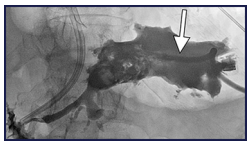

Outcomes after Transgastric Drainage of Pancreatic Duct Leaks

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ABSTRACT

Purpose: To determine the outcomes of transgastric drainage (TGD) of pancreatic duct leaks (PDLs), including fluid collections and pancreaticocutaneous fistulae (PCFs).

Materials and Methods: Fifty-four patients who underwent attempted TGD of a PDL from 1992 to 2020 were identified. Data regarding patient comorbidities, fluid collection characteristics, technical success, drain exchanges and removals, recurrent collections, and complications were analyzed.

Results: Forty-one patients (41/54, 76%) had a history of pancreatitis. Sixteen patients (16/54, 30%) had a history of recent abdominal surgery. Peripancreatic fluid collections were 11.2 cm ± 4.6 in greatest dimension prior to drainage. Twenty-one collections (21/54, 39%) demonstrated biochemical and/or imaging evidence of an active communication to the pancreatic duct, and 16 (16/54, 30%) of these patients had a PCF due to a direct percutaneous drain prior to TGD. TGD was technically successful in 53 patients (53/54, 98%). During the follow-up period, 46 patients (46/53, 87%) were able to undergo drain removal after resolution of the fluid collection, with a mean catheter indwelling time of 3 months and a median of 1 catheter exchange. There were 2 severe (2/53, 4%) and 4 moderate (4/53, 8%) complications, the most common of which was drain dislodgement requiring repeat transgastric puncture. Recurrent fluid collections were observed in 8 patients (8/53, 15%) after a mean of 5 months following drain removal. There were no recurrent PCFs.

Conclusions: TGD of PDLs is technically feasible and efficacious in the vast majority of patients with a relatively low complication rate. This technique is effective in preventing or treating the long-term debilitating complication of PCF.

ABBREVIATIONS

PCF = pancreaticocutaneous fistula, PDL = pancreatic duct leak, TGD = transgastric drainage

Pancreatic duct leaks (PDLs), which include peripancreatic fluid collections, internal pancreatic fistulae, and pancreaticocutaneous fistulae (PCFs), can be seen in the setting of pancreatitis, pancreatic surgery, or trauma (1). In addition to facing mortality rates of up to 30% in the setting of necrotizing pancreatitis, patients with pancreatic fistulae have longer hospital admissions and are more likely to require intensive care unit–level care, be readmitted, or require repeat intervention than patients without fistulae (2,3).

Current guidelines for the management of peripancreatic collections in the setting of necrotizing pancreatitis advocate for a step-up approach consisting of percutaneous drainage or endoscopic transmural drainage, followed by percutaneous or endoscopic necrosectomy and surgical debridement if needed (4). For clinically stable patients, a slight preference is given to an endoscopic approach because of the concern of forming a PCF with direct percutaneous drainage, which can be seen in up to 32% of cases (5). However, there are a few limitations to endoscopic drainage. First, guidelines advocate delaying endoscopic drainage until the collection is at least 4 weeks old because of the concern for perforation or leakage in the absence of a mature cyst wall (6,7). Higher mortality rates have also been observed with early endoscopic intervention (8). Second, some collections may be anatomically unfavorable because the collection must be adherent to the gastric wall for an endoscopic approach to be feasible (6). Third, endoscopic drainage of PDLs often requires general anesthesia (9).

Transgastric drainage (TGD) by interventional radiology was first described in 1984 and addresses these limitations (10); TGD can be performed regardless of the age of the collection and does not require the PDL to be directly apposed to the gastric wall. A mature cyst wall is not necessary for TGD because of the ability to initially drain externally. Furthermore, TGD prevents the formation of a PCF by allowing drainage into the stomach. TGD can also be used to manage an existing PCF by diverting flow from the fistula into the stomach.

