CHAPTER 27

Pancreatic fluid collection drainage

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Endoscopic ultrasonography (EUS)-guided drainage has emerged as the preferred treatment modality for symptomatic walled-off pancreatic fluid collections. Alternative drainage techniques such as non-EUS-guided endoscopic transmural drainage, percutaneous drainage, and surgical cystogastrostomy are considered second-line options. This chapter reviews the rationale for EUS guidance and the advantages it provides, the technique of EUS-guided drainage, and the results of key published studies.

Definitions

The definitions used for acute pancreatitis and peripancreatic fluid collections were recently updated [1]. The terminology used in this chapter will be based on these new definitions. A pancreatic pseudocyst is defined as an encapsulated collection of fluid with a well-defined inflammatory wall, usually outside the pancreas, with minimal or no necrosis. This entity usually occurs more than 4 weeks after onset of interstitial edematous pancreatitis. A walled-off pancreatic necrosis is a mature, encapsulated collection of pancreatic and/or peripancreatic necrosis that has developed a well-defined inflammatory wall. Walled-off necrosis usually occurs >4 weeks after onset of necrotizing pancreatitis. The original Atlanta Classification [2] included the term "pancreatic abscesses," defined as a "localized collection of purulent material without significant necrotic material." This finding is extremely uncommon, and because the term is confusing and not widely adopted, it is now abandoned.

Indications and criteria for drainage

Symptomatic pseudocysts causing pain and mechanical obstruction of the gastric outlet or biliary system require drainage. Drainage of infected pseudocysts and infected walled-off necrosis is required for the effective control of sepsis. Drainage is also indicated if the pseudocyst continues to increase in size without resolution after 6 weeks, in order to avoid subsequent development of complications such as hemorrhage, perforation, or secondary infection. A prerequisite for EUS-guided drainage is the presence of a well-defined mature wall. For pseudocysts, a timeframe of 4–6 weeks is required for the formation of a mature wall. The fluid collection must be accessible endoscopically; for example, it might be located within 1 cm of the duodenal or gastric walls. Paracolic collections cannot be accessed and would require adjunctive methods such as percutaneous drainage. Coagulopathy, if present, should be corrected [3].

Rationale

EUS guidance has several advantages over alternatives such as surgical, percutaneous, and non-EUS-guided endoscopic drainage [4, 5]. It is less invasive than surgery, and does not require general anesthesia. A retrospective case–control study [6] and a subsequent prospective randomized study [7] both showed that EUS-guided drainage had equal efficacy to surgery but was associated with lower morbidity, faster recovery, and lower costs. Surgery, especially via a minimally invasive approach, still has an important role as adjunctive or rescue therapy.

EUS-guided drainage can avoid local complications related to percutaneous drainage. Because the endoscope is just adjacent to the fluid collection, it can have direct access to the fluid cavity, unlike percutaneous drainage, which traverses the abdominal wall. Complications such as bleeding, inadvertent puncture of adjacent viscera, secondary infection, and prolonged periods of drainage with resultant pancreaticocutaneous fistula may be avoided. In addition, with endoscopy, endoscopic necrosectomy may be performed via a transmural approach. Percutaneous drainage remains an important adjunctive treatment in situations where collections cannot be accessed endoscopically, or where the walls of the collections are immature [5].

The difference between EUS- and non-EUS-guided endoscopic drainage is at the initial step of gaining access to the pancreatic fluid collection. All subsequent steps are similar (i.e., insertion of guidewires with fluoroscopic guidance, insertion of transmural stents or nasocystic catheters, balloon dilatation of the cystogastrostoma, endoscopic necrosectomy). Non-EUS-guided endoscopic drainage is a blind procedure, and the presence of endoscopic bulging is a prerequisite. The fluid collection is punctured at the site of maximum endoscopic bulging. There is also a potential risk of hemorrhage from interposed vessels during transmural drainage.

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On the other hand, with EUS guidance, the fluid collection is visualized during the entire puncture process, and endoscopic bulging is not mandatory. One might potentially decrease the bleeding rate by avoiding interposed blood vessels through the use of Doppler ultrasound. EUS can also differentiate a pseudocyst from a cystic tumor, and ascertain the nature of a fluid collection and guide the drainage strategy; for example, a pseudocyst may be treated by placing transmural stents, whereas a necrotic collection requires additional endoscopic debridement. The importance of EUS was highlighted in a case series in which EUS was used to evaluate pseudocysts prior to attempting endoscopic drainage. It was shown that EUS provided essential information that led to a change in management strategy in 37.5% of cases [8]. Another case series showed that EUS could be used to guide pseudocyst drainage in patients with portal hypertension, thereby reducing the bleeding risk [9]. Two randomized studies comparing EUS- with non-EUS-guided drainage demonstrated a higher success rate of the EUS-guided approach (100 vs. 33% [10] and 96.3 vs. 66.7% [11]). This was due to the feasibility of draining non-bulging pseudocysts.

