Acute and early EUS-guided transmural drainage of symptomatic postoperative fluid collections

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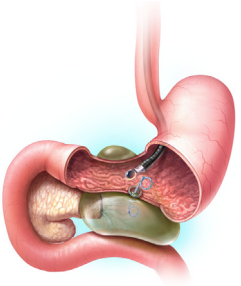
GRAPHICAL ABSTRACT



Background and Aims: EUS-guided postoperative drainage (EUS-POD) of postoperative fluid collections (POFCs) is typically delayed until a thick wall has formed to optimize safety. Thus, percutaneous drainage is the mainstay of early POFC management. The primary aim of this study was to compare technical and clinical success and adverse event (AE) rate between early (0-30 days postoperative) compared with delayed (>30 days) EUS-POD. The secondary aim was to determine predictors for clinical success and AE rate associated with early compared with delayed EUS-POD.

Methods: This was a retrospective analysis of consecutive patients undergoing EUS-POD between November 2013 and November 2018 at a single tertiary academic center. Demographic, procedural, and outcomes data were recorded. Clinical success was defined as resolution of symptoms and the fluid collection on cross-sectional imaging without recurrence after transluminal stent removal.

Results: Seventy-five patients underwent EUS-POD; 42 (56%) were early, of whom 20 were acute. Sixty-three patients (84%) had undergone distal pancreatectomy. Technical success was 100%, and clinical success was achieved in 70 patients (93%) after a mean 2.2 procedures (range, 1-5). Prior percutaneous drainage had been performed in 13 patients (17.3%). Both acute and early drainage versus delayed EUS-POD demonstrated similar rates of clinical success (95% and 93% vs 94%, $P = .99$) and AEs (21.4% and 15% vs 30.3%, $P = .43$). Necrosectomy was required less often in the early versus the delayed group. No predictors of clinical success were identified. Early EUS-POD was not a predictor of AEs ($P = .65$). Infection and collection size >10 cm correlated with increased AE risk ($P = .048$ and .007, respectively).

Conclusions: Early and even acute EUS-POD of POFCs appears to be technically feasible, clinically effective, and safe. EUS-POD should be considered for definitive management of early symptomatic POFCs. (Gastrointest Endosc 2020;91:1085-91.)

(footnotes appear on last page of article)

EUS-guided postoperative fluid collection drainage (EUS-POD) with placement of transmural, plastic, double-pigtail stents and/or lumen-apposing metal stents (LAMSs) has been reported for management of postoperative fluid collections (POFCs).[1-3] EUS-POD is often delayed until the POFC has formed a thick wall to optimize the safety of EUS-POD. Percutaneous drainage has been the mainstay of acute POFC management in this setting, although preliminary data suggest that EUS-POD may be as safe and effective as percutaneous drainage.[4-7]

The primary aim of the study was to compare technical and clinical success and adverse event (AE) rate between early (0-30 days postoperative) and delayed (>30 days postoperative) EUS-POD. The secondary aim was to determine predictors for clinical success and AE rate associated with early as compared with delayed EUS-POD.

METHODS

Patients who underwent EUS-POD between November 2013 (when early EUS-POD was begun at our institution) and November 2018 at a single tertiary academic medical center were enrolled in a retrospective database. Demographic, procedural, and outcomes data were recorded.

Only patients with a symptomatic POFC were considered for EUS-POD. Timing of the procedure (early vs delayed) was at the discretion of the referring surgical team, but in general, patients were referred as soon as symptoms (including nausea, vomiting, abdominal pain, failure to advance diet) developed in the setting of a radiographically identified POFC.

All procedures were performed with the patient under general anesthesia with endotracheal intubation by expert advanced endoscopy trained clinicians proficient in therapeutic EUS. All patients received periprocedural antibiotics. A therapeutic curvilinear echoendoscope (GF-UCT180; Olympus America, Central Valley, Pa, USA) was used in all cases. The fluid collection was examined to ensure no intervening vasculature and that the collection was within 10 mm of the gastric wall. Either a 19-gauge fine needle or an electrocautery enhanced catheter system (AXIOS; Boston Scientific, Natick, Mass, USA) was used to access the collection. In general, for cases using FNA, fluid was aspirated to partially decompress the collection, and then a similar volume of contrast was injected to perform a cystogram under fluoroscopic guidance. In some cases, the aspirated fluid was collected for diagnostic fluid analysis. For most cases, a .025- or .035-inch guidewire was then placed into the cavity and coiled several times under EUS and fluoroscopic guidance. Some cases using electrocautery-enhanced LAMSs did not use a guidewire. Dilation of the tract was performed when indicated, ranging from 7F to 10 mm using a tapered biliary dilation catheter or through-the-scope dilation balloon catheter. After tract dilation, either a plastic double-pigtail stent (including 7F and 10F), a fully covered self-expanding metal stent (10 mm), or a LAMS either with or without electrocautery (also referred to as a cold AXIOS stent) were deployed with 1 flange positioned within the collection versus the other within the bowel lumen. In most cases using a LAMS, a coaxial plastic double-pigtail stent was placed to ensure ongoing patency of drainage.

