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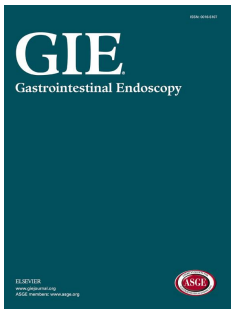

EUS-guided drainage of post-surgical fluid collections using lumen-apposing metal stents: a multicenter study

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EUS-guided drainage of post-surgical fluid collections using lumen-apposing metal stents: a multicenter study

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Background and Aim: Post-surgical fluid collections (PSFCs) are traditionally drained either percutaneously or surgically. Endoscopic drainage offers several advantages compared to either percutaneous or surgical approaches including avoiding repeat surgery, or the need to have a percutaneous drain in place for weeks. There are very little data regarding use of lumen apposing metal stents (LAMSs) in the drainage of PSFCs. We aim to study the technical and clinical success and adverse events of using LAMSs in the drainage of PSFCs.

Methods: Collaborators from 8 centers retrospectively reviewed their endoscopic databases to find procedures using LAMSs for drainage of post-surgical collections. Technical success (successful placement of LAMSs into the fluid collection), clinical success (complete resolution of the fluid collection on repeat imaging or endoscopy), and intra- and post-procedure adverse events (AEs) were measured.

Results: A total of 47 patients were identified with PSFCs after various surgeries. Thirteen patients had failed previous percutaneous or surgical drainage attempts. Fluid collections averaged 78.6 mm (47-150 mm) in size. The most common site of stent placement was transgastric, followed by rectum and duodenum. Technical success rate was 93.6 %, and clinical success rate was 89.3%. The intraprocedural AE rate was 4.25% and postprocedural AE rate was 6.4 %. There was one death unrelated to the procedure.

Conclusion: The use of LAMSs to drain post surgical fluid collections has a high technical and clinical success rate with low AEs. For collections that are favorably located adjacent to the stomach, duodenum or rectum, LAMS placement is a viable alternative to repeat surgery or percutaneous drainage.

Introduction

Post-surgical fluid collections (PSFCs) can be a major cause of morbidity and mortality.[1] Depending on the type and location of the surgery, they may occur in the chest, abdomen, or pelvis. In addition, these collections may become infected necessitating drainage. Repeat surgery to drain the PSFCs is an invasive option and is associated with increased morbidity.[2] As a result, image guided percutaneous drainage (PCD) has been the traditional route for drainage.[2,3]

The success rate of PCD varies from 60% to 84%.[2-5] However, PCD may be less successful in infected collections. In addition, significant fluid and electrolyte loss may occur, and there is an increased risk of a cutaneous fistula.[1,4,6] These drains may need frequent changing or repositioning, flushing to maintain patency, monitoring output to determine the appropriate timing of drain removal, and often require visiting nurse services.[1,4,7] Overall, the presence of a PD may negatively affect a patient's quality of life for the weeks or months that the drains remain in place.

With recent advances in endoscopic technology, collections adjacent to the GI tract can be drained endoscopically, typically under EUS guidance. EUS allows accurate assessment of fluid collections, surrounding vessels, and organs. This aids in transmural drainage and also helps reduce adverse events like bleeding and perforation.[6] There are many case series of successful EUS-guided drainage of PSFCs, particularly after distal

pancreatectomy. In almost all these cases, plastic stents have been used with technical success ranging from 96% to 100% and clinical success rates ranging from 80% to 100%.[1,4-10]

In the last 2 years, lumen apposing metal stents (LAMSs) are being used extensively for transmural drainage of peripancreatic fluid collections (PFCs) such as pseudocysts and walled-off necrosis.[11-15] There have also been a few case reports of management of non-pancreatic fluid collections using LAMSs. These have included a mediastinal abscess, liver abscesses, and loculated ascites.[16-19]

Aside from case reports, the literature for drainage of PSFCs using LAMSs is limited. We aimed to study the safety and efficacy of using LAMSs in the drainage of PSFCs using a large multi-center cohort.

