

The Safety of Endoscopic Ultrasonography-Guided Drainage of Pancreatic Fluid Collections Without Fluoroscopic Control: a Single Tertiary Center Experience

Andrada Seicean¹, Roxana Stan-Iuga¹, Radu Badea¹, Marcel Tantau¹, Teodora Mocan², Radu Seicean³, Cornel Iancu⁴, Oliviu Pascu¹

1) Third Medical Clinic; 2) Department of Physiology; 3) First Surgical Clinic; 4) Third Surgical Clinic, University of Medicine and Pharmacy "Iuliu Hatieganu", Cluj-Napoca, Romania

Abstract

Background: Endoscopic ultrasonography (EUS) is preferred for guiding drainage of pancreatic fluid collections, with a success rate exceeding 90% when fluoroscopy is used. When fluoroscopy cannot be used, drainage can still be performed, but no data regarding the safety of such a procedure have yet been published. **Aim:** To establish the safety of EUS-guided drainage without fluoroscopic control and to identify criteria for the selection of suitable patients. **Methods:** The pancreatic fluid collections considered suitable for EUS-guided drainage were >5 cm in diameter, symptomatic, without ductal communication. We attempted EUS-guided drainage of PC prospectively in 24 patients: 9 with abscesses and 15 with pseudocysts. **Results:** Drainage was successful in 20 cases (83.3%), with complete resolution after a median 18 months' follow-up. EUS-guided drainage failed in four patients (16.7%): one in the abscess group due to symptomatic pneumoperitoneum and three in the pseudocyst group due to thick wall. Drainage failure was associated with a diameter <6 cm and wall thickness >2 mm and was considered to be due to the sliding of the cystotome on the pseudocyst wall. During follow-up there was one procedure unrelated death (4.1%) and no pancreatic fluid collections relapses. **Conclusions:** Fluoroscopic control represents a helpful tool, but it is not always necessary for EUS-guided drainage of pancreatic fluid collections. EUS-guided drainage is possible, efficient and safe without fluoroscopy in selected pancreatic fluid collections with a diameter larger than 6 cm and a thin wall. Collections with a thick wall should be drained under fluoroscopy or referred directly for surgery.

Keywords

EUS drainage fluid collection – pseudocyst – abscesses – treatment – pancreas.

Introduction

Pancreatic fluid collections (pseudocysts or abscesses) are due either to disruption or obstruction of the major pancreatic duct and/or peripheral ductules, or to localized autodigestion and necrosis of pancreatic parenchyma as a result of an acute or chronic pancreatitis. Some of these collections resulting from acute pancreatitis may resolve spontaneously during a period of 4-6 weeks after onset, but pseudocysts associated with chronic pancreatitis disappear spontaneously only in 10% of cases [1, 2]. The collections that persist can become complicated or associated with symptoms, and then therapy is mandatory [1]. Therapeutic intervention is indicated when at least one complication is present (compression of large vessels, obstruction of duodenum, stomach or common bile duct, infection, hemorrhage into pancreatic pseudocyst, pancreatico-pleural fistula), when symptoms occur (satiety, pain, nausea or vomiting, upper gastrointestinal bleeding) or, exceptionally, when asymptomatic pancreatic pseudocysts larger than 5 cm increase rapidly in size, for avoiding complications [1-4].

Various techniques of drainage have been performed in the past. Open surgical drainage, associated with a mortality of 0-2.5% and morbidity of 16% and with a 90-100% success rate, was the first [5-8]. Transpapillary drainage, introduced in 1980, has a morbidity of 6% and no mortality, but it is limited to collections communicating with the major pancreatic duct. Since 1985, many studies of transmural conventional endoscopic drainage have been published, with morbidity of 9-17% and a success rate of 74--94%, but the technique is difficult to perform when portal hypertension is present and no endoscopic wall bulging is noticed [9, 10]. Since 1996, several series of endoscopic ultrasound (EUS)-guided drainage have been reported, with a technical success rate of up to 88%; the main limitation of this procedure is location of the fluid collection more than 1 cm from the

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Address for correspondence:

Andrada Seicean, M.D., Ph.D.
Third Medical Clinic
Croitorilor Street 19-21,
400162 Cluj-Napoca, Romania
Email: andradaseicean@yahoo.com

gut wall [11-13]. The use of fluoroscopy optimizes access into the pseudocyst and maintenance of the position of the various devices used. Very little is known about the reasons for technical failure when fluoroscopy is not used either due to endoscopist preferences or to lack of availability in the EUS room.