Cross-sectional imaging assessment was typically performed 1 to 4 weeks postprocedure as guided by the collection morphology and clinical status. Worsening or persistent symptoms of abdominal pain and/or fever and inability to tolerate oral intake prompted reintervention and often tract dilation, insertion of additional stent(s), and direct endoscopic necrosectomy as needed. In cases where prior percutaneous drainage had been attempted and failed, we typically requested removal of the percutaneous drain at least 2 to 3 days before EUS-POD to allow for fluid reaccumulation to enhance the "target" lesion for EUS-guided drainage.

Technical success was defined as successful placement of a transgastric and/or transduodenal stent into the POFC. Clinical success was defined as resolution of symptoms and the fluid collection as determined by cross-sectional imaging without recurrence after removal of the transluminal stent(s). A collection was defined as infected if there were systemic inflammatory response criteria met, with or without evidence of air (from gas-forming organisms) within the collection on cross-sectional imaging or if frank purulence was seen within the collection during the transmural drainage procedure. Systematic follow-up was ensured by our postoperative (surgical) protocol, which automatically includes follow-up visits at 3 and 6 months postoperatively. If a patient died within this time frame, which occurred in several patients with the diagnosis of pancreatic ductal adenocarcinoma, then family or power of attorney were contacted to gather information regarding the date and cause of death, which was recorded in the electronic medical record. If a patient was unfit to travel for the 6-month follow-up appointment or admitted to another healthcare facility, a virtual or phone visit was recorded in the medical record.

Patients were followed closely in the postprocedure period, with clinical evaluation and cross-sectional imaging performed within 4 weeks, repeated until collection and symptom resolution. AEs related to the EUS-POD procedure were defined using the Cotton lexicon.[8] These AEs included all events that occurred during and after the procedure, including stent maldeployment or migration, nausea/vomiting, fever, stent occlusion, bleeding, perforation, peritonitis, pneumoperitoneum, recurrence of the collection, and any other events noted in the medical record. An AE was labeled "periprocedural" if this occurred during the procedure or before discharge from the endoscopy unit. All other AEs were labeled "delayed." This study was approved by the Institutional Review Board of the Mayo Clinic (no. 18-007238).

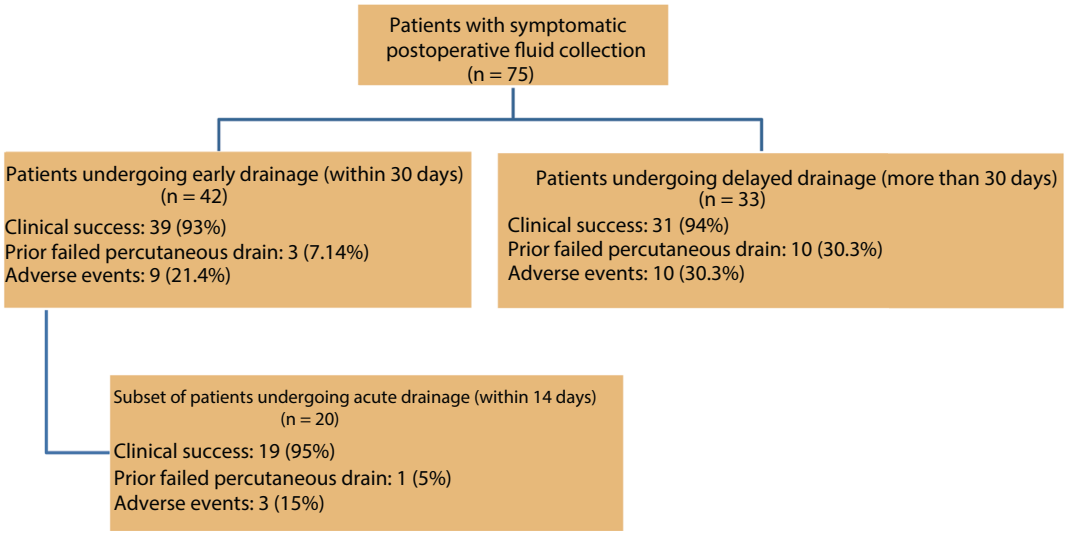


Figure 1. Flow diagram of patients undergoing EUS-guided postoperative fluid collection drainage.