Patients and Methods

This is a retrospective analysis of cases from 8 academic tertiary care referral centers in the United States. Institutional review board approval for the study was obtained by all the participating centers. Post-surgical fluid collection was defined as any collection in the chest, abdomen, and pelvis developing as a result of a surgical procedure. All patients with PSFCs in whom EUS-guided drainage using a LAMS was attempted from January 2012 to August 2016 were included in the study. The collections were identified by a cross-sectional imaging study before endoscopic procedure. The PSFCs that were

amenable to EUS access were included. Data were collected on demographics, type of surgery, postoperative day the collection was first noted, location and size of the collection, previous non-endoscopic attempts to drain the collection, date of EUS-guided drainage of the collection, and the size of the LAMS that was used. In addition, data were collected on adverse events (AEs) both during and after the procedure (bleeding, infections, perforation, misdeployment of stent, and stent migration, death).

Technique

All of the procedures were performed with the patient under general anesthesia or monitored anesthesia control (MAC). Antibiotics were given pre- and post-procedure. A therapeutic linear array echoendoscope (GF-UCT180, Olympus, Center Valley, Pa, USA) or a forward-viewing echoendoscope (TGF-UC180J Olympus, Center Valley, Pa, USA) was used to perform the procedure. The AXIOS lumen-apposing metal stent (Boston Scientific, Marlborough, Mass, USA) was used. This stent comes available in electrocautery enhanced ("hot") or non-electrocautery enhanced ("cold") versions. The stent diameter (10 mm or 15 mm) and use of cautery-enhanced stent were at the discretion of the endoscopist.

LAMS technique

Under EUS guidance, the fluid collection is located. A 19-gauge needle is used to puncture into the collection once Doppler confirms absence of vessels in the path of the EUS needle. Use of contrast injection into the collection, to confirm the location of the

needle in the fluid collection, is at the discretion of the endoscopist. A 0.035-inch or 0.025-inch-long (450 cm) biliary guidewire is then advanced through the needle and coiled into the cavity under fluoroscopic guidance. The needle is withdrawn as the guidewire is left in the collection. The tract was then dilated using wire-guided biliary dilation balloon. In some cases, a cautery with a biliary needle knife over the guidewire was used to gain access into the collection. In these cases, tract dilation with a biliary balloon is not performed. The LAMS delivery system is then advanced over the wire and locked into position on the echoendoscope. Using the manufacturer's recommended technique, we introduced the constrained stent into the collection under EUS guidance, and the distal flange deployed, again under EUS guidance. The deployment of the proximal flange is then done under endoscopic guidance. The stent lumen may be immediately dilated up to the LAMS diameter (10 mm or 15 mm) using a through-the-scope dilating balloon; this was at the endoscopist's preference. Immediate endoscopic debridement of necrotic material in the collection may be performed at the discretion of the endoscopist.

The electrocautery-enhanced LAMS has the capability of application of cautery by means of a cautery ring at the distal tip of the device's introducer. This allows passage of the catheter into the collection without the need for prior dilation of the tract. It can also avoid the need for use of the initial needle puncture and guidewire placement. Details on stent delivery are otherwise the same as the non-electrocautery-enhanced version.

Patient follow-up

Follow-up cross-sectional imaging was performed to assess the resolution of the PSFCs after LAMS placement. Timing was at the discretion of the endoscopist, but was usually performed between 1 and 8 weeks. If there was resolution of the collection on imaging, then repeat endoscopy was performed to remove the stent.

Outcome measures

The primary outcome of this study was the efficacy of LAMSs to drain PSFCs. Efficacy was measured by technical and clinical success. Technical success was defined as the ability to successfully place a LAMS transmurally into the fluid collection under EUS guidance. Clinical success was defined as successful drainage of PSFC with complete resolution of the fluid collection on repeat imaging/endoscopy.

The secondary outcome was the safety of LAMSs for PSFCs. Safety was measured by intra-procedural and post-procedural adverse events (AEs) associated with LAMS use. Intraprocedural bleeding was defined as significant bleeding during the procedure needing either endoscopic, interventional radiology, or surgical intervention. Postprocedural bleeding was defined as significant bleeding anytime after the procedure needing either endoscopic, interventional radiological, or surgical intervention. Perforation was defined as presence of pneumoperitoneum or pneumomediastinum.

