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Outpatient percutaneous endoscopic gastrostomy in selected head and neck cancer patients

Gustavo Francisco de Souza e Mello · Hannah Pitanga Lukashok · Gilmara Coelho Meine · Isabele Ávila Small · Roberto Luiz Teixeira de Carvalho · Denise Peixoto Guimarães · Gilberto Reynaldo Mansur

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Abstract
Background Percutaneous endoscopic gastrostomy (PEG) is a relatively simple and safe method of providing access for enteral feeding. The procedure is usually performed in hospitalized patients. The feasibility of PEG as an outpatient procedure has not been well estabilished in the medical literature. The main objective of this study was to investigate the feasibility and safety of PEG as an outpatient procedure in a selected group of head and neck cancer patients.
Patients and methods In this prospective cohort study, head and neck cancer subjects in good clinical condition were selected and enrolled in a close follow-up protocol of outpatient PEG. The clinical and demographic variables evaluated were age, gender, early complications, and timing of PEG.
Results Of a total of 136 PEG patients, 129 (94.8%) were discharged 3 h after the procedure. Three were excluded from the study and four were hospitalized because of moderate abdominal pain. The rate of minor complications was 17.6% (local pain, 7.4%; wound infection, 6.6%; abdominal pain, 2.9%; hematoma, 0.7%). Major complications occurred in 2.2% of the procedures (buried bumper syndrome, 1.5%; early tube displacement, 0.7%). There was no mortality.
Conclusion Ambulatory placement of gastrostomy tubes is viable and safe in head and neck cancer patients in good clinical condition. The early complication rates are similar to those described for hospitalized patients. Unnecessary admissions are avoided and costs of hospitalization are reduced.

Keywords Percutaneous endoscopic gastrostomy · Head and neck cancer · Outpatient · Day case · Ambulatory

G. F. de Souza e Mello (✉) · H. P. Lukashok · G. C. Meine · R. L. T. de Carvalho · D. P. Guimarães · G. R. Mansur
Department of Digestive Endoscopy, Cancer Hospital I, National Cancer Institute, Rio de Janeiro, RJ, Brazil
e-mail: gmello@inca.gov.br; gmello@br.inter.net

I. Á. Small · D. P. Guimarães
Department of Clinical Research, Research Center, National Cancer Institute, Rio de Janeiro, RJ, Brazil

Percutaneous endoscopic gastrostomy (PEG), first described by Gauderer et al. [1, 2], is now the procedure of choice to provide long-term enteral access for patients unable to swallow but with a functional gastrointestinal tract. In general, the procedure is performed in hospitalized patients and feedings begin on average 12 h later [3, 4]. So far, only few retrospective studies enrolling a small number of patients have shown the feasibility of an outpatient PEG procedure in individuals in stable condition and with good cognitive status [5–9].

Due to the increasing number of head and neck cancer patients that need PEG placement for nutritional support, concern for resource allocation, low availability of hospital beds, prolonged hospitalization stays, and a necessity to optimize nutritional outcome for these patients before or during their treatment, establishing the feasibility of PEG as an outpatient procedure may have a substantial clinical and economic impact. In our institution we have had previous limited but satisfactory clinical experience with a few head and neck cancer patients who had outpatient PEG without complications (data not published).

The major aim of this study was to investigate the success rate and safety of PEG as an outpatient procedure

and evaluate the rate of early complications (first 15 days) in a selected group of head and neck cancer patients.

Materials and methods

Study design

This was a prospective cohort study designed to have a close follow-up protocol to investigate the feasibility and early outcomes of outpatient PEG in a selected group of head and neck cancer patients. Written informed consent for the study was obtained before the procedure from all the patients or from a family member. This study was approved by the National Cancer Institute institutional review board (Research Ethics Committee).

Study population

From September 2002 to September 2007, a total of 360 PEGs were performed in 356 cancer patients (261 with head and neck malignancies) at the Department of Digestive Endoscopy of the Cancer Hospital I, National Cancer Institute, Rio de Janeiro, Brazil. During this period, 136 head and neck cancer patients were prospectively selected for outpatient PEG placement. Clinical data of the PEG outpatients were entered into an Excel spreadsheet (Microsoft Corp., Redmond, WA, USA).

