



# Percutaneous radiologic gastrostomy with single gastropexy using balloon-assisted tract dilatation: comparison with peel-away sheath

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## PURPOSE

To evaluate the safety and efficacy of percutaneous radiologic gastrostomy (PRG) with balloon-assisted tract dilatation (BATD) using a single gastropexy.

## METHODS

This retrospective study was approved by the institutional review board. From August 2018 to October 2022, 61 patients (53 male and 8 female, mean age 67 years, age range 27–90 years) underwent PRG with balloon-retained tubes for enteral nutrition. Single gastropexy was performed in all cases. Patients were divided into two groups based on the tract dilatation technique used. In the first group, BATD (n = 48) was performed. In the second group, a 24-Fr peel-away sheath (PAS) was used for tract dilatation (n = 13). Patient demographics, technical success rate, clinical success rate, fluoroscopy time, cumulative radiation dose, and complications were retrospectively evaluated. The Mann–Whitney U test for continuous variables and Fisher’s exact test for categorical variables were performed to compare the two groups.

## RESULTS

All procedures were successfully performed with 100% technical and clinical success rates in both groups. The mean fluoroscopy time for the BATD group vs. the PAS group ( $1.68 \pm 0.93$  min vs.  $3.56 \pm 2.41$  min,  $P < 0.001$ ) and mean cumulative radiation dose ( $12.98 \pm 9.28$  mGy vs.  $33.01 \pm 15.14$  mGy,  $P < 0.001$ ) were significantly lower in the BATD group compared with the PAS group. There was one major complication of peritonitis that led to death in the PAS group (1/13, 7.7%) and no major complications in the BATD group. Minor complications such as pneumoperitoneum, abdominal pain, leakage, and balloon deflation occurred in 16 patients: 12 (12/48, 25.0%) patients in the BATD group and 4 (4/13, 38.5%) patients in the PAS group. The overall rate of major and minor complications was higher in the PAS group but did not show statistically significant differences (odds ratio: 1.875, 95% confidence interval: 0.514–6.841,  $P = 0.486$ ).

## CONCLUSION

BATD using a single gastropexy is a safe and effective technique for PRG.

## KEYWORDS

Fluoroscopy, gastropexy, gastrostomy, radiology, interventional, stomach

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Received 05 June 2023; revision requested 03 July 2023; accepted 27 July 2023.



Epub: 31.08.2023

Publication date: 07.11.2023

DOI: 10.4274/dir.2023.232342

Percutaneous radiologic gastrostomy (PRG) is an enteral nutrition method widely performed in patients in whom oral intake is unsafe or impossible and is now widely recognized as a safe procedure with low complication rates.<sup>1,2</sup> Since Preshaw<sup>3</sup> first performed PRG in 1981, the procedure’s anchor technique and method of tract dilatation have undergone several modifications.

A previous study reported that PRG with a single gastropexy using a tract separate from the one used for tube placement is technically feasible and has a low complication rate.<sup>4</sup> However, the study only placed 12- or 14-Fr pigtail-retained catheters, which are not currently

available in Korea, and used dilators for tract dilatation. In addition, several researchers have reported that small-bore gastrostomy tubes are more prone to tube dysfunction, and large-bore tubes perform better in terms of the time it takes to achieve the feeding goal.<sup>5,6</sup> Another study reported on the safety and effectiveness of large-bore gastrostomy catheter placement using balloon-assisted tract dilatation (BATD), but the study used three gastropexy T-fasteners for stomach fixation.<sup>7</sup>

To date, there is no report of PRG with a single gastropexy using BATD. The aim of this study was to compare this technique to conventional methods using a peel-away sheath (PAS) and assess BATD's technical feasibility and overall complication rate.

## Methods

### Patients

This is a retrospective study that was approved by the Kosin University Gospel Hospital (KUGH 2022-08-014, 25/08/2022). Due to the retrospective nature of the study, informed consent of the patients was not required.

From August 2018 to October 2022, 61 patients who underwent PRG with balloon-retained tubes for enteral nutrition were included in this study. The mean age of the patients was 67 (range: 27–90) years, and there were 53 males and 8 females. Underlying diseases included head and neck cancer (n = 29), esophageal cancer (n = 14), cerebrovascular disease (n = 10), dysphagia (n = 4), Parkinson's disease (n = 2), benign esophageal stricture (n = 1), and tracheostomy state (n = 1). Patients were divided into two groups based on the types of tract dilatation techniques used. In the first group, the authors used the BATD technique (n = 48, 78.7%). In the second group, tract dilatation was performed using a 24-Fr PAS (n = 13, 21.3%).