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Results

A total of 47 patients with 47 PSFCs underwent EUS-guided drainage using a LAMS. There were 26 males, and the average age of the study population was 54 years (range 19-75 years). Most of the PSFCs (26/47, 55%) were result of pancreatic duct leaks after pancreatic resections (23 tail and 3 head). Other surgical procedures resulting in PSFCs managed with LAMS placement included liver transplantation, liver resection, cholecystectomy, colorectal resection, gynecologic, or bariatric surgery (Table 1).

The PSFC was first noted on cross-sectional imaging on average 37 days (range 4-180 days) after the surgery. Previous attempts of drainage were made by placement of a percutaneous catheter in 12 patients (25.5%). One patient had an attempt at surgical drainage. The cases in whom percutaneous drainage was attempted included 8 peripancreatic collections (5 tail resections, 3 head resections), 3 pelvic collections, and 1 gallbladder fossa collection. A surgical attempt at drainage was made in a gastric bypass patient. ERCP with pancreatic duct stent placement in addition to LAMS placement was performed in one patient with pancreatic duct leak. The mean size of the drained PSFCs was 78.6 mm (range 47-150 mm). The linear-array echoendoscope was used in all but one procedure in which a forward-viewing echoendoscope was used. Transgastric drainage was performed in 34 cases (72%), transduodenal drainage in 5 cases (11%), and transrectal in 8 (17%). A 15-mm AXIOS stent was used in 70% of the cases and a 10-mm LAMS in the remainder. Hot AXIOS was used in 76% cases. Based on type of fluid that was drained from the collection PSFCs were characterized into

inflammatory fluid collection draining clear fluid, abscesses draining pus, and bilomas if bile was drained. There were 24 inflammatory fluid collections, 19 abscesses, and 4 bilomas. The LAMS was dilated immediately after placement in 85% (40/47) of cases per endoscopists' preference. Reasons in favor of immediate dilation were as follows: ensures immediate apposition of the tissues, maximizes initial drainage, and allows direct access for debridement. Direct endoscopic debridement was performed at the time of stent placement in 6 procedures (Table 2) (Figure 1).

Technical success

The procedure was technically successful in 93.6% (44/47). Two of the technical failures were due to stent misdeployment. In one case, the LAMS failed to deploy, and initial drainage was obtained with 2 double-pigtail plastic stents, and a LAMS placed 1 month later. In the other, the LAMS was deployed within the fluid collection, but the intragastric flange could be grasped with a rat-tooth forcep and repositioned successfully. In one case the fluid collection decompressed before stent could be deployed. Technical success rate was 94% for transgastric placement, 80% for transduodenal, and 100% for transrectal route. (Table 3) (Figures 1 and 2).

Clinical Success

The overall clinical success rate in the study cohort was 89.3% (42/47) with resolution of the PSFC on repeat imaging. The clinical success rate excluding the technical failures was 95.45% (42/44). One patient had dual modality treatment with a percutaneous drain in

addition to the LAMS. In the second case, the patient died due to sepsis. This was unrelated to the procedure itself. Clinical success also varied based on site of the LAMS placement—transgastric 91.2%, transduodenal 80%, and transrectal 87.5%. The mean number of days for resolution of the PSFCs after LAMS placement was 27.4 days (range 5-75 days). The average number of days the stent was left in before removal was 36 days (7-102 days). (Table 3) (Figures 1 and 2).

Adverse events

Intraprocedural adverse event (AE) rate was 4.25% (2/47). Both were stent misdeployments. There were no cases of intraprocedural bleeding.

The postprocedural AE rate was 6.4 %. There was 1 perforation noted 12 hours after the procedure requiring surgical repair. There was 1 instance of stent migration. One patient developed infection manifested by fever. There was 1 death in the study cohort. This was not related to the procedure itself. The patient developed PSFC after left colectomy. The LAMS was successfully placed. She was later admitted for sepsis due to either or a combination of endometritis and a sacral decubitus. endometrium. Hospice care was initiated. No postprocedural bleeding was seen. (Table 3)

Pancreatic surgeries versus non-pancreatic surgeries

Our study included 26 PSFCs resulting from pancreatic resections: 23 tail resections, 3 head resections, and 1 resulting from pancreas injury. The technical success and clinical

success in this group was 100% and 96%, respectively. There were 20 PSFCs resulting from non-pancreatic surgeries. The technical success and clinical success in this group was 85% and 80%, respectively. Both the stent misdeployments and one perforation described in the adverse event section occurred in this cohort.