Inclusion and exclusion criteria

All adult patients selected for outpatient PEG placement were in good clinical condition (Karnofsky Performance Status Scale of 70 or more). Only patients classified with American Society of Anesthesiologists (ASA) Physical Status Classification System grades I and II were included. To be eligible to participate in the study the patients had to be able to communicate without interpretation, had a responsible adult at home, accepted and understood the procedure and the follow-up care instructions, and were able to return to the hospital promptly if complications occurred. Preoperative laboratory tests included complete blood count, coagulation profile, and serum chemistry. Patients who could not come for regular visits due to poor clinical status, those who were unable to understand the procedure and follow-up care, and those who lived too far from the hospital (more than a 1 h drive) were hospitalized for the procedure. Advanced age per se was not an exclusion criteria.

Operative technique

Prophylactic IV antibiotics (cephazolin 2 g) were given 30 min preoperatively. Under oximetric monitoring and conscious sedation with intravenous midazolam and meperidine, a thorough endoscopic examination of the upper gastrointestinal tract was made. PEG was performed using the "pull" method (Gauderer-Ponsky technique) using commercially available kits (PEG 24-Pull, Wilson-Cook Medical, Winston-Salem, NC, USA; MIC PEG 24 Fr, Ballard Medical Products, Draper, UT, USA; and EndoVive PEG 24 Fr, Boston Scientific Corporation, Natick, MA, USA) or "homemade" kits (modified 22 Fr Foley catheter). Commercially available kits were used in 129 procedures. The procedure was performed with the patient in the supine position. The stomach was inflated to displace the colon downward and the liver laterally and to appose the anterior gastric wall to the abdominal wall. External transillumination of the endoscope light should be visible through the abdominal wall and an internally sharp indentation of the anterior gastric wall caused by the tip of the palpating finger should be identified. The needle of the lidocaine-filled syringe for local anesthesia was inserted through the abdominal wall into the stomach while aspirating, under direct vision of the endoscopist, to ensure there was no hollow viscus in the track. An incision was made through the skin and aponeurosis layers. The stomach was puntured with a 14-gauge Teflon cannula, through which a metal wire was inserted and internally grasped by a polypectomy snare and pulled up out through the mouth. The metal wire was knotted to the loop of the gastrostomy tube and pulled back through the abdominal wall to the exterior. The internal bumper was positioned against the anterior gastric wall. An external fixation device was then attached to prevent displacement of the tube. A second-look endoscopy was done to check the position of the feeding tube in the stomach and the abdominal site was dressed surgically.

Postoperative and follow-up care

The patients were observed in the endoscopy department for 3 h after the procedure. Patients (and caregivers) received the following recommendations: (1) home rest as possible for the first 5 days; (2) clean the gastrostomy site two times a day or when soiled; (3) avoid pulling or tractioning the catheter; (4) return immediately to the hospital in the case of catheter dislodgment or any sign of infection. A nutritionist prescribed the diet, beginning at home 4 h after the procedure. The patients returned for regular visits at scheduled intervals (on postprocedure days 2, 4, and 7, then weekly during the first month, and then monthly) during the period of PEG use, until either the tube was removed or the patient died. The patients were also advised to return if they had abdominal pain, signs of inflammation, tube displacement or obstruction, leakage, or excessive granulation tissue at the gastrostomy site. Access to

emergency services was available 24 h a day. No patients were lost to follow-up during the 15-day period.

Terminology and definitions

Outpatient (or day-case or ambulatory) procedure: The patient is discharged during the same day of the procedure (this is not equivalent to a stay of less than 24 h in a hospital). An overnight stay excludes the patient from being categorized as an ambulatory, day-case, or outpatient.

Early complications: Those occurring within the first 15 days postprocedure (during the gastrostomy tract maturation period).

Late complications: Those occurring after 15 days postprocedure.

Minor complications (require only conservative therapy): Wound infection, peristomal leakage, dermatitis, granulation tissue, pneumoperitoneum, punction site hematoma, temporary ileus, local or abdominal pain, gastric outlet obstruction, tube dysfunction.

Major complications (often necessitate further endoscopic therapy or surgical intervention): Buried bumper syndrome, gastric ulceration, gastric bleeding, complicated hematoma, gastric perforation, inadvertent early tube removal, peritonitis, necrotizing fasciitis, gastrocolocutaneous fistula, stomal tumor seeding, aspiration.

Statistical analysis

Statistical analysis of the data was performed using SPSS software v13.0 (SPSS Inc., Chicago, IL, USA). The correlation of the clinical and demographic variables (age, gender, early complications, and timing of PEG) and PEG procedures was assessed by the χ^2 test. Results were considered statistically significant when $p \leq 0.05$.

