Complication Rate of Percutaneous Balloon-Retention versus Locking-Loop Gastrostomy and Gastrojejunostomy Tube Insertion: A Comparison from a Canadian Tertiary Care Centre

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Arab J Intervent Radiol 2024;8:105–111.

Abstract

Purpose The aim of this study is to compare 30-day complications, procedure-related mortality, and overall mortality rates for de novo enteral feeding tube insertion with fluoroscopy-guided percutaneous balloon-retention versus traditional locking-loop tubes.

Methods A retrospective analysis was conducted on adult patients who underwent fluoroscopically guided gastrostomy or gastrojejunostomy tube insertions at two tertiary care centers. We categorized complications based on the Society of Interventional Radiology Standards of Practice for Gastrointestinal Access. Factors including the indication for the procedure, the number of gastropexy anchors, and the tube size were analyzed. Statistical analysis was performed using chi-square tests, and the results were compared with patients who underwent locking loop insertions.

Results A total of 118 patients underwent percutaneous balloon-retention gastrostomy (BRG) or gastrojejunostomy (BRGJ) tube insertions in 2018. These were compared with 559 adult patients who had locking loop insertions at the same institutions from 2011 to 2014. Minor and major complications were higher for the balloon-retention tubes for both BRG (minor: 40.8% vs 4.7%, $p < 0.001$; major: 1.4% vs 1.2%, $p = 0.891$) and BRGJ tubes (minor: 80.9% vs 11.8%, $p < 0.001$; major: 12.8% vs 1.7%, $p < 0.001$). Complications were lowest with two gastropexy anchors and highest with three anchors. The 12-F and 14-F balloon-retention tubes had similar complication rates. Although not statistically significant, the balloon-retention tubes were associated with higher procedure-related deaths (1.7% vs 0.7%, $p = 0.300$) and all-cause mortality (9.3% vs 5.9%, $p = 0.171$).

Conclusion Percutaneous BRG or BRGJ tubes had significantly higher 30-day complication rates. There was no significant difference in the 30-day mortality rate.

Keywords
- fluoroscopy-guided gastrostomy
- balloon-retention feeding tubes
- percutaneous radiologic gastrostomy
- interventional radiology

article published online
June 12, 2024

DOI https://doi.org/10.1055/s-0044-1786829.
ISSN 2542-7075.

Thieme Medical and Scientific Publishers Pvt. Ltd., A-12, 2nd Floor, Sector 2, Noida-201301 UP, India

Introduction

Enteral feeding is the preferred nutritional support method in patients who have a functional gastrointestinal tract but cannot maintain sufficient oral intake.[1] Nasogastric and nasojejunal tubes can provide temporary enteral feeding. A permanent feeding tube should be considered if nutritional support is required for longer than 4 weeks.[2] Gastrostomy (G) and gastrojejunostomy (GJ) tubes can provide a long-term route for enteral nutrition, hydration, and medication administration in patients with prolonged inadequate oral intake who can safely tolerate tube insertion into their gastrointestinal tract.[3] G and GJ tubes are inserted percutaneously into the stomach; G tubes are designed explicitly for prepyloric feeding, meaning the food is delivered directly into the stomach. Conversely, GJ tubes are longer and are inserted in the same manner as G tubes but are intended for postpyloric feeding; this means that the tube goes further down into the small intestine. The decision to use either a G or GJ tube is dependent on the medical condition and unique needs of the patient.[2]

The placement of a tube is often indicated in cases where patients are experiencing difficulty with swallowing, which may be attributed to head and neck cancer or its treatment, neurological impairment resulting from a stroke or traumatic brain injury, gastroparesis, and other neurological disorders that render them vulnerable to aspiration and malnutrition.[4,5]

G and GJ tubes may be inserted endoscopically, surgically, or radiologically. Percutaneous endoscopic gastrostomy and radiologically inserted gastrostomy tubes are most commonly used. While G and GJ tube insertions improve quality of life, several complications have been reported. Minor complications of tube insertion include tube malfunction (i.e., migration, dysfunction, occlusion), peristomal infection, inadvertent removal, persistent pain at the insertion site, ileus, stomal leakage, buried bumper, gastric ulcer, and fistulous tracts.[6] Major complications include death, major bleeding, peritonitis, periprocedural aspiration, and necrotizing fasciitis.[6] Recent literature has demonstrated higher rates of minor complications from locking loop GJ (LLGJ) tube insertion (11.8%) compared with locking loop G (LLG) tube insertion (4.7%), with no significant difference in major complication or mortality rates.[7]

Although various studies have compared complication and mortality rates for LLG and LLGJ tube insertion, larger studies have not yet explored complication and mortality rates comparing newer percutaneous balloon-retention (BR) insertion techniques.[8–11] This study aims to compare 30-day major and minor complications, procedure-related mortality, and overall mortality rates for tube insertion using fluoroscopy-guided percutaneous BR techniques versus traditional locking loop (LL) tube insertions. This study will also evaluate complication rates by the number of gastropexy anchors and the catheter French size used.