Discussion

This study shows that EUS-guided drainage using LAMSs is safe and effective for drainage of PSFCs. Overall, there was a high technical and clinical success rate with low rate of AE. For collections that are favorably located adjacent to the stomach, duodenum, or rectum, LAMS placement is a viable alternative to repeat surgery or PCD.

PSFCs are not rare, particularly after pancreatic surgery. In a large study of 908 patients who underwent pancreatic tail resection, 158 (17%) developed clinically significant fistula, leak or abscess. In these 158 patients, 436 CT scans, 310 image-guided procedures, and 26 reoperations were performed. Additionally, an average of 38 days of drainage was required, as well as a 22% intensive care unit (ICU) admission rate and readmission rate of 50%. An adverse event-specific mortality rate of 5% was observed.[20] Other studies have shown a comparable leak rate.[21-24] Several studies have investigated risk factors for pancreatic leak after resection, as well as techniques to try to limit leak.[25-30] However, even in the best of surgical hands, post-resection leaks can occur.

Fluid collections may also occur after non-pancreatic surgery. For example, bilomas may occur in the region of the gallbladder fossa after cholecystectomy.[31-34] Other examples include pelvic fluid collections and abscesses, which may be seen after low anterior resection, colectomy, appendectomy, and gynecological surgeries.[35-41]

Traditionally, such PSFCs have been drained surgically or percutaneously, with surgical drainage avoided if possible due to increased morbidity and mortality.[1] In addition, PCD, though less invasive, is associated decreased quality of life, risk of infection, permanent fistula formation, and fluid and electrolyte losses.[1,4,6,7]

Recently, there have been a few reports of successful EUS-guided drainage of PSFCs. Technical success of the procedure ranged from 96% to 100% and clinical success 80% to 100%. Plastic stents were used in all of these studies (Table 4).[1,4-10] In 3 retrospective studies where EUS-guided drainage was compared with percutaneous drainage, both had similar technical and clinical success rates and adverse event rates.[4,5,7] EUS-guided transmural drainage offers many advantages over percutaneous drainage. The fluid collections are drained internally so there is less chance of infection and fluid and electrolyte disturbances. The endoscopic approach also provides opportunity to do necrosectomy and debridement if needed.[7] In addition, endoscopic drainage is associated with shorter hospital stays and fewer CT scans.[4]

Plastic stents have several potential disadvantages including smaller diameter, higher migration rates, and the need to place multiple stents to ensure adequate drainage.[11,13] There is some published experience with the use of biliary fully covered self-expanding metal stents (FCSEMSs), but these have a number of disadvantages as well including risk of stent migration, abutment of the end of the stent against lumen wall causing bleeding and tissue injury, and inability to perform direct endoscopic necrosectomy through the stent.[12,13]

Recently, a fully covered lumen-apposing metal stent (LAMS) has become available for transmural drainage (AXIOS and AXIOS-EC, Boston Scientific, Marlborough Mass).[11-13,15] This stent is specifically designed for transmural drainage and has several advantages including large diameter, saddle shaped design decreasing migration risk, and an easy deployment system allowing high technical success.[12] The large inner stent diameter and anchoring flanges allows direct endoscopic debridement by passage of standard gastroscope through the stent lumen.[13]

LAMSs are being used extensively in the drainage of pancreatic fluid collections (PFCs) with high technical and clinical success rates.[11-13] To our knowledge, this the first study evaluating the role of LAMSs in the drainage of PSFCs. The technical and clinical success rates were 92.5% and 87.5%, respectively. This is similar to other studies evaluating the role EUS-guided drainage of PSFCs. Our adverse event rates were similar as well.[1,4-10]

In our study, there were 8 cases of transrectal drainage of pelvic fluid collections using LAMSs with technical and clinical success of 100% and 87.5%, respectively. EUS-guided drainage of pelvic fluid collections was first reported by Giovannini et al in 2003 using plastic stents.[42] Since then, there have been a few case series describing EUS-guided drainage of pelvic abscesses with clinical success ranging from 75% to 100%.[41-49] Trevino et al described the technique of using a 10F drainage catheter in addition to the stents for pelvic abscesses to facilitate abscess resolution. The drainage catheter was used to irrigate the abscess cavity with saline (50 mL every 4 hours) until aspirate was clear. The drainage catheter was removed in 36 hours whereas the plastic stents were left in place until the resolution of the fluid collection.[44] LAMSs with their large inner diameter would allow better drainage of pelvic fluid collections without the need for a drainage catheter, and DEN can performed if needed through the stent. This also decreases the chances of the stent getting clogged with fecal mater.