Results

Patients

Of the 261 head and neck cancer patients who had an indication for a PEG at our instituition, 136 (52.1%) met all the criteria for outpatient care and were included in this study. Three patients (two males and a female) without secured airways had to be excluded from the study immediately before PEG placement because of acute airway obstruction after the administration of sedation. None required emergency tracheostomy. The PEG procedure was successfully performed in 133 patients. The primary sites of malignancy of the PEG patients are outlined in Table 1. There were 104 males (78.2%) and 29 females (21.8%) ranging in age from 24 to 80 years (mean = 56.1 years). Twenty-nine patients (21.8%) were 65 years old and over. A total of 136 PEG procedures were performed in the 133 patients (three patients were submitted to two procedures each).

Table 1 Primary site of malignancy

	n (%)
Pharynx	41 (30.8%)
Larynx	39 (29.3%)
Oral cavity	25 (18.8%)
Mandible	10 (7.5%)
Cavum	9 (6.8%)
Maxillary sinus	4 (3.0%)
Others	5 (3.8%)
Total	133 (100%)

Eight patients (6.0%) had stenosis of the pharyngoesophageal anastomosis and were dilated with Savary-Gilliard bougies immediately before PEG, without complications. Cervical fístulas and pharyngoesophagostomies were the access route for the endoscope and the PEG tube in six patients (4.5%).

All but 4 of the PEG patients were discharged after 3 h. The 4 patients (two males and two females) who were hospitalized after PEG had moderate to severe postoperative abdominal pain. Therefore, the success rate of PEG as an outpatient procedure was 94.8% (129/136).

The outpatients represented 38.2% of all cancer patients submitted to PEG in our department. This percentage increased continuously over the years of the study.

Complications

Early complications (in the first 15 postoperative days) related to the PEG were diagnosed in 19.8% of the procedures (Table 2). Minor early complications occurred in 17.6% of the procedures (gastric hematoma, 0.7%; abdominal pain, 2.9%; wound infection, 6.6%; and local pain, 7.4%). The four patients with postprocedure abdominal pain were hospitalized and treated with intravenous analgesics. There were no signs of peritonitis and these patients were discharged the following day. The patients with wound infection and local pain were treated at home with enteral antibiotics and analgesics, respectively. The small punture site gastric hematoma was tamponed by application of pressure with the inner bumper of the PEG catheter.

Major early complications occurred in only three procedures (2.2%). Two patients developed early partial buried bumper syndrome (on days 7 and 9 postprocedure)

Table 2 Early complications of outpatient PEG insertion

	n (%)
PEG procedures	136 (100%)
Early complications	27 (19.8%)
Major complications	3 (2.2%)
BBS	2 (1.5%)
Early tube dislodgment	1 (0.7%)
Minor complications	24 (17.6%)
Local pain	10 (7.4%)
Wound infection	9 (6.6%)
Abdominal pain	4 (2.9%)
Gastric hematoma	1 (0.7%)

PEG percutaneous endoscopic gastrostomy; *BBS* buried bumper syndrome

and were treated by simple repositioning of the feeding tube under endoscopic control. The other had the tube accidentally displaced on day 10 postprocedure. He immediately returned to the emergency room, had the tube replaced through the same gastrostomy site under endoscopic control, and was discharged shortly thereafter without further complications.

A χ^2-based test between age, gender, and early complications showed no statistically significant association. On the other hand, there was an increase of complications in the patients submitted to PEG during ($p = 0.05$, HR = 0.28, CI = 0.06-1.20) or after treatment ($p = 0.027$, HR = 0.25, CI = 0.06-1.03), either exclusive of radiotherapy, chemotherapy plus radiotherapy, or surgery, when compared to pretreatment PEG (Table 3). There was no mortality related to the PEG procedure.

Discussion

Since the introduction of the PEG technique by Gauderer et al. in 1980, it has become the procedure of choice for prolonged enteral feeding access [1, 2, 10]. PEG is usually performed in hospitalized patients who have been in the hospital from 1 to 7 days [3]. In general, enteral feeding begins 12-24 hours postprocedure [4], given the clinical concern for leakage of gastric contents into the peritoneal cavity or aspiration after PEG placement. However, recent data support the safety of early gastric feeding without the need of intravenous fluids or caloric support [4, 9, 11–14].

