

EUS-guided drainage of pancreatic fluid collection, using a modified technique of cystotome alone without a FNA needle

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Abstract

Background: Endoscopic ultrasound (EUS)-guided drainage for pancreatic fluid collection (PFC) involves puncture with a fine-needle aspiration (FNA) needle, followed by tract dilation involving exchange of multiple accessories, and finally deployment of stent. The procedure is time consuming and carries a risk of loss of wire access and hence technical failure. We used a modified technique with a 10-F cystotome alone instead of a FNA needle and dilators.

Methods: We retrospectively analysed records of consecutive patients who had undergone EUS-guided drainage of PFC using a modified technique, with puncture of PFC using a 10-Fcystotome, followed by passage of a guidewire through it into the PFC cavity and deployment of a biflanged, 2-cm-long, fully covered self-expanding metal stent over it. Technical and clinical success rates and procedure time were assessed.

Results: Forty-five patients underwent PFC drainage, median age was 35 (12–76), and 35 (77.8%) were males. The median (range) duration of symptoms was 125 (38–1080) days, while the median PFC size was 11.8 × 11 × 11 cm, and the follow-up period after stent removal was 111 ± 72 (18–251) weeks. The procedure took 10 (8–12) min and had technical and clinical success rates of 100 and 97.8%, respectively. Minor complications occurred in six (13.3%) patients, while recurrence occurred in one.

Conclusion: EUS-guided drainage of PFC using a cystotome is a quick, effective and safe procedure. It may also be less expensive since it obviates the use of FNA needles and dilators, and is likely to be a useful alternative to the conventional technique.


Keywords: Cystotome, endoscopic ultrasound, fully covered self-expanding metal stent, lumen apposing metal stent, pancreatic fluid collection, pancreatic necrosis

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INTRODUCTION

Pancreatic fluid collections (PFCs) are circumscribed fluid collections that develop in patients with acute or chronic pancreatitis, or as a result of traumatic or iatrogenic

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pancreatic duct injury. These collections are mostly asymptomatic, and resolve spontaneously. However, therapeutic drainage of the collection is required if a PFC becomes infected or if it enlarges leading to compressive symptoms, such as abdominal pain, early satiety, jaundice, or gastric outlet obstruction.^[1] Drainage can be done surgically, percutaneously, through endoscopic transpapillary route, or by a transluminal route under endoscopic ultrasonographic (EUS) guidance.

In recent time, EUS-guided placement of transmural stents has become the drainage procedure of choice for PFC.^[2-4] The procedure has a high rate of success (87–97%), and low rates of adverse events (6–34%) and mortality (0–1%).^[2,4-6] It involves placement of one or more plastic double-pigtail stents, 7–10 Fr in diameter or of a fully covered self-expanding metal stent (FCSEMS) between the cyst cavity and the lumen of stomach or duodenum.^[7,8] Typically, double pigtail plastic stents are used for this procedure as the pigtail feature of these stents prevents migration, but their narrow lumen has been reported to cause premature occlusion in up to 18% of cases. This results in frequent stent exchanges or placement of additional stents. Moreover, placing multiple plastic stents can be technically difficult and tedious because of the need to repeatedly access the cyst cavity, or the need to use two wires simultaneously to maintain access.^[7] Metal stents, by contrast, have advantages of larger diameter (up to 10 mm), which permits quicker drainage and a lower risk of occlusion, in addition to easier deployment and high success rates of 78–100%.^[8-10] Although metal stents have been used to compensate for the demerits of plastic stents, there is no definitive evidence so far in published literature that favours metal over plastic in PFC. The choice of stent is based on the discretion of the endoscopist rather than evidence-based findings.

The standard technique of PFC drainage involves a puncture of the cyst using a 19-gauge fine-needle aspiration (FNA) needle, followed by placement of a guidewire and multiple exchanges of dilators of increasing diameters over the guidewire for dilation of the tract, before final placement of the stent. This standard multistep method is time consuming and carries the risk of slippage of the wire from the cyst cavity during the several exchanges involved. Further, it needs the use of several costly accessories, adding to the total cost of the procedure, a particular problem in low- and middle-income countries.