#### Main points

- Percutaneous radiologic gastrostomy (PRG) is a procedure widely performed in patients with conditions that make oral intake unsafe or impossible.
- There have been several modifications of the PRG procedure in anchor technique and method of tract dilatation.
- PRG with a single gastropexy using balloon-assisted tract dilatation appears to be a safe and effective technique.

The baseline characteristics of all patients are presented in Table 1.

### Technique

All procedures were performed by two board-certified interventional radiologists at our hospital. Gastrostomy procedures were performed under fluoroscopic guidance using local anesthesia without intravenous sedation, and all patients received balloon-retained catheters.

Patients fasted for at least 24 hours before the procedure and received 20 mg of butylscopolamine just before the procedure. The abdomen was prepped and draped in a sterile fashion. Through an indwelling nasogastric tube, the stomach was inflated with approximately 500 mL of air. Under fluoroscopic and ultrasound guidance, a site for gastrostomy placement was selected and marked in the epigastric region, avoiding the transverse colon and left lobe of the liver. Local anesthesia was administered at the selected site for gastropexy and gastrostomy. In this region, an incision of approximately 5 mm was made in the skin, and a 17-gauge introducer needle preloaded with an anchor (Cope Gastrointestinal Suture Anchor Set, Cook, Bloomington, IN, USA) was used to access the insufflated stomach. Then, a single suture anchor was deployed and pulled tight to fix the anterior stomach wall against the abdominal wall. After using fluoroscopy to confirm its location within the stomach, a 0.035-inch guidewire was passed into the stomach, and a small dilator (8-Fr) was introduced over the guidewire.

In the BATD group, an Amplatz Super Stiff Guidewire (Boston Scientific, Marlborough,

MA, USA) was also inserted into the stomach through the dilator, and the gastrostomy tube (Entuit Gastrostomy BR Balloon Retention Feeding Tube, Cook, Bloomington, IN, USA) was preloaded on the shaft of a high-pressure balloon. Depending on the diameter of the tube, different balloon sizes were used: 8 mm for the 20-Fr tube, 7 mm for the 18- and 16-Fr tubes, and 6 mm for the 14-Fr tube. The inflation time for ballooning was approximately 30 seconds. As the balloon was deflated, the gastrostomy tube and balloon catheter were advanced together over the wire into the stomach. After removal of the balloon catheter, the retention balloon of the gastrostomy tube was then inflated with a contrast-saline mixture. A contrast medium injection was used to confirm the gastrostomy tube was in the appropriate location. The anchor was then sutured to the abdominal wall, and the gastrostomy tube was fixed to the skin (Figure 1).

In the PAS group, the tract was dilated using a telescoping serial dilator with a 24-Fr peel-away introducer sheath (Peel-away Introducer Set, Cook, Bloomington, IN, USA), and the gastrostomy tube was inserted into the stomach through the PAS. The sheath was then removed, and the retention balloon was inflated with a contrast-saline mixture. After confirming the location of the gastrostomy tube using contrast injection, a suture anchor was sutured to the skin with a small plastic disk. Suture was released 7–10 days after procedure. The sheath was then removed, and the retention balloon was inflated with a contrast-saline mixture (Figure 2).

After the procedure, patients were evaluated for pneumoperitoneum by radiograph and observance of clinical symptoms, such as abdominal pain and fever. If no abnor-

**Table 1.** Characteristics of all patients

	Overall (n = 61)	BATD group (n = 48)	PAS group (n = 13)
Mean age (range)	67 (27–90)	68 (27–90)	62 (49–74)
<b>Sex</b>			
Male	53	41	12
Female	8	7	1
<b>Underlying disease</b>			
Head and neck cancer	29	20	9
Esophageal cancer	14	12	2
Cerebrovascular disease	10	8	2
Dysphagia	4	4	0
Parkinson's disease	2	2	0
Benign esophageal stricture	1	1	0
Tracheostomy state	1	1	0

BATD, balloon-assisted tract dilatation; PAS, peel-away sheath.

malities were present, patients were administered 100 cc of water three times through the gastrostomy tube the day after the procedure, and if there were still no abnormal symptoms, liquid intake was initiated.