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RESEARCH HIGHLIGHTS

- Transgastric drains can be successfully placed in the majority of patients (98% in this patient cohort).
- Transgastric drainage successfully treated 87% of pancreatic duct leaks and 94% of pancreaticocutaneous fistulae.
- Recurrent pancreatic duct leaks were observed in 15% of patients. However, there were no recurrent pancreaticocutaneous fistulae.
- The moderate and severe adverse event rates following transgastric drainage were 8% and 4%, respectively.

STUDY DETAILS

Study type: Retrospective, observational, descriptive study

Level of evidence: 4 (SIR-D)

Despite these advantages, experience with TGD by interventional radiology is scarce within the existing literature and is limited to a few small case series. Therefore, the purpose of this study was to assess the feasibility, efficacy, and safety of TGD of PDLs.

MATERIALS AND METHODS

Institutional review board approval by the University of Pennsylvania was obtained for this retrospective study, which was performed in full compliance with the Health Insurance Portability and Accountability Act. Between December 1992 and October 2020, 62 patients who underwent TGD for a PDL were identified using the Montage Search and Analytics platform (Montage Healthcare Solutions, Philadelphia, Pennsylvania). Eight patients were excluded because of incomplete medical records. This yielded a final cohort of 54 unique patients (mean age, 57 years; 31 men and 23 women) who underwent TGD for PDL. Data regarding patient demographics, comorbidities, fluid collection characteristics, TGD procedures, drain exchanges and removals, recurrent collections, and complications were obtained from paper-based charts and the electronic medical record (Epic, Verona, Wisconsin).

Patients with pancreatitis were categorized according to the revised Atlanta classification for acute pancreatitis (11,12). Patients with postoperative fluid collections in the absence of pancreatitis were confirmed to have a postoperative pancreatic fistula according to the definition provided by the International Study Group of Pancreatic Surgery (13). A PCF was defined as a fluid collection that had an indwelling direct percutaneous drain prior to TGD and demonstrated either active communication with the pancreatic duct on fluoroscopy and/or continuous high drain output (>20 mL/d) with drain amylase levels consistent with pancreatic secretions.

The decision to initially drain a PDL via a transgastric route versus direct percutaneous route depended on both operator preference and patient anatomy. In general, direct percutaneous drainage was attempted first if a safe anatomic window was available in the setting of necrotizing pancreatitis, which could potentially require future debridement; transgastric drains would be placed if a direct percutaneous drain could not be safely placed, the patient had a simple fluid collection in the setting of acute interstitial edematous pancreatitis, or direct percutaneous drainage failed and the patient needed diversion to heal a PCF.

Transgastric drains were placed under fluoroscopic or computed tomography (CT) guidance. The stomach was insufflated with a nasogastric tube and punctured with a 16-gauge needle to place a single point gastropexy anchor (Cook Medical, Bloomington, Indiana) and an 8-F or 9-F sheath (Terumo Medical, Somerset, New Jersey). If the collection compressed the stomach lumen based on preintervention cross-sectional imaging, direct through-and-through drainage was performed. Otherwise, a 20-cm 18-gauge or 21-gauge needle (Cook Medical) was introduced through the gastrostomy sheath and used to puncture through the posterior wall of the stomach. If drainage was performed primarily under fluoroscopic guidance, landmarks that could be correlated with preintervention cross-sectional imaging, such as vertebral body level, were used to localize the collection. If there was no drain within the collection prior to TGD, contrast injection through the needle was performed to confirm access in the collection. A 0.035-inch Glidewire (Terumo Medical) was advanced through the needle, serial dilation was performed, and a locking loop drainage catheter was placed. Representative images from a primary transgastric drain placement are shown in Figure 1. If a direct percutaneous drain was present prior to TGD with chronic output consistent with PCF, the drain was removed over a wire and an Amplatz GooseNeck Snare (ev3 Endovascular, Plymouth, Minnesota) was placed in the drain tract, serving as a target for the needle introduced through the gastrostomy sheath. A 0.035-inch guide wire was passed through the gastrostomy sheath needle, captured by the snare, and pulled through the drain tract and out through the skin site to provide through-and-through access. After serial dilation, a locking loop drainage catheter was placed with the pigtail terminating in either the stomach or collection/fistula. In general, the pigtail was placed in the stomach if the collection/fistula was not large enough to form the pigtail in a stable manner. Additional side holes were introduced as needed in the drainage catheter to allow communication between the PDL and stomach. A guide wire was used to measure the length of the catheter requiring side holes. A drainage catheter was replaced within the previous percutaneous drain tract to track the amount of drainage; this catheter was removed when it had minimal output. Representative images from conversion from a direct percutaneous drain to a transgastric drain are shown in Figure 2.

