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Randomized Control Trials

Tolerability and safety of early enteral nutrition in children after percutaneous endoscopic gastrostomy placement: A multicentre randomised controlled trial

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SUMMARY

Background & aims: We assessed the tolerability and safety of implementing early enteral nutrition in children at 3 h after percutaneous endoscopic gastrostomy (PEG) placement to establish an optimum feeding mode in paediatric patients that reduced the fasting period, the inadequate nutritional support interval, and the hospitalisation time.

Methods: Children with clinical indications for PEG placement were recruited from six medical centres in Poland to participate in the study. The patients were centrally randomised to receive the first bolus feed, which comprised a polymeric diet (1 kcal/mL), via a feeding tube at 3 h (group 1) or 8 h (group 2) after PEG placement. The pre-procedural preparation, the post-operative care, and the resumption of feeding were performed on all of the patients in accordance with the study's protocol. The primary endpoint was the number of patients who consumed a full feed, which contained their total fluid and caloric requirements, within 48 h of the first bolus feed. The secondary endpoints were the number of complications and the duration of hospitalisation after PEG placement.

Results: Of the 97 randomised patients, 49 were assigned to group 1 and 48 were assigned to group 2. There were no differences between the groups regarding feeding tolerability (81.6% vs. 91.6%), the number of complications (25.5% vs. 37.5%), or the duration of hospitalisation after PEG placement ($p > 0.05$). Full feed post PEG placement was achieved within 24–48 h in most cases (74% vs. 82%). Most of the complications were mild. Two patients in group 2 due to dislocation of the PEG were qualified for laparotomy (at 6 days post-PEG placement in one case and at 14 days post-PEG placement in the other case). One patient in group 2 died at 7 days post-PEG placement; the death was unrelated to the investigation.

Conclusions: Introducing feeding at 3 h post-PEG placement in children appears to be well tolerated. The early initiation of post-PEG feeding was not associated with an increase in the number of complications and it had no impact on the duration of hospitalisation.

Clinical trial registry: www.clinicaltrials.gov (NCT02777541; registration date: 18/05/2016).

Abbreviation: PEG, percutaneous endoscopic gastrostomy.

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1. Introduction

Percutaneous endoscopic gastrostomy (PEG) is the preferred method for providing long-term enteral nutrition in children with insufficient oral intakes [1]. Limited research has been undertaken in children in relation to the appropriate time at which enteral nutrition should be initiated post-PEG placement. Despite data from investigations into adults suggesting that PEGs can be used immediately after insertion [2] and evidence from a single trial involving children indicating that feeding can be initiated within ≤4 h of PEG insertion, most paediatric patients are fasted for at least 12 h following PEG placement.

This study aimed to reduce the fasting period, the inadequate nutritional support interval, and the hospitalisation time, and to establish an optimum standard procedure for paediatric patients who qualify for PEG insertion in Poland.

2. Materials and methods

2.1. Study design

This was a multicentre randomised controlled open-label trial. The patients were recruited from six medical centres in Poland, as follows: the Department of Gastroenterology, Hepatology and Feeding Disorders and the Department of Paediatrics, Nutrition and Metabolic Disorders at the Children's Memorial Health Institute in Warsaw, the Department of Paediatrics, Gastroenterology, Hepatology and Nutrition at the Medical University in Gdańsk, the Department of Allergology, Gastroenterology and Nutrition at the Medical University in Łódź, the Department of Paediatrics at the Medical University of Silesia in Katowice, and the Department of Paediatrics and Gastroenterology at the Area Hospital in Toruń.

2.2. Inclusion and exclusion criteria

The study's inclusion criteria were patients aged between 1 month and 18 years, patients who were indicated for PEG placement, and the receipt of informed consent to participate in the study that was signed and dated by the subject's parent/legal guardian and by the patient themselves if they were aged >16 years. The patients were excluded from the study if they had serious uncorrectable coagulation disorders, upper gastrointestinal endoscopy could not be performed, because of laryngeal or oesophageal strictures, a concomitant fundoplication was required, or if PEG placement could not be performed, because of a lack of technical ability.

2.3. Ethical considerations

All of the procedures were reviewed and approved by an independent review board (Komisja Bioetyczna IP CZD; approval number: 73/KBE/2013). The patients and their caregivers provided written informed consent before any procedure began.

2.4. Randomisation

At the baseline visit, the participants were centrally randomised (1:1) to one of two treatment groups, namely, group 1, which was the early enteral feeding group, in which feeding began at 3 h after PEG implantation, and group 2, which was the late enteral feeding group, in which feeding began at 8 h after PEG implantation. The nursing staff could not be blinded to the patients' feeding times.

