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Retrospective comparison of outcomes and associated complications between large bore radiologically inserted gastrostomy tube types

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Abstract

Purpose: Multiple approaches to radiologically inserted gastrostomy (RIG) exist. The goal of this study was to compare 30-day outcomes and associated complications between large bore balloon-retained (BR), loop-retained (LR), and pull-type (PT) RIG devices.

Methods: Data on 1477 patients who underwent RIG between January 1, 2005 and December 31, 2016 were collected retrospectively using a dedicated interventional radiology database and electronic medical record. Statistical analysis was performed to compare complication rates between BR, LR, and PT devices.

Results: Ninety-eight percent (1477/1507) of the procedures were successfully performed. A total of 752 BR, 323 LR, and 402 PT gastrostomy tubes were placed. The overall complication rate for BR catheters was 5.7% (25 major [3.3%] and 18 minor [2.4%]). The overall complication rate for PT catheters was 3.7% (8 major [2.0%] and 7 minor [1.7%]). The overall complication rate for LR catheters was 1.6% (4 major [1.4%] and 1 minor [0.8%]). Compared to BR catheters, LR catheters had significantly fewer total complications ($P = 0.01$) but not minor complications ($P = 0.052$). There were no significant differences in the number of complications between LR and PT catheters or between BR and PT catheters.

Conclusions: Use of BR, LR, and PT devices for RIG is safe with a low incidence of complications. Compared to BR catheters, primary insertion of a LR gastrostomy was associated with significantly fewer overall complications within the first 30 days. Therefore, for initial tube placement, large bore LR catheters may be preferred over BR devices.

Key words: Radiologically inserted gastrostomy—Balloon-retained—Loop-retained—Pull-type

Abbreviations

BR	Balloon-retained
LR	Loop-retained
PT	Pull-type
RIG	Radiologically inserted gastrostomy

Gastrostomy is a well-established method for providing long-term enteral feeding in patients with an intact gastrointestinal tract but in whom oral intake is either impossible, unsafe, or insufficient to meet their dietary requirements [1–3]. Such a scenario is often encountered in patients with neurogenic dysphagia as a result of stroke, obstructive head and neck or esophageal malignancies, and malnourishment as a result of chronic disease.

In general, RIG is typically performed in one of two ways. The first is a pure percutaneous approach and involves puncturing the stomach through the abdominal wall and then serially dilating the puncture site until either a LR or BR catheter can be placed into the stomach along a guidewire. These catheters, commonly referred to

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as "push-type" catheters, rely on the use of a locking loop or inflatable balloon to retain the device in the stomach. The second method involves puncture of the stomach followed by passage of a guidewire through the gastroesophageal junction and into the oropharynx where a large bore (20-F) "pull-type" (PT) catheter can be attached. It is then advanced through the oropharynx and esophagus and into stomach where it is retained by a semi-rigid dome at the distal end of the tube.

While prior studies have compared outcomes and associated complications between these two methods and the various catheter types they utilize, most have involved a few hundred patients or less [4–12]. Given the relatively low frequency of catheter-associated complications, many of these studies have been underpowered to detect significant differences between methods and/or tube types. Additionally, in these studies, the diameter of the gastrostomy tube often differed substantially with LR devices ranging from 12 to 14-F while the BR and PT gastrostomies ranged from 18 to 24-F. Advocates of primary insertion of BR and PT gastrostomies over LR tubes often cite the larger bore which is thought to be less prone to clogging and malfunction as the primary benefit.

In our practice, primary insertion of LR gastrostomy is performed with an 18-F catheter. Therefore, we aimed to retrospectively compare outcomes and associated complications between primary insertion of large bore LR, BR, and PT devices within a cohort of 1477 patients that underwent RIG across three hospitals at a tertiary academic medical center over the span of 12 years in order to better understand the advantages of the differing RIG methods and ultimately improve patient outcomes.