Methods

Study Design

This retrospective cohort study was approved by our institution's Research Ethics Board (#2020-113566-35616) with a waiver for individual consent. Consecutive patients who received fluoroscopic-guided percutaneous BR gastrostomy (BRG) and BR gastrojejunostomy (BRGJ) tube insertion were identified at two tertiary care institutions between April 2018 and October 2018 ($n = 118$). Patient information was collected from their electronic medical record, including demographic information, indication for tube insertion, and major and minor complications that occurred within 30 days postprocedure. Additional data, including the number of gastropexy anchors and tube size, were also collected. Tube insertions were performed by one of six interventional radiologists with 2 to 15 years of experience. Complication and mortality rates from these patients were compared with those from a retrospective set of 559 consecutive patients who received percutaneous LLG and LLGJ tube insertion at the same institutions from 2011 to 2014.

Insertion Technique

Prior to the procedure, written informed consent was acquired from all patients or their substitute decision makers. All procedures were conducted under conscious sedation using titrated doses of midazolam and fentanyl. If the patient did not already have a nasogastric tube in place, a 5-F Kumpe catheter (AngioDynamics Inc, Latham, New York, United States) was inserted into the stomach under fluoroscopy guidance. The epigastric region was thoroughly prepped and draped, and the stomach was insufflated with air until sufficiently dilated to oppose the anterior abdominal wall and displace the transverse colon. In our practice, preprocedure barium swallow, enema, or antimuscarinic medications are not administered. Cope Gastrointestinal Suture Anchor Set (Cook Medical Inc, Bloomington, Indiana, United States) would be used for the LLG or LLGJ tube insertion. Through the same access, a 12-F multipurpose drainage catheter (Cook Medical Inc) is inserted using the Seldinger technique after tract dilatation.[12]

The BR tubes are inserted using a similar approach. However, the insertion package includes multiple absorbable anchors and a larger peel-away sheath, as recommended by the manufacturer (Halyard Health Inc, Alpharetta, Georgia, United States). For these BR tubes, a minimum of three punctures and serial dilations are recommended to fit the tube through a larger hole, as they require a sheath two sizes above the size of the tube (e.g., 16-F sheath over a 14-F tube) to accommodate the blunt tip and balloon. The additional dilation and exchanges required can lead to stomach deflation and leakage.

Patients are usually admitted overnight for observation; feeding is started 24 hours postinsertion if no complications occur.

Study Population

A total of 118 enteral BR tubes were consecutively inserted in 118 patients. Of these, 47 (40%) were BRGJ tube insertions and 71 (60%) were BRG tube insertions. The mean patient age was 61 ± 14.2 years (ranging from 18 to 90 years). The comparative data set consisted of 559 consecutive enteral LL tubes inserted in 559 patients, totaling 473 (85%) LLGJ and 86 (15%) LLG tube insertions. The mean patient age in the

comparison dataset was 63 years (ranging from 18 to 94 years).

Outcome Measures and Follow-up

All patients were followed for 30 days after the procedure or until the date of their death, whichever occurred first. Patients were stratified based on whether they underwent gastrostomy or gastrojejunostomy. Indications for insertion were recorded (►**Table 1**).

Complications were categorized as major or minor based on the Multidisciplinary Practical Guidelines for Gastrointestinal Access for Enteral Nutrition and Decompression from the Society of Interventional Radiology and American Gastroenterological Association (AGA) Institute, with endorsement by the Canadian Interventional Radiological Association (CIRA) and Cardiovascular and Interventional Radiological Society of Europe (CIRSE).[13] The 30-day mortality rates and major, minor, and total complication rates were calculated as percentages for general percutaneous tube insertion as well as for GJ and G tube insertions individually.

Statistical Analysis

Complications and mortality rates of BR and LL tubes were compared using chi-square tests. Statistical analysis was performed with a significance level (alpha) of 0.05.

