CLINICAL STUDY

Randomized Trial Comparing Radiologic Pigtail Gastrostomy and Peroral Image-Guided Gastrostomy: Intra- and Postprocedural Pain, Radiation Exposure, Complications, and Quality of Life

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ABSTRACT

Purpose: To prospectively compare radiologically created pigtail gastrostomy (PG), in which the tube is inserted directly through the abdominal wall, versus peroral image-guided gastrostomy (POG), in which the tube is inserted through the mouth. Pain profiles (primary outcome measure), fluoroscopy times, total room times, technical success, complications, and quality of life (QOL) were measured.

Materials and Methods: Sixty patients were prospectively randomized to receive 14-F PG or 20-F POG tubes. All patients received prophylactically created gastrostomies before radiation therapy for head and neck squamous-cell carcinoma. Patients receiving palliative treatment were excluded, as were those with established pharyngeal obstruction. Pain was measured by numeric rating scale (NRS) scores for 6 weeks after the procedure and by intraprocedural fentanyl and midazolam doses and postprocedural 24-h morphine doses. Fluoroscopy times, total room times, technical success, complications up to 6 months, and gastrostomy-related QOL (using the Functional Assessment of Cancer Therapy–Enteral Feeding questionnaire) were determined.

Results: Fifty-six patients underwent the randomized procedure. The POG group required significantly higher intraprocedural midazolam and fentanyl doses (mean, 1.2 mg and 67 μg, respectively, for PG vs 1.9 mg and 105 μg for POG; $P < .001$) and had significantly longer fluoroscopy times (mean, 1.3 min for PG vs 4.8 min for POG; $P < .0001$). NRS scores, morphine doses, total room times, technical success, complication rates, and QOL did not differ significantly between groups. The one major complication, a misplaced PG in the peritoneal cavity, followed a technical failure of POG creation.

Conclusions: Despite the differences in insertion technique and tube caliber, the measured outcomes of POG and PG are comparable.

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ABBREVIATIONS

FACT-EF = Functional Assessment of Cancer Therapy–Enteral Feeding [questionnaire], HNSCC = head and neck squamous-cell carcinoma, NRS = numeric rating scale, PEG = percutaneous endoscopic gastrostomy, PG = pigtail gastrostomy, POG = peroral image-guided gastrostomy, QOL = quality of life, RIG = radiologically inserted gastrostomy

Gastrostomy is used to maintain nutritional requirements in patients with dysphagia from radiation therapy for locoregionally advanced head and neck squamous-cell carcinoma (HNSCC) (1,2). At our institution, gastrostomy is undertaken prophylactically in this population, and the tube is inserted radiologically. Radiologically guided percutaneous gastrostomy tube insertion is a safe alternative technique to percutaneous endoscopic gastrostomy (PEG) (3). Radiologically inserted gastrostomy (RIG) was first described in 1983 (4–6), and peroral image-guided gastrostomy (POG) was reported a decade later (7,8). RIG is usually performed by using a pigtail catheter–retained or balloon-retained gastrostomy tube. POG uses a larger-bore gastrostomy tube with a mushroom retainer that is inserted perorally after a fluoroscopically guided gastric puncture through the anterior abdominal wall, and a wire directed retrogradely through the esophagus and mouth. The technical success and complications of RIG and POG have been reported in prospective and retrospective series (9–15), but data comparing patients' tolerance of these two gastrostomy tubes, particularly in terms of intra- and postprocedural pain and gastrostomy-related quality of life (QOL), are lacking.

The aim of the present prospective randomized study was to compare the following outcomes between two radiologically guided gastrostomy creation techniques of PG and POG: the primary outcome was the level of intra- and postprocedural pain, and secondary outcomes were fluoroscopy time, total room time, technical success rate, complication rate, and gastrostomy-related QOL.

MATERIALS AND METHODS

Patients

This prospective randomized pilot study was approved by the institutional research ethics board. Sixty consecutive adult patients were recruited who met the inclusion criterion of undergoing prophylactic percutaneous radiologically guided gastrostomy creation before (chemo) radiation therapy with curative intent for HNSCC. Exclusion criteria included established pharyngeal obstruction and gastrostomy tube insertion for palliative treatment. There were no previous data in the literature from which to derive a power calculation for the primary outcome measure of pain. As a result of a change in study doctor, 37 patients were recruited from June to September 2013 and 23 patients were recruited from January to March 2014. The same script and questions were used for all patients. Patients gave written informed consent in the inpatient unit and were randomized to one of two parallel groups: creation of a 14-F PG or 20-F POG. Participants were block-randomized in a 1:1 ratio by using sealed envelopes. Participants and study personnel could not be blinded to the technique of insertion because a POG tube is inserted perorally.

Techniques

PG and POG procedures were performed under conscious sedation with titrated doses of intravenous midazolam and fentanyl (Sandoz, Boucherville, Quebec, Canada) administered by a registered nurse. Standard initial doses administered for both groups were 1 mg midazolam and 50 μg fentanyl unless contraindicated. Patients were assessed every 5 minutes, and additional dose increments of 0.5 mg midazolam/25 μg fentanyl were administered if required, aiming for a sedation score of 2–4 on the Ramsay sedation scale (16). If more than 100 μg of fentanyl per hour was required, radiologist approval was required before administration.

For PG, air was insufflated through a nasogastric tube by using a barium puffer (E-Z-EM, Anjou, Quebec, Canada). The fluoroscopically guided puncture site was infiltrated with 1% lidocaine (Alveda Pharmaceuticals, Toronto, Ontario, Canada), an 18-gauge, 15-cm two-part trocar needle (Cook, Bloomington, Indiana) was inserted, and intragastric position was confirmed with Visipaque-270 contrast medium (GE Healthcare, Waukesha, Wisconsin). An 80-cm Amplatz extra-stiff wire (Cook) was introduced through the needle, and the tract was dilated with a 14-F Coons dilator (Cook) followed by placement of a multipurpose 14-F pigtail catheter (Cook). PG position was confirmed by contrast medium injection. An enteral feeding adaptor (Cook) was placed, and the tube was fixed to the skin with Tegaderm (3M, Berkshire, United Kingdom).

For POG, a 20-F PEG Systems-FLOW/PEG Push Technique tube kit (Cook) was used. An orogastric tube was inserted and the stomach was insufflated with air. Intragastric position of the trocar needle was confirmed, the esophagus was cannulated in retrograde fashion with a 45-cm, 5-F Kumpe catheter (Cook), and a hydrophilic wire (Terumo, Tokyo, Japan) was advanced through the mouth. If a difficult esophageal cannulation was encountered, the snare contained in the kit was inserted through the mouth into the stomach and the hydrophilic wire was snared and pulled out through the mouth. The hydrophilic wire was exchanged for an 0.035-inch, 260-cm wire, and a 20-F gastrostomy catheter with a mushroom retainer was inserted in antegrade fashion over the wire