In the medical literature, only five studies have retrospectively evaluated the feasibility of PEG as an outpatient procedure [5–9]. Larson et al. [5] studied 314 consecutive PEG patients who underwent the "pull" technique. Two hundred ninety-seven patients (93%) were hospitalized and 23 (7%) were outpatients who were discharged 2 h postprocedure. The outpatients were in stable clinical condition and none had complications related to PEG. Kurchin and Kornfield [6] also reported the feasibility of PEG as outpatients. They performed the procedure using the "pull" technique in eight patients and none had postprocedure complications. Cullado et al. [7] performed elective repeat PEG in ten patients after removal of the original PEG. Six cases were performed as an outpatient procedure. No complications were attributed to repeat PEG, and

Table 3 Demographics and therapeutic risk factors for early complications after PEG procedures

Variable	Total	PEG complication group	PEG noncomplication group	*p* value
Procedures	136 (100%)	27 (19.8%)	109 (80.2%)	
Age (years)[a]				0.125
<65	106 (77.9%)	24 (22.6%)	82 (77.4%)	
>65	30 (22.1%)	3 (10.0%)	27 (90.0%)	
Sex[a]				0.588
Male	106 (77.9%)	20 (18.9%)	86 (81.1%)	
Female	30 (22.1%)	7 (23.3%)	23 (76.7%)	
Timing of PEG[b]				
Pretreatment	32 (23.5%)	2 (6.2%)	30 (93.8%)	
Peritreatment	40 (29.4%)	9 (22.5%)	31 (77.5%)	0.05*
Post-treatment	60 (44.1%)	15 (25.0%)	45 (75.0%)	0.027**

PEG percutaneous endoscopic gastrostomy

* χ^2-based measure of the association between pre- and peritreatment timing of PEG

** χ^2-based measure of the association between pre- and post-treatment timing of PEG

[a] Three of the 133 patients underwent two PEG procedures each, at different times. The discrepancy of numbers relates to the total number of PEG procedures

[b] Four patients received no treatment

full-volume feeding was begun immediately in all cases. They concluded that after maturation of the gastrostomy tract, adhesion of the stomach to the abdominal wall allowed repeat PEG to be safely performed as an outpatient procedure. Mandal et al. [8] designed a study to evaluate the success rate, complications, and long-term outcomes following outpatient PEG by the "pull" technique in 33 patients. All patients were discharged after 3-4 h. Six patients (18%) had minor complications (abdominal pain, peristomal leakage, local infection, and a small subcutaneous hematoma). One patient (3%) had a major complication (tube displacement and subsequent hematemesis) and died some days after. Despite this, the authors concluded that PEG can be performed as an outpatient procedure in stable patients, with no increase in the complication rate, morbidity, or mortality. In the study of Dubagunta et al. [9], of the 77 PEG patients, 27 (35%) were outpatients who had no complications. The authors concluded that this protocol was not only safe but afforded significant cost savings by avoiding hospital admission.

To our knowledge, this prospective study represents the largest series to date that describes the experience with PEG as an outpatient procedure (Table 4). Complications of PEG were classified as *early* (first 15 days) or *late* (more than 15 days) according to the postprocedure period, and *minor* (requiring only conservative therapy) or *major* (often needing further endoscopic therapy or surgical intervention) according to severity [15–18]. In this study we focused on complications arising in the first 15 days postprocedure, a period in which hospitalization could possibly have an advantage over the outpatient approach. Minor complications occurred in 17.6% and major complications in 2.2% of the procedures, with no mortality. This is in line with the short-term follow-up complication rates described in the literature, varying from 3.8 to 28.8% for minor complications and from 2.2 to 5.0% for major complications [19].

In other head and neck cancer PEG patients series, morbidity as high as 42% has been reported [20]. The lower early PEG morbidity rate in our study was probably due to the very strict inclusion criteria, supported by a tight follow-up protocol. These results underscore the importance of careful patient selection for inclusion and exclusion for outpatient PEG. Also, a formal post-treatment follow-up schedule is essential to identify and deal with different types of PEG problems and complications affecting head and neck cancer outpatients.

Most PEG complications can usually be solved in the ambulatory setting [21]. With the exception of the four patients with abdominal pain, all the other patients' complications (local pain, gastric hematoma, wound infection, tube dislodgement, and buried bumper syndrome) were treated without hospitalization.