Results

Between April and October 2018, 118 adult patients underwent fluoroscopically guided percutaneous BRG or BRGJ tube insertion. Of the 71 (60%) patients who received BRG tube insertion, 30 (42.3%) individuals experienced complications, including 29 (40.8%) minor and 1 (1.4%) major complications (infected ascites requiring drainage). There were no reported deaths related to the procedure.

Of the 47 (40%) patients who received BRGJ tube insertion, 44 (93.6%) patients experienced complications. Among these, there were six (12.8%) major complications that included bleeding from artery puncture ($n = 2$), pneumatosis intestinalis ($n = 1$), ischemic bowel leading to death ($n = 1$), atrial fibrillation and hypotension postinsertion ($n = 1$), and aspiration of blood and respiratory failure leading to death ($n = 1$). Furthermore, there were 38 (80.9%) minor complications and 2 (4.3%) deaths related to the procedure.

Patients who underwent BR tube insertion were compared with 559 consecutive adult patients who underwent LLG or LLGJ tube insertions between 2011 and 2014. Minor complications rates were significantly higher for the percutaneous BRG tubes compared with the LLG tubes, while there were no statistically significant differences in major complications (minor: 40.8% vs 4.7%, $p < 0.001$; major: 1.4% vs 1.2%, $p = 0.891$) (►**Fig. 1**). Both minor and major complication rates were higher with BRGJ tubes compared with LLGJ (minor: 80.9% vs 11.8%, $p < 0.001$; major: 12.8% vs 1.7%, $p < 0.001$) tubes (►**Table 2**).

The most frequent minor complications for the BR tubes were tube malfunction, abdominal pain, and pneumoperitoneum (►**Table 3**). Major complications included arterial hemorrhage and ischemic bowel. Complication rates were lowest with two gastropexy anchors and highest with three anchors. Complication rates were similar for 12-F and 14-F tubes (►**Fig. 2**).

The use of BR tubes led to higher percentages of procedure-related deaths (1.7% vs 0.7%, $p = 0.300$) and all-cause mortality (9.3% vs 5.9%, $p = 0.171$) than the use of LL tubes (►**Table 4**, ►**Fig. 3**). However, the relative difference did not reach statistical significance.

Table 1 Patient demographics and indications for enteral feeding tube placement

	Balloon-retention tube insertion ($n = 118$)			Locking loop tube insertion ($n = 559$)		
	BRGJ	BRG	Overall	LLGJ	LLG	Overall
Number of patients	47	71	118	473	86	559
Male	34	53	87	328	52	380
Female	13	18	31	145	34	179
Indication						
Head and neck cancer	9	24	33	134	59	193
Esophageal cancer	11	10	21	112	4	116
Neurological	9	15	24	66	3	69
Other causes of dysphagia	8	10	18	59	9	68
Failure to thrive/need for long-term feed	6	6	12	78	9	87
Aspiration	2	4	6	24	2	26
Gastroparesis	1	1	2	0	0	0
Severe nausea	1	0	1	0	0	0
Small bowel obstruction/venting	0	1	1	0	0	0

Abbreviations: BRG, balloon-retention gastrostomy; BRGJ, balloon-retention gastrojejunostomy; LLG, locking loop gastrostomy; LLGJ, locking loop gastrojejunostomy.