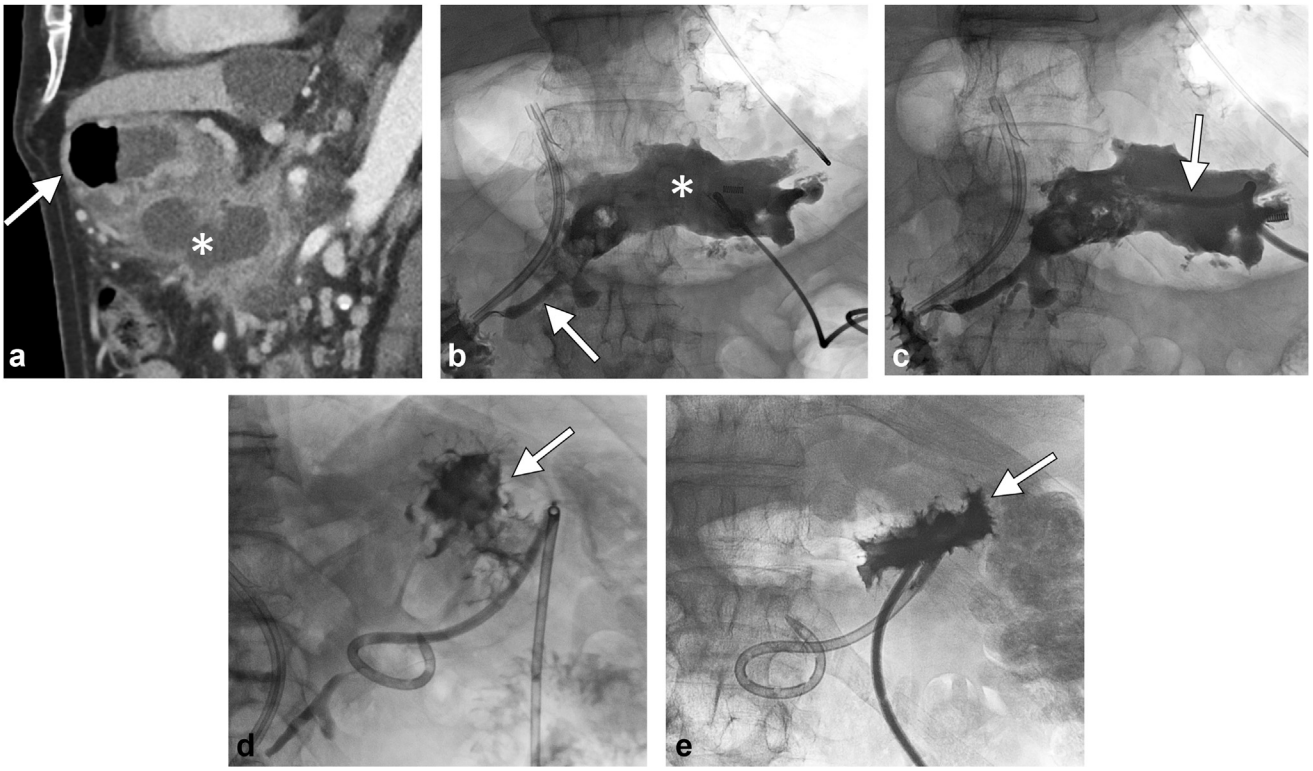

Figure 1. Primary transgastric drain placement. **(a)** A preprocedural computed tomography scan in the sagittal plane demonstrated walled-off necrosis (asterisk) posterior to the stomach (arrow) in this patient with necrotizing pancreatitis. **(b)** After single point gastropexy, a needle was advanced through the stomach and into the collection (asterisk) and contrast was injected. The collection was communicating with the pancreatic duct (arrow). **(c)** After advancing a wire into the collection and performing serial dilation, a drain was placed in the collection (arrow). **(d)** The patient was later converted to an internal/external drain with side holes in the stomach (arrow). There was a persistent fistula to the pancreatic duct. **(e)** After an additional 2 months, the collection and fistula resolved, with contrast only opacifying the stomach via communicating side holes (arrow). The drain was removed, and the patient has not had a recurrent collection in 4 years of follow-up.

Early in the institution's experience, attempts were made to cross the sites of pancreatic duct injury or obstruction in patients with disconnected pancreatic duct syndrome diagnosed on endoscopic retrograde cholangiopancreatography, especially if visualized. With experience, it was determined that diverting PDL alone was sufficient. The technique of placing transgastric drains in these patients with isolated pancreatic duct segments has been described in detail previously (14).