Technique

The equipment and accessories used are shown in Table 27.1. The current single-step approach, which has a few minor variations due to differences in accessories, will be described in detail. This procedure requires a therapeutic echoendoscope and access to fluoroscopy. The old two-step approach referred to puncturing of the collection under the guidance of a linear echoendoscope, followed by guidewire insertion, and then exchange of the linear echoendoscope for a therapeutic duodenoscope to complete the rest of the drainage procedure. The currently available therapeutic linear echoendoscopes have larger working channel diameters of 3.7–3.8 mm, which allows transmural stent placement.

Initial puncture using a 19-gauge needle

After excluding the presence of vasculature in the path of the needle by using color Doppler ultrasound, a 19-gauge fine-needle aspiration (FNA) needle is used to puncture the pseudocyst under EUS guidance (Figure 27.1). A 0.025–0.035 inch guidewire is introduced through the needle and is coiled within the pseudocyst under fluoroscopic guidance (Figure 27.2).

Initial puncture-tract dilatation

The puncture tract must next be further dilated in order to allow stent placement. This can be achieved using cautery- or non-cautery-based techniques. Cautery-based techniques involve the use of either the cystostome catheter or a wire-guided needle knife. Non-cautery-based techniques involve the use of coaxial dilators. Cautery techniques are especially useful when thick cyst walls preclude insertion of endoscopic retrograde cholangiopancreatography (ERCP) catheters or coaxial dilators for tract dilatation.

Table 27.1 Equipment for EUS-guided drainage.

Therapeutic echoendoscope with 3.7–3.8 mm working channels 19-gauge FNA needle 0.025–0.035 inch guidewires
A. Initial puncture-tract dilatation
1 Cautery-based technique for tract dilatation
(a) Cystotome catheter; or
(b) Wire-guided needle knife
2 Non-cautery-based technique for tract dilatation
(a) Coaxial dilators, such as 6–10 Fr Soehendra biliary dilators
B. Subsequent balloon dilatation
1 10–15 mm biliary balloon dilators (e.g., CRE balloon dilators from Boston Scientific or Hurricane balloon from Cook)
8.5–10 Fr double-pigtail stents

Figure 27.1 Pseudocyst accessed with a 19-gauge FNA needle.

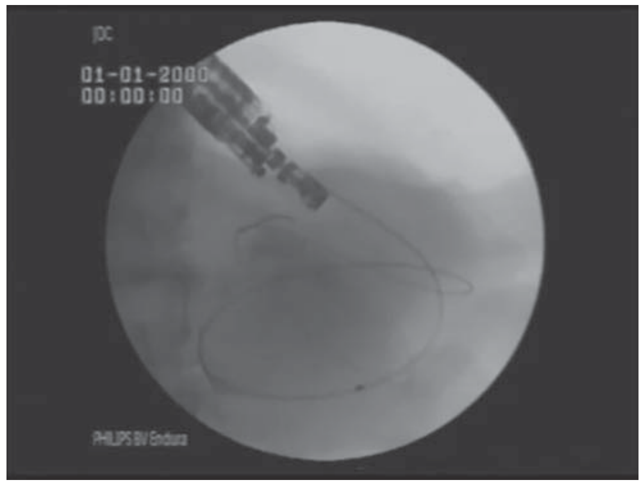

Figure 27.2 Passage of a 0.035 inch guidewire into the pseudocyst under fluoroscopy.

Cautery-based techniques

- Needle-knife technique: After a guidewire has been coiled within the pseudocyst by a 19-gauge FNA needle, the transmural tract is dilated using electrocautery administered through an over-the-wire needle-knife catheter (rather than using an ERCP cannula). The challenge of the technique is the fact that the tip of the needle knife is parallel to the guidewire, such that if it is not properly oriented and positioned, it may not adequately follow the direction of the inserted guidewire. To increase safety, it is best to only protrude out a short length of the needle knife, in order to achieve maximum alignment.
- Cystostome-catheter technique: After a guidewire has been coiled within the pseudocyst by a 19-gauge FNA needle, the transmural tract is dilated using electrocautery administered through the

over-the-wire diathermy sheath of a cystostome. Unlike in the needle–knife approach, where the tip of the fine needle is parallel to the guidewire, there is a diathermy ring at the tip that completely encloses the guidewire, such that the axis can be maintained correctly during the process of electrocautery.