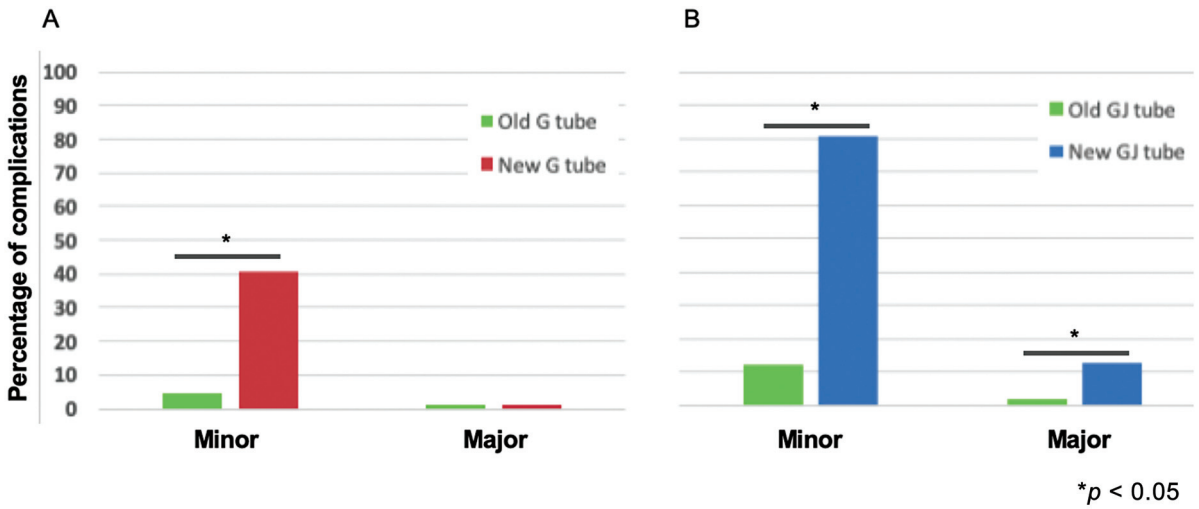

Fig. 1 (A) Minor and major complication rates for balloon-retention (BR) versus locking loop (LL) G tube insertion. (B) Minor and major complication rates for BR versus LL GJ tube insertion ($^{*}p < 0.05$).

Table 2 Description and rates of major and minor complications for percutaneous G and GJ tube insertion by interventional radiology

	BRGJ	BRG	Overall
Balloon retention tube insertion			
Complication, *n*	47	71	118
Overall	44 (93.6)	30 (42.4)	74 (62.7)
Minor	38 (80.9)	29 (40.8)	67 (56.8)
Tube malfunction, *n*	16	8	24
Pain, *n*	11	11	22
Pneumoperitoneum, *n*	5	8	13
Infection, *n*	2	1	3
Nausea and vomiting, *n*	3	0	3
Leak, *n*	1	1	2
Major	6 (12.8)	1 (1.4)	7 (5.9)
Major bleed from artery puncture, *n*	2	0	2
Pneumatosis intestinalis, *n*	1	0	1
Infected ascitic fluid requiring drainage, *n*	0	1	1
Ischemic bowel, *n*	1	0	1
Atrial fibrillation and hypotension postinsertion, *n*	1	0	1
Aspiration and respiratory failure leading to death, *n*	1	0	1
	LLGJ	**LLG**	**Overall**
Locking loop tube insertion			
Complication, *n*	473	86	559
Overall	64 (13.5)	5 (5.8)	69 (12.3)
Minor	56 (11.8)	4 (4.7)	60 (10.7)
Minor leak or peristomal infection, *n*	29	0	29
Tube malfunction, *n*	17	4	21
Other, including pain or free air, *n*	10	0	10
Major	8 (1.7)	1 (1.2)	9 (1.6)
Intra-abdominal sepsis requiring surgical intervention, *n*	5	0	5
Intra-abdominal sepsis leading to death, *n*	3	1	4

Abbreviations: BRG, balloon-retention gastrostomy; BRGJ, balloon-retention gastrojejunostomy; G, gastrostomy; GJ, gastrojejunostomy; LLG, locking loop gastrostomy; LLGJ, locking loop gastrojejunostomy.
Note: Values are *n* (%) unless otherwise indicated. Overall complication is the total number of major and minor complications combined.

Table 3 Indication-specific, anchor-specific, and French-specific complications for percutaneous balloon-retention enteral tube insertion

	Number of tubes inserted	Number of complications	Complication rate (%)
Indication			
Head and neck cancer	33	26	78.8
Esophageal cancer	21	15	71.4
Neurological	24	11	45.8
Other causes of dysphagia	18	12	66.7
Failure to thrive/need for long-term feed	12	2	16.7
Aspiration	6	2	33.3
Gastroparesis	2	5	250.0
Severe nausea	1	0	0
Small bowel obstruction/venting	1	1	100.0
Number of anchors			
1	2	1	50.0
2	37	11	29.7
3	74	59	79.7
4	4	3	75.0
5	1	0	0
French size			
12-F	23	16	69.6
14-F	92	55	59.8
16-F	3	3	100.0