#### Data collection and definition

Data from all patients were collected, reviewed, and recorded, including the radiolo-

gy information system and electronic medical record (EMR).

Technical success was defined as when the gastrostomy tube was effectively placed into the stomach, and clinical success was defined as when the feeding tube functioned correctly. The follow-up period was determined as days of hospitalization after

the procedure. Data on fluoroscopy time and radiation dose during the procedure were also collected. Complications were categorized as major and minor according to the Society of Interventional Radiology.<sup>8</sup> Major complications were defined as conditions that were life-threatening, causing gastrostomy malfunction, or requiring additional intervention. Minor complications were defined as conditions requiring only minimal medical management or local wound care.

#### Statistical analysis

Univariable analyses were performed using the Mann–Whitney U test and the Fisher's exact test for continuous data and categorical data, respectively. The following data were evaluated: age, sex, underlying disease for PRG, technical and clinical success, and major or minor complications, and  $P < 0.05$  was considered to indicate a statistically significant difference. All statistical analyses were performed using IBM SPSS Statistics for Windows (version 28.0. Armonk, NY: IBM Corp).

#### Results

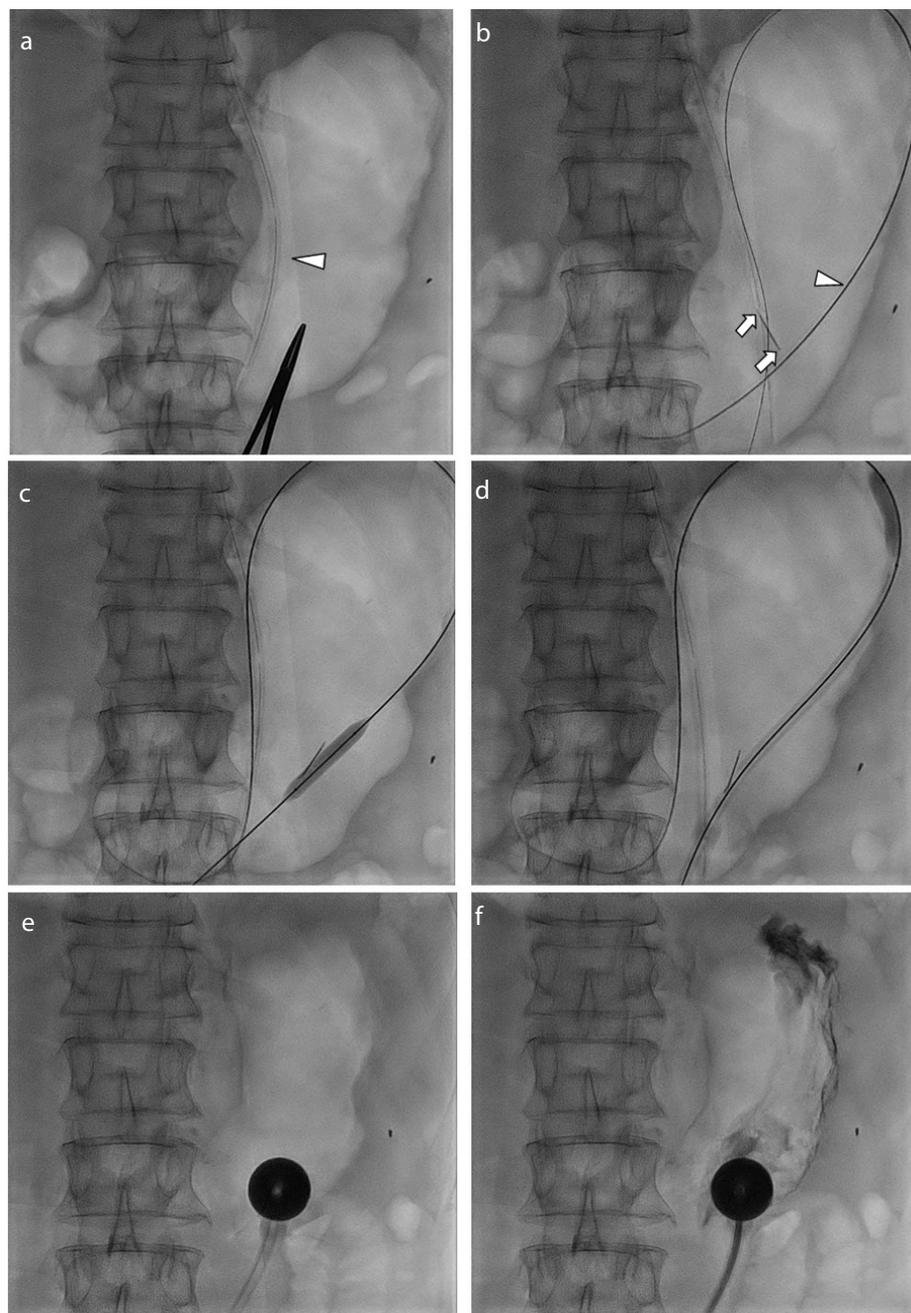
In 48 patients (78.7%), BATD was used, and the 24-Fr PAS was used in 13 patients (21.3%). A single gastropexy was performed in all cases.