Materials and methods

Patient selection and data collection

In accordance with the institutional review board, a retrospective analysis of all patients who underwent gastrostomy tube placement between January 1, 2005 and December 31, 2016 at three academic medical centers was performed by examining the records from a dedicated interventional radiology database (HI-IQ; ConexSys, Lincoln, Rhode Island). In total, 1477 RIG tubes were placed in 1440 patients (917 men and 560 women; age range, 15–102 years; mean age, 65.7 years) in 1507 attempts (Table 1). Of the procedures that were unsuccessful, 83% (25/30) were due to lack of a safe window in which to place the catheter between the abdominal wall and stomach. All catheters were placed by one of 25 fellowship-trained interventional radiologists with an average of 9 years in practice at time of publication with or without the aid of a fellow, resident, or medical student in an inpatient interventional radiology suite. Seven hundred fifty-two 18 or 20-F (and rarely, 22 or 24-F) single-use BR catheters (MIC; Kimberly-Clark, Roswell, GA), 323 18-F LR catheters (Luer Lock Cook-Cope Type Locking Loop Multipurpose Drainage Catheter; Cook, Bloomington, IN), and 402 20-F PT catheters (Bard Access Systems, Salt Lake City, Utah) were inserted. Catheter type and size were placed on the basis of the attending physician's preference and/or hospital practice; however, LR and BR catheters were preferentially placed in patients with head and neck or esophageal malignancies.

Table 1. Patient demographics by tube type

	Balloon	Loop	Pull-type	Total
Male (# of patients)	416	317	184	917
Female (# of patients)	336	6	218	560
Age (years)	65.2	64.9	67.4	65.7

The electronic medical records of these patients were examined for procedural details including technical success, complications, and type of gastrostomy tube. For every complication, the procedural note was reviewed to determine whether the complication was attributable to the tube placement. Eleven patients had 2 complications within the 30-day period. In 6 of those patients, the complications were independent of one another, while in 5 patients, the second complication was either a consequence of the first, and therefore not considered independent, or not attributable to the tube. Complications included intra-procedural and post-procedural events. Complications were categorized as major or minor as defined by the Society for Interventional Radiology Standards of Practice Guidelines [13]. In general, minor complications are defined as requiring no additional therapy or intervention, while major complications are defined as requiring additional therapy, hospitalization longer than overnight, or resulting in permanent adverse sequelae or death. Complications were further subdivided into 1 of 5 categories: (1) device malfunction with adverse event (e.g., balloon rupture or device dislodgement/obstruction within 48 h of placement), (2) bleeding or hemorrhage from the access site, (3) local infection, (4) malposition, and (5) large volume pneumoperitoneum requiring surgical intervention and/or peritonitis.

Data interpretation and statistical analysis

To account for multiple gastrostomy tube procedures in certain patients, mixed effects logistic regression was used to ascertain the primary outcomes of type and number of complications. Parameters such as patient age and sex were not associated with outcome and thus not considered confounders. Specific complication types were rare and necessitated the use Fisher's exact test, precluding the use the hierarchical data modeling for those subgroups. Significance was defined as $P < 0.05$. All analyses were performed using STATA version 14.2 (StataCorp, College Station, TX).

Gastrostomy placement

Before all procedures, patients were kept NPO for at least 6 h. Patients who were coagulopathic (defined as having a prothrombin time > 17 s or international normalized ratio > 1.92) or thrombocytopenic (defined as having platelets < 150,000/μL blood) received blood products to correct deficiencies prior to the procedure to obtain a platelet count of at least 50 k. All patients received peri-procedural antibiotics (1 g ampicillin sodium/500 mg sulbactam sodium or 1 g ceftriaxone unless allergic) at the start of the procedure. Intravenous midazolam and fentanyl citrate were administered for sedation and analgesia and all patients were monitored by an Advanced Cardiac Life Support-certified member of the radiology nursing staff with critical care credentials. After the procedure, the catheter was placed to gravity drainage overnight and water boluses were started the following day after evaluation by interventional radiology staff. Tube feeds were then started if water boluses were tolerated. In our hospital system, all but 2 LR gastrostomies were placed at the VAMC based on preference of interventionalists and referring physicians at this institution.

