Single-step EUS-guided transmural drainage of simple and complicated pancreatic pseudocysts

Mainor R. Antillon, MD, Raj J. Shah, MD, Gregory Stiegmann, MD, Yang K. Chen, MD
Denver, Colorado, USA

**Background:** Single-step EUS-guided transmural drainage of pseudocysts has been reported, but there are no published prospective studies on clinical outcomes.

**Objective:** To assess the safety and the efficacy of single-step EUS-guided placement of large endoprostheses to treat simple and complicated pseudocysts.

**Design:** Prospective cohort study.

**Setting:** Single tertiary referral center.

**Patients:** Consecutive patients referred for management of symptomatic chronic pancreatic pseudocysts >4 cm in size.

**Interventions:** Single-step EUS-guided transmural pseudocyst drainage performed with a linear-array echoendoscope for placement of 10F stents in adults and 7F stents in children.

**Main Outcome Measures:** Complete or partial (>50% reduction) resolution of pseudocyst on follow-up imaging, recurrence, clinical response, and procedure-related complications. Recurrence was defined as the reappearance of a pancreatic pseudocyst in the same location.

**Results:** There were 33 patients, with a mean age of 43 years. Median pseudocyst size was 8.5 cm (range, 4-20 cm). Fourteen patients (42%) had infected pseudocysts, 8 patients (24%) had gastric varices, and 16 patients (48%) had no visible endoscopic bulge. Stent placement was successful in 31 patients (94%). Twenty-seven patients (82%) had complete resolution of a pseudocyst; 4 patients (12%) had partial resolution, with symptom relief. There were 2 major complications and 3 minor complications. Recurrence of a pseudocyst was observed in only 1 patient over a median follow-up of 46 weeks.

**Limitations:** No randomized treatment arm comparing this technique with conventional endoscopic drainage.

**Conclusions:** Single-step EUS-guided transmural drainage with large endoprostheses is a safe and effective therapy for patients with simple and complicated pancreatic pseudocysts. (Gastrointest Endosc 2006;63:797-803.)

Endoscopic drainage of symptomatic pancreatic pseudocysts is a proven treatment and can be performed via a transpapillary and/or transmural approach.1,2 There is general agreement that optimal drainage of large pseudocysts is best accomplished by placing multiple large-caliber stents. The conventional technique uses a duodenoscope with fluoroscopic guidance, and gastric varices or non-bulging pseudocysts are usually considered contraindications for transmural drainage.

With the introduction of EUS, EUS-assisted drainage has been advocated for added safety, by allowing proper selection of an optimal site for the needle puncture, thus avoiding major vessels and adjacent structures. However, this technique requires a sequential approach.3 Initially, an echoendoscope is used to evaluate the pseudocyst and surrounding structures and to identify the best site for drainage. Then a duodenoscope with a 4.2-mm operating channel is used with fluoroscopic guidance for placement of large endoprostheses. This sequential approach likely increases procedure time as well as cost. Furthermore, when switching from echoendoscope to duodenoscope, the best angle of puncture cannot be assured. Real-time EUS monitoring of the
puncture site and the needle angle is particularly important in patients with known or suspected gastric or duodenal varices, and drainage of nonbulging pseudocysts can be performed with greater confidence.

More recently, single-step EUS-guided pseudocyst drainage has been described. The small operating channel (2.8 mm) of first-generation curved linear-array (CLA) echoendoscopes initially limited stent options to 8.5F diameter or less. One small case series described EUS-guided placement of a 6F nasobiliary catheter for drainage of pseudocysts in 6 patients with portal hypertension and intervening vessels. With the availability of CLA echoendoscopes with a larger (3.7 mm) operating channel, placement of large (10F) endoprostheses now is feasible. Two single case reports described the placement of a single 10F stent into a pseudocyst; however, there are no reports of placement of more than one 10F stent during a single EUS procedure.

The purpose of this prospective study was to evaluate the safety and the efficacy of performing single-step EUS-guided drainage in consecutive patients referred for treatment of a symptomatic pancreatic pseudocyst.

**PATIENTS AND METHODS**

The study was approved by the Colorado Multi-Institutional Review Board. All patients gave informed consent. During the study period, beginning on December 1, 2001, 34 consecutive patients presented to the University of Colorado Hospital for treatment of symptomatic pancreatic pseudocysts at least 4 cm in size and more than 8 weeks old. One patient underwent surgical drainage without being considered for endoscopic drainage; the remaining 33 patients with chronic pseudocysts were enrolled in this study.