It is possible that the rate of complications found in our study resulted from the malignant disease morbidity itself, from its treatment (surgery or chemoradiation therapy), or especially because of the close follow-up protocol we adopted. It is important to note that all of our outpatients had head and neck cancer. This pathology represents 73.3% of the indications for PEG in our institution. It is estimated that before any therapy, 25-50% of patients with head and neck cancer are malnourished because of impaired swallowing, heavy smoking, and alcohol abuse [22–24]. Moreover, investigators reported 10% or greater loss of initial body weight during chemoradiation therapy [24]. Therefore, these patients often require an extraoral route for nutritional support, usually a gastrostomy tube. PEGs should be placed early during treatment to maintain good nutrition so that maximum benefit can be derived [23, 25]. Special situations such as obstructive lesions of the pharyngoesophageal region and cervical fistulas do not preclude the procedure and were not associated with additional morbidity [25–28]. Because of existing tumor or postresection anatomic changes of the upper respiratory tract, head and neck cancer patients are at high risk for intraoperative airway obstruction and respiratory distress, especially when sedated [25, 29].

One factor that could be of clinical importance for the patients' outcome is the timing of the PEG procedure in relation to the treatment course. PEG placement can be

Table 4 Studies of outpatient PEG

Authors	Year	Study size (*n*)	Success rate (%)	Early complications (%)		PEG-related death (%)
				Minor	Major	
Larson et al. [5]	1987	23	N/A	0	0	N/A
Kurchin and Kornfield [6]	1989	8	100	0	0	0
Cullado et al. [7]	1990	6	100	0	0	0
Mandal et al. [8]	2000	33	97	18	3	3
Dubagunta et al. [9]	2002	27	N/A	N/A	0	0
Present study		136	94.8	17.6	2.2	0

PEG percutaneous endoscopic gastrostomy; *N/A* not available

performed before treatment, during chemo and/or radiotherapy, or after tumor resection in patients who develop dysphagia. However, the impact of the timing of PEG on the complication rates remains to be fully established. Raynor et al. [23] showed a significantly lower overall frequency of complications when intraoperative PEG was performed after tumor resection compared to that of pretreatment PEG. In this study we found a significant increase in the complication rate when PEG was performed during or after treatment compared to when PEG was performed pretreatment. The immunosuppression resulting from chemotherapy, radiotherapy, and malnutrition could possibly explain these results. However, a randomized study enrolling a larger population is needed to clarify this specific issue.

Three major endoscopic techniques for placement of a gastrostomy tube have been described [19]. The pull (Gauderer-Ponsky) method is the original and most widely used PEG technique [1, 2]. The push (Sachs-Vine) method differs from the pull technique in that the PEG tube is pushed (and not pulled) by a guidewire through the oral cavity, esophagus, stomach, and abdominal wall. In the introducer (Russell) method, a guidewire is placed in the stomach under endoscopic visualization and the tract is then serially dilated to allow the insertion of a PEG tube through the abdominal wall into the stomach. Comparision of the techniques has shown them to be equivalent in safety and success of placement. When compared to the pull or the push technique, the introducer method, although technically more difficult, avoids transoral passage and theoretically may have the advantage of decreased infection rate and lower risk of PEG site metastasis. Similarly, a radiologic gastrostomy method of tube placement allows direct percutaneous catheter insertion under fluoroscopic guidance without the use of endoscopy, but it requires gastric insufflation by a nasogastric tube. In all techniques, T-fasteners may be used to attach the stomach to the abdominal wall. In our study of head and neck cancer patients, we had no case of tumor implantation at the PEG stoma.

Because clinical data on the pathways used for ambulatory placement of PEG are lacking in the literature, for the purposes of this prospective study we decided to establish a tight follow-up schedule for the outpatients. In clinical practice, however, this follow-up protocol is clearly unnecessary, impractical, and not cost-effective.

Outpatient procedure, day-case procedure, and ambulatory procedure are synonymous terms that mean the patient is discharged during the same day. This is not equivalent to a stay of less than 24 h in a hospital, and by definition an overnight stay excludes the patient from being categorized as an ambulatory, day-case, or outpatient [30]. The outpatient setting is an effective and efficient approach for many surgical and endoscopic procedures, offering several advantges to patients, staff, the hospital, and society. With an adequate selection of patients, it potentially offers healthcare as effective as the traditional approach and at lower cost. Its potential advantages include the shortening of the waiting list for admission to the hospital because an increased number of beds and personnel would be available for patients with more serious pathologies [31, 32].

We conclude that PEG as an outpatient procedure is feasible, effective, and safe in a selected group of head and neck cancer patients who are in stable clinical condition. Unnecessary admissions are avoided and hospitalization costs are reduced without increasing mortality or complication rates compared to the procedure performed in hospitalized patients.

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