In 10 patients, the transgastric drain was later internalized by cutting the external portion before advancing the drain over the wire to allow further maturation of the tract. The decision to internalize a drain was based on operator and patient preference. Internalized drains were removed by interventional radiology using a transoral snare. Several patients had the drain intentionally left in place after resolution of the collection for at least 4 months following initial drain placement to develop a mature tract to the stomach to prevent recurrence. However, this was left to the discretion of the attending physician managing the drain.

Follow-up cross-sectional imaging was reviewed for each patient after drain removal to assess for recurrent collections, defined as the reaccumulation of fluid in the same anatomic space that was previously drained. Complications that occurred during drain placement or in the follow-up period were categorized using the latest adverse event classification developed by the Society of Interventional Radiology (15).

Statistical comparison for subgroup analysis was performed using the Fisher exact test for categorical variables and Student t test for continuous variables. Results were considered statistically significant if $P < .05$.

RESULTS

Fifty-four patients underwent attempted TGD of a PDL. Acute pancreatitis was present in 41 patients (41/54, 76%). Sixteen patients (16/54, 30%) had a history of abdominal surgery within 1 month of the PDL being first detected on imaging, which involved pancreatic resection (eg, Whipple procedure, distal pancreatectomy) in the majority of cases. Three patients (3/54, 6%) had both acute pancreatitis and recent abdominal surgery. Peripancreatic fluid collections were 11.2 cm ± 4.6 in greatest dimension prior to drainage. Twenty-one collections (21/54, 39%) demonstrated an active communication to the pancreatic duct by imaging or

