in disabled individuals who require enteral nutritional support. Moreover, some data from the literature demonstrate the poor effectiveness of antireflux procedures in this specific subset of individuals. Pearl et al.²³ reported that individuals with neurodegenerative diseases require reoperation four times more often than those without central nervous system damage. Also, Goessler et al.²⁴ stated that 15% of individuals required reoperation because of the recurrence of serious reflux symptoms, regardless of the technique used to perform the surgery (Thal/Nissen fundoplication). At the same time, in children with neurological impairments who had gastrostomy alone, a subsequent fundoplication procedure was needed in 17%, as reported recently by Viswanath et al.²⁵

In summary, identification of the optimal method of handling neurologically impaired children who necessitate PEG for nutritional support will require more research. Similar to earlier investigations of this subject, our study was limited by ethical restrictions that preclude study designs that directly

compare the results of conservative treatment against the surgical option. On the other hand, our study investigated GOR features using both the most recommended technique, MII/pH monitoring, and clinical evaluation in a systematic, prospective way and in settings resembling each participant's real-life conditions.

CONCLUSIONS

Our results indicate that (1) the identification of GOR based on MII/pH procedure in neurologically impaired children does not exclude a good clinical response to enteral nutrition through the gastrostomy; (2) the clinical relevance of the shift in physiochemical parameters of GOR observed after PEG placement needs further evaluation; and (3) the choice of route of feeding and assessment of qualification for the fundoplication procedure in children with neurological impairments should be based on the complex evaluation of general condition and clinical tolerance of enteral nutrition, whereas the prognostic value of the MII/pH remains inconclusive.

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