The aims of this study were to establish the safety of EUS-guided drainage of pancreatic fluid collections without fluoroscopic control and to identify criteria enabling selection of the patients who might benefit from this method.

Methods

All patients referred for EUS-guided drainage at a tertiary center during a period of 22 months (June 2007 to February 2009) were enrolled prospectively. The inclusion criteria were: consecutive patients with well-delineated pancreatic fluid collections larger than 5 cm and persisting for more than 6 weeks from the onset of acute pancreatitis, or pseudocysts associated with chronic pancreatitis [1, 9]. Patients presenting earlier than 6 weeks after onset of acute pancreatitis and those in whom cross-sectional imaging aroused suspicion of cystic pancreatic tumors were excluded from the study, as were those with coagulation problems (prothrombin >1.5 INR or platelet count <50,000/ μ l), collections situated more than 1.5 cm from the gut wall (measured by EUS) [14], or collections communicating with the pancreatic duct (to avoid pseudocyst relapse). Patients referred for drainage in critical status (SIRS or septic shock) were excluded. We defined pancreatic pseudocyst as a collection of pancreatic juice enclosed by a nonepithelialized wall that occurs as a result of acute pancreatitis, pancreatic trauma, or chronic pancreatitis [4, 15]. Acute pancreatic fluid collections and walled-off pancreatic necrosis (a poorly demarcated area of unviable pancreatic tissue, usually associated with peripancreatic fat necrosis) [4] also represented grounds for exclusion. The collections that communicated with the pancreatic ductal system were selected by means of EUS and MRI, followed by ERCP in doubtful cases.

The study was approved by the authors' institutional Ethics Committee conforming to the provisions of the Declaration of Helsinki, and all patients provided written consent for the procedures performed and for their inclusion in this study.

Protocol of EUS-guided drainage

EUS examination was performed by one endoscopist with experience of more than 1,500 diagnostic procedures (A.S.). All patients were screened by transabdominal ultrasound; in doubtful cases, MRI and ERCP were performed to exclude communication of pseudocysts with the pancreatic duct. Before the drainage procedure, EUS was performed to detect any contraindication for transmural drainage and to evaluate the following criteria: presence of a well-defined wall; distance between pseudocyst and gut wall; identification of vessels in needle tract; exclusion of vascular pseudoaneurysms; differentiation from other cystic lesions of the pancreas; and anatomy of pancreatic

duct. For each collection the following characteristics were noted: location; best "window" of access for drainage; size; thickness and vascularization of the wall; presence of septa and inhomogeneous content; portal hypertension in the gut wall; aspect of fluid. All the endoscopic procedures were performed with the patient under conscious sedation with midazolam.

All procedures were conducted using a therapeutic linear-array echo-endoscope (GF-UCT 140 AL5, Olympus), with the patient in left lateral position, after administration of at least one dose of IV ciprofloxacin (400 mg). Fluoroscopy was not available in the EUS room. Under EUS guidance and after color Doppler assessment for vessel interposition, the most declive and closest location to the gut wall was chosen for drainage. We used the 10-Fr cystotome (Wilson Cook CST10, Limerick, Ireland) - mostly three attempts with the inner sheet - using the cutting setting 120 W/s, with entry confirmed by extraction of the intracystic liquid. The procedure then continued with placement under EUS guidance of one or two 0.035-Fr guidewires, and then insertion through the created cystostoma of a double-pigtail plastic stent of 8.5 Fr, length 6 or 9 cm (Medwork GmbH, Hochstadt, Germany) or a nasocystic drain of 7 Fr (Olympus, Hamburg, Germany) (Figs. 1-4). In cases with a heterogeneous aspect on EUS or purulent aspirated fluid a nasocystic drainage was inserted to allow saline flushing of the catheter and to avoid early obstruction of the stent.