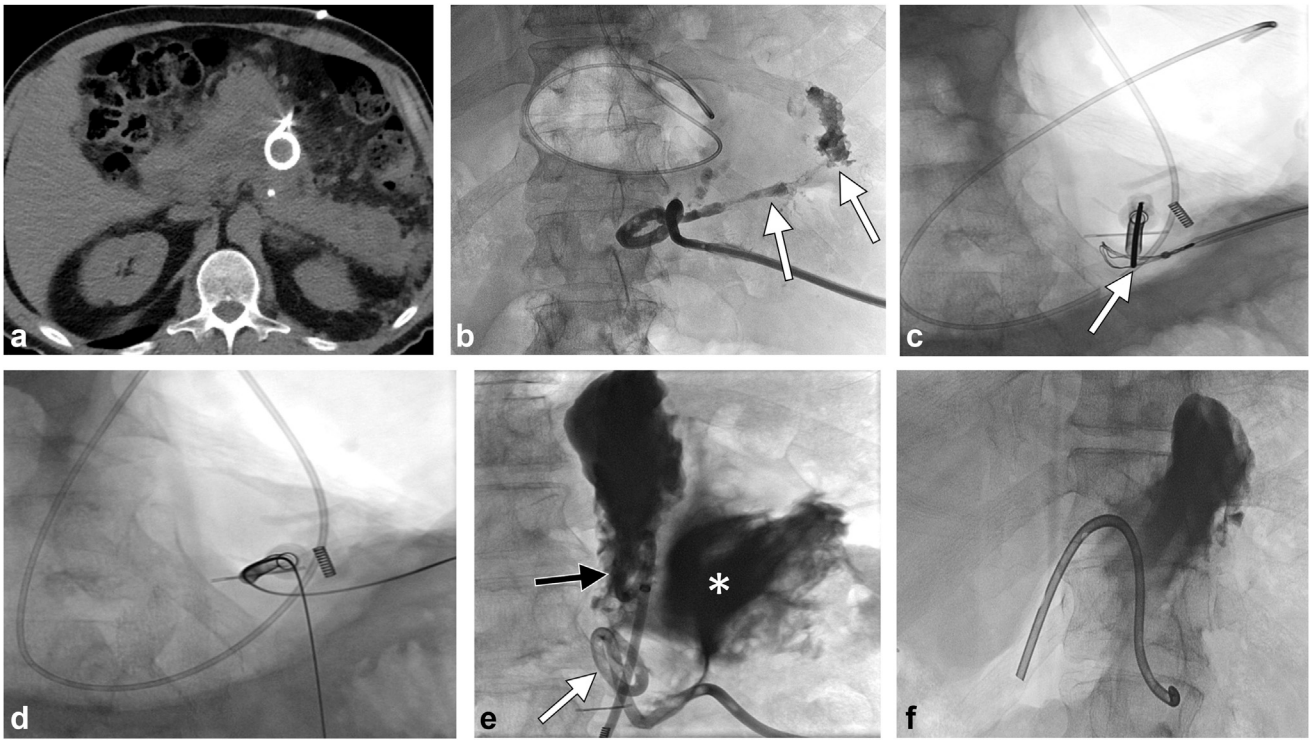

Figure 2. Conversion from direct percutaneous drain to transgastric drain. **(a)** A preprocedural computed tomography scan demonstrated a direct percutaneous drain terminating in the peripancreatic region with phlegmonous changes. This patient had persistent high output from the drain suggestive of pancreaticocutaneous fistula. **(b)** Initial contrast injection of the direct percutaneous drain outlined the peripancreatic collection (arrows). **(c)** The direct percutaneous drain was exchanged for a gooseneck snare. After single point gastropexy, a sheath was placed. A needle was introduced through the sheath, targeting the snare (arrow). **(d)** A wire was introduced through the gastrostomy sheath needle and snared, providing through-and-through access. **(e)** A locking loop drainage catheter was placed with pigtail terminating in the stomach (white arrow) and side holes communicating with the peripancreatic collection (asterisk). An additional pigtail catheter was placed in the stomach (black arrow) for future access using the gastrostomy access. **(f)** The patient subsequently had their drain completely internalized at a follow-up appointment. This was later retrieved transorally once the collection resolved on computed tomography.

drain amylase levels; 16 (16/54, 30%) of these patients had a PCF due to a direct percutaneous drain prior to TGD and 7 (7/54, 13%) had disconnected pancreatic duct syndrome. Additional baseline clinical characteristics are summarized in Table 1.