Balloon- and loop-retained catheter placement

The technique for placing LR catheters was similar to that as previously described by Brown et al. [14]. Briefly, following gastric insufflation with the use of a nasogastric tube, local anesthesia was administered at the point of gastric puncture followed by two-point gastropexy (Cope gastrointestinal suture anchor; Cook, Bloomington, IN). A stiff guide wire was then inserted and the tract serially dilated to 18-F. After insertion of the catheter, iodinated contrast was injected to confirm appropriate positioning. Gastropexy sutures were cut within 1 week of the procedure. After approximately 4 weeks, patients were scheduled to return for exchange of the LR gastrostomy for an 18-F BR device.

The technique for placing BR catheters at our institution has been previously described in detail [6]. In brief, the stomach was insufflated using a nasogastric tube followed by administration of local anesthesia at the site of gastric puncture. A two-point gastropexy was performed followed by placement of a stiff guide wire into the stomach. The tract was serially dilated to 18, 20, or 24-F and an equally sized peel-away sheath was inserted over the wire into the stomach. A BR catheter was then placed through the sheath and the sheath removed. Following inflation of the balloon, iodinated contrast was injected to confirm satisfactory positioning. Gastropexy sutures were cut within 1 week of the procedure.

Pull-type catheter placement

PT catheters were placed using a technique similar to that described by Szymski et al. [15]. Briefly, following gastric insufflation with the use of a nasogastric tube, local anesthesia was administered at the point of gastric puncture and the stomach, and entered using an 18-gauge trocar needle under fluoroscopic guidance. Iodinated contrast solution was injected to confirm positioning within the stomach. A guide wire was then inserted through the needle and out of the stomach and esophagus into the oropharynx, where it was retrieved with a sterile hemostat. A PT catheter was attached to the guide wire and then advanced from the oral cavity into the stomach and through the site of gastric puncture. Following this, iodinated contrast was injected to confirm appropriate positioning.

Results

Patient demographics

Of the patients that underwent RIG placement, 917 (62.1%) were male and 560 (37.9%) were female (Table 1). Compared to PT catheters, BR devices were more frequently placed in men (55.3% male for BR devices vs. 45.8% male for PT devices; $P = 0.002$; Table 1) and LR catheters were more frequently placed in men than either BR or PT devices (98.1% male; $P < 0.001$; Table 1). The average patient age was 65.7 years. There was no significant difference in patient age between BR and LR or PT devices; however, patients that received PT devices were significantly older than those that received LR devices by 2.5 years ($P < 0.05$; Table 1). Demographic data listed by catheter type can be found in Table 1.

Indications for gastrostomy placement

The most common indication for gastrostomy placement was head and neck cancer (HNC), which occurred in 380 (25.7%) patients (Table 2). Compared with BR and PT catheters, LR catheters were more often placed in patients with HNC ($P < 0.001$), as were BR devices relative to PT catheters ($P < 0.001$; Table 2). This latter result was anticipated, since PT devices are a relative contraindication in patients with HNC. Cerebrovascular accidents (CVA), most commonly ischemic stroke, were the indication for 274 (18.5%) gastrostomy placements (Table 2). Compared with BR and LR catheters, PT catheters were more often placed in patients with CVA ($P < 0.001$), as were BR devices when compared to LR catheters ($P < 0.001$; Table 2). The third most common indication for gastrostomy placement was cancer, excluding esophageal, HNC, and cancer causing peritoneal carcinomatosis, which were other common indications and thus considered separate categories. One hundred and twenty-six (8.5%) patients had cancer