Statistical analysis

The Fisher exact test was used to compare technical and clinical success, defined as having the transmural stents removed with no recollection on follow-up, as well as the AE rate between the groups. Logistic regression was used to determine independent predictors for clinical success and AE. Available clinical parameters were analyzed using logistic regression including age, sex, timing of EUS-POD, metal or plastic stent, presence of necrosis, presence of infection, collection size >10 cm, and route of drainage (transduodenal or gastric). Significant predictors on univariate analysis ($P < .05$) were inputted into the multivariable analysis along with timing of postoperative EUS drainage as our main variable of interest. Interactions were assessed between the predictors. All statistics were analyzed using SAS JMP Pro 14.1 (SAS Institute, Cary, NC, USA).

RESULTS

Seventy-five unique patients underwent EUS-POD; 42 (56%) were early (of whom 20 were acute) and 33 were delayed (Fig. 1). Collections resulted from various abdominal surgeries (Table 1), with most developing secondary to distal pancreatectomy and splenectomy in 63 patients (84%). Prior percutaneous drainage had been performed and failed in 13 patients (17.3%), including 3 early and 10 delayed EUS-POD cases. Percutaneous drains were in situ at the time of EUS-POD in 2 cases. Patients with prior failed percutaneous drainage had median collection size of 7.2 cm (range, 3.0-14.7).

Technical success was achieved in all patients across all groups (100%). Clinical success was achieved in 70 patients (93%) after a mean of 2.2 procedures (range, 1-5). No patients were lost to follow-up. Median follow-up was 264 days (range, 21-1844).

In patients who underwent plastic double-pigtail stent placement, 2 side-by-side stents were placed in 29 of 35 cases (83%), with a range of 2 to 4 stents placed across all patients. Double-pigtail stents of 7F were most commonly used in 31 patients (89%).

Most patients required at least 2 procedures, with the first to initiate drainage and the final to remove the stent(s). Patients who required only 1 procedure had stent(s) placed at EUS-POD and died or were placed into hospice care before stent retrieval. Repeat procedures for additional stent placement(s) or necrosectomy were required in 9 delayed EUS-POD patients using LAMSs and 4 early EUS-POD patients, of which 2 used LAMSs and 2 used double-pigtail stents. All additional procedures were performed when there was a lack of improvement in clinical symptoms related to the POFC, which required endoscopic investigation of the cavity and necrosectomy and placement of additional stents in all 13 procedures.

In patients undergoing acute drainage (within 14 days postoperatively), technical success was 100% in all 20 patients (Supplementary Table 1, available online at www.giejournal.org). Clinical success was achieved in 19 patients (95%), with 3 mild delayed AEs noted as defined by the Cotton lexicon. These included 1 incidence each of fever, self-limited hemorrhage, and nausea/vomiting. No periprocedural AEs including pneumoperitoneum, perforation, or bleeding occurred in these acute cases.

No significant differences were observed between acute and early drainage versus delayed EUS-POD in terms of clinical success (95% and 93% vs 94%, $P = .99$) and AE rate (21.4% and 15% vs 30.3%, $P = .43$). Patients with early EUS-POD were less likely to have solid necrosis compared with those with delayed EUS-POD (26.2% vs 63.6%; $P = .002$). Furthermore, the number of repeat