In the BATD group, the mean age was 68.5 years, and in the PAS group, the mean age was 62 years. There were 7 females and 41 males in the BATD group and 1 female and 12 males in the PAS group. There was no statistical difference in the age ( $P = 0.976$ ) and sex ( $P = 0.453$ ) between the two groups.

The technical success rate using a single gastropexy under fluoroscopic guidance was 100% in both groups, and the clinical success rate was 100% in both groups. The mean follow-up time was 24 days (range: 1–209 days).

The diameters of the placed tubes were varied in the BATD group: 20-Fr tubes in 10 patients, 18-Fr tubes in 12 patients, 16-Fr tubes in 21 patients, and 14-Fr tubes in 5 patients. In the PAS group, all patients received a 24-Fr tube.

The mean fluoroscopy time in the BATD group was  $1.68 \pm 0.93$  min (range: 0.68–5.93 min) and in the PAS group was  $3.56 \pm 2.41$  min (range: 1.62–11.35 min) ( $P < 0.001$ ). The mean radiation dose in the BATD group was  $12.98 \pm 9.28$  mGy (range: 2.6–46.8 mGy) and in the PAS group was  $33.01 \pm 15.14$  mGy (range: 19.0–71.0 mGy) ( $P < 0.001$ ) (Table 2).



**Figure 1.** Successful percutaneous radiologic gastrostomy in patient with a single gastropexy using balloon-assisted dilatation. (a) Stomach insufflated with 500 mL of air through a nasogastric tube (arrowhead). Scissor indicates a site for gastrostomy placement. (b) After introducer needle advanced into the inflated stomach, suture anchor (arrow) was deployed into the stomach. A stiff guidewire (arrowhead) was inserted into the stomach through the needle. (c) The gastrostomy tube was preloaded on the shaft of a high-pressure balloon, and the balloon was inflated for 30 seconds. (d) As the balloon was deflated, the gastrostomy tube and balloon catheter were advanced together over the wire into the stomach. (e) The gastrostomy tube was secured in place by inflation with a contrast–saline mixture. (f) Finally, a contrast medium was injected through the gastrostomy tube to fluoroscopically confirm the intragastric location.

Major complications (such as peritonitis, migration, bleeding, and pneumonia) occurred in one patient from the PAS group. The patient underwent PRG for esophageal cancer and had no acute symptoms, and the abdominal radiograph the day after the procedure did not indicate pneumoperitoneum. He routinely tried 100 kcal of feeding liquids two days after the procedure, after which the patient complained of severe abdominal pain, and an abdominal radiograph revealed pneumoperitoneum. When subsequent computed tomography indicated that the gastrostomy tube had exited the stomach and migrated to the abdominal cavity, the tube was immediately removed, and the patient received supportive treatment, such as antibiotics and total parenteral nutrition. However, he died 11 days after the procedure.

