Original Article

Complications of Fluoroscopically Guided Percutaneous Gastrostomy With Large-bore Balloon-retained Catheter in Patients With Head and Neck Tumors

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Background/Purpose: To review the complications, mortality rate and nutritional status of patients with head and neck cancer after fluoroscopically guided percutaneous gastrostomy (FPG).

Methods: We retrospectively recruited 110 patients who had undergone FPG using 14-French balloon-retained catheters. The mortality rate, procedural and catheter-related complications, and Eastern Cooperative Oncology Group performance status were reviewed. Peritonitis, abscess, septicemia and bleeding were defined as major complications. Tube-related problems, including dislodgment, obstruction, leakage, vomiting and infection, were classified as minor complications.

Results: Patients were stratified according to Eastern Cooperative Oncology Group performance status as follows: grade 0 (n = 6); grade 1 (n = 22); grade 2 (n = 44); grade 3 (n = 29); and grade 4 (n = 7). The respective complication rates were 21%, 24%, 26%, and 29% for grades 1–4; however, there were no significant inter-grade differences. The rates of major and minor complications were 1.9% and 20.0%, respectively. A total of 47 (43.5%) patients succumbed due to cancer deterioration; however, there was no gastrostomy-induced mortality. The catheter-occlusion rate of 3.7% in this cohort was significantly lower than that reported in other pigtail-retained gastrostomy studies.

Conclusion: FPG is a safe method with low mortality and complication rate for constructing long-term enteral access in patients with head and neck cancer and esophageal abnormalities, who have no endoscopic access to the stomach.

Key Words: balloon-retained catheter, complication rate, fluoroscopically guided percutaneous gastrostomy, head and neck cancer

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Cancer patients and those with dysphagia frequently need nutritional support to improve their nutritional status and reverse weight loss. Head and neck cancer patients are generally identified as a subgroup that might be helped by caloric supplementation. Fluoroscopically guided percutaneous gastrostomy (FPG) is a currently acceptable means of feeding patients with tumors of the head and neck or esophagus, as well as those with neurological or gastrointestinal disorders that hamper normal oral intake. FPG was first described in 1983, and is a variation of radiological gastrostomy, with a longer catheter that extends from the stomach to the proximal jejunum. FPG is performed as a percutaneous procedure under fluoroscopic guidance and local anesthesia, and it has a low rate of complications and a high rate of technical success. Radiologically-guided placement of gastrostomy tubes has a higher success rate than endoscopic placement, although complication and overall survival rates do not differ significantly.

The purpose of this study was to review the complication and mortality rates in a sample population of head and neck cancer patients who underwent FPG.

**Materials and Methods**

**Patients, instruments and medications**

The institutional review board of our hospital approved this retrospective study. From November 2002 to February 2008, 110 patients (17 female, 93 male) underwent FPG at our institution, with the procedure \( n = 121 \) repeated once in nine cases and twice in two cases, using 14-French balloon-retained catheters (Balloon Replacement Tube, PEG-BRT; Cook, Bloomington, IN, USA). All patients received 1 g intravenous ceftizoxime sodium for antibiotic prophylaxis (Cefizox, Fujisawa Holland B.V. Houten, the Netherlands). In addition to local anesthesia, the patients received intravenous sedation with 5 mg midazolam (Dormicum; Roche, Basel, Switzerland) and fentanyl citrate (Sublimaze; Abbott Laboratories, North Chicago, IL, USA). Oxygen saturation, blood pressure, and heart rate and rhythm were monitored by noninvasive means. Intravenous hyoscine-N-butylbromide (40 mg. Buscopan; Boehringer Ingelheim, Ingelheim, Germany) was administered before gastric insufflation. Enteric contrast material for colonic opacification and sonographic localization of the left hepatic lobe were not routinely performed.

**Balloon-retained catheter placement**

The stomach was insufflated using a nasogastric tube or a 4-French angiocatheter (the latter was used for patients with high-grade narrowing of the oropharynx, or cervical or thoracic esophagus). The midbody of the stomach was punctured using fluoroscopic guidance after subcutaneous administration of local anesthesia. Modified gastropexy using two T-fasteners (Cope Gastrointestinal Suture Anchor Set; Cook) were placed around the intended catheter site. A 3–4-mm incision was made in the center of the gastropexy fasteners, the stomach was accessed through the incision, and the tract was serially dilated to accept a 19-French, peel-away introducer sheath (Figures A–C). A 14-French balloon-retained catheter was then inserted through the sheath into the stomach \( (n = 7/103) \) (Figure D). The outer sheath of the peel-away introducer sheath was removed (Figures E and F). Finally, 5 mL water-soluble contrast medium (60% iothalamate meglumine, Conray 60; Mallinckrodt Canada, Pointe-Claire, Quebec, Canada) was injected into the gastrostomy balloon until the balloon was fully inflated (Figures G and H). Technical success was checked fluoroscopically at the end of the procedure with 10 mL water-soluble contrast medium injected via the feed port of the catheter, to confirm that the gastrostomy catheter was correctly placed within the stomach. The T-fasteners were cut off 14 days after tube insertion.