Transgastric drain placement was technically successful in 53 patients (53/54, 98%). The only failure was an attempted transgastric pancreatic duct drain in a patient with disconnected duct syndrome in which the pancreatic duct could not be accessed; this was early in the institution's experience when the operators tried to cross the site of pancreatic duct injury/obstruction and, in retrospect, a drain could have been placed in the fistula. Additional details regarding initial transgastric drain placement are summarized in Table 2.

Patients were followed up for a median of 22 months (interquartile range, 4–47 months) after TGD. In the follow-up period, patients underwent a median of 1 catheter exchange (interquartile range, 0–2). Ten patients (10/53, 19%) had their transgastric drains completely internalized during their clinical course. PDLs resolved in 46 patients (46/53, 87%), including 15 (94%) of the 16 patients with PCFs, who were able to undergo drain removal after a catheter indwelling time of 3 months ± 2. Four patients (4/53, 8%) had their transgastric drain removed during surgical debridement for necrotizing pancreatitis; necrosectomy was performed less than a month after TGD in all 4 of these patients. Two patients (2/53, 4%) passed away in the follow-up period with their transgastric drain in place. One patient (1/53, 2%) was lost to follow-up while the transgastric drain was in place.

Recurrent fluid collections were observed in 8 patients (15%) after 5 months ± 4 following drain removal. There were no recurrent cutaneous fistulae. Six of the 8 patients with recurrent fluid collections underwent repeat direct percutaneous or TGD; 3 patients had resolution of the recurrent fluid collection with repeat percutaneous drainage, whereas half of the patients required additional endoscopic or surgical management.

There were 4 moderate adverse events (4/53, 8%) related to TGD, including 2 patients who had drains that dislodged from the collection requiring repeat transgastric puncture under moderate sedation. One patient required catheter exchange for an occluded drain with pericatheter leakage.

Table 1. Baseline Clinical Characteristics (n = 54)

Age (y)	57 ± 17
Sex (male), N (%)	31 (57)
Pancreatitis, N (%)	41 (76)
Interstitial edematous pancreatitis	14 (26)
Acute peripancreatic fluid collection	5 (9)
Pseudocyst	5 (9)
Fluid collection age unknown	4 (7)
Necrotizing pancreatitis	27 (50)
Acute necrotic collection	10 (19)
Walled-off necrosis	11 (20)
Fluid collection age unknown	6 (11)
Antecedent surgery*, N (%)	16 (30)
Surgery involving pancreatic resection	12 (22)
Other abdominal surgery	4 (7)
Prior attempt at endoscopic intervention, N (%)	12 (22)
Successful pancreatic duct stent placement	4 (33)
Failed pancreatic duct stent placement	6 (50)
Failed endoscopic drainage	2 (17)
Longest dimension of fluid collection prior to any drain placement (cm)	11.2 ± 4.6
Age of PDL prior to transgastric drain placement (d)	59 ± 111
<28 d old, N (%)	25 (46)
>28 d old, N (%)	18 (33)
Unknown age	11 (20)

Note–Data are presented as mean ± standard deviation as appropriate.
PDL = pancreatic duct leak.
*Surgery performed within 1 month of the pancreatic duct leak being first detected on imaging.

Table 2. Transgastric Drain Placement (n = 54)

Pre-existing direct percutaneous drain, N (%)	
Yes (convert to transgastric drain)	22 (41)
No (primary transgastric drain)	32 (59)
Time from the first direct percutaneous drain to transgastric drain (d)	124 ± 161
Technically successful transgastric drain placement, N (%)	53 (98)
Fluoroscopic guidance	44 (83)
CT guidance	9 (17)
Initial transgastric drain tip position, N (%)	
Collection	41 (77)
Pancreatic duct	2 (4)
Stomach*	8 (15)
Duodenum†	2 (4)
Drain size (F), N (%)	
8	4 (8)
10	9 (17)
12	22 (42)
14	17 (32)
16	1 (2)
Initial drainage, N (%)	
External	37 (70)
Internal/external	16 (30)

Note–Data are presented as mean ± standard deviation as appropriate.
CT = computed tomography.
*Includes 1 patient in whom the pancreatic duct was crossed.
†The pancreatic duct was crossed in both patients.