Possible minor complications included pneumoperitoneum, abdominal pain, skin infection, leakage, and balloon deflation. In the BATD group, 12 patients (25.0%) reported minor complications, including pneumoperitoneum (9/46, 19.6%), abdominal pain (4/46, 8.7%), and leakage (1/46, 2.2%), and two of those patients complained of both pneumoperitoneum and abdominal pain. In

the PAS group, four patients (38.5%) reported minor complications, including pneumoperitoneum (2/13, 15.4%), abdominal pain (2/13, 15.4%), and balloon deflation (1/13, 7.7%), and one of those patients complained of both pneumoperitoneum and abdominal pain.

The overall complication rate was higher in the PAS group; however, the difference was statistically non-significant [odds ratio (OR): 1.875, 95%; confidence interval (CI): 0.514, 6.841;  $P = 0.486$ ] (Table 3).

Twenty-two patients in the BATD group and 13 patients in the PAS group received a large-bore (18- or 20-Fr) gastrostomy tube. Four of these patients in the BATD group (4/22, 18.2%) experienced minor complications: pneumoperitoneum and abdominal pain were reported in three patients and one patient, respectively. Five patients in the PAS group (5/13, 38.5%) who received 20-Fr tubes experienced complications, including one major complication. The overall rate of large-bore tube insertion complications was higher in the PAS group; however, the difference was statistically non-significant (OR: 2.813, 95%; CI: 0.593, 13.336;  $P = 0.243$ ) (Table 4).

## Discussion

There are various ways to perform PRG. Usually, PRG is performed by puncturing the stomach and inserting a gastrostomy tube, either a balloon-retained or pigtail-retained catheter. Pigtail-retained catheters have been widely used because they are easy to insert,<sup>9,10</sup> but they are currently not available in Korea. Several radiologists have placed catheters via the oropharynx using a mushroom-retained catheter and reported that this method was less prone to tube dysfunction and resulted in lower complication rates.<sup>6,11</sup> However, considering that half of the patients in this study were head and neck cancer patients, a mushroom-retained catheter was inappropriate because the catheter must pass through the mouth. Therefore, in the present study, a balloon-retained catheter was used for the gastrostomy procedure.

The PRG procedure has become safer and more effective through several modifications in the anchor technique.<sup>4,12,13</sup> Gastropexy devices provide stabilization of the stomach to the anterior abdominal wall, especially when large-bore catheters are used.<sup>13,14</sup> One prospective randomized study suggested routine performing of T-fastener gastropexy for all PRG procedures.<sup>15</sup> Another retrospective study found that the use of gastropexy is superior to non-gastropexy gastrostomy in terms of preventing leakage.<sup>16</sup> However, gastropexy-related complications, such as suture-related pain, suture rupture, migration, or wound infection, can occur.<sup>17,18</sup> Although removing the T-fasteners can resolve gastropexy-related complications,<sup>15</sup> using more anchors can increase complications such as bleeding and infection.<sup>19</sup> Therefore, many surgeons have tried to minimize the number of suture anchors while allowing safe and easy maneuvering of catheters.<sup>4,20,21</sup> Milovanovic et al.<sup>22</sup> reported one major complication (1.4%) and three minor complications (4.3%) in 69 patients using a single-puncture, multi-anchor technique. Although the complication rate was lower than in the current study, most gastrostomy tubes had a diameter of 12-Fr (86.9%), and there was only one tube larger than 18-Fr.<sup>22</sup> The difference in tube diameter makes it difficult to compare the complication rates. This study shows a safe and effective procedure to ensure the fixation of large-diameter gastrostomy tubes using a single gastropexy. While inserting the balloon dilatation catheter through the guidewire, the surgeon should pull the anchor to attach the anterior stomach wall to the abdominal wall. At the same time, this

**Table 2.** Statistical analysis of fluoroscopy time and radiation dose

	Overall (n = 61)	BATD group (n = 48)	PAS group (n = 13)	P value
Fluoroscopy time (min)	2.05 ± 1.36	1.68 ± 0.93	3.56 ± 2.41	<0.001
Radiation dose (mGy)	17.39 ± 13.66	12.98 ± 9.28	33.01 ± 15.14	<0.001

Data are presented as mean ± standard deviation. BATD, balloon-assisted tract dilatation; PAS, peel-away sheath.