TABLE 1. Patient and procedural characteristics

Characteristics	Early EUS-POD: 0-30 days after surgery (n=42)	Delayed EUS-POD: >30 days after surgery (n=33)
Patient		
Mean age, y	60.2 ± 13.2	58.7 ± 14.1
Male sex	21 (50)	19 (58)
Surgery		
Distal pancreatectomy	36 (86)	27 (82)
Partial hepatectomy	2 (4.8)	—
Other*	4 (9.5)	6 (18)
Pathology		
Pancreatic ductal adenocarcinoma	13 (31)	9 (27.3)
Pancreatic neuroendocrine tumor	12 (28.6)	11 (33.3)
Mucinous cystic neoplasm	3 (7.1)	3 (9.1)
Intraductal papillary mucinous neoplasm	4 (9.5)	3 (9.1)
Other†	10 (23.8)	7 (21.2)
Mean postoperative EUS-POD date, days (range)	15 (6-30)	49 (31-198)
Inpatient	26 (62)	13 (39.4)
If inpatient, median days in hospital after EUS-POD (range)	2 (1-17)	2 (1-15)
Mean maximum diameter, cm	7.7 ± 3.5	7.9 ± 3.2
Solid necrosis present	11 (26.2)	21 (63.6%)
Procedure		
Transgastric access	39 (93)	30 (91)
Transduodenal access	3 (7)	3 (9)
Stent used		
Hot lumen-apposing metal stent	10 (24)	10 (30.3)
Cold lumen-apposing metal stent	8 (19)	10 (30.3)
Plastic double-pigtail stent(s)	24 (57)	11 (33.3)
Self-expanding metal stent	—	2 (6.1)
Infected collection	17 (40.5)	20 (60.6)
Median stent duration, days (range)	48 (25-158)	53 (20-269)
Mean number of GI interventions (range)	2.0 (1-4)	2.4 (1-5)
Prior percutaneous drainage attempt	3 (7.14)	10 (30.3)
Duration of follow-up median, days (range)	262 (39-1485)	214 (38-1844)

Values are mean ± standard deviation or n (%) unless otherwise defined.
EUS-POD, EUS-guided postoperative drainage; —, none.
*Other surgeries (n = 10) included pancreaticoduodenectomy (n = 3), partial hepatectomy (n = 2), pancreatic enucleation (n = 2), retroperitoneal tumor resection (n = 2) partial gastrectomy (n = 1).
†Other pathology (n = 17) included serous cystadenoma (n = 3), soft tissue sarcoma (n = 3), cholangiocarcinoma (n = 2), metastatic colon adenocarcinoma (n = 2), renal cell carcinoma (n = 1), diffuse large B cell lymphoma (n = 1), mantle cell lymphoma (n = 1), periduodenal pancreatitis (n = 1), pseudopapillary tumor (n = 1), gastric intestinal metaplasia (n = 1), pancreatic intraepithelial neoplasia type 1a (n = 1).

interventions for stent manipulations and necrosectomy was significantly lower in early versus delayed EUS-POD (mean of 2.04 and 2.45 procedures, respectively; P = .009).

Among the entire cohort, periprocedural AEs, which were all mild by the Cotton lexicon, included 2 patients with self-limited postprocedure vomiting and 1 patient with LAMS maldeployment (displaced into the stomach during deployment) requiring a second successful LAMS attempt during the same procedure. Delayed AEs were noted in 16 cases, of which 12 were mild and 4 were moderate (Table 2). All 4 moderate delayed AEs were because of collection recurrence at the same site of previous collection, requiring a new EUS-POD procedure. Mean time to recurrence of the collection in these 4 cases was 27 days (range, 11-37). Of the 4 patients who

TABLE 2. Outcomes comparison including immediate technical and clinical success, acute adverse events, and delayed adverse events across early and delayed EUS-POD cases

	Early EUS-POD (n = 42)	Delayed EUS-POD (n = 33)	*P* value
Technical success	42 (100)	33 (100)	—
Clinical success	39 (93)	31 (94)	.99
All adverse events	9 (21.4)	10 (30.3)	.43
Periprocedural adverse events	2 (4.8)	1 (3)	.99
Nausea/vomiting	2 (4.8)	—	—
Stent maldeployment	—	1 (3)	—
Delayed adverse events	7 (16.7)	9 (27.3)	.39
Fever	2 (4.8)	—	—
Systemic inflammatory response syndrome	—	2 (6.1)	—
Recurrent collection	2 (4.8)	2 (6.1)	—
Hemorrhage	2 (4.8)	2 (6.1)	—
Nausea/vomiting	1 (2.4)	—	—
Superior mesenteric vein thrombosis	—	1 (3)	—
Pneumonia	—	1 (3)	—
Stent migration	—	1 (3)	—

Values are n (%).
EUS-POD, EUS-guided postoperative drainage; —, none.

experienced recurrence of fluid collection, 3 had been managed with transgastric LAMSs and 1 with two 7F transgastric double-pigtail stents. In all cases, LAMSs were placed at the second EUS-POD procedures with complete resolution of the recurrent collections, ultimately achieving clinical success, although we have classified these initial cases as clinical failures given the recurrent fluid collection formation.