Table 3. Subgroup Analysis: Time to Drain Removal and Risk of Recurrent Collection

Comparison	Time to drain removal (mo)	Risk of recurrent fluid collection
Presence vs absence of pancreatitis	3.3 vs 2.5, *P*=.12	20.0% vs 0%, *P*=.18
Necrotizing pancreatitis vs IEP	2.6 vs 3.3, *P*=.28	11.5% vs 18.5%, *P*=.7
Presence vs absence of active pancreatic duct communication	3.6 vs 2.6, *P*=.11	20.0% vs 12.1%, *P*=.45
Age of PDL, <28d vs >28d	2.6 vs 3.0, *P*=.48	8.0% vs 22.2%, *P*=.22

IEP = interstitial edematous pancreatitis; PDL = pancreatic duct leak.

One patient with a history of partial gastrectomy required a colonic drainage tube and overnight observation due to transcolonic access on the initial attempt for transgastric drain placement. This patient subsequently had successful transgastric drain placement under CT guidance.

There were 2 severe complications (2/53, 4%). One patient had worsening nausea and vomiting following conversion to an internal-external drain with side holes in the stomach, requiring prolonged admission. Symptoms resolved after the patient was converted back to an external TGD catheter. One patient had a prolonged admission due to sepsis from an occluded drain, requiring catheter exchange.

In subgroup analysis, there was a trend toward longer indwelling catheter time for patients with pancreatitis compared with those without pancreatitis. Although this did not meet significance (3.3 months vs 2.5 months, $P = .12$), the patient population of this study may be too small to detect a difference and no sample size determination was performed. All recurrent fluid collections occurred in patients with pancreatitis, compared with 0 recurrent fluid collections in patients without pancreatitis (20% vs 0%, $P = .18$). Patients with collections that demonstrated an active communication to the pancreatic duct at the time of transgastric drain placement also trended toward longer indwelling catheter times, although this did not meet significance (3.6 months vs 2.6 months, $P = .11$). The age of the PDL did not impact time to drain removal or odds of recurrence. Additional data from subgroup analysis are summarized in Table 3.

DISCUSSION

The treatment paradigm of necrotizing pancreatitis and associated PDLs has evolved considerably over the years. However, the most recent evidence in the literature has shown that conservative and minimally invasive approaches, such as catheter drainage, lead to fewer complications and decreased mortality compared with more invasive treatment options, such as necrosectomy (16,17). In a long-term follow-up study of the PANTER trial, Hollemans et al (18) showed that patients with infected

necrotizing pancreatitis randomized to a minimally invasive step-up approach had lower composite mortality and major complication rates than those in the open necrosectomy group (44% vs 73%) without an increased risk of reintervention (11% vs 13%). The results of the present study demonstrate that percutaneous TGD of PDLs is technically feasible, safe, and efficacious, which supports TGD as a minimally invasive treatment that can be offered to these patients. In addition, TGD offers unique advantages compared with alternative minimally invasive treatments; these include the ability to treat or prevent the debilitating complication of PCF, which can be caused by direct percutaneous drainage, and the ability to drain PDLs, which are either too immature or inaccessible by an endoscopic approach.

One limitation of TGD is that access to the PDL through the stomach may be extremely tenuous for percutaneous or video-assisted debridement. Therefore, as described in the methodology, direct percutaneous drainage is recommended in the setting of necrotizing pancreatitis in which future debridement may be required, provided that a safe anatomic window is available. Primary TGD may be performed if there is no suitable access for direct percutaneous drainage or in the setting of simple fluid collections resulting from acute interstitial edematous pancreatitis to prevent a PCF.