Before the procedure, all patients were evaluated, and prior imaging studies were reviewed. All patients received a single dose of intravenous prophylactic antibiotics (500 mg levofloxacin intravenous piggyback) followed by 5 to 7 days of oral antibiotics after the drainage procedure. Pancreatography was not routinely performed and was done only at the discretion of the endoscopist.

EUS-guided transmural drainage of the pseudocysts (endoscopic cystgastrostomy or cystduodenostomy) was performed by using a single-step technique in the following manner:

1. EUS and endoscopic inspection of the pseudocyst(s), the gastric and duodenal walls, and the surrounding organs and structures was performed by using a large-channel CLA echoendoscope (Aloka GF-UCT140-AL5 [3.7-mm operating channel, 12.6-mm insertion tube]; Olympus America Corp, Melville, NY). A smaller echoendoscope (Aloka GF-UC140P-AL5 [2.8-mm operating channel, 11.8-mm insertion tube]; Olympus) was used for younger pediatric patients with a small body size. The best site for drainage was then identified by using only EUS guidance (usually the most dependent portion of the pseudocyst that can be safely accessed, regardless of location of endoscopically visible bulge, if present) and a 19-gauge needle (Echotip Ultra Endoscopic Ultrasound Needle; Cook Endoscopy, Winston-Salem, NC) was used to puncture the wall under real-time EUS guidance to gain access to the cavity (Fig. 1). The stylet was removed, and a cyst fluid sample was submitted for analysis, if appropriate.

2. With simultaneous EUS and fluoroscopic guidance, a 0.035-inch guidewire with a 5-cm hydrophilic tip was advanced through the needle into the pseudocyst, creating a generous loop of wire inside the cavity. The needle was then removed, leaving the guidewire in place (Fig. 2).

3. The opening of the cystgastrostomy or the cystduodenostomy was created by using limited bursts of diathermy ERBE, Endocut at 200 W (ERBE USA, Marietta, Ga) with a RX needle-knife sphincterotome over the guidewire (Microvasive Endoscopy, Boston Scientific Corp, Natick, Mass).

4. The opening was enlarged by using a 6- to 10-mm wire-guided Hurricane RX Balloon Dilator (Microvasive Endoscopy) (Figs. 3 and 4).

5. Placement of the first 10F, 2- or 3-cm double-pigtail stent (Cook Endoscopy) was performed over the wire, with simultaneous endoscopic and fluoroscopic guidance.

6. The 0.035-inch wire was reinserted into the same opening by using the echoendoscope, following delivery of the second 10F double-pigtail stent. (Figs. 5 and 6). Only one 10F stent was placed if the cyst cavity was not large enough to accommodate 2 stents or if it was not possible to pass 2 stents.

Capsule Summary

**What is already known on this topic**

- Conventional endoscopic drainage of pancreatic pseudocysts is generally performed only in selected patients who have bulging and uncomplicated pseudocysts.
- CLA echoendoscopes with a larger (3.7 mm) operating channel allow placement of large (10F) endoprostheses.

**What this study adds to our knowledge**

- In a prospective study of 33 consecutive patients, single-step, EUS-guided, transmural drainage of symptomatic pancreatic pseudocysts with large endoprostheses was safe and effective in patients with both simple and complicated pseudocysts.
- The EUS-guided approach allows endoscopic drainage in patients with nonbulging pseudocysts or gastric fundal varices.
Pseudocyst infection was suspected if the presence of hyperechoic material within the cyst occupied more than 50% of the cyst cavity. A diagnosis of infected pseudocyst was made if pus was noted during endoscopic drainage and/or if the cyst fluid was positive for an infectious organism on cultures.

All patients were reevaluated at 4 to 8 weeks by EUS, with or without interim CTs, for complete resolution of the pseudocyst, and stents were removed during the same encounter if no residual cyst was found. Follow-up was performed by clinic visits, chart review, and telephone calls thereafter.

Figure 1. EUS-guided puncture of a pancreatic pseudocyst with a 19-gauge fine needle introduced through the operating channel of a therapeutic CLA echoendoscope.

Figure 2. Fluoroscopic view of the placement of a 0.035-inch guidewire into the pseudocyst cavity.

Figure 3. Fluoroscopic view of balloon dilation to enlarge a gastric wall/pseudocyst fistula previously created by wire-guided needle-knife cautery.