Table 2. Indications for gastrostomy by tube type

	Balloon	Loop	Pull-type	Total	*P* values		
					Loop vs. balloon	Loop vs. pull	Balloon vs. pull
AID	21 (2.8)	3 (0.9)	8 (2.0)	32 (2.2)	0.07	0.36	0.55
AMS	24 (3.2)	2 (0.6)	10 (2.5)	36 (2.4)	**0.009**	0.08	0.59
ASP	30 (4.0)	6 (1.9)	22 (5.5)	58 (3.9)	0.09	**0.01**	0.30
CO	84 (11.2)	8 (2.5)	34 (8.4)	126 (8.5)	< **0.001**	< **0.001**	0.15
CVA	149 (19.8)	7 (2.2)	118 (29.4)	274 (18.6)	< **0.001**	< **0.001**	< **0.001**
DYS	30 (4)	8 (2.5)	21 (5.2)	59 (4.0)	0.28	0.08	0.37
ESO	31 (4.1)	20 (6.2)	4 (1.0)	55 (3.7)	0.16	< **0.001**	**0.002**
FTT	60 (8.0)	9 (2.8)	30 (7.5)	99 (6.7)	**0.001**	**0.007**	0.82
HNC	138 (18.4)	226 (70.0)	16 (4.0)	380 (25.7)	< **0.001**	< **0.001**	< **0.001**
INF	10 (1.3)	1 (0.3)	10 (2.5)	21 (1.4)	0.19	0.03	0.16
NDD	19 (2.5)	10 (3.1)	40 (10)	69 (4.7)	0.68	< **0.001**	< **0.001**
NEU	26 (3.5)	3 (0.9)	8 (2.0)	37 (2.5)	**0.02**	0.36	0.20
NMD	9 (1.2)	11 (3.4)	9 (2.2)	29 (2.0)	**0.02**	0.37	0.21
OTH	42 (5.6)	8 (2.5)	24 (6.0)	74 (5.0)	**0.03**	**0.03**	0.79
PER	56 (7.5)	0 (0)	37 (9.2)	93 (6.3)	< **0.001**	< **0.001**	0.31
PSY	2 (0.3)	1 (0.3)	0{0)	3 (0.2)	1.00	0.45	0.55
PUL	21 (2.8)	0 (0)	11 (2.7)	32 (2.2)	**0.001**	**0.002**	1.00
Total	752	323	402	1477			

Values in parentheses are percentages
AID, autoimmune/inflammatory disease; AMS, altered mental status; ASP, aspiration/reflux; CO, cancer other; CVA, cerebrovascular accident; DYS, dysphagia not otherwise specified; ESO, esophageal cancer; FTT, failure to thrive; HNC, head and neck cancer; INF, infectious; NDD, neurodegenerative disease; NEU, neurological (other); NMD, neuromuscular disease; OTH, other (e.g., stricture, trauma, multiple comorbidities, genetic disorder); PER, peritoneal carcinomatosis; PSY, psychiatric; PUL, pulmonary disease

requiring gastrostomy, in which BR and PT devices were more often placed than LR devices (Table 2). As a whole, the three most common indications (HNC, CVA, and cancer not including esophageal or peritoneal carcinomatosis) accounted for 780 (52.7%) gastrostomy placements (Table 2). The remaining 14 categories of indication for RIG placement and their significance with respect to RIG type are listed in Table 2.

Balloon-retained devices

BR devices had an overall complication rate of 5.7% (43/752; Table 3). Twenty-five of these were considered major complications (3.3%) and 18 were considered minor (2.4%; Table 3). For BR catheters, the frequency of device malfunction resulting in an adverse event was 1.1% (8/751; 5 major [0.7%] and 3 minor [0.4%]; Table 3). In 3 of these instances, the balloon ruptured resulting in migration of the catheter tip into the peritoneal cavity. The frequency of bleeding was 1.1% (8/751; 3 major [0.4%] and 5 minor [0.7%]; Table 3). In 3 of the major bleeding complications, the patients either required transfusion, embolization, or additional surgery to stop the bleeding. The frequency of local infection was 0.7% (5/751; 4 major [0.5%] and 1 minor [0.1%]; Table 3). In 3 of these instances, the patient had to be taken to surgery for debridement. The frequency of malposition was 2.3% (17/751; 11 major [1.5%] and 6 minor [0.8%]; Table 3). In the majority of these cases, the tube came dislodged and required a repeat procedure to reinsert it. The frequency of pneumoperitoneum/peritonitis was 0.7% (5/751; 2 major [0.3%] and 3 minor [0.4%]; Table 3). The two major complications were characterized by perforation of a hollow viscus, resulting in the formation of a gastrocolic fistula in 1 patient.