In the series of this study, 87% of patients were able to undergo removal of the transgastric drain following resolution of the PDL. Although 15% of patients experienced a recurrent fluid collection following drain removal, it is encouraging that most of these patients were adequately treated with repeat drainage and that there were no recurrent cutaneous fistulae. Overall, the efficacy of TGD in this study is well above the suggested 76% threshold for "curative and partial success" established by the Society of Interventional Radiology quality improvement guidelines for image-guided drainage/aspiration of abscesses (19). Similarly, complications in the patient cohort of this study, such as bowel transgression (1.9%) and sepsis (1.9%), were observed at frequencies lower than the suggested thresholds (2% and 4%, respectively) established by the same guidelines (19).

Existing literature on TGD of PDLs is scarce and limited to small case series. Davies et al (20) reported outcomes after percutaneous TGD of symptomatic pancreatic fluid collections or abscesses in 19 patients using an external transgastric catheter followed by an internalized double mushroom stent. In the follow-up period, 89% of patients underwent stent removal after resolution of the fluid collection, similar to the proportion of patients who were able to undergo drain removal in the present study. Only 1 patient (5%) in their series experienced a symptomatic recurrent collection. However, complications were relatively frequent, including 4 patients (21%) who developed sepsis requiring intervention. Matzinger et al (21) studied 12 patients with symptomatic pseudocysts treated with a percutaneous transgastric catheter left to external drainage. Complete resolution of the pseudocysts with percutaneous drainage alone was only achieved in 8 patients (66%); however, it is possible that some patients may have proceeded to surgical intervention prematurely because this study was reported when necrosectomy was performed more frequently. None of the patients in this series experienced a major complication. More recently, Curry et al (22) reported outcomes after single-step percutaneous transgastric cystgastrostomy with an internalized stent in 12 patients for symptomatic pseudocysts. Complete resolution of the pseudocyst was observed in 75% of patients. Two patients (17%) developed superinfection of the pseudocyst requiring further intervention. In comparison with prior studies, the present study describes not only the outcomes from a larger patient cohort but also a unique subset of patients with PCFs that were effectively managed with TGD.

The efficacy and safety of percutaneous TGD observed in the present study are also comparable with outcomes observed with other minimally invasive treatment options, such as endoscopic cystgastrostomy. Renelus et al (23) recently performed a meta-analysis of 17 studies and 1,708 patients who underwent endoscopic ultrasound-guided cystgastrostomy stent placement for peripancreatic fluid collections. The pooled technical success rate, defined as complete resolution of the fluid collection, was 88%. The adverse event rates for metal and plastic stents were 14% and 18%, respectively. These outcomes may improve with increased use of lumen-apposing self-expandable metallic stents, such as the Axios stent (Boston Scientific, Marlborough, Massachusetts) (24). However, there are still inherent limitations to the endoscopic approach, including the requirement of a mature cyst wall and anatomic considerations (6,7).

This study has several limitations. Owing to the retrospective nature of the study, there was no standardized follow-up for patients after transgastric drain removal. Therefore, it is possible that the frequency of recurrent PDL is underestimated, although asymptomatic recurrent collections that were not imaged may be clinically irrelevant. Inclusion of patients across multiple decades contributed to a larger patient cohort. However, this could have led to an underestimate in the efficacy of TGD because the 4 patients who proceeded to necrosectomy prior to drain removal were treated in the 1990s, a decade in which the step-up algorithm was not yet favored. Finally, although the present study examines a patient cohort larger than those in prior studies, the sample size is still relatively small; therefore, comparisons in the subgroup analysis that did not reach significance are likely underpowered.

In conclusion, TGD of PDLs is technically feasible and efficacious in the vast majority of patients with an acceptable complication rate. TGD is also effective in preventing or treating PCFs. The unique advantages of TGD compared with alternatives, such as direct percutaneous drainage or endoscopic cystgastrostomy, reinforce its niche within the minimally invasive treatment options for PDLs.

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