We therefore used a modified technique for EUS-guided placement of FCSEMS in PFC. This technique involves an initial puncture of the cyst using a 10-Fr cystotome, without

the use of FNA needle and dilators. In this procedure, the cystotome performs the dual functions of a puncture device and of a dilator. In this report, we describe our experience with the use of this technique and its technical and clinical success rates, adverse events, and procedure time.

METHODS

Study design

We undertook a hospital-based retrospective look-back analysis of our prospectively maintained database of consecutive patients who had undergone an attempt at EUS-guided drainage of PFC using our modified technique at our institution, which is a tertiary referral centre.

Patients

All patients included in the analysis had a walled off pancreatic necrosis (WOPN) which consisted of a mature, encapsulated collection of pancreatic and/or peripancreatic necrotic tissue contained within an enhancing wall of reactive tissue (according to the Revised Atlanta Classification^[11]). All WOPN had been diagnosed either at computed tomography (CT) or at magnetic resonance imaging. A drainage procedure was offered only to those patients who had symptomatic or an infected WOPN. Contraindications included neoplastic cystic lesions, presence of varices at endoscopy, thrombocytopenia (platelet count <50,000/ μ L), coagulopathy (prothrombin time, international normalized ratio >1.5) and a distance between the WOPN wall and the gastric or duodenal wall of >1.0 cm at imaging. Patients who had undergone a prior attempt at drainage via interventional radiology or at surgery were excluded.

Cross-sectional imaging data were reviewed and the number, size, and locations of WOPN were recorded. From the clinical records, information on demographic features, clinical presentation, investigations, indications for drainage, technical details of the procedure, hospital course and follow-up were retrieved. Follow-up data had been obtained either during outpatient visits or by telephonic contact. Our institution's Ethics Committee approved this study. Written informed consent was obtained from all participants.

Technique

All patients first underwent a EUS examination using a linear array echo-endoscope (GF-UCT 180; Olympus). This included assessment of the amount of solid debris in the collection and of the presence of an intervening blood vessel between the collection and the adjacent stomach/duodenum, using a Doppler probe and deciding an optimal site for puncture. The WOPN was then punctured with a 10-Fr cystotome (ENDO-FLEX, Voerde, Germany)

using the knife-tip of the inner catheter using electrocautery (ERBE generator, ERBE USA Inc., Marietta, GA, USA; settings: Auto-cut, 80–100 W, effect = 4). The metal part of the inner catheter was then withdrawn leaving the teflon catheter in the WOPN. The outer 10-Fr sheath of the cystotome, equipped with the diathermy ring, was then advanced through the puncture using electrocautery, thereby enlarging the puncture site. The contents of the WOPN were aspirated to confirm that the tip of cystotome was in the cyst lumen and to obtain the fluid for laboratory testing. Then, a 0.035" guidewire was inserted through the cystotome into the cyst cavity, under fluoroscopic guidance. The cystotome was then withdrawn, leaving the guidewire in the cyst. This was followed by deployment of a FCSEMS (NAGI stent; diameter of lumen: 14 mm, length: 2.0 cm, diameter of flares: 23 mm) over the guidewire [Figure 1a-f]. In addition, an endoscopic nasocystic drain (10-Fr) was placed through the metal stent in patients with infected WOPN. The NAGI was removed in all patients at 3 months.

All patients underwent a CT of the abdomen 3 days after drainage and endoscopic nasocystic drain was removed in patients who had symptomatic improvement with >50% reduction in size of WOPN. Patients with new onset fever or worsening of existing symptoms with persistent WOPN on CT underwent endoscopic necrosectomy. Endoscopic necrosectomy was carried out using a gastroscope (GIF-190H; Olympus), which was inserted through the metal stent into the cyst cavity. Debris was extracted using the cold snare technique. Nasocystic irrigation was continued between necrosectomy sessions. Patients were referred for surgery if response was suboptimal

after four direct endoscopic necrosectomy sessions. Broad-spectrum antibiotics were given and were tailored according to culture reports.

A pancreatic stent was placed in patients with pancreatic duct leak on pancreatogram done at the time of FCSEMS removal and removed after 4 weeks.