**Table 3.** Postprocedural complications

	Overall (n = 61)	BATD group (n = 48)	PAS group (n = 13)	P value
Overall complications	17 (27.9%)	12 (25.0%)	5 (38.5%)	0.486
Major complications	1 (1.6%)	0	1 (7.7%)	
Minor complications	16 (26.3%)	12 (25.0%)	4 (30.8%)	
Pneumoperitoneum	11 (18.0%)	9 (19.6%)	2 (15.4%)	
Abdominal pain	6 (9.8%)	4 (8.7%)	2 (15.4%)	
Skin infection	0	0	0	
Leakage	1 (1.6%)	1 (2.2%)	0	
Balloon deflation	1 (1.6%)	0	1 (7.7%)	

Data are presented as mean ± standard deviation. BATD, balloon-assisted tract dilatation; PAS, peel-away sheath.

**Table 4.** Complications of large-bore gastrostomy tube in two groups

	BATD group with large-bore tube <sup>a</sup> (n = 22)	PAS group (n = 13)	P value
Complications	4 (18.2%)	5 (38.5%)	0.243
No complications	18 (81.8%)	8 (61.5%)	

Data are presented as number (percent). <sup>a</sup>Large-bore tube includes 20- and 18-Fr gastrostomy tubes. BATD, balloon-assisted tract dilatation; PAS, peel-away sheath.

technique should be performed gently, as applying too much tension can cause damage to the stomach wall or break the anchor itself.

There are two reports for the placement of gastrostomy tubes using BATD.<sup>7,23</sup> Research indicates that BATD allows for rapid dilatation of the gastrostomy tract, and insertion of the tube can be performed in a single step, which reduces procedural time.<sup>7</sup> In the study, fluoroscopy time and cumulative radiation dose were significantly lower in the BATD group compared with the PAS group ( $P < 0.001$ ). This suggests that BATD is more effective than using a PAS, with the benefit that it lessens radiation exposure for

both surgeons and patients, in line with the principle of reducing radiation doses to “as low as reasonably achievable.”<sup>24</sup> Complication rates also show consistent results. Major complications did not occur in the BATD group, whereas one patient in the PAS group experienced a major complication (peritonitis). Patients in each group experienced minor complications: 25% (12/48) for the BATD group and 38.5% (5/13) for the PAS group. Complication rates were lower in the BATD group, but there was no statistical difference between the two groups ( $P = 0.486$ ). The PAS group used a 24-Fr PAS, and considering that the gastrostomy tube is 20-Fr, the PAS expands the gastrostomy tract more than necessary. In contrast, using BATD, the gastro-

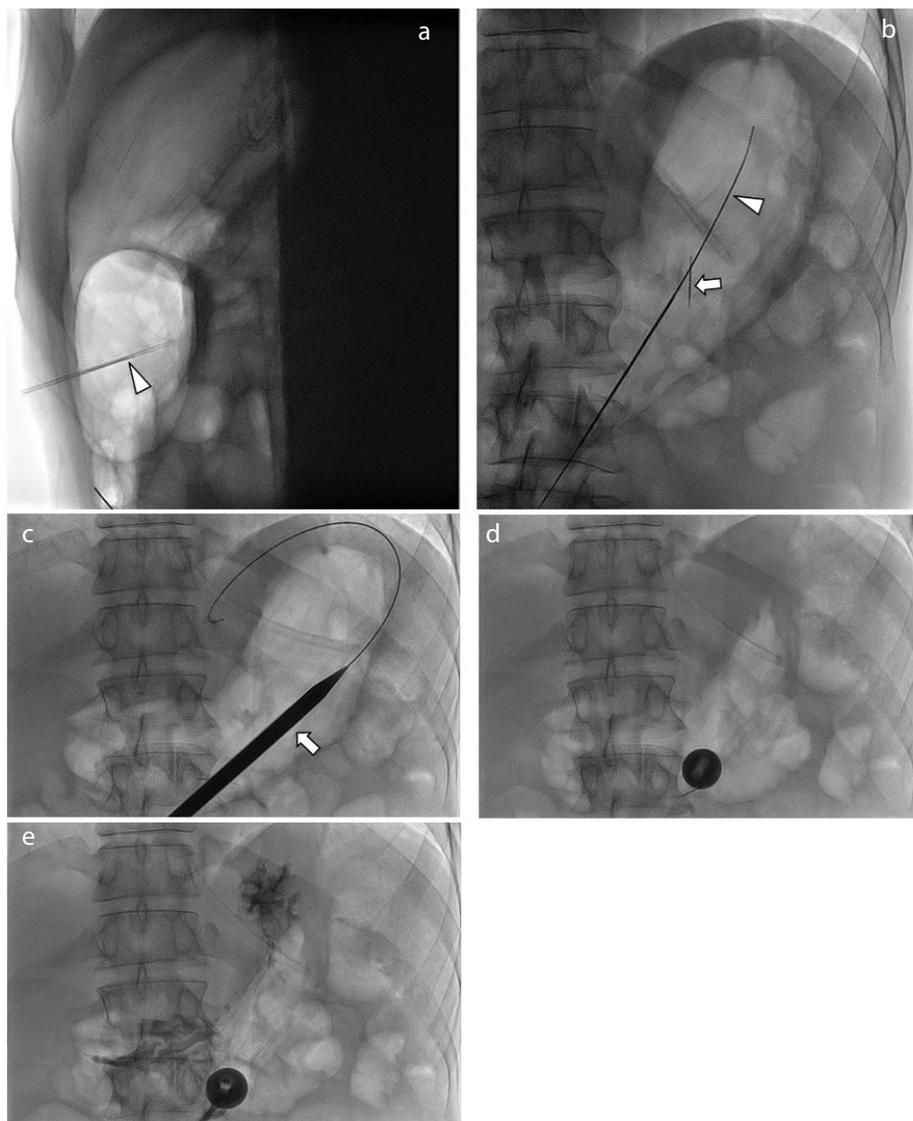
tomy tract can be expanded appropriately to the diameter of the tube, thereby lessening the probability of complications.