Table 3. Complications by tube type

	Gastrostomy tube type		
	Balloon	Pull-type	Loop
Overall complications	**43 (5.72)**	15 (3.73)	**5 (1.55)**
Major	25 (3.32)	3 (1.99}	4 (1.24)
Minor	13 (2.39)	7 (1.74)	1 (0.31)
Complications by subtype			
Malfunction total	8 (1.1)	2 (0.5)	0 (0)
Major	5 (0.7)	2 (0,5)	0 (0)
Minor	3 (0.4)	0 (0)	0 (0)
Bleeding total	8 (1.1)	1 (0.2)	1 (0.3)
Major	3 (0.4)	1 (0.2)	1 (0,3)
Minor	5 (0.7)	0 (0]	0 (0)
Infection total	5 (0.7)	4 (1.0]	3 (0.9)
Major	4 (0.5)	0 (0)	2 (0.6)
Minor	1 (0.1)	4 (1.0)	1 (0.3)
Malposition total	17 (2.3)	5 (1.2)	0 (0)
Major	11 (1.5)	3 (0.7)	0 (0)
Minor	6 (0.8)	2 (0.5)	0 (0)
Pneumoperitoneum total	5 (0.7)	3 (0.7)	1 (0.3)
Major	2 (0.3)	2 (0.5)	1 (0.3)
Minor	3 (0.4)	1 (0.2)	0 (0)

Values in parentheses are percentages
Values in bold indicate tube types are significantly different

Loop-retained devices

LR catheters had an overall complication rate of 1.6% (5/323), which was significantly lower than BR

($P = 0.01$) but not PT devices ($P = 0.10$; Tables 3, 4). Four of these were considered major complications (1.24%) and 1 was considered minor (0.31%; Table 3). There was a borderline insignificant reduction in minor complications with respect to BR ($P = 0.052$) but not PT devices ($P = 0.10$; Table 4). The majority of complications with LR catheters were infection, of which there were 3 (0.9%; 2 major [0.6%] and 1 minor [0.36%]; Table 3). The minor infection resolved with antibiotics, while the major infections required either readmission or an additional procedure. There was 1 major bleeding complication resulting in an upper gastrointestinal bleed that required endoscopic clipping for hemostasis. There were no complications resulting from malposition. The frequency of pneumoperitoneum/peritonitis was 0.3% (1/323; 1 major [0.4%] and 0 minor [0%]; Table 3). In one case of pneumoperitoneum/peritonitis, the patient developed an acute abdomen and was taken to surgery for laparotomy and washout. Relative to BR catheters, LR devices had significantly fewer major complications associated with device malpositioning ($P = 0.04$). There were no other significant differences between LR and BR or PT devices for any of the other complications listed.

Pull-type devices

PT devices had an overall complication rate of 3.7% (15/402; Table 3). Eight of these were considered major complications (2.0%) and 7 were considered minor (1.7%; Table 3). The frequency of PT device malfunction resulting in an adverse event was 0.5% (2/402; 2 major [0.5%] and 0 minor [0%]; Table 3). In both instances, there was fluid and/or contrast in the esophagus or subcutaneous soft tissues, resulting in dyspnea and hypoxia in one case and necessitating drainage in the other. The frequency of bleeding was 0.2% (1/402; 1 major [0.2%] and 0 minor [0%]; Table 3). In this instance, the patient had to be sent to the intensive care unit where they required blood transfusion and embolization of the left gastric artery. The frequency of local infection was 1.0% (4/402; 0 major [0%] and 4 minor [1.0%]; Table 3). The frequency of malposition was 1.2% (5/402; 3 major [0.7%] and 2 minor [0.5%]; Table 3). In the majority of these cases, the tube came dislodged and required a repeat procedure to reinsert it. The frequency of pneumoperitoneum/peritonitis was 0.7% (3/402; 2 major [0.5%] and 1 minor [0.2%]; Table 3). One of the major complications was gastric perforation resulting in massive pneumoperitoneum, necessitating a gastric wedge resection. While there were no significant differences in complication rates between PT catheters and BR or LR devices, LR devices had a lower overall complication rate than PT catheters (1.6% vs. 3.7%, $P = 0.10$; Tables 3, 4), with a borderline insignificant difference in the rate of overall complications due to malpositioning (1.2% vs. 0%, $P = 0.07$; Tables 3, 5).

Non-device-related complications

There were no deaths associated with RIG placement; however, 7 (0.47%) patients expired within 30 days of the procedure from unrelated causes (Table 6). Within the cohort of patients that received LR and BR catheters, 5 (0.47%) had gastropexy-related complications that were minor in nature (Table 6). There were 5 (0.34%) cases of hypoxia, 4 of which were major and associated with RIG placement (Table 6). Four of these occurred following the procedure in the recovery area, while 1 occurred during gastric insufflation and was thought to be secondary to aspiration causing hypoxic cardiopulmonary arrest. Fortunately, resuscitation efforts were successful and the patient survived. In 4 (0.27%) cases, the patients

Table 4. *P* values for complications by tube type

	OR	CI	RR	CI	*P*
P value, OR, and RR (compared to loop)					
Overall complications					
Balloon	5.4	1.4–20.3	3.7	1.5–9.2	**0.01**
Pull-type	3.3	0.8–13.4	2.4	0.9–6.6	0.10
Major complications					
Balloon	3.9	0.7–22.7	2.7	0.9–7.7	0.13
Pull-type	1.9	0.3–13.2	1.6	0.5–5.3	0.53
Minor complications					
Balloon	7.4	1.0–55.S	7.7	1.0–57.7	0.05
Pull-type	5.7	0.7–46.6	5.6	0.7–45.5	0.10
P value, OR, and RR (compared to balloon)					
Overall complications					
Pull-type	0.6	0.3–1.5	1.5	0.9–2.7	0.28
Major complications					
Pull-type	0.5	0.1–1.9	1.7	0.8–3.7	0.13
Minor complications					
Pull-type	0.8	0.3–1.9	1.4	0.6–3.3	0.57

Values in bold indicate significant difference

Table 5. *P* values for complication subtypes by tube type

	Loop vs. balloon	Loop vs. pull-type	Balloon vs. pull-type
Overall malfunction	0.11	0.51	0.51
Major	0.33	0.51	1.00
Minor	0.56	1.00	0.56
Overall bleeding	0.29	1.00	0.17
Major	1.00	1.00	1.00
Minor	0.33	1.00	0.17
Overall infections	0.70	1.00	0.73
Major	1.00	0.20	0.30
Minor	0.51	0.39	0.05
Overall malposition	**0.003**	0.07	0.27
Major	**0.04**	0.26	0.40
Minor	0.19	0.51	0.72
Overall pneumoperitoneum	0.67	0.63	1.00
Major	1.00	1.00	0.61
Minor	0.56	1.00	1.00

Values in bold indicate significant difference

Table 6. Non-device-related complications

30-day mortality	7 (0.47)
Gastropexy related	5 (0.47)
Hypoxia	5 (0.34)
Medication related	4 (0.27)
Respiratory arrest	2 (0.14)
Respiratory/pulmonary	2 (0.14)
Vascular	2 (0.14)
Nausea/vomiting	1 (0.07)
Malposition	1 (0.07)

Values in parentheses are percentages

were overly sedated requiring reversal with naloxone HCl (Table 6). In 1 instance of tube malposition that was unrelated to the tube insertion, a patient removed the tube (Table 6). A list of the remaining RIG-related complications can be found in Table 6.

Discussion

Percutaneous endoscopic gastrostomy (PEG) was first described in the early 1980s [16–20] and since then a number of endoscopic and radiological gastrostomy approaches have been described [10, 21–23]. Although PEG is widely available and generally regarded as a safe and effective procedure, radiologically inserted gastrostomy (RIG) has become an increasing utilized alternative that has been proven to be as technically successful and safe as PEG [1, 10, 24]. Moreover, there are circumstances in which PEG cannot be performed, such as in patients with obstructive head and neck or esophageal lesions or in patients where conscious sedation may be contraindicated, such as in those with advanced neuromuscular disease.

Gastrostomy can be performed using a variety of methods. In the present study, we compared 30-day outcome and associated complications between three types of large bore RIG devices. Two of these devices—the BR and LR catheters (also known as "push-type" devices)—are placed using a pure percutaneous approach, which is also referred to as percutaneous radiological gastrostomy (PRG). Although for simplicity we included pull-type devices under the umbrella term of RIG/PRG, this hybrid technique involves passage of the gastrostomy tube perorally into the stomach and is also referred to as "internal-external pull-type" or "peroral image-guided gastrostomy" (PIG). Alternative methods include percutaneous endoscopic gastrostomy (PEG) and surgical gastrostomy, the final of which has largely been supplanted by the use of PEG and RIG/PRG given its greater cost and morbidity [1, 16, 17, 23, 25, 26].

Depending on the method used, there are a variety of catheter types to choose from. The majority of RIG tubes are either mushroom-retained (MR), disc-retained (DR), pigtail- or loop-retained (LR), or balloon-retained (BR) devices. In general, MR, BR, and DR devices tend to be large bore (18 or 20-F), while LR devices are typically small bore (12 or 14-F), though most can be obtained in a variety of sizes. Given the diversity of gastrostomy insertion techniques and catheter types to choose from, there have been a plethora of studies examining outcomes and complications associated with technique and catheter type [1, 27]. However, many of these studies have examined rather small cohorts of patients [2, 4, 5, 7, 9–12, 28–34]. Advocates of primary insertion of BR and PT gastrostomies argue that their larger bore decreases the risk of clogging and malfunction compared to smaller caliber LR tubes [6, 35]. Unlike prior studies comparing LR catheters to other devices, in our patient population, the primary LR gastrostomy was 18-F and thus more similar but still smaller in caliber to many of the BR devices and all of the PT devices to which they were compared. This difference in size may ultimately contribute to the lower complication rates observed with LR devices. Nevertheless, while tube occlusion was not one of the criteria analyzed, the rate of tube malfunction in the LR devices within the first 30 days of placement was less than with the other devices although not statistically significant.

In the present study, the technical success rate for RIG placement was 98%, which is similar to that reported in other studies [1, 4, 6, 27]. There were no deaths that occurred as a result of RIG placement and the 30-day mortality rate was 0.47%, which falls within the lower range of that reported in the literature [1, 4, 5, 24, 27, 32]. The major complication rates for BR, LR, and PT devices were 3.3%, 1.2%, and 2.0%, respectively, while the minor complication rates were 2.4%, 0.3%, and 1.7%. Busch et al. recently published a study comparing 30-day outcome and associated complications between 10.5-F LR and 14 or 15-F BR devices [4]. In this study, they reported the 30-day major complication rate for BR and LR devices to be 0.6% and 0%, respectively, while the minor complication rate was 4.1% and 6.5%,

respectively [4]. However, the criteria used to define major and minor complications differ between their study and the current study, such that a more appropriate comparison would be overall complication rate, in which case we found 5.7% and 1.6% for BR and LR, respectively vs. 4.7% and 6.5% for Busch et al. [4]. Due to the significantly higher frequency of minor complications associated with LR devices, Busch et al. recommended the use of BR catheters over LR devices [4]. This study, however, was limited by relatively small patient cohorts (46 LR and 170 BR). Another slightly larger study out of the United Kingdom reported no significant differences in the rates of infection, bleeding, or mortality between LR and BR devices; however, the sizes of the devices were not directly reported [5]. They also found that LR devices were associated with a significantly lower incidence of pain peri-procedurally when compared to BR devices, but that this was likely a consequence of LR catheters generally being a smaller bore than BR catheters [5]. Another even smaller study compared tube performance and complication rates between 20-F BR, 14-F LR, and 20-F PT catheters and found no difference in terms of major or minor complications between any of the tubes [6]. However, LR devices were more prone to tube dysfunction (e.g., tube occlusion) and patients with LR devices were less likely to meet their feeding goals, thereby leading the authors to conclude that BR and PT devices were preferable to LR devices on the basis of their smaller internal diameter [6].

A number of studies also exist comparing PT to BR and LR devices. Yang, Düber, and Pitton found a higher technical success rate with PT devices than with BR catheters and a significantly lower peri-interventional complication rate, leading the authors to conclude that PT catheters are preferable to BR devices [9]. Laasch et al. published a study comparing PEG, PT, and LR devices and found that small bore LR devices were significantly more likely to obstruct than PT devices, thereby necessitating tube replacement [10]. There were no significant differences in infection or bleeding rates [10]. Similar results have been published by Funaki et al. [8]. Another study comparing PT and small bore LR devices found no differences in technical success, complication rates, or quality of life measures between the two groups, while PT devices required significantly higher intra-procedural sedation and longer fluoroscopy times [11]. Lastly, a recent prospective randomized controlled trial comparing small bore LR devices to PT tubes in a cohort of 100 patients found that PT tubes had lower minor complication rates than LR devices at the expense of increased mean fluoroscopy time [12].