Fig 1. The EUS image of the cystotoma inside a hypoechoic structure corresponding to a pseudocyst.



Fig 2. The EUS image of a stent as a parallel hyperechoic structure inside a hypoechoic structure corresponding to a pseudocyst.



Fig 3. The endoscopic image of a stent placed into a pseudocyst after EUS-guided drainage. A greenish liquid is seen coming out through the stent.

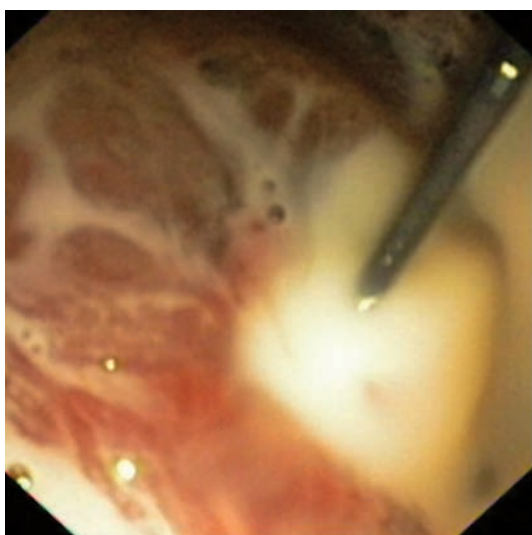


Fig 4. The endoscopic image of pus coming out from a bulging abscess after wall penetration with a cystotoma, seen as a black linear structure.

The nasocystic catheters were progressively removed over a number of days in large and/or necrotic collections. In the event of technical failure, the patient was referred directly for surgery. In no case were both transpapillary and transmural techniques used. Patients were discharged home as soon as they were afebrile, had a normal white cell count, did not require major medication for pain control, and displayed improvement of symptoms. All patients were evaluated again within 4 weeks by means of contrast-enhanced CT or transabdominal ultrasonography. In the case of the initial resolution of the collection, the stent was left in place for 3 months and then removed.

Definitions

We defined technical success as the ability to access or drain a pancreatic pseudocyst by placement of a transmural

drain and/or stent. Technical failure of the drainage was considered when drainage was not achieved. Treatment success was defined as complete resolution or decrease in size of a pseudocyst to less than 2 cm after 3 months' follow-up, with clinical resolution of symptoms. Patients with treatment failure were those in whom the collection was more than 2 cm in diameter after 3 months' follow-up or had decreased by less than 30% in size (transabdominal ultrasound) at 24 h after the procedure [14, 16, 17], or drainage-related death. The aspirated fluid was classified as infected in the presence of pus, heterogeneous in the presence of necrotic debris without pus, or clear in the absence of both pus and debris. Bleeding was any hemorrhagic event occurring during or after the procedure that necessitated a blood transfusion or any other intervention [18]. Pneumoperitoneum was considered to be present when peritoneal signs were noted associated with intraperitoneal air on imaging. Stent migration was defined as the need to retrieve a stent from within the pancreatic pseudocyst or enteral lumen [18]. The following outcomes were recorded: technical success, treatment success in long-term follow-up, immediate and late complications. The predictive factors which influenced the outcome were searched from the following variables: age of the patient, etiology, location and size of the collection, presence of portal hypertension, thickness of wall collection, the presence of septa, anechoic aspect of collections, the aspect of aspirated liquid.

Follow-up examinations were performed 1 month and 3 months after the drainage by means of transabdominal ultrasound or during admissions for late complications.