Figure 4. Endoscopic view of the opening into the pseudocyst cavity after balloon dilation.

RESULTS

Characteristics of study patients and pseudocysts

Thirty-three patients had a total of 35 attempts at EUS-guided transmural pseudocyst drainage; 1 patient required EUS-guided drainage of 2 pseudocysts, whereas another patient had 2 failed attempts at EUS drainage. There were 15 men and 18 women, with a mean age of 42 years (range, 9-69 years); 2 patients were children ages 9 and 10 years. Etiology of pancreatitis were ethanol abuse (n = 21), after ERCP (n = 2), gallstone pancreatitis (n = 2), trauma (n = 1), unresectable pancreatic cancer (n = 1), and idiopathic (n = 6). The pseudocysts were located in the pancreatic body (n = 27), head (n = 4),...
and tail (n = 2). The median size of pseudocysts was 8.5 cm (range, 4-20 cm). Twenty-three patients (70%) had significant comorbid conditions. Seven patients had chronic liver disease, including 3 with cirrhosis. Three patients had splenic thrombosis secondary to pancreatitis. Other associated comorbidities were diabetes mellitus (n = 4), hypertension (n = 4), hypothyroidism (n = 3), coronary artery disease (n = 1), Crohn’s disease (n = 1), breast cancer (n = 1), and pancreatic cancer (n = 1).

Eighteen of 33 patients (55%) had a pancreatography either before or concurrent with the EUS-drainage procedure. Eight of these 18 patients (44%) had radiographic evidence of pancreatic-duct communication with the pseudocyst; the status of the remaining 15 patients was not known.

The stomach was the best site for EUS-guided drainage in 28 patients (85%). Bulging of the cyst into the stomach was noted endoscopically in 15 patients (54%). The duodenum was the best site for EUS-guided drainage in 5 patients (15%). Bulging of the cyst into the duodenum was found in 2 of the 5 patients. Thus, EUS imaging was the sole guide to the cyst puncture site in 16 of the 33 patients (49%) in this series. Furthermore, 8 patients (24%) had gastric varices, 3 (38%) of whom were detectable only by EUS; this finding was not considered to be a contraindication for EUS-guided drainage.

**Technical outcomes of EUS drainage**

Transmural drainage was successfully established in 31/33 patients (94%), but failed in 2 adult patients. Of the 29 adults with established drainage, 25 patients had placement of two 10F double-pigtail stents through the same puncture site; 2 patients required only one 10F stent because of a smaller cyst size; 1 patient had successful placement of one 10F stent by using the echoendoscope, but a second 10F stent was delivered into the same opening by using a duodenoscope; 1 patient had 2 successful cystgastrostomy procedures for separate pseudocysts, performed on different days.

A smaller echoendoscope (Aloka GF-UC140P-AL5; Olympus) was used for the 2 pediatric patients in this series, because of their small body size. One patient had successful placement of two 7F double-pigtail stents through the same puncture site. The other patient had large gastric varices and received only one 7F stent before the procedure was terminated for bleeding at the puncture site that compromised endoscopic visibility; the latter required transfusion of 3 units of packed red blood cells but no additional intervention for control of bleeding was necessary.

Only 3 of the 8 patients (38%) with proven communication of pseudocysts were treated with transpapillary stent placement (5F or 7F) in conjunction with EUS-guided transmural drainage. Transpapillary drainage was not attempted in any of the remaining 30 patients. In 2 patients, an 8.5F nasocystic tube was placed into the pseudocyst alongside the two 10F double-pigtail stents by using the echoendoscope during the same session, for short-term irrigation of thick cystic fluid (neither patient had transpapillary stent placement).

Complete resolution of the pseudocyst was achieved in 27 (82%) of the 33 patients at the index procedure or in 87% of 31 patients who had successful stent placement. Four additional patients (12%) had only partial resolution (>50% reduction in cyst size), accompanied by symptom resolution (1 pediatric patient and 3 adult patients). Endoscopic treatment was reattempted in only 1 patient after a failed initial procedure but was not reattempted in any of the patients who had partial resolution.

A total of 14 patients (42%) had infected pseudocysts. Eight of 14 (57%) had pancreatic abscesses (evidence of pus), and 6 others had confirmed infection by positive
microbiologic analysis of EUS-guided cyst-fluid aspirates. All infected pseudocysts were treated with a course of antibiotics. The presence of infection did not adversely affect the outcomes of pseudocyst drainage.