The strengths of our study are that it was a multicenter study and we included PSFCs resulting from variety of surgical procedures. It is the first study, to our knowledge,

evaluating LAMSs for post-surgical drainage. Our study is limited by its retrospective nature. It is also limited by heterogeneity in the technique, size of stent used, decision to perform DEN, timing of cross-sectional imaging, and follow-up after stent placement. We would have missed PSFCs that were assessed via cross-sectional imaging or EUS, but LAMS drainage was not attempted due unfavorable anatomy. We only had short-term follow-up; hence, we cannot comment on the long-term success rate of using a LAMS in PSFCs and whether there was recurrence after stent was removed. However, this study does confirm the safety and effectiveness of the use of LAMSs in these patients.

In conclusion, EUS-guided drainage of PSFCs using LAMSs is a viable alternative to repeat surgery or percutaneous drainage for collections that are favorably located adjacent to the stomach, duodenum, or rectum.

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Table 1. Demographics and baseline characteristics of the study cohort

Variable	
Number of patients	47
Number of fluid collections	47
Males	26
Females	21
Average age in years (range)	54 (19-75)
Type of surgery	
Pancreatic tail resection	23
Pancreatic head resection	3
Orthotopic liver transplantation	2
Cholecystectomy	2
Colectomy	2
Ovarian cystectomy	2
Liver lobe resection	2
Hepaticojejunostomy	1
Billroth II	1
Sleeve gastrectomy	1
Reversal of Roux-En-Y Bypass, subtotal gastrectomy	1
Low anterior resection	1
Appendectomy	1
Splenectomy	1
Graham's patch for perforated ulcer	1
Laproscopic Hysterectomy	1
Retroperitoneal mass resection	1
Surgical pancreas injury	1
Prior attempts at drainage (surgical/IR)	13(27.6%)
Average size of the fluid collection	78.65 mm (47-150 mm)
Type of fluid collection drained	
Inflammatory fluid collections	24
Abscess	19
Bilomas	4

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Table 2. Procedure details and technical aspects

Type of echoendoscope	
Curvilinear	46
Forward viewing	1
Site of drainage	
Transgastric	34(72%)
Transduodenal	5 (11%)
Transrectal	8 (17%)
LAMS size	
15 mm	33 (70%)
10 mm	14 (30%)
Type of LAMS	
Hot AXIOS	76%
Cold AXIOS	24%

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Table 3. Outcomes- technical and clinical success, adverse events

Overall technical success	44/47 (93.6%)
Site specific technical success	
Transgastric	32/34 (94.1%)
Transduodenal	4/5 (80%)
Transrectal	8/8 (100%)
Overall Clinical success	42/47 (89.3%)
Site specific clinical success	
Transgastric	31/34 (91.2%)
Transduodenal	4/5 (80%)
Transrectal	7/8 (87.5%)
Adverse events	
Intraprocedural-stent migration	2 (4.25%)
Postprocedural	3 (6.4%)
Stent migration	1 (2.1%)
Perforation	1 (2.1%)
Infection	1 (2.1%)