Maroun et al.<sup>7</sup> investigated the efficiency and safety of balloon-assisted gastrostomy. The previous study used three gastropexy T-fasteners, a 9–10 mm balloon for a 20-Fr tube, and 1–2 minutes for balloon inflation. In the current study, the authors used a single gastropexy for stomach fixation, a 6–8 mm balloon for a 14- to 20-Fr tube, and approximately 30 seconds for balloon inflation. Compared with the previous study, the balloon capacity was smaller, and the inflation time was shorter. The authors tried to minimize the tract dilatation, resulting in no migration and a low leakage rate (2.2%) in the BATD group.

It may be argued that differences between tube diameters could affect the complication rates. In the BATD group, tubes of various diameters from 14-Fr to 20-Fr were used, but in the PAS group, only 20-Fr tubes were used. Therefore, it may be thought that many complications in the PAS group occurred because larger-diameter tubes were used. However, the overall rate of large-bore tube (18 or 20-Fr) insertion complications was more than two times higher in the PAS group (5/13, 38.5%) than those in the BATD group with a large-bore tube (4/22, 18.2%). Therefore, rather than the diameter of the tube, the method of tract dilatation seems to be more related to the complication rate, but statistical significance was not found ( $P = 0.243$ ).

There were several limitations of the present study. First, it was a small study population from a single institution, and, therefore, institutional bias may make it difficult to generalize the results of this study. Second, the number of patients who underwent PRG with the PAS technique was much smaller compared to the number of patients who underwent PRG with the BATD technique, and the disproportionate number of the two groups may exaggerate or reduce the differences between them. Third, it is possible that complications went unreported because this information was retrospectively collected by review of EMRs. Thus, if post-procedural complications were not included in these records, the presence of complications could not be confirmed.

In conclusion, PRG with a single gastropexy using BATD appears to be a safe and effective technique and results in lower radiation exposure and incidence of complications than using a PAS for tract dilatation.



**Figure 2.** Successful percutaneous radiologic gastrostomy in patient with a single gastropexy using a 24-Fr peel-away sheath. (a) Introducer needle preloaded with anchor (arrowhead) was accessed to inflated stomach. (b) Suture anchor (arrow) was deployed into stomach. A guidewire (arrowhead) was inserted into the stomach through the needle. (c) Tract dilatation using a serial dilator and 24-Fr peel-away introducer sheath (arrow) was performed. (d) The gastrostomy tube was secured in place by inflation with a contrast-saline mixture. (e) Finally, a contrast medium was injected through the gastrostomy tube to fluoroscopically confirm the intragastric location.

## Conflict of interest disclosure

The authors declared no conflicts of interest.

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