Outcome measures

The primary outcome measure was the rate of clinical success, defined as a complete resolution of the PFC at a CT scan done 3 months after the initial procedure, accompanied by absence of any residual symptoms. The secondary outcomes included technical success rate, procedure time, adverse events and number of patients needing endoscopic reinterventions or having PFC recurrence after stent removal. Technical success was defined as successful transmural placement of the stent. Any adverse events that occurred within 1 week after the procedure were considered as procedure related. Reintervention was defined as the need for repeat PFC drainage by any route, irrespective of the cause, whether stent occlusion, infection of the cavity or persistence/reappearance of symptoms. Quantitative data were expressed as median and range, and categorical data as proportions.

RESULTS

Characteristics of subjects and of PFC

We identified 45 patients, median (range) age (years) was 35 (12–76) and 35 (77.8%) were males [Table 1] who had undergone EUS-guided drainage of PFC, over a 4-year period. Of these, 39 (87%) had underlying acute pancreatitis and the

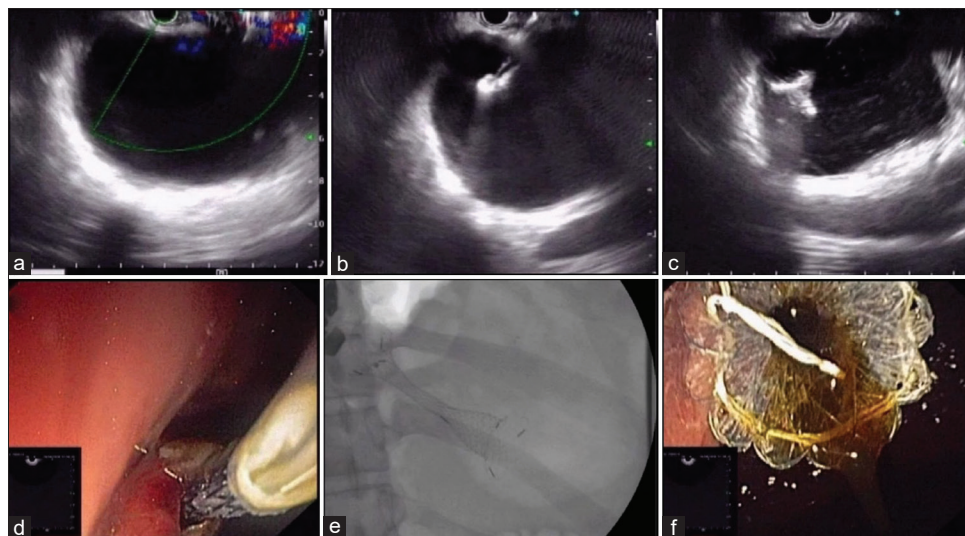


Figure 1: (a) EUS shows a pseudocyst and colour Doppler shows no intervening vessels. (b) Puncture of pseudocyst with 10-French cystotome. (c) Flanges of the stent seen in the pseudocyst cavity. (d) Endoscopic image of the stent being deployed. (e) Fluoroscopic image of the deployed stent. (f) Endoscopic image of the deployed stent

other six (13%) had chronic pancreatitis. The most common causes of acute pancreatitis were alcohol ($n = 15$, 33.3%) and biliary stones ($n = 11$, 24.4%). The median duration of symptoms was 125 days (range 38–1080 days). The common symptoms at presentation were epigastric pain, early satiety, fever and vomiting. All the patients had a solitary WOPN, with a median volume (length \times width \times height) of $11.8 \times 11 \times 11$ (range: $4 \times 4 \times 4$ – $27 \times 20 \times 20$) cm [Table 1 and Figure 1]. Nearly one-third of the patients had fever with leucocytosis, or of purulent appearance or the presence of bacteria on Gram stain and/or bacterial culture of the fluid drained. Seven patients had clinical features of gastric outlet obstruction.

Drainage procedure

All the patients underwent EUS-guided trans-gastric drainage of PFC using FCSEMS stent. A nasocystic drain was placed in 14 patients with fever. Twelve patients had trans-papillary 5-Fr pancreatic duct stents placed for suspected pancreatic duct leak; none of the patients had a disconnected duct; all of these were removed at 4 weeks, and the pancreaticogram done at this time did not show a pancreatic duct leak in any patient. The median numbers of endoscopic sessions performed in patients with WON were 2 (range 1–3). Nine patients underwent 1 session, 20 underwent 2 sessions and 16 underwent 3 sessions for endoscopic necrosectomy via an upper endoscope through the lumen-apposing metal stents (LAMS).