**Procedure-related complications**

Two patients (6%) had major complications from the procedure. Perforation, with a subphrenic abscess, occurred in 1 patient after EUS-guided cyst-duodenostomy. This patient required exploratory laparotomy, drainage of the abscess, and repair of the perforation 3 days after a failed attempt at transmural drainage. The patient recovered uneventfully. One pediatric patient with large gastric fundal varices bled at the gastric puncture site and required transfusion of 3 units of blood; on follow-up CT, the single stent was noted to have migrated into the partially obliterated cyst cavity, but no therapy was required. Minor procedure-related complications occurred in 3 other patients (9%) and required hospitalization for observation (asymptomatic pneumoperitoneum, minor bleeding into the cyst, and minor bleeding at the puncture site). Thus, the overall procedure-related complication rate was 5 of 33 patients (15%). There were no mortalities.

**Follow-up**

The median follow-up was 46 weeks (interquartile range [IQR], 34-71 weeks), and no patient was lost to follow-up during the study period. Stents were removed after a median of 6 weeks (IQR, 5-9 weeks). Symptoms thought to be related to the pseudocyst completely resolved after EUS drainage in 26 of the 33 patients (79%), including 4 patients who had only partial resolution (>50% reduction in size) of the pseudocysts. Of the 27 patients with complete resolution on follow-up imaging, 22 (82%) became asymptomatic; the other 5 patients continued to have pain despite complete resolution, presumably because of underlying chronic pancreatitis. Of the 4 patients who had only partial resolution of the pseudocyst, all remained asymptomatic; 3 had no further tests or interventions during follow-up; the fourth patient had 2 follow-up CTs, during a 10-month period, that showed no change in size.

One patient who had a previously failed surgical drainage had only partial resolution after EUS drainage; this patient subsequently underwent a successful percutaneous drainage. Two patients had surgery during the follow-up period: 1 patient who had EUS-guided drainage of an infected pseudocyst subsequently required surgical debridement of infected pancreatic necrosis; the other had surgical drainage of a de novo infected pseudocyst not previously treated endoscopically.

At a median follow-up of 46 weeks, only 1 patient (4%) of 27 who had complete resolution after EUS-guided transmural drainage developed a recurrence of the pseudocyst. Three weeks after stent removal (7 weeks after EUS drainage), this patient was hospitalized at another facility for severe abdominal pain; a pseudocyst (presumably at the same location) was found, and this was drained percutaneously, with eventual complete resolution, although the pain has remained unchanged.

**DISCUSSION**

This is the largest prospective study that evaluated the feasibility, safety, and efficacy of single-step EUS-guided transmural pseudocyst drainage in a cohort of consecutive patients referred for treatment of symptomatic pancreatic pseudocysts. We report the success and recurrence rates over a median follow-up of 46 weeks, as well as the procedure-related complications of EUS-guided delivery of large-caliber endoprosthesis (10F) by using only 1 endoscope at a single session. During the study period, only 1 patient was inadvertently excluded from our series; this patient was admitted to our Surgical Service for surgical drainage without being considered for endoscopic treatment. This consecutive series included a large proportion (more than half) of cases that normally would be considered contraindicated or more difficult to treat by using the conventional approach: infected pseudocysts (42%), nonbulging pseudocysts (48%), and gastric varices (24%). Two large (10F) endoprosthesis were delivered via a transgastric or transduodenal approach, except in children who were treated by using a smaller-diameter echoendoscope (2.8-mm operating channel) and two 7F stents.

In this prospective study, the procedure was technically successful in 94% of all patients. By intention-to-treat analysis, complete resolution of pseudocysts was achieved in 82% of all patients or in 87% of 31 patients who were successfully stented. Eighty-five percent had a transgastric drainage, whereas the remainder had transduodenal drainage. With the exception of 2 major complications, the overall morbidity was low. These results compare very favorably with conventional endoscopic drainage. Howell et al12 reviewed the published literature through 1998 and found that, among 141 patients with pseudocysts treated endoscopically, transmural drainage as the only method of drainage achieved initial complete resolution in only 26 of 37 patients (70%), with a morbidity of 19% and a recurrence rate of 16% after a variable duration of follow-up. In this review, the transduodenal approach was found to be more effective (80%-100%) than the transgastric approach (30%)12 whereas, we found that both transgastric and transduodenal drainage equally had excellent outcomes when using the EUS-guided approach. Despite the fact that EUS-guided drainage was largely established via a transgastric approach (85%) in this study, complete resolution was achieved in 82%, and the recurrence rate was only 4% at a median follow-up of 46 weeks.