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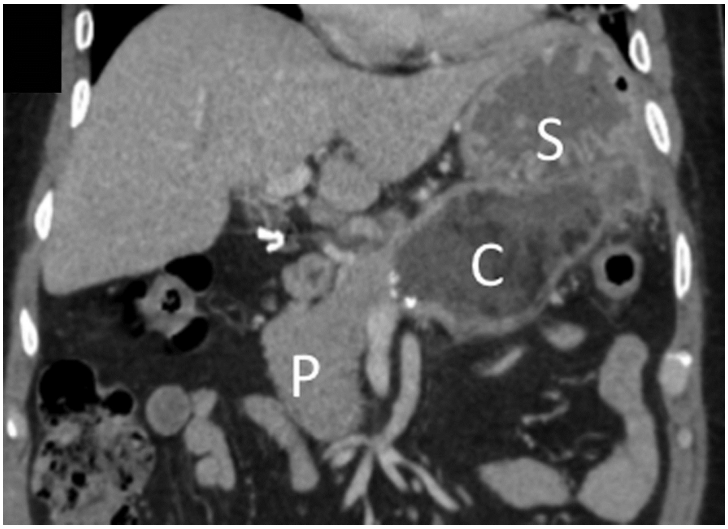
Figure 1. A patient with pancreatic adenocarcinoma underwent distal pancreatectomy and developed post-surgical fluid collection. This was successfully drained by placing a lumen apposing metal stent. A, CT showing post-surgical fluid collection adjacent to the stomach. B, Necrosum inside the cavity of the post-surgical fluid collection after placement of the lumen apposing stent. C, CT scan showing resolving post surgical collection after placement of lumen apposing stent. D, CT scan showing resolved post surgical collection after placement of lumen apposing stent. (Abbreviations: A- Lumen apposing metal stent (AXIOS); C-post-surgical fluid collection; P-pancreas; S-stomach)

Figure 2. Postsurgical fluid collection after Roux-en-Y gastric bypass successfully drained by placing a lumen-apposing metal stent. A, CT showing post-surgical fluid collection adjacent to the gastric pouch. B, CT scan showing resolved postsurgical collection after placement of lumen-apposing stent. (Abbreviations: A-lumen-apposing metal stent (AXIOS); C-post surgical fluid collection; G-gastric bypass)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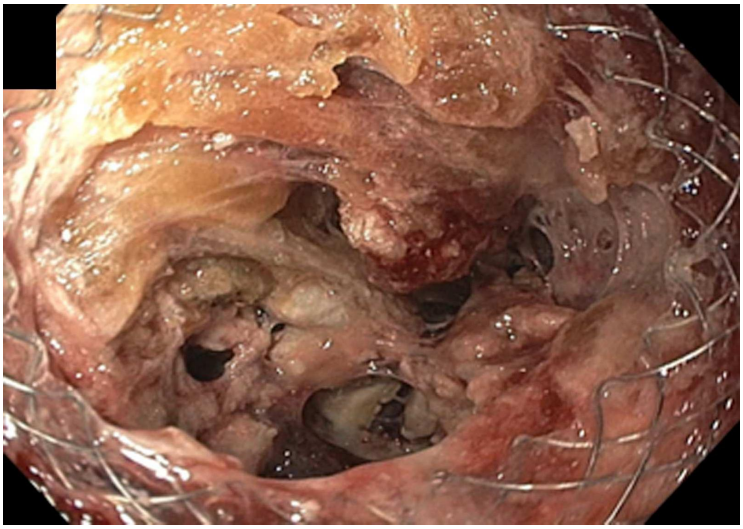