Non-cautery-based techniques

The tract is sequentially dilated under fluoroscopic guidance by use of coaxial dilators such as the Soehendra biliary dilators (6–10 Fr) or by use of a 4.5 or 5.0 Fr ERCP cannula over the guidewire.

Further balloon dilatation and stent insertion

Conceptually, it is possible to just insert a single double-pigtail 10 Fr stent if a coaxial 10 Fr dilator is used. However, it is preferable to dilate the puncture tract further, so that the fluid can drain out both around and through the stent. Further dilation is performed using an over-the-wire biliary balloon dilator (Figure 27.3). If only transmural stenting is required, then dilatation to 10 mm should suffice. If endoscopic necrosectomy is intended, then dilatation to 15 mm isrequired to allow passage of a gastroscope. Following dilation, a 10 Fr double-pigtail stent is deployed within the pseudocyst under fluoroscopic guidance (Figure 27.4). Multiple stents and a 7 or 10 Fr nasocystic drainage catheter may have to be deployed in patients with infected pancreatic fluid collection for periodic flushing and evacuation of the cyst contents. This is achieved after recannulating the cavity and inserting a guidewire. Double-pigtail stents are preferred over straight stents as they minimize the risk of migration.

Double-guidewire techniques

Because of the advantage of easily allowing repeat stent placement, the current trend is to insert two guidewires. This “double-wire” approach, in which two guidewires are inserted through the same catheter prior to stent placement, has been used to avoid the need to recannulate the pseudocyst after gaining initial transmural access. Recannulation of the cavity may be potentially difficult, due to a tangential axis of puncture and poor visibility from fluids flowing out from the pseudocyst. The current most commonly used technique is to insert a second guidewire through an 8.5–10.0 Fr cystostome catheter. In this technique, a 19-gauge needle is used to puncture the pseudocyst, and a guidewire is inserted. The cystostome catheter is then inserted over the guidewire into the pseudocyst cavity [12]. Other, similar approaches include the use of a novel prototype three-layer puncture kit that allows the simultaneous insertion of two guidewires at the initial puncture [13] and the use of a 10 Fr Soehendra biliary dilator [14], which is inserted into the pseudocyst cavity over the single guidewire inserted at the initial EUS-guided puncture and then followed by a second guidewire. Sequential transmural stent and drainage catheter placement can then be performed without loss of access to the pseudocyst cavity. A very important technical issue to note is that the working channel of a therapeutic EUS scope is 3.7 mm. With two guidewires of 0.025–0.035 inches within the working channel, the diameter of the first transmural stent cannot be 10 Fr, because there will be no space. Hence, in such a situation, an 8.5 Fr double-pigtail stent is inserted first. Thereafter, one guidewire is removed and a 10 Fr double-pigtail stent is inserted over the remaining one. To facilitate the insertion of double-pigtail stents, silicone lubricant can be applied over the stent surface. This technique can potentially enable the placement of more guidewires for multiple stent placements.

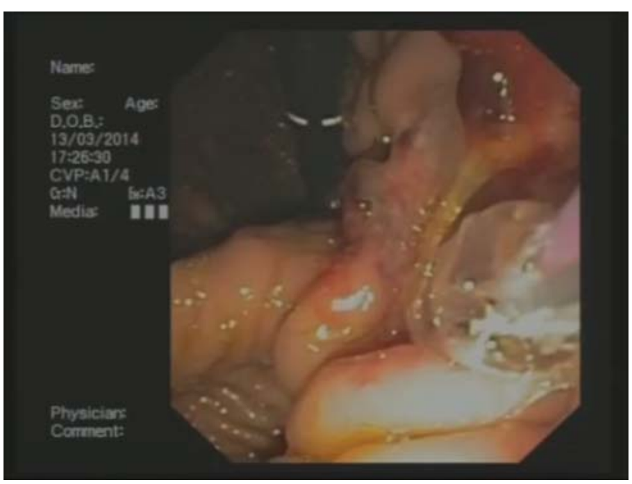

Figure 27.3 Balloon dilatation of the puncture site.