**Follow-up**

All patients were followed up for 14, 30 and 60 days after the procedure, and every 90 days thereafter. The technical success, procedural and catheter-related complications, cancer staging (according to TNM classification), and baseline
Figure. (A) Spot radiograph shows a T-fastener mounted inside an 18-G needle. An anchor was pushed into the stomach via the 18-G puncture needle through the anterior gastric wall. (B) Spot radiograph shows a completed gastropexy using two T-fasteners. (C) A 19-French peel-away introducer sheath was inserted through the percutaneous tract into the stomach. (D) The peel-away sheath with coaxial balloon-retained catheter was inserted into the stomach. (E) The outer sheath of the introducer was peeled off. (F) Photograph at completion of the procedure, with the outer retention plate placed at the skin layer. (G) Spot radiograph after insertion of the peel-away sheath shows the gastrostomy catheter inside the sheath and the balloon sufficiently inflated. (H) Spot radiograph shows the water-soluble contrast medium injected via the feed port into the stomach to confirm the position of the gastrostomy catheter.
and post-procedural body weight were recorded. All relevant discharge summaries and laboratory reports were reviewed. Peritonitis, abscess, sepsis, and bleeding were defined as major complications. Tube problems, such as dislodgment, obstruction, leakage and infection, were defined as minor complications. In addition, status with respect to chronic disease (e.g. diabetes mellitus, hypertension and renal dysfunction) and antibiotic use were recorded. Patients were assessed according to the Eastern Cooperative Oncology Group (ECOG) performance status scale\(^7\) (Table 1) and indication type. Two patients were lost to follow-up.

### Results

The mean age of this cohort was 65.4 years. Medical history of underlying diseases was as follows: diabetes mellitus \((n=25)\), hypertension \((n=22)\) and renal disease \((n=17)\). Indications were prophylactic placement of the tube because we anticipated that the patients would have difficulty in swallowing during and/or after treatment \((n=41; 38\%)\); poor nutrition \((n=27; 25\%)\); and inability to feed orally \((n=40; 37\%)\). Nine patients underwent two gastrostomies and two underwent three, with a successful outcome in 119 (98\%) of 121 procedures. Patients were assessed for ECOG performance status: grade 0 \((n=6)\); grade 1 \((n=22)\); grade 2 \((n=44)\); grade 3 \((n=29)\); and grade 4 \((n=7)\). A breakdown of major \((1.9\%)\) and minor \((19.4\%)\) complications is presented in Table 2. Two \((1.9\%)\) patients were cancer stage I, 26 \((24\%)\) stage II, 30 \((28\%)\) stage III, 41 \((38\%)\) stage IV, and nine \((8.1\%)\) were unclassified. The subjects were also stratified according to decreased or increased body weight into group A \((n=36; 33\%)\) or group B \((n=72; 67\%)\), respectively, with mean pre/post-treatment \((12\) months\) values of 68.6 ± 3.4/62.2 ± 4.1 kg and 67.1 ± 2.5/79.6 ± 2.9 kg, respectively. Mean hospital stay was 3.2 days for the procedure. Forty-seven \((43.5\%)\) patients expired due to cancer deterioration; however, there was no gastrostomy-induced mortality. The interval from gastrostomy to death ranged from 19 to 347 days.

### Discussion

Fluoroscopically guided gastrostomy is typically performed by stomach puncture, followed by serial dilation of the puncture site, and advancement

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**Table 1.** Eastern Cooperative Oncology Group performance status scale

<table>
<thead>
<tr>
<th>Grade</th>
<th>Status</th>
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</thead>
<tbody>
<tr>
<td>0</td>
<td>Fully active, able to sustain all pre-disease activities without restriction</td>
</tr>
<tr>
<td>1</td>
<td>Restricted in physically strenuous activity but ambulatory and able to perform light/sedentary work (e.g. light household duties or office work)</td>
</tr>
<tr>
<td>2</td>
<td>Ambulatory and capable of all self-care but unable to perform any work activities. Up and about for &gt;50% of waking hours</td>
</tr>
<tr>
<td>3</td>
<td>Capable of only limited self-care, confined to bed/ chair &gt;50% of waking hours</td>
</tr>
<tr>
<td>4</td>
<td>Completely disabled. Unable to provide any self-care. Totally confined to bed or chair</td>
</tr>
<tr>
<td>5</td>
<td>Died</td>
</tr>
</tbody>
</table>

**Table 2.** Complications in head and neck tumor patients after fluoroscopically guided percutaneous gastrostomy \((n=108)\)