A major limitation of conventional endoscopic drainage is the requirement for an endoscopically visible bulge in the wall of the stomach or the duodenum. One single-center
study reported a 42% incidence of nonbulging pseudocysts over a 2-year period\(^1\); this is similar to our experience where 48% of patients presented with a nonbulging pseudocyst. Additionally, 8 patients (24%) in our series had evidence of gastric varices, 5 of whom also had a nonbulging pseudocyst. Thus, 19 of 33 patients (58%) in our study cohort would have been considered inappropriate candidates for conventional endoscopic drainage. Given the fact that conventional endoscopic drainage is generally performed only in highly selected patients with bulging and uncomplicated pseudocysts, the overall success rates observed in this cohort of unselected patients when using the EUS-guided approach is clearly superior.

Until recently, EUS-guided transmural drainage of pseudocysts was limited by the inability to place large-caliber stents at the initial procedure.\(^4\)\(^-\)\(^6\) Sanchez Cortes et al\(^1\)\(^3\) described 33 patients in whom a small-caliber (6.5F) stent or nasocystic drain was placed with EUS guidance. However, a second procedure was required several days later to up-size to larger (10F) stents by using a duodenoscope with a 4.2-mm operating channel.\(^1\)\(^3\) Thus, this was really a sequential approach, requiring 2 separate procedures with 2 different endoscopes. By using this 2-step approach, their technical success rate approximated our success rates when using a single-step, EUS-guided technique.

Combined transmural and transpapillary drainage in patients with a communicating pseudocyst has been advocated by some, with reported success rates in the range of 70% to 100%.\(^1\)\(^2\) However, superiority of the combined approach over transmural drainage alone has not been established in a prospective, randomized study. Because we did not routinely perform ERCP before EUS-guided drainage, the prevalence of communicating pseudocysts in our cohort is unknown. However, at ERCP, ductal communication has been reported in anywhere from 23% to 66% of patients who present for pseudocyst drainage.\(^1\)\(^1\)\(^1\)\(^1\) In our study, EUS-guided transmural drainage was the only technique used in all but 3 patients. One patient had concurrent transpapillary placement of a 7F stent into the cyst. A second patient had concurrent transpapillary placement of a 5F stent into the pancreatic duct that traversed the communicating fistula. The third patient had persistent pancreatic ascites and pleural effusion, despite complete resolution of the pseudocyst after transmural drainage. At ERCP, a complete downstream obstruction of the main pancreatic duct could not be traversed by using the transpapillary approach; the ascites and effusions subsequently resolved after upstream placement of two 5F stents via EUS-guided pancreaticogastrostomy. We conclude that excellent overall outcomes can be achieved by using EUS-guided transmural drainage alone, without having to routinely obtain a pancreatogram to identify ductal communication and to perform transpapillary drainage. Nasocystic irrigation of infected pseudocysts (42% of the cohort) also appears to be unnecessary, particularly when EUS-guided drainage can be established with 2 large-bore stents.

At a median follow-up of 46 weeks, only 1 (4%) of 27 patients who had initial complete resolution developed a pseudocyst recurrence. In contrast, up to 16% of recurrences has been observed after conventional endoscopic drainage.\(^1\)\(^2\) Without a randomized comparison, it is not clear if the low recurrence rate and excellent overall outcome is attributable solely to our EUS technique (ie, selecting the most dependent and appropriate drainage site by using EUS guidance alone), or to the use of dual large-caliber stents, or to both. Similarly, despite the inclusion of patients with gastric varices and nonbulging pseudocysts, the overall morbidity was only 13% after EUS drainage, which compares favorably with the reported morbidity after conventional transmural drainage.\(^1\)\(^2\)

In summary, single-step EUS-guided transmural drainage with placement of 1 or more large endoprosthesis is a very safe and effective therapy for symptomatic pancreatic pseudocysts. The EUS-guided approach substantially extends the reach of endoscopic drainage to include patients with nonbulging pseudocysts and gastric fundal varices, and pseudocyst infection does not appear to adversely impact the outcome. Randomized studies are needed to directly compare the safety and efficacy of EUS-guided drainage with conventional endoscopic drainage.

DISCLOSURE

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REFERENCES