Statistical analysis

Frequency tables (count, percent) as well as dispersion and centrality measures (median, interquartile range) were calculated. To detect differences between groups, the chi-square test or Fisher's test were used according to standard criteria. The odds ratio (OR) and 95% confidence interval (CI95%) were calculated. The Mann-Whitney U-test was used for between-group analysis of continuous variables. Such variables were also evaluated using receiver operating characteristic (ROC) analysis, with calculation of the area under the ROC curve (AUC), including the CI95% of area. All correlations were considered significant at $p \leq 0.05$.

Results

Patients' characteristics

Thirty-six patients with pancreatic fluid collections were initially included in the study, of whom 12 were later excluded. The reasons for exclusion were EUS diagnosis of non-inflammatory cystic lesions in three cases, a caudal pseudocyst secondary to pancreatic head tumor in one case, collections communicating with the pancreatic duct in six cases after MRI and/or ERCP, septic shock in two patients. The symptoms indicating drainage were pain ($n=20$, 83.3%), fever ($n=6$, 25%), vomiting ($n=5$, 20.83%), and weight loss ($n=6$, 25%). The median time from the onset of symptoms to inclusion of the patients into the study was 10.7 months

(range 4--27 months). According to the Atlanta classification, after initial EUS evaluation with fluid aspiration the patients were divided into those with abscesses (n=9; group A) and those with uncomplicated pseudocysts (n=15; group B) and scheduled for EUS-guided drainage therapy [15]. The patients' characteristics are summarized in Table I.

Table I. Patients' characteristics (shown as mean \pm SD or numbers \pm percentage).

Feature	Group A Abscesses	Group B Pseudocysts	Total
No. of patients	9 (37.5%)	15 (62.5%)	24 (100%)
Age (years)	53.5 \pm 12 (42--68)	56 \pm 14 (17--71)	53 \pm 13
Male:female ratio	6:3	11:4	17:7
Etiology			
Acute (alcoholic: biliary)	3:1	6:2	9:3
Chronic (alcoholic: idiopathic)	5:0	6:1	11:1
Location (head: body:tail)	3:3:3	1:7:7	4:10:10
Endoscopic bulging	4 (44.4%)	1 (6.6%)	5 (22.7%)
Size (mm)	70 \pm 28.7	71.5 \pm 28.1	71.5 \pm 28
Size >6 cm in diameter	7/9 (77.7%)	10/15 (66.6%)	8/22 (36.36%)
Anechoic: hypoechoic	6:3	12: 3	18:6
Thick wall (>2 mm)	3 (33.3%)	4 (26.6%)	7 (29.1%)
Septa	2 (22.2%)	3 (20%)	5 (22.7%)
Fluid aspect (clear: brownish:pus)	0:0:9	7:8:0	7:8:9
Portal hypertension signs	4 (44.4%)	5 (33.3%)	9 (37.5%)

The drainage was performed via the stomach in 18 cases (75%) and via the duodenum in 6 cases (25%).

The median duration of follow-up was 18 months (range 2 to 30 months).

Technical failure: In group A, a stent with nasocystic drain was placed in 4 patients and stents only were placed in 4 patients. Failure was registered in one case (11%), due to immediate complications.

In group B, a stent was placed in 10 patients and a stent with a nasocystic drain in 2 patients. Technical failure occurred in 3 cases (20%) due to a thick cystic wall in patients with chronic pancreatitis. No significant difference was seen between the two groups concerning technical failure (p=0.251) (Table II).

Immediate complications were seen in two cases (8.3%). In group A, one case of symptomatic pneumoperitoneum was successfully treated by surgery, despite successfully

Table II. Results of EUS-guided drainage.