<table>
<thead>
<tr>
<th>Type of complication</th>
<th>(n) (%)</th>
</tr>
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<tbody>
<tr>
<td>Major</td>
<td></td>
</tr>
<tr>
<td>Peritonitis</td>
<td>1</td>
</tr>
<tr>
<td>Abscess</td>
<td>0</td>
</tr>
<tr>
<td>Septicemia</td>
<td>0</td>
</tr>
<tr>
<td>Bleeding</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>2 (1.9)</td>
</tr>
<tr>
<td>Minor</td>
<td></td>
</tr>
<tr>
<td>Tube dislodgement</td>
<td>7</td>
</tr>
<tr>
<td>Tube obstruction</td>
<td>4</td>
</tr>
<tr>
<td>Tube leakage</td>
<td>7</td>
</tr>
<tr>
<td>Infection</td>
<td>3</td>
</tr>
<tr>
<td>Total</td>
<td>21 (19.4)</td>
</tr>
</tbody>
</table>
Fluoroscopically guided percutaneous gastrostomy

of a pigtail/balloon-retained catheter into the stomach over a guide wire. Smaller pigtail-retained catheters are inserted directly, whereas large-bore balloon-retained tubes are inserted via a peel-away sheath or in tandem with a leading angioplasty balloon.8 This technique is straightforward and has recently been used for tube insertion in patients with obstructing head and neck or esophageal carcinomas. There are also potential advantages of FPG over PEG (percutaneous endoscopic gastrostomy). In patients who have head and neck or esophageal cancer with high-grade narrowing of the oropharynx and/or upper esophagus, there is no endoscopic access to the stomach. In some patients who have received surgery, such as wide neck dissection or subtotal mandibulectomy, endoscopy might destroy the reconstructed flaps and grafts in the head and neck regions, therefore, FPG serves as an alternative. FPG can be performed by a single radiologist, whereas more operators are required for the surgical and endoscopic approaches. Only local sedation is required for FPG, in contrast to the general anesthesia which is required for the surgical procedures.

In agreement with other studies, we found that percutaneous gastrostomy had a high success rate when compared with endoscopic and surgical gastrostomy. In consideration of cost, endoscopic and fluoroscopic gastrostomies are similar but the surgical approach is significantly more expensive.

In this study of FPG, the technical success, complication and mortality rates were similar to those in other studies of surgical, endoscopic and fluoroscopic tube placement. In our study, there was no procedure-related mortality, and major and minor complications occurred in 1.9% and 19.4%, respectively, compared with 1.6–1.9% and 15–22% in other studies with fluoroscopic tube placement,2,10,13 whereas the major complication rates could be up to 19–25% and 3–7% for surgical and endoscopic approaches, respectively.11–15 The range of reported minor complications also reached 29–35% and 13–24% for the latter two procedures.

In this study, balloon-retained catheters were used instead of pigtail-retained catheters, and we demonstrated similar major and minor complication rates compared with those in the study of Baere et al (1.4% and 21%, respectively).9 However, the occlusion rate of balloon-retained catheters was much lower in our study. We postulated that this disparity might be because of the larger end-aperture used for balloon-retained gastrostomy compared with the side-hole in the pigtail variant; hence, the incidence of occlusion was reduced in the former method.

The results of previous investigations reflect the significance of associated illness in terms of elevated mortality rate.2,10 In a similar study in which head and neck cancer patients were recruited, Ryan et al10 did not take into consideration the co-morbidity of their patients. Similarly, in the study of Halkier et al, there were no specific exclusion criteria to avoid any confounding effect of co-morbidity on mortality rate.2 In our cohort of 110 patients, 47 died during the follow-up period; all of those cases related to cancer deterioration, without gastrostomy-related problems. Our observations suggest that the mortality rate related to FPG is probably minimal.

The present study demonstrates that cancer staging might be an index for complication rate. The two patients with major complications were stage III and IV, whereas the patients with minor complications were stage II (n = 2), III (n = 17) and IV (n = 3). Cancer stage appears to be associated with complication rate. In a previous study, Wollman et al found that 75% of patients with FPG-induced complications had stage III and IV cancer.16 Funaki et al divided their patients into two groups based on cancer stage (≤II or >II), with respective complication rates of 14% and 86%.17 Our complication rates for groups stratified according to the above criteria (8.3% and 91.7%) were comparable.

Body weight is a common indicator for nutritional status. In the present cohort, body weight increased in 67% of our patients, and although the body weight of group A had decreased after 1 year, there was no significant difference compared with baseline. In contrast, the body weight of group B significantly increased from baseline.
at 12 months. It appears reasonable to suggest, therefore, that the net effect of gastrostomy on body weight is positive.

In an analysis of the relationships with complication rate, McLoughlin and Gibney demonstrated that ECOG performance status and illness are the two most accurate predictors for complication rate. Pitman et al demonstrated that ECOG performance status was the best reference for clinical physicians for selection of appropriate treatment; however, relative data were not supplied. In our cohort, the relationship between ECOG performance and complication rate was not apparent, and this might be explained by the multivariate nature of the complication rate.

In conclusion, we recommend FPG as the method of choice for catheter insertion in patients with advanced head and neck cancers with no endoscopic access to the stomach. FPG is a safe and simple method with low mortality and complication rates for constructing enteral access for nutritional supplement before, during and after treatment. Balloon-retained gastrostomy is the recommended choice of catheter, with a low rate of occlusion.

References