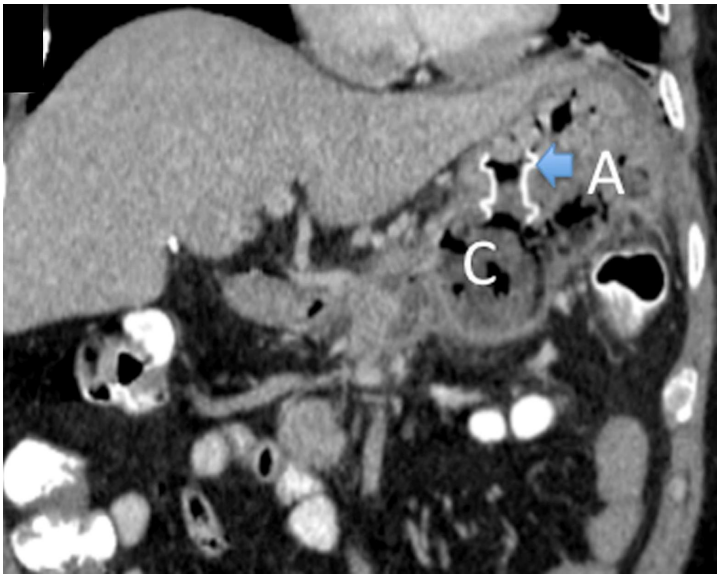

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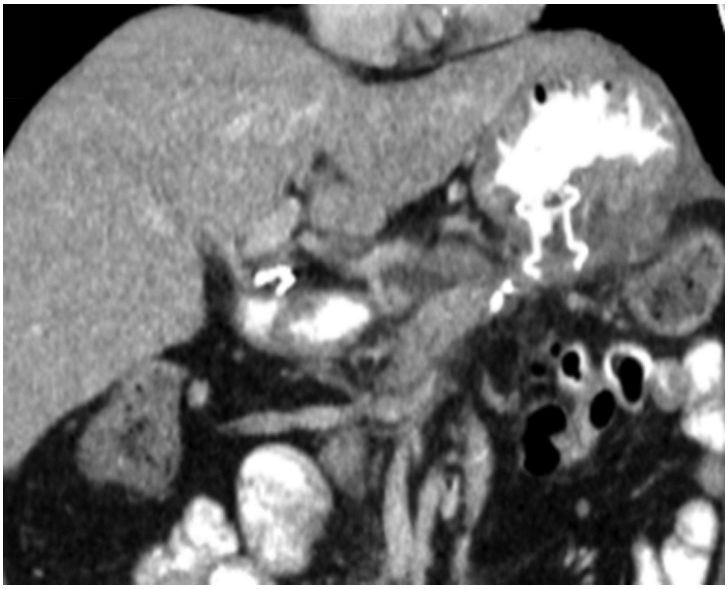

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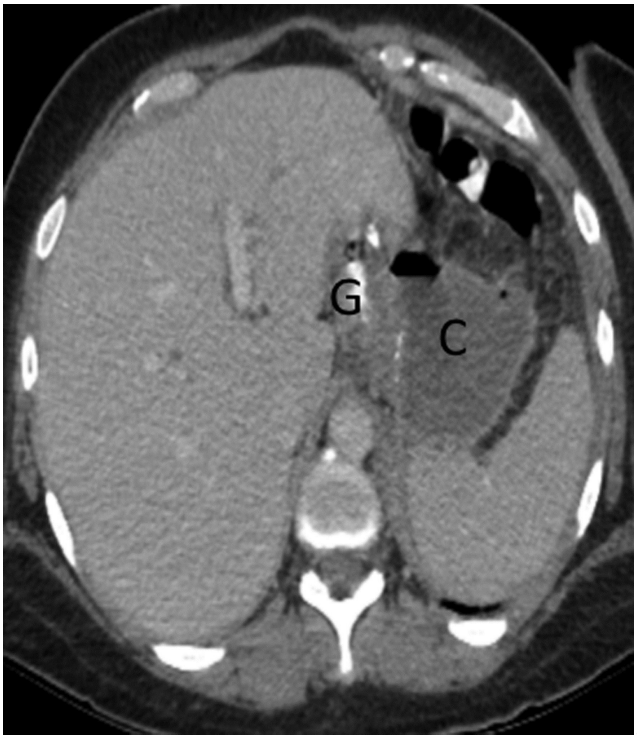

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Author Contributions

1. Prashant R Mudireddy: Conception and design of the study, data collection, analysis and interpretation of the data, drafting of the manuscript.
2. David L. Diehl: Conception and design of the study, analysis and interpretation of the data, critical revision of the manuscript.
3. Amrita Sethi: Data collection, critical revision of the manuscript.
4. Ali A. Siddiqui: Data collection, critical revision of the manuscript
5. Douglas G. Adler: Data collection, critical revision of the manuscript
6. Jose Nieto: Data collection, critical revision of the manuscript
7. Harshit Khara: Data collection, critical revision of the manuscript
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10. Sammy Ho: Data collection, critical revision of the manuscript
11. Peter V. Draganov: Data collection, critical revision of the manuscript
12. Dennis Yang: Data collection, critical revision of the manuscript
13. Shaffer Mok: Data collection, critical revision of the manuscript
14. Bradley Confer: Data collection, critical revision of the manuscript

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Acronyms:

AE-adverse events
EUS- endoscopic ultrasound
LAMS-lumen apposing metal stent
PSFC-post surgical fluid collection
PCD-percutaneous drainage

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