Parameter	Total (n=24)	Group A Abscesses (n=9)	Group B Chronic pseudocysts (n=15)	P value
No of procedures, median (IQR)	1 (1-2)	1	1 (1-2)	NS
Place of drainage				
Stomach	18 (75%)	6 (66.6%)	12 (80%)	NS
Duodenum	6 (25%)	3 (33.3%)	3 (20%)	
Hospital stay, days, median (range)	10 \pm 5.4 (6-24)	11 \pm 4 (6-18)	10 \pm 6 (2-24)	NS
Technical success, n (%)	20/24 (83.3%)	8/9 (88.8%)	12/15 (80%)	NS
Clinical resolution after intention-to-treat drainage, n (%)	19/24 (79.1%)	8/9 (88.8%)	11/15 (73.3%)	NS
Clinical resolution after successful drainage, n (%)	19/20 (95%)	8/8 (100%)	11/12 (91.6%)	NS
Recurrence rate	0%	0%	0%	-
Complications, n (%)				
Immediate	2/24 (8.3%)	1/9 (11.1%)	1/15 (6.6%)	NS
Late	2/24 (8.3%)	0/9 (0%)	2/15 (13.3%)	NS
Need for surgery	5/24 (20.8%)	1/9 (11.1%)	4/15 (26.6%)	NS
Intention-to-treat drainage, n (%)				
Need for surgery after successful drainage	1/20 (5%)	1/9 (11.1%)	0	
Deaths, n (%)	1*	0	1*	NS

IQR, interquartile range; * unrelated to the procedure

stent placement, while in group B, massive bleeding from gastric varices in a patient with portal hypertension forced the discontinuation of the procedure, with a good outcome for the patient under conservative treatment.

Late complications: No late complications were seen in group A. Two patients (13.3%) presented late complications in group B: one showed parietal bleeding at the site of stent placement, followed by death (worsening of his acute episode of chronic obstructive pulmonary disease, an event which occurred two months after the procedure) and one displayed late stent migration followed by abscess forming, treated surgically (Table II).

Relapses: No relapses were seen during follow-up.

Mortality: One unrelated death was seen in the patient with parietal bleeding at the gastric stent site due to

pulmonary problems associated (COPD).

Surgical treatment was performed in three patients in whom the wall could not be penetrated with the cystotome due to its thickness, in one case due to an immediate complication (symptomatic pneumoperitoneum) and in one case with late stent migration and abscess forming.

Treatment failure in intention-to-treat patients (16.6%) was due to technical failure and immediate complications. Clinical resolution after successful drainage was 95%, with no significant difference between groups A and B ($p=0.64$) (Table II).

Predictive factors for technical failure were wall thickness over 2 mm ($p=0.05$) and collection diameter under 60 mm (AUC=0.875, CI 95%=0.67-0.92, $p=0.005$). Predictive factors for technical failure were diameter under 60 mm in group B (AUC=0.83, CI95%=0.55-0.96, $p=0.018$) and no factor studied was significant in group A.

No significant predictive factors for treatment failure were found.

Symptoms thought to be related to the pseudocyst were completely resolved in patients with successful drainage.

Discussion

EUS-guided pseudocyst drainage, first reported in 1992, was later introduced as a one-step technique and then extended to the drainage of pancreatic necroses and abscesses [11-13, 19-22]. The previously prevailing endoscopic conventional transmural drainage was limited technically in pseudocysts with no bulging onto the gut wall, in patients with parietal vessels due to portal hypertension, and in cases of difficult positioning of the endoscope inside the stomach [14, 17, 18]. Moreover, EUS-guided drainage has been retrospectively demonstrated to be advantageous to surgical drainage for the treatment of uncomplicated pancreatic fluid collections, with the same success rate, but with fewer repeated procedures and lower costs [23].

In this study, we investigated the safety of performing EUS drainages without fluoroscopy. A success rate comparable with previously published studies using fluoroscopy, and different predictive factors were found. One impeding factor during the procedure was a thick wall of the collection, as already noted in other studies, associated with the sliding of the cystotome on the wall surface and difficult wall penetration, especially in patients with uncomplicated pseudocysts [16, 24, 25]. The EUS visibility of the cystotome sometimes decreases when it passes a thick wall, and attempts to improve its endoscopic visualization using air inflation are usually followed by worsening EUS visibility; fluoroscopy represents a salvage method to maintain the fixed scope position and to ensure that the device is out of the working channel. However, lack of fluoroscopy cannot be incriminated as the sole reason for difficult penetration of a thick wall. No comparative studies of the use of different devices for creating the communication between gut and collection cavity have yet been published. The use of the cystotome with fluoroscopy has been described in