No patient required rescue percutaneous drainage or surgery for management of a recurrent collection. One case of self-limited postprocedure hemorrhage, presenting as melena, was managed conservatively without the need for blood transfusion. In this patient nonurgent EGD performed 5 days after the stent placement procedure showed a small amount of clot on the LAMS without the need for endoscopic or other intervention. A patient admitted to another institution 20 days after EUS-POD developed self-limited hematemesis 2 days into the hospital admission and died with comfort care and diagnosis of pneumonia 25 days after transgastric double-pigtail stent placement after open distal pancreatectomy for pancreatic adenocarcinoma. Review of their medical record suggested that EUS-POD was not causative in the patient's death. No patients experienced perforation, pneumoperitoneum, or severe sepsis. Another recorded delayed AE of indeterminate significance included a single individual with mesenteric vein thrombosis. Although mesenteric vein thrombosis could not be directly attributed to the EUS-POD procedure, given that this was diagnosed within 30 days of the procedure, we have included it as an AE.

Given the high clinical success rate, no factor was predictive of clinical success on univariable logistic regression. Timing of drainage, age, sex, stent type, prior percutaneous drainage, route of drainage (transduodenal vs transgastric), and presence of necrosis were not associated with the AE rate (Table 3). Collection size (>10 cm) and infected collections were associated with increased AEs. On multivariable logistic regression, timing of drainage remained nonsignificant, after adjusting for both collection size and presence of infections, also available in Supplementary Table 1. There were no significant interactions between the size of the collection and infection ($P = .40$). On multivariate regression adjusting for covariates, early versus delayed EUS-POD was not associated with AEs ($P = .65$). An infected collection and collection size greater than 10 cm both correlated with increased AE risk ($P = .048$ and .007, respectively) (Table 3).

DISCUSSION

Guidelines suggest that endoscopic drainage of inflammatory fluid collections, including pseudocysts and walled-off necroses, should be delayed 4 weeks or longer to allow for encapsulation.[9] In theory, a mature wall may reduce the risk of AEs with endoscopic drainage, including infection and perforation. Although the guidelines do not specifically address postoperative intra-abdominal fluid collections, a similar approach of delaying endoscopic drainage has been widely adopted. A prior study of 17 patients suggested the safety of EUS-POD

TABLE 3. Univariable and multivariable analyses for factors associated with adverse events

Variable	Odds ratio (95% CI)	*P* value
	Univariable analysis	
Delayed drainage	.77	.65
Metal stent	1.05	.92
Necrosis	2.33	.13
Prior percutaneous drainage	2.6	.14
Collection size >10 cm	5.5	.005
Transduodenal access	2.81	.99
Infected collection	3.16	.053
Age	.96	.098
Sex	.75	.6
	Multivariable analysis	
Delayed drainage	.58 (.16-2.1)	.39
Infected collection	3.63 (1.01-13.1)	.048
Collection size >10 cm	5.57 (1.6-19.8)	.007

CI, Confidence interval.

performed within 30 days of surgery,[3] and another study of 41 patients concluded that the duration between surgery and EUS drainage was not related to AE rate.[1] Our study further suggests that EUS-POD, as early as 6 to 14 days postoperatively, is both safe and effective for the management of postoperative intra-abdominal fluid collections. This series dispels the notion that a postoperative collection must form a thick wall before it can be safely drained with EUS guidance. However, given the low rate of AEs across all groups, further evaluation of the ideal technique and timing of EUS-POD is needed. Also different from endoscopic drainage of walled-off necroses and pancreatic pseudocysts, in our series no patient undergoing EUS-POD required an ERCP for pancreatic sphincterotomy and/or pancreatic duct stent placement.