Outcomes

Using the cystotome-based technique, stents were placed successfully in all the 45 patients, with a technical success rate of 100%. Median procedure time from cystotome puncture to stent deployment was 10 (range: 8–12) min. Clinical success was achieved in 44 (97.8%) patients, with one patient requiring an additional percutaneous drainage of the WOPN [Table 2].

Six (13.3%) of the 45 patients had adverse events [Table 3]. One patient had pneumoperitoneum, which regressed completely on conservative management. Three patients had stent block; all could be managed successfully without surgery, including two with placement of a double pigtail stent through the metal stent and the third (referred to above as clinical failure) with percutaneous drainage. Two patients had spontaneous extrusion of the stent into the stomach after resolution of the WOPN and needed stent removal using endoscopy. No patient had bleeding, frank gastrointestinal perforation or mortality.

DISCUSSION

In our experience, EUS-guided drainage of PFC, using a cystotome instead of the usual FNA needle and dilators,

Table 1: Baseline characteristics of study patients (n=45)

Characteristic	N(%)
Age, years, mean \pm SD	37.6 \pm 13.2
Male, number (%)	35 (78%)
Cause of pancreatitis	
Alcohol	15 (33%)
Biliary	11 (24%)
Idiopathic	19 (43%)
Type of pancreatitis	
Acute	38 (84%)
Chronic	7 (16%)
Duration of pseudocyst, weeks, median (range)	22 (6-78)
Pseudocyst volume, mL median (min - max)	11.8 \times 11 \times 11
(Length \times Width \times Height)	(4 \times 4 \times 4-27 \times 20 \times 20) mL
Pseudocyst location	
Head	5 (11%)
Body and tail	40 (89%)
Infection in the pseudocyst	14 (31%)

All data are shown as number (%), unless specifically indicated

had a technical success rate of 100% and clinical success rate of 97.8%, with only 1 of 45 patients needing supplemental treatment with percutaneous drainage. The procedure could be performed quickly, within an average of 10 min. Adverse events were infrequent and minor and were easily managed. There was no procedure-related death. These results compare well with the previously published reports of EUS-guided drainage using the conventional technique.

EUS-guided drainage is firmly established as the best treatment option for the drainage of walled-off PFCs^[12,13] because of its high clinical efficacy, low morbidity and low cost. In the standard technique, the PFC is first assessed using a linear echo-endoscope to determine the ideal puncture site and excluding the presence of blood vessels along the intended puncture tract using colour Doppler. Then, the PFC is punctured with a 19-gauge needle, and a 0.035-inch guidewire is placed through it allowing it to coil in the cyst cavity. The needle is then withdrawn, leaving the guidewire *in situ* and the track is dilated using either electrocautery or balloon dilator(s), followed by placement of a metal stent, or one or two double-pigtail plastic stents.

However, despite its excellent efficacy and safety, EUS-guided drainage of PFC is not used universally. Thus, according to a recent multicentre survey conducted by the Asian EUS group, only 77% of the participating Asian

Table 2: Outcome of EUS-guided drainage of walled of pancreatic necrosis (n=45)

Outcome	N(%)
Technical success, number (%)	45 (100%)
Treatment success, number (%)	44 (98%)
Complications, number (%)	6 (13%)
Clinical failure, number (%)	1 (2%)
Median follow up, weeks, median (range)	111 (18-251)

Table 3: Complications encountered in subjects undergoing endoscopic ultrasound-guided drainage

Complication	Number (%) of patients	Management of complication	Final outcome
Pneumoperitoneum	1 (2.2%)	Conservative	Resolved
Stent block	3 (6.7%)	Placement of double pigtail plastic stent (n=2); Percutaneous drainage (n=1)	Resolved (n=3)
Stent migration	2 (4.4%)	Endoscopic stent removal	Resolved

endoscopists preferred EUS-guided approach for PFC drainage.^[14] Also, the technique used varied widely between centres, with nearly two-thirds of respondents placing two guidewires, 84% dilating the tract to 8–10 mm diameter, 92% placing plastic stents rather than metal stents and 61% leaving the stents *in situ* for 3–6 months, which may be too long. This, we believe, highlights dissatisfaction with current lack of consensus on the optimal technique for the EUS-guided drainage of PFC.