2.5. Study endpoints

The study's primary endpoint was the number of patients who consumed a full feed, which contained their total fluid and calorie requirements, within 48 h of receiving the first bolus feed. The study's secondary endpoints were the number of complications and the duration of hospitalisation after PEG placement.

2.6. PEG placement and feeding

All of the subjects received one dose of augmentin (30 mg/kg) that was administered intravenously before PEG implantation. If the patient was hypersensitive to beta-lactam antibiotics, clindamycin (3–6 mg/kg) and metronidazole (10 mg/kg) were administered. All of the participants underwent primary gastrostomy button placements under general anaesthesia using the standard 'pull' technique and Flocare® PEG tubes (Nutricia Medical Devices BV, Schiphol, The Netherlands). All of the subjects received the same post-operative care as stipulated in the study's protocol.

If there were no contraindications the first feed according to the study protocol comprised a polymeric diet (1 kcal/mL) that was administered at a volume that was equivalent to 30% of the total recommended portion. If the first feed was well tolerated, the sizes of the subsequent feeds were increased by 30% of the recommended portion. Each portion was introduced through an enteral feeding pump (Flocare® Infinity; Nutricia Medical Devices BV) over 30 min, with 3 h breaks between feeds. All of the patients were infused with a 5% glucose solution that contained electrolytes through an intravenous line to maintain their fluid requirements. In some cases hydrolyzed or amino-acid formula was administered in the form of intermittent or continuos feeding modes.

2.7. Statistical analyses

An appropriate chi-squared test was used to compare the frequencies of the primary endpoint, depending on the expected numbers. The intention-to-treat analysis involved determining the proportions of the patients who achieved the primary endpoint. Regarding the analysis of the secondary endpoints, namely, the complication rates and the durations of hospitalisation, appropriate chi-squared tests were used to compare the qualitative variables and the Mann–Whitney U test was used to compare the quantitative variables.

2.8. Determination of sample size

Assuming the probability of an event in the control group of 0.6 and the probability of an event in the experimental group of 0.85, control per case subject 1, 0.8 statistical power, 0.05 alpha coefficient, the required size of each group was estimated at 50 (100 in total) with the Chi-square test.

3. Results

3.1. Patients' characteristics

Since January 2015 to December 2016 a hundred consecutive patients were qualified for PEG insertion in six medical centers in Poland. Three patients were excluded from the study. Oesophageal stricture was identified during upper gastrointestinal endoscopy in on case and PEG placement could not be performed because of a lack of technical ability in two other patients. Of the 97 patients who participated in the study, 49 were randomly assigned to group 1 and 48 were randomly assigned to group 2. Table 1 presents the

Table 1
Patients' characteristics.

	Group 1 (n = 49)	Group 2 (n = 48)
Age, months		
Mean ± SD (range)	67 ± 107 (4–215)	87 ± 157 (5–212)
Median	46.5	90
Indications for PEG insertion, n		
Dysphagia	32	24
Malnutrition	37	36
Aspiration	16	12
Increased caloric requirements	27	26
Anthropometric characteristics		
Weight, kg		
Mean ± SD (range)	13.8 ± 7.71 (4.8–44)	15.6 ± 11.8 (4.7–76)
Median	12 (n = 47)	13.4 (n = 46)
Height, cm		
Mean ± SD (range)	99.6 ± 25.2 (58–144)	103.05 ± 31.1 (57–172)
Median	92.5 (n = 46)	101 (n = 43)
Arm circumference, cm		
Mean ± SD (range)	14.8 ± 3.4 (10–26.5)	14.82 ± 3.7 (10–30)
Median	13.5 (n = 37)	14 (n = 31)
Triceps skinfold, cm		
Mean ± SD (range)	2.6 ± 2.9 (0.2–12)	1.56 ± 1.7 (0.3–8)
Median	1.35 (n = 38)	1 (n = 31)
BMI, kg/m^2		
Mean ± SD (range)	13.5 ± 3.0 (8.3–21.7)	13.7 ± 3.2 (8.4–26)
Median	13.1 (n = 45)	13.9 (n = 43)
BMI SDS, SD		
Mean ± SD (range)	−2.06 ± 1.6 (−6.22–1.82)	−1.54 ± 1.54 (−4.7–1.53)
Median	−1.83 (n = 45)	− 1.4 (n = 43)
Laboratory data		
HCT, %		
Mean ± SD (range)	37.9 ± 4.4 (29.2–49.5)	37.08 ± 3.4 (26–43.8)
Median	38 (n = 49)	37.7 (n = 48)
HGB, g/dL		
Mean ± SD (range)	12.5 ± 1.4 (9.4–16.3)	12.4 ± 1.2 (8.9–14.5)
Median	12.6 (n = 49)	12.7 (n = 48)
RBC, × 10^6/μL		
Mean ± SD (range)	4.5 ± 0.5 (3.4–5.9)	4.4 ± 0.4 (3.08–5)
Median	4.5 (n = 49)	4.4 (n = 48)
Albumin, mg/dL		
Mean ± SD (range)	42.3 ± 4.7 (27.5–52)	41.6 ± 4.6 (28–50)
Median	43 (n = 47)	42 (n = 48)
Total cholesterol, mg/dL		
Mean ± SD (range)	152.4 ± 32.6 (87–267)	154.2 ± 44.2 (99–323)
Median	146 (n = 49)	144 (n = 47)
Na, mmol/L		
Mean ± SD (range)	138 ± 3.5 (127–145)	139.27 ± 4.4 (124–154)
Median	138 (n = 46)	139.8 (n = 48)
K, mmol/L		
Mean ± SD (range)	4.4 ± 0.5 (3.3–5.6)	4.6 ± 0.5 (3.6–6)
Median	4.3 (n = 46)	4.6 (n = 47)
Ca, mmol/L		
Mean ± SD (range)	2.26 ± 0.43 (0.94–2.67)	2.24 ± 0.48 (1.1–3.3)
Median	2.4 (n = 46)	2.37 (n = 47)
Fe, mmol/L		
Mean ± SD (range)	62.52 ± 37 (13.8–148)	69.2 ± 47.1 (37–190)
Median	60 (n = 46)	59 (n = 44)
Mg, mmol/L		
Mean ± SD (range)	1.08 ± 0.4 (0.49–2.6)	1.16 ± 0.5 (0.74–2)
Median	0.9 (n = 45)	0.92 (n = 44)
D-25(OH)D3, ng/mL		
Mean ± SD (range)	32.6 ± 25.3 (4.9–143)	31.1 ± 20.8 (7–102)
Median	27 (n = 45)	25.7 (n = 40)

PEG = percutaneous endoscopic gastrostomy; BMI = body mass index; SD = standard deviation; BMI SDS = body mass index standard deviation score; HCT = hematocrit; HGB = haemoglobin; RBC = red blood cell; Na = sodium; K = potassium; Ca = calcium; Fe = iron; Mg = magnesium; D-25(OH)D3 = serum 25-hydroxyvitamin D.

patients' characteristics. Weight and height used to derive BMI as kg/m2. BMI was adjusted for age and gender providing BMI SDS using Polish 1999 Growth Reference Data.

3.2. Tolerability of early feeding

In groups 1 and 2, 81.6% and 91.6% of the patients, respectively, achieved their maximum calorie and fluid intakes within 48 h of the first feed being administered (Table 2). There was no statistically significant difference between the groups with respect to feeding tolerability ($p = 0.147$) and the time to get to a full feed ($p > 0.05$) (Table 3).

3.3. Safety of early feeding

Complications occurred in 13 patients in group 1 (25.5%) and in 18 patients (37.5%) in group 2. Most of the complications were mild see (Table 4).

There were no statistically significant differences between the groups with respect to the number of complications ($p = 0.118$). Two patients in group 2 qualified for laparotomies, because the PEGs became dislodged, of which one was dislodged at 6 days post-PEG placement, and the other was dislodged at 14 days post-PEG placement. Surgical interventions were not required for the patient who had bleeding from the gastrointestinal tract or for the patient who had a gastrointestinal perforation. In the case who had the gastrointestinal perforation, enteral feeding began after 10 days of observation. One patient in group 2 died at 7 days post-PEG placement; this death was not related to the investigation. The groups did not differ with respect to the length of the hospital stay ($p > 0.05$). The median length of the hospital stay was 5 days for group 1 (n = 46) and group 2 (n = 48).

4. Discussion

Initiating feeding as early as possible after PEG placement enables many patients to avoid acute care hospital stays, unnecessarily prolonged intravenous access and medication courses, and to

Table 2
Time needed to cover total individual caloric and fluid requirement.

	Group 1	Group 2
Time to get to a full feed, n (%)		
Within 12 h	4 (8%)	5 (10%)
Within 24 h	20 (41%)	24 (50%)
Within 48 h	40 (82%)	44 (92%)
More than 48 h	9 (18%)	4 (8%)

Table 3
Feeding tolerability.

	Group 1	Group 2
Number of portions fed, n		
Mean ± SD (range)	5.0 ± 1.3 (1–7)	4.6 ± 1.5 (1–8)
Median	5 (n = 44)	5 (n = 46)
Volume of portion fed, mL		
Mean ± SD (range)	263 ± 268.5 (70–1400)	206.3 ± 154.4 (30–1000)
Median	180 (n = 45)	170 (n = 46)
Type of feeding formula, n		
Polimeric	35	35
Hydrolyzed or amino-acid	10	10
Lack of data	4	2
Modes of delivery, n		
Intermittent feeding	44	40
Continuos feeding	5	8
Energy intake, kcal/kg. 24 h		
Mean ± SD (range)	112.2 ± 177.9 (30–1000)	181 ± 289.3 (17–1300)
Median	77 (n = 41)	79 (n = 39)

SD = standard deviation.

Table 4
Reported complications.

Type of complication	Number of patients	
	Group 1	Group 2
Reddening around the stoma canal	2	1
Leakage of the gastric contents	0	2
Vomiting	3	1
Vomiting and reddening around the stoma canal	1	2
Vomiting and fever	1	1
Nausea	0	1
Regurgitation	3	1
Gastrointestinal track infection	1	0
PEG dislodged (laparotomy)	0	3 (2)
Fever and local infection	0	1
Fever	0	3
Apnoea, status epilepticus	1	0
Arrhythmia	0	1
Bleeding from the gastrointestinal tract	0	1
Gastrointestinal perforation	1	0
Total number (%) of reported complications	13 (25.5)	18 (37.5)

PEG = percutaneous endoscopic gastrostomy.

receive robust nutrition earlier. The findings from studies into early nutrition in adults, which was defined as 4 h [3], ≤4 h [4], 3 h [5–8], or 1 h [2] post-PEG placement, suggest that early feeding is a safe alternative to delayed or next-day feeding, and that hospital stays can be shortened. The European Society for Paediatric Gastroenterology, Hepatology and Nutrition indicates that introducing feeds at 4 h post-PEG placement to children appears to be safe [9]; however, the authors emphasise the paucity of the paediatric literature on this subject. Recommendations about the introduction of early feeding are based on the data from one prospective randomised controlled study involving 69 patients that compared feeding at 4 h and 12 h post-PEG placement [10]. This study's authors concluded that early feeding was safe and well tolerated, and that it shortened hospital stays.

Werlin et al. evaluated the safety of early feeding in children at 6 h post-PEG placement [11], and found that the complication rate did not increase if the patients received earlier feeds. Corkins et al. conducted a prospective randomised study that investigated early feeding at 3 h and 6 h post-PEG implantation in 40 children [12], and they did not find any increase in the complication rate in association with the earlier feeding time. Jansen et al. [13] undertook a retrospective review of 1048 paediatric patients after gastrostomies that were inserted endoscopically in 48.9%, laparoscopically in 44.9%, and using an open approach in 6.2% of the patients. The investigators found that feeding within the first 6 h of the procedure was not associated with an increase in complications, irrespective of the placement method, and they stressed that initiating feeding earlier may shorten hospital stays and decrease overall hospital costs.

In our study we defined early feeding as 3 h post-procedure. PEG implantation is performed on paediatric patients under general anaesthesia. Most children for whom PEG feeding is indicated are affected by many diseases, and some cases require post-operative follow-up in intensive care units. Initiating enteral feeding at 3 h post-PEG placement seems to be the earliest possible time for most cases. To the best of our knowledge, this is the first multicentre randomised controlled trial to be conducted on such a large paediatric population (n = 97). The indications for PEG placement in this study included mainly dysphagia and malnutrition. There were no statistically significant differences between the groups, and introducing enteral feeding formula (polymeric in most cases, hydrolyzed or amino-acid formula in 20% of patients) via PEGs at 3 h and at 8 h post-procedure was similarly well tolerated, which concurs with the findings from the study undertaken by Corkins et al. [12]. It was possible to achieve full feed within 24–48 h in most cases. In 8% of patients in group 1 and in 10% in group 2 total individual caloric and fluid requirement was covered within 12 h. There were no differences between the groups regarding the number of complications, most of which were mild. Only two patients in group 2 required surgical intervention, because the PEGs became dislodged. The early introduction of enteral feeding did not reduce the hospitalisation time in our patients. However, an earlier feeding time could reduce the starvation duration by 5 h.

Conclusions

Early feeding at 3 h post-PEG placement was well tolerated in this paediatric population, it was not associated with an increase in the number of complications, and while it did not impact upon the hospitalisation duration, it reduced the period of starvation. This study's results provide reliable evidence on which an optimum feeding method post-PEG placement can be established for paediatric patients that will shorten the periods of fasting and inadequate nutritional support and could reduce overall hospital costs.

Statement of authorship

AW and JK conceived the study, contributed to the design of the study, and were responsible for patient recruitment, data collection, data analysis, and drafting the manuscript. MM, AS-S, ET-K, KP, UC-G, and EH contributed to the study's design, and were responsible for patient recruitment, data collection, and essential revisions of the manuscript for important intellectual content. All of the authors read and approved the final manuscript.

Conflicts of interest

All of the authors declare that they have no conflict of interest.

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