a few studies in which multiple sessions of drainage were performed in the same patient [25-28]. In one study of the drainage of abscesses, with a median two procedures per patient ($n=9$ patients), a success rate of 100% was described [26], against only 75% when one procedure was performed per patient as in our study. Success rates as low as 71% have been described after the first attempt for EUS drainage of pancreatic pseudocysts using a cystotoma and balloon dilatation [28]. In the case of drainage of uninfected pseudocysts using a cystotome, the success rate was reported as 95% when two procedures per patient were performed [26] and 71-82% with one procedure per patient, while we obtained a success rate in intention-to-treat patients of 83.3% with a median of one procedure per patient and no significant difference between abscesses and pseudo cysts groups [27, 28]. In the literature it was shown that the use of the Giovannini needle was associated with a success rate of 94% [24, 29], but the rate of success after the first attempt was only 84% [29]. The use of the needle-knife or balloon-dilatation techniques was associated with a 93-100% success rate [14, 17, 23, 30, 31], with a low rate of perforation and bleeding with balloon-dilatation [14, 16, 17], but a higher perforation rate with the needle-knife technique [30-33]. Larger comparative studies will be necessary to assess the best device with the highest success rate and the lowest complication rate. The prototype "transluminal balloon accessotome", which combines a needle-knife and a dilating balloon, will probably allow easier drainage in one single step, reducing the exchange of accessories and simplifying the procedure [34]. Moreover, the use of the prototype three-layer puncture kit, which allows the simultaneous insertion of two guidewires at the initial puncture in one step, or the use of a larger working channel in the echo-endoscope would allow safer and faster drainage [22].

Most studies included collections more than 4 cm in diameter [14, 16, 33]. We included only collections over 5 cm in diameter, and found that a diameter less than 6 cm was a predictive factor for technical failure of drainage, suggesting that, if fluoroscopy is not used, this might represent an important factor in the exclusion of patients for such treatment. In our study, all failures were due to the sliding of the cystotome on the wall of a small pseudocyst, in which the lack of fluoroscopy could play a role; failure was never due to the loss of the intracystic guidewire during stent placement. The relevance of collection size to the outcome of invasive treatment of pancreatic fluid collections has not been confirmed in some studies that used fluoroscopy control [35].

The main limitation of this study was the small number of patients included. The lack of fluoroscopic control may explain the occurrence of pneumoperitoneum as immediate complication in a successfully stented pseudocyst of the pancreatic tail, with a difficult position on the posterior gastric wall and repeated endoscopic visualization of the puncture site. Also, late complications in the pseudocyst group, such as stent migration in a patient with a small collection, followed by secondary infection could have been avoided by using

fluoroscopic control, which helps to achieve a better declive placement of the stent in a pseudocyst visualized previously by contrast injection.

To date, only one case series of drainage without fluoroscopic assistance has been published: among 11 fluid collections there was one case (9%) with complications, namely internal migration of the stent [36]. In our study, we recorded a 13% rate of late complications, similar to other published data, and no late complications in the abscess group. As a late complication, delayed parietal bleeding, seen in one case, was previously reported in a patient with nasocystic drainage [26]. Because we excluded all collections communicating with the pancreatic ducts we had no relapse of collections, described in 4-17% of cases after 6-9 months' follow-up in other studies [16, 24, 29, 33, 37].

Conclusion

Fluoroscopic control represents a helpful tool but is not always necessary for EUS-guided drainage of pancreatic fluid collections. The rate of technical success without fluoroscopy use was comparable with previously published data. It is possible and safe to perform EUS-guided drainage without fluoroscopy in pancreatic fluid collections with a diameter larger than 6 cm and without a thick wall. Patients with a thick-walled pancreatic fluid collection should be referred directly for surgery, until new devices for wall penetration will be created.

Disclosure

The authors report that they have no conflicts of interest or financial ties to disclose.

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