Although a relatively large body of literature exists comparing outcomes and associated complications between various gastrostomy methods and tube types—literature which is at times contradictory in nature—several consistent findings have emerged. First is that tube diameter generally correlates with the rate of tube occlusion, such that smaller bore tubes are more prone to blockages, thereby requiring additional revisions [4, 6, 21, 35]. Furthermore, smaller bore devices may lead to delays in achieving feeding goals [6]. Second is that ''push-type'' devices, including BR and LR devices, are more prone to dislodgement than PT devices [7–10, 12, 35]. This is likely due to the fact that PT devices are retained by rigid bumpers, while LR and BR devices are held in place by threads and fluid filled balloons, respectively, which are at risk of degrading over time due to prolonged exposure to gastric acid or spontaneous rupture. The drawback to using PT devices is that they must be inserted perorally, which can be difficult if not impossible in patients with obstructive head and neck or esophageal malignancies. There have also been several reports that PEG and/or PIG tubes can cause metastatic spread from head and neck cancers to the gastrostomy site [9, 36]. In addition, other studies have suggested that catheters that traverse the oropharynx expose the gastrostomy tube and track to oral flora, increasing the risk of infection. However, widespread prophylactic antibiotic use has largely alleviated this concern, and studies have shown that perorally advanced catheters have similar infection rates as pure percutaneous approaches when antibiotic prophylaxis is applied [10]. Indeed, we found no significant differences in the rates of infection between any of the catheter types examined in this study.

One significant difference between LR and BR catheters is the number of complications resulting from malposition, of which 17 (2.3%) were associated with BR types and none with LR devices. Of the 17 complications, 11 were major and necessitated repeat gastrostomy or open surgery. In addition, although differences in associated complications related to device malfunction did not reach statistical significance for any of the tube types examined, BR catheters were associated with five major device malfunction complications, whereas LR devices were associated with none. In all five of these instances, the patients required either repeat gastrostomy or open surgery. While the aforementioned complications may be directly attributable to the type of gastrostomy tube and the technique used to insert it, other complications, such as the formation of fistulas, may be more difficult to link to specific devices. Indeed, one potentially important difference between insertion of PT and LR devices compared to BR devices is the extent to which the tract is maximally dilated. While PT and LR devices are the exact size of the tract they inhabit, tracts of BR devices are over-dilated by the sheath. In effect, BR devices provide less of a tamponade effect on the surrounding tissue, potentially contributing to increased risk of bleeding.

Limitations of this study include its retrospective design, therefore selection bias and variability in patient

follow-up cannot be excluded. In addition, catheter choice was based upon institutional practice and attending preference rather than randomized selection. We also found that patient floor unit (e.g., intensive care unit patient vs. outpatient) negatively confounded the results, while hospital location was as a positive confounder. However, neither of these were adjusted for in our final model since there was an insufficient number of complications when stratifying by factor subtype to support both of these confounders, as the models were overfit with excessive variance. Lastly, this study did not examine gastrostomy associated complications beyond 30 days from the procedure, nor did it examine the incidence of tube occlusion and pericatheter leakage—factors which ultimately influence the decision to use one type of catheter over another. Given these limitations, a future large-scale prospective randomized control trial to assess complication rates, device performance, and quality of life measures may be warranted.

Conclusion

In summary, this study directly compares 30-day outcomes and associated complications between large bore LR, BR, and PT gastrostomy devices. In agreement with previous studies, our results support the notion that RIG is an overall safe procedure with minimal complications. There were no deaths directly attributable to RIG out of 1507 attempts. Although LR tubes have a lower complication rate, they do require exchange after 4 weeks with BR types, once the tract has matured. In addition, they are still smaller than those placed via the other techniques. Due to the fact that complications differ between the catheter types, an understanding of these differences is relevant to the operating physician and patient caregivers and should therefore be taken into account when choosing a catheter type.

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Compliance with ethical standards

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