The rationale for using LAMS for WOPN drainage is that the larger diameter of the stent allows for faster and more complete drainage of necrotic contents. Incomplete drainage can result in persistent symptoms and infection that may cause prolonged hospitalization and increased need for further interventions. A multicentric retrospective study compared the efficacies of plastic stent, LAMS and fully covered self-expandable metal stent for drainage of WOPN; treatment success was lowest and the number of reinterventions was the highest for patients treated with plastic stents.^[15] However, two other retrospective studies showed that the treatment outcomes were similar except for the procedure duration, which was shorter when placing LAMS.^[16,17]

In our modified technique, the main difference is that the puncture and wire placement into the PFC are done using a 10-Fr cystotome instead of a FNA needle. The cystotome itself then serves as a dilator for the newly created tract, thereby reducing the number of accessory exchanges, and hence the procedure time. Furthermore, in this technique, the risk of loss of wire access to the PFC cavity is minimized. In addition, since the FNA needle and dilators are not used, the cost of the procedure comes down. Using this technique, we were able to achieve a technical success rate of 100% and the clinical success rate of 97.8%, which are similar to those reported with the conventional technique.

We believe that the use of 10F cystotome for initial puncture without tract dilation was the primary reason for the high success rate of our procedure, since it reduced the number of wire exchanges and the risk of loss of wire access. It also shortened the procedure time to a median of only 10 min, with the maximum being 12 min, which compares favourably with the median times of 30 (range: 12–90) and 40 (25–55) min reported previously for the conventional

technique.^[18,19] A shorter procedure time also implies a reduced fluoroscopy duration and hence radiation exposure.

Our technique was also fairly safe with adverse events occurring in only six (13.3%) patients, fairly comparable to the 10.7% complication rate reported for the conventional technique.^[1] The risk of dissection with a cystotome though rare can happen if the axis of the puncture with the cystotome is not nearing perpendicular, and hence proper axis of puncture and experience is needed for performing the procedure safely. All the complications encountered were relatively minor and were easily managed, with only patient needing a percutaneous PPC drainage.

The previous experience with PFC using a 10F cystotome instead of an FNA needle has been quite limited [Table 4].^[20-22] These studies had only a few patients ($n = 11-16$) and each placed plastic stents. By comparison, we studied a much larger number of patients, more than the aggregate number in the three previous reports, and placed metal stents. The success and complication rates in our experience were similar to those in these previous reports; the only major difference was a migration rate of 17.6% in the report by Heinzow *et al.* and none in our patients, possibly because of our use of metal stents.^[21]

One step delivery device has been made commercially available recently.^[23] However, the cost of this device is at least four times as that of the technique using cystotome and hence is a major prohibitive factor in developing countries.

Our study does have some limitations. First, it reports a retrospective experience, with its inherent limitations. Second, the procedures were performed by an expert operator with substantial experience in PFC drainage in a tertiary-care institution, and hence the results may not be generalizable. Further, there was no comparison group and the follow-up was only medium term; a comparative group would have provided firmer evidence for the safety and efficacy of the modified technique in drainage of PFC. However, despite these limitations, the marked reduction in procedure time and the relative ease of our modified technique argues for its widespread use.

In conclusion, EUS-guided drainage of PFC using the 10-Fr cystotome for initial puncture instead of the FNA

Table 4. Summary of previous reports of pancreatic fluid collection drainage using a 10-Fr cystotome, without a fine-needle aspiration needle

Study	n	Technical success rate (%)	Clinical success rate (%)	Type of stent	Mean procedure time (min)	Complications
Ahlawat <i>et al.</i> , 2006	11	100	82	Plastic	Not available	Nil
Heinzow <i>et al.</i> , 2011	16	94	88	Plastic	36±9	Migration: 17.6%
Mangjaviillano <i>et al.</i> , 2012	13	92	100	Plastic	Not available	Nil

needle is safe, effective, and is associated with a short procedure time. Further, this technique may also reduce the cost of the procedure. The procedure should be particularly advantageous in sick patients because of its relative speed. Prospective controlled studies should help further clarify its advantages over the conventional technique.

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Conflicts of interest

There are no conflicts of interest.

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