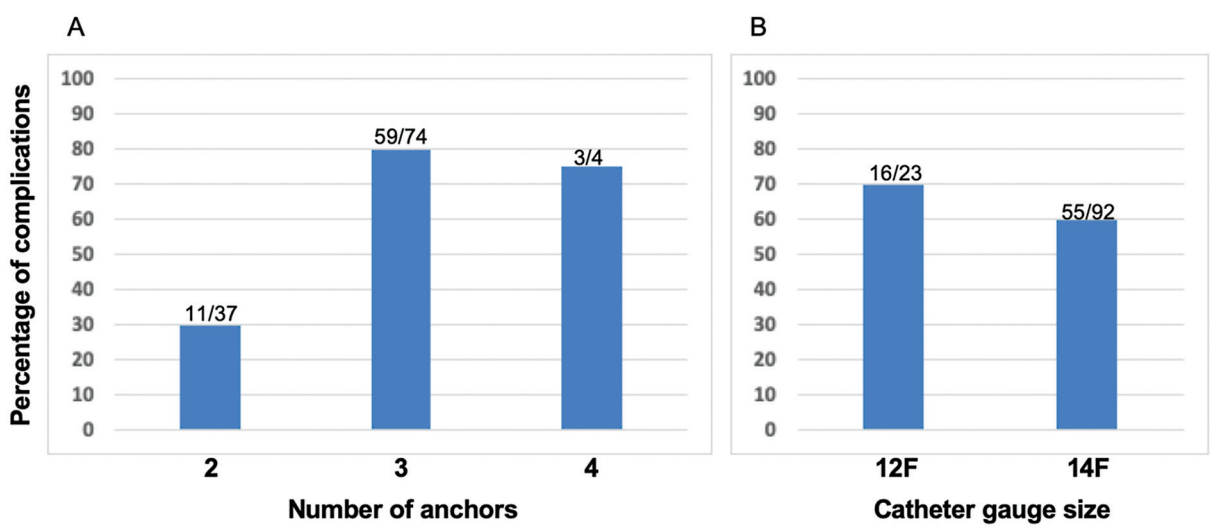

Fig. 2 (A) Balloon-retention tube insertion complication rates by the number of gastropexy anchors used. (B) Balloon-retention tube insertion complication rates by catheter gauge size used.

Discussion

In this comparative study, the 30-day rates of major and minor complications, procedure-related mortality, and overall mortality rates were analyzed for fluoroscopy-guided percutaneous BR tube insertion and LL tube insertion. The results suggest that the use of BR insertion is associated with a higher likelihood of major and minor complications.

We found that tube malfunction was among the most frequent complications of BR tubes. This is a well-documented

Table 4 Rates of procedure-related death and death within 30 days for percutaneous radiologic G and GJ tube insertion

Balloon-retention tube insertion	BRGJ ($n=47$)	BRG ($n=71$)	Overall ($n=118$)
Number of procedure-related deaths	2 (4.3)	0 (0)	2 (1.7)
Incidence of death within 30 d			11 (9.3)
Locking loop tube insertion	**LLGJ ($n=473$)**	**LLG ($n=86$)**	**Overall ($n=559$)**
Number of procedure-related deaths	3 (0.6)	1 (1.2)	4 (0.7)
Incidence of death within 30 d			33 (5.9)

Abbreviations: BRG, balloon-retention gastrostomy; BRGJ, balloon-retention gastrojejunostomy; G, gastrostomy; GJ, gastrojejunostomy; LLG, locking loop gastrostomy; LLGJ, locking loop gastrojejunostomy.
Note: Values are n (%) unless otherwise indicated.

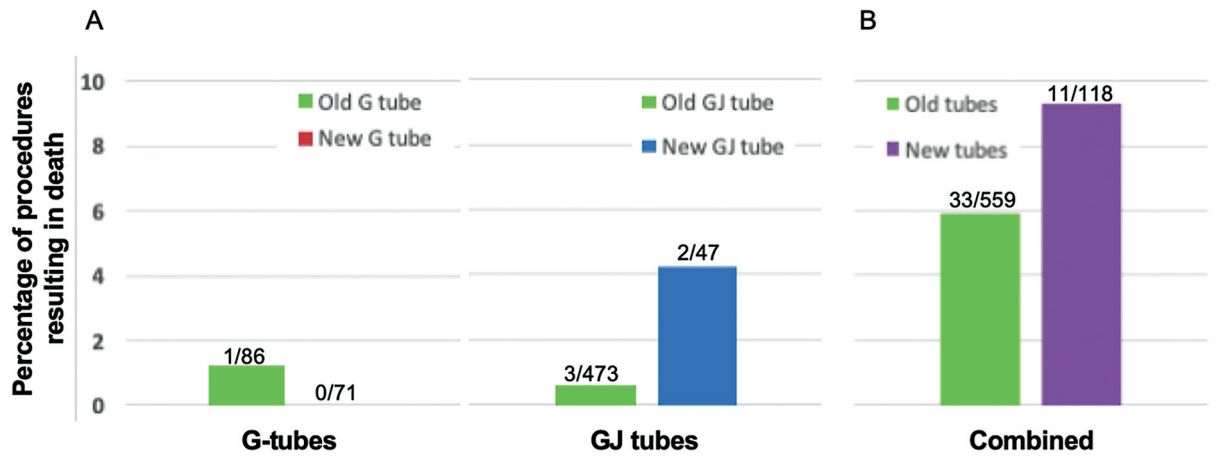

Fig. 3 (**A**) Procedure-related mortality rates of balloon-retention (BR) versus locking loop (LL) G and GJ tube insertion. (**B**) 30-day mortality rates of BR versus LL tube insertion.