Figure 27.4 Placement of a double-pigtail transmural stent.

Use of a forward-viewing echoendoscope

A forward viewing therapeutic echoendoscope (Olympus, Tokyo, Japan) has been developed. Unlike the conventional echoendoscope, its endoscopic and ultrasonic axes are aligned. It has a narrower ultrasonic view and does not have an elevator. The basic technique of EUS-guided drainage is similar to what was described earlier, the main difference being the axis for puncture and drainage. A multicenter study compared the use of forward viewing and oblique-viewing linear echoendoscopes for pseudocyst drainage. There was no difference in ease of drainage or procedure safety and efficacy [15]. However, from a practical view point, due to the absence of an elevator and the direction of the insertion axis, there may be situations where it may potentially be difficult to adequately transmit the pressure needed for stent placement.

Insertion of self-expandable metallic stents

As an alternative to standard plastic double-pigtail stents which has a maximum inner diameter of 3.3 mm (10 Fr), recent publications have explored the use of self-expandable metallic stents (SEMS). These were initially adopted from enteral SEMS but that gave rise to the problem of stent migrations. Specifically designed SEMS for drainage purpose have been introduced [16, 17]. The

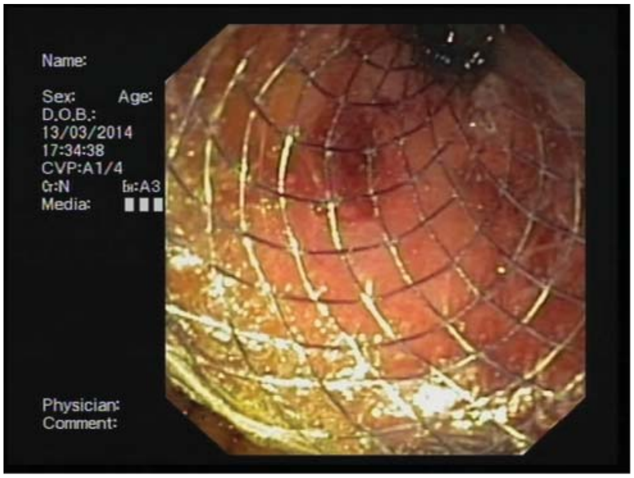

Figure 27.5 Endoscopic view after insertion of NAGI SEMS.

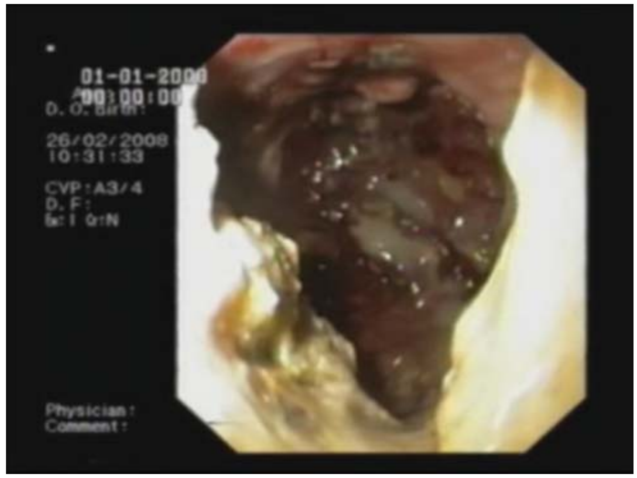

Figure 27.7 View within the cavity of infected walled-off necrosis.

lumen-apposing stent (AXIOS, Xlumena Inc, Mountain View, California, USA) is a fully covered, 10 mm-diameter, nitinol, braided stent with bilateral anchor flanges. When fully expanded, the flange diameter is twice that of the “saddle” section and is designed to hold tissue layers in apposition [16]. The stent is delivered constrained through a 10.5 F catheter which is inserted over the guidewire within the pseudocyst cavity. The “NAGI” covered SEMS (Taewoong-Medical Co., Seoul, South Korea) is another specially designed SEMS with a 10, 12 or 16 mm diameter in the center and 20 mm ends which can reduce the risk of migration (Figures 27.5 and 27.6) [17]. The potential advantage of SEMS is a larger drainage orifice and the possibility of facilitating repeat entry into the cavity for endoscopic necrosectomy in the context of infected walled off necrosis. Its potential utility is probably limited to the management of infected walled off necrosis [18]. However, