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SURGICAL ENDOSCOPY
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Complication rate lower after percutaneous endoscopic gastrostomy than after surgical gastrostomy: a prospective, randomized trial

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Abstract
Background: Percutaneous endoscopic gastrostomy (PEG) has increasingly replaced surgical gastrostomy (SG) as the primary procedure for the long-term nutrition of patients with swallowing disorders. This prospective randomized study compares PEG with SG in terms of effectiveness and safety.
Methods: This study enrolled 70 patients with swallowing disorders, mainly attributable to neurologic impairment. All the patients, eligible for both techniques, were randomized to PEG (pull method) or SG. The groups were comparable in terms of age, body mass index, and underlying diseases. Complications were reported 7 and 30 days after the operative procedure.
Results: The procedures were successfully completed for all the patients. The median operative time was 15 min for PEG and 35 min for SG ($p < 0.001$). The rate of complications was lower for PEG (42.9%) than for SG (74.3%; $p < 0.01$). The 30-day mortality rates were 5.7% for PEG and 14.3% for SG (nonsignificant difference).
Conclusion: The findings show PEG to be an efficient method for gastrostomy tube placement with a lower complication rate than SG. In addition, PEG is faster to perform and requires fewer medical resources. The authors consider PEG to be the primary procedure for gastrostomy tube placement.

Key words: Percutaneous endoscopic gastrostomy — Surgical gastrostomy — Swallowing disorders — Stomach — Complications

Gastrostomy is widely used to provide stomach access for the long-term enteral feeding of patients with swallowing disorders who need nutritional support. Most commonly, this condition occurs in patients with neurologic diseases, impairment after a stroke, or obstructive head and neck tumors. The basic conditions indicating a gastrostomy are the patient's expected survival for a reasonable time and normal gut function. In addition, ethical considerations are of importance [18, 22]. If performed under correct indications, a gastrostomy generally is accepted to be a successful method of enteral feeding, so the demand for gastrostomy insertion has increased over recent years.

The available techniques for placing a gastrostomy tube have changed. In France, Verneuil performed the first successful surgical gastrostomy (SG) in 1876 [14]. The SG procedure remained the method of choice until 1980, when Gauderer et al. [7] introduced percutaneous endoscopic gastrostomy (PEG). These authors achieved access to the stomach without laparotomy by inserting the gastrostomy tube percutaneously under endoscopic guidance.

Currently, PEG has gained acceptance in most clinical settings as the procedure of choice for the long-term enteral feeding of patients with prolonged swallowing difficulties. The main advantages are that it can be performed in most cases without the need for general anesthesia, and that it avoids the morbidity associated with a laparotomy [13, 16, 21]. However, PEG tube placement also may be associated with complications. Recent studies have suggested a higher rate of major complications and mortality after PEG than initially reported [4, 10, 12, 23]. Studies comparing PEG and SG have been performed, but most of these are retrospective analyses [11, 25].

In the current study, patients eligible for both techniques were randomized to either PEG or SG and prospectively followed to determine effectiveness, complications, and mortality. The main aim of this study was to evaluate whether one of the methods is superior to the other in terms of safety and function.

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Patients and methods

The Research Ethics Committee at Uppsala University approved the study. Before inclusion in the study, informed consent was given by the patient, or by a close relative if the patient because of medical incapacity was unable to do so.

During a period of 45 months, patients with impaired swallowing and a need for long-term (>4 weeks) enteral feeding, irrespective of the cause, were considered for this study. For inclusion, both techniques (PEG and SG) had to be feasible. Patients with previous surgery in the upper gastrointestinal tract and those for whom endoscopy was not possible because of obstructions from tumors in the pharyngoesophageal region were excluded. Two patients considered for this study refused to participate. For patients outside the study, the most appropriate gastrostomy technique was used.

A total of 70 patients were randomly assigned to PEG ($n = 35$) or SG ($n = 35$) by sealed envelopes opened after their inclusion in the study. The randomization was nonstratified, and all the envelopes were prepared before the start of the study. The two groups were comparable in age (69 vs 65 years), body mass index (BMI) (22 vs 21 kg/m^2), and underlying diseases (Table 1).

Surgical procedures

Basic laboratory tests including hemoglobin, coagulation, and inflammatory parameters were obtained. Preoperatively, all the patients were administered an intravenous single 1.5-g dose of cefuroxime in accordance with generally accepted recommendations [1, 5]. All the procedures but six were performed or supervised by one of the two authors. After placement of the tube, the patients returned to their ordinary wards. Feeding through the gastrostomy tube was delayed 24 h for all the patients, according to our routines.

In most cases, PEG was performed in the endoscopy suite. An upper gastrointestinal endoscopy was carried out to confirm normal anatomy and stomach emptying. After light sedation, the appropriate puncture site was located. Local anesthetics were applied after sterile washing, and the puncture cannula was advanced into the stomach under endoscopic control. The guidewire was inserted through the cannula, grasped with biopsy forceps, and drawn out together with the gastroscope. The oral end of the wire was attached to the PEG tube (Ponsky Pull PEG 20-Fr catheter; BARD Endoscopic Technologies, Billerica, MA, USA, or Compat PEG 22-Fr catheter; Novartis Nutrition, Minneapolis, MN, USA), which was pulled into the stomach and out through the abdominal wall. The tube was secured, and the dressings were applied. In selected cases only, the endoscope was reintroduced to verify that the tube was correctly positioned.

The SG procedure was performed through a short upper midline incision. Two purse-string sutures were placed around the intended entrance site on the stomach wall, and a 22-Fr gastrostomy tube (Compat-Gastrotube, Novartis Nutrition) was introduced through a stab wound in the left subcostal area. The tube was inserted into the stomach, and by tying of the purse-string sutures, a short serosal tunnel was created over the tube. Finally, the adjacent part of the stomach was attached to the abdominal wall by interrupted sutures, and a skin suture was secured the tube at the exit site.

Evaluation of outcome and complications

The variables analyzed included procedure duration, technical success, and complications. The patients were evaluated daily for major and minor complications, which were reported on a structured questionnaire 7 and 30 days after the gastrostomy tube placement. The complications were divided into early (days 1–7) and late (days 8–30). A patient was considered to be having a wound infection if at least two of the following conditions were present: peristomal erythema, induration, or purulent discharge. Concerning mortality, the patients were followed for a minimum period of 6 months.

Statistical analysis

Statistical analysis was performed using STATISTICA (StatSoft Inc, Tulsa, OK, USA). Values are given as median and range unless stated otherwise. Differences between groups were tested by analysis of variance (ANOVA) and Student's *t*-test, and differences in 30-day mortality were tested using the chi-square test. A p value less than 0.05 was considered statistically significant.

Table 1. Clinical data for 70 patients randomized to percutaneous endoscopic gastrostomy (PEG) or surgical gastrostomy (SG)[a]

	PEG ($n = 35$)	SG ($n = 35$)
Age (years)	69 (22–82)	65 (19–88)
BMI (kg/m^2)	22 (14–31)	21 (13–27)
Gender (M/F)	21/14	12/23
Underlying disease		
Stroke	17	13
Neurologic disease	10	13
Oropharyngeal cancer	4	7
Cerebral trauma	4	2

BMI, body mass index
[a] Data for age and BMI are given as median (range)

Results

All planned procedures were successfully completed, and there were no perioperative complications. The median operative time for PEG, from introduction of the endoscope to completed dressings, was 15 min (range, 9–31 min). The corresponding operative time for SG was 35 min (range, 20–65 min) ($p < 0.001$ vs PEG). Moreover, the total time for induction of anesthesia, operation, and awakening in the operative theater for the SG group was 85 min (range, 45–125 min).

Complications

There was no perioperative mortality. In the PEG group, one patient died of gastrointestinal hemorrhage on postoperative day 2 in his ward. Another patient died of a restroke on postoperative day 9, giving a total 30-day mortality of 5.7%. One patient experienced a major complication (local peritonitis), but was successfully treated conservatively. In the PEG group, 12 patients (34%) had minor complications (wound infection, leakage at the gastrostomy site, or dislocation of the PEG tube) during the 30-day follow-up period (Table 2).

In the SG group, the 30-day mortality rate was 14.3% (5 patients). Two patients died of aspiration pneumonia, and three patients died of aggravation to their underlying diseases. Pneumonia developed in two other patients, but was treated successfully by antibiotics. This was considered a major complication (Table 2). During the 30-day follow-up period, minor complications at the gastrostomy site developed in 19 patients (54%). Dislocation of the tube occurred in six patients. In four of these patients, it could be replaced easily, whereas two patients required reoperation. Also, the total number of patients with a complication was lower in the PEG group ($n = 13$) than in the SG group ($n = 25$) ($p < 0.01$) (Table 2).

Table 2. Mortality and overall complications after percutaneous endoscopic gastrostomy (PEG) and surgical gastrostomy (SG) evaluated 7 and 30 days after operation[a]

	PEG (n = 35)	(%)	SG (n = 35)	(%)	p
Mortality	2 (1[b], 1)	5.7	5 (2, 3)	14.3	0.238
Complications	15	264	2.9	74.3	0.007
Major complications:					0.562
Pneumonia	0		2 (1, 1)	5.7	
Local peritonitis	1 (1, 0)	2.9	0		
Minor complications:					0.054
Peristomal infection	6 (5, 1)	17.1	6 (3, 3)	17.1	
Stomal leakage	4 (2, 2)	11.4	7 (1, 6)	20.0	
Dislodged tube	2 (1, 1)	5.7	6 (1, 5)	17.1	
No. of patients with complications	13	37.1	25	71.4	0.003

[a] Data are presented in absolute numbers as total (day 7, day 30) and percentage. Statistical differences were evaluated by Student's t-test
[b] Procedure-related death, gastrointestinal bleeding

Discussion

This prospective, randomized study demonstrated that PEG was associated with a lower rate of complications than SG. Moreover, PEG was performed with a shorter operative time and required fewer medical resources. Consistent with our findings, Stiegmann et al. [28] concluded from a prospective, randomized trial conducted in 1990 that PEG was more cost effective, but found no differences in technical success or procedure-related morbidity or mortality.

In the current study, the total number of patients with a complication was significantly lower in the PEG group (37%) than in the SG group (71%). This difference was mainly attributable to an increased incidence of minor complications (peristomal infection, leakage, or tube dislocation) in the SG group. We believe that this rather high rate of registered complications was shown by the prospective, daily evaluation according to the study protocol. At the same time, we think it reflects the clinical situation. The incidence of major, nonlethal complications was slightly lower after PEG (2.9%) than after SG (5.7%), but at the rate of about 3% reported in the literature [9, 13, 15, 26].

The 30-day mortality rate was 5.7% in the PEG-group and 14.3% in the SG-group. One patient died 2 days after a PEG with clinical signs of a moderate gastrointestinal bleeding. Although no autopsy was performed, out of respect for the relatives' wishes, we considered this death as procedure-related. Gastrointestinal bleeding is an unfortunate drawback of the percutaneous technique and a known lethal complication after PEG [6]. In the literature, the reported 30-day mortality rate ranges from 3.5% to 30% after PEG [3, 6, 8, 17, 20, 26–28, 31], and from 21% to 41% after SG [2, 17, 19, 29–31]. The main reason for the high mortality rate is recognized to be the disabled condition of the patients.

When performing a PEG, we prefer the pull technique. This one standard approach provides a quick and safe procedure, even for patients not fully cooperating, as demonstrated in the current study by the 100% intraoperative success rate. We emphasize the risk of the blind puncture to the abdominal wall, and to date have had no patient with tube misplacement. After placement of the gastrostomy tube, all our patients receive detailed written instructions concerning potential complications and feeding schedules, and are encouraged to contact the PEG outpatient clinic if necessary. Our trained endoscopic assistants are able to give telephone advice, treat peristomal complications, and perform tube changes for patients with an established stoma. Our experience is that this organization satisfies the needs of the patients. In a recent study by Sanders et al. [24], problems with gastrostomies requiring telephone advice were documented in 24% of the patients during the first 6 months.

In conclusion, this study demonstrated a lower rate of complications after PEG than after surgically performed gastrostomy. These findings may be those expected by most colleges, but in this study, they were proved in a randomized, prospective manner. In addition, PEG can be performed on an outpatient basis without the need for general anesthesia. These major advantages make PEG a more attractive alternative than surgical gastrostomy, especially with the current increasing demand for enteral nutrition among patients with swallowing disorders. However, gastrostomy insertions are associated with high morbidity and mortality, so it is of great importance to consider both medical and ethical aspects for every single patient. In the effort to reduce the incidence of complications further, we emphasize a discussion of the indications for a gastrostomy in every single patient.

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