problem with BR tubes; one study found that BR tubes had a 68% tube complication rate, significantly higher than mushroom-retained gastrostomy catheters with a 3.6% tube complication rate.[14] Furthermore, the study found that BR tubes needed to be replaced every 2 months on average, while mushroom-retained tubes generally did not require replacement.[14] Most BR tubes were found to be lost from balloon breakage, followed by balloon deterioration and deflation in equal frequency.[15]

Our study found that BR tubes resulted in greater rates of minor complications in BRG tubes and both major and minor complications in BRGJ tubes compared with LL tubes. This may be partially explained by the fact that BRGJ tube insertion procedures tend to be longer and require more manipulation. Comparative complication rates of BR tubes vary within the literature. Funaki et al found that the incidence of pain within the first 24 hours was significantly increased with the use of BR tubes compared with loop-retained tubes.[14] Moreover, the severity of pain for patients with BR tubes was higher, with 59% moderate and 2% severe pain, compared with 13% moderate and 2% severe pain in patients with loop-retained tubes.[10] In comparison, Busch et al found that the risk of tube dislodgement, per catheter leakage, and obstruction was lower in BR versus loop-retained catheters.[16] A consensus on comparative complication rates between BR and LL tubes has not been reached.

Two randomized controlled studies have provided a clear answer to the question of whether gastropexy is necessary for enteral feeding tube insertion. The studies showed that the gastropexy technique resulted in fewer complications and increased technical safety. However, it is essential to note that gastropexy can also cause pain and other complications.[17,18] Kim et al described a one-anchor technique for percutaneous radiologically inserted gastrostomy, with a technical success rate of over 99%. However, this technique was associated with more technical difficulties and major complications than other groups using multiple gastropexies.[19] Nevertheless, Alghamdi et al found that gastropexy did not reduce complications following LLG tube insertion but was linked to an increased risk of superficial infection.[20] Our study found that using two gastropexies was associated with the lowest complication rates among the other numbers.

The results of this study have led to a change in our local practice. Most GJ requests have been converted to G tubes as long as clinically acceptable and inserting BR tubes at the initial insertion has greatly reduced. Instead, multipurpose tubes with one dilation are inserted, as the peel-away sheaths are also harder to obtain. If the patient requires a GJ tube, a longer pigtail catheter is usually inserted at the initial insertion. Once the tract matures, a conversion to BR enteral tubes where appropriate is done. Otherwise, we use a

pigtail tube if it suits the individual patient. A future study could evaluate the improved outcomes we have observed.

Study Limitations

This retrospective study had inherent limitations. Patients could not be randomized to LL versus BR cohorts, and therefore, an element of selection bias could not be excluded. Nevertheless, we included all consecutive patients to reduce the risk of selection bias. Tube placement was performed by one of six different interventional radiologists for BR tubes and one of five interventional radiologists for LL tubes. Such variability in clinical practice and experience could have affected outcomes. For example, preparation protocols, choice of tubes, use of sutures or adhesive dressings, use of postprocedural analgesia, and patient training postprocedure could differ between the physicians and potentially affect outcomes. Another limitation of the study would be a presumed inherent learning curve associated with learning how to deploy a new device by interventional radiologists who otherwise had the same experience and expertise.

Other factors beyond tube type could have contributed to differences in complication rates between LL and BR tubes. For example, technical aspects such as interventional radiology suite equipment could have played a role. In addition, our study did not address the effect that indication for choice of tube type had on complication rates. Comparing LL tubes with BR tubes for specific indications may warrant further study.

Conclusion

Compared with LLG and LLGJ tubes, higher rates of minor complications and both minor and major complications were found with BRG and BRGJ tubes, respectively. There was no significant difference in procedure-related deaths and all-cause mortality within 30 days of insertion between the LLG/LLGJ and BRG/BRGJ tubes.

Conflict of Interest
None declared.

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