In our subset of patients who had failed percutaneous drainage, all were successfully managed (3 underwent early EUS-POD and 10 underwent delayed EUS-POD) with EUS-POD. Our data suggest that earlier treatment of POFCs is less likely to contain solid necrosis and debris, which permits more efficient drainage and reduces the need for additional endoscopic necrosectomy procedures. Although our study was not designed to determine the mechanism of necrosis formation in POFCs, we hypothesize that early intervention may improve the disease course by the earlier removal of pancreatic enzymes from the resection bed, thereby decreasing the risk of subsequent necrosis. Although both LAMSs and plastic double-pigtail stents were effective in early collections, given a lack of a mature wall in these cases some endoscopists prefer the use of LAMSs, whereas others prefer small-caliber pigtail catheters, especially if the collection is primarily fluid. A recent retrospective series of 47 patients with postsurgical fluid collections from 8 centers studied over a 3.5-year period demonstrated high technical and clinical success rates, 93.6% and 89.3%, respectively, with LAMSs with a low rate of AEs (6.4%).[10] Our series that includes a similar number of patients with LAMS placement (n = 38) also reports high technical and clinical success rates of 100% and 92.1%, respectively, and with an acceptable rate of mild to moderate AEs (21.7%) with no severe or greater AE encountered.

Our data suggest that infection and collection size greater than 10 cm correlated with increased risk for AEs. The association between infected collection and risk for AEs is likely at least partially explained by the fact that patients with infected collections were likely to experience and report symptoms of fever and/or systemic inflammatory response syndrome after their drainage procedure, which were defined as AEs. Close monitoring, peri- and postprocedure antibiotics, and in some cases inpatient care may be needed for patients undergoing EUS-POD of an infected collection. Caution and close monitoring should also be considered for patients with collections greater than 10 cm, which appears to be a risk factor for increased rate of AEs.

Aside from the retrospective nature of our study, another limitation is inherent selection bias, because some patients with POFCs at our institution are occasionally managed with percutaneous drainage, especially in the acute phase of POFCs. One perceived advantage of percutaneous drainage is the ability to monitor daily drain output, which is not possible with endoscopic drainage. Additionally, some collections, including those with deep paracolic gutter extension and those that are not closely apposed to the gastric or duodenal wall, may be more ideally managed with percutaneous drainage. Regardless of the drainage approach, it is important to acknowledge that many POFCs will resolve spontaneously, and referral for a drainage procedure is currently only considered in patients with symptomatic fluid collections. Randomized, prospective study of percutaneous versus endoscopic drainage in the early and acute postoperative time frames would help to elucidate the ideal timing and type of transmural drainage for patients with fluid collections after abdominal surgery. However, such studies are unlikely to be conducted given the established and perceived advantages of (internal) endoscopic drainage. Based on our ongoing experience, endoscopic drainage has become the preferred approach for anatomically accessible early and acute collections that require therapy.

Early and even acute EUS-POD of symptomatic POFCs without a thick wall appears to provide comparable technical and clinical success and safety as compared with delayed EUS-POD, regardless of stent type. In appropriately selected patients, EUS-guided drainage may be offered in the acute setting to treat POFCs.

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Abbreviations: AE, adverse event; EUS-POD, EUS-guided postoperative fluid collection drainage; LAMS, lumen-apposing metal stent; POFC, postoperative fluid collection.

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SUPPLEMENTARY TABLE 1. Patient and procedural characteristics for acute (0-14 days after surgery) EUS-POD patients (n = 20)

Characteristics	Value
Patient	
Mean age, y	56.5 ± 15
Male sex	8 (40)
Surgery	
Distal pancreatectomy	18 (90)
Pancreatic enucleation	2 (10)
Pathology	
Pancreatic ductal adenocarcinoma	5 (25)
Pancreatic neuroendocrine tumor	6 (30)
Mucinous cystic neoplasm	2 (10)
Intraductal papillary mucinous neoplasm	2 (10)
Other	5 (25)
Median postoperative EUS-POD days (range)	11 (6-14)
Inpatient	12 (60)
If inpatient, median days in hospital after EUS-POD (range)	2 (1-17)
Mean maximum diameter, cm	7.66 ± 2.4
Solid necrosis present	4 (20)
Procedure	
Transgastric access	20 (100)
Transduodenal access	0
Stent used	
Lumen-apposing metal stent	8 (40)
Plastic double-pigtail stent(s)	12 (60)
Self-expanding metal stent	—
Infected collection	6 (30)
Median stent duration (range)	49 (25-73)
Mean number GI interventions (range)	1.85 (1-2)
Prior percutaneous drainage attempt	1 (5)
Duration of follow-up median, days (range)	258 (73-1485)

Values are mean ± standard deviation or n (%) unless otherwise defined.
EUS-POD, EUS-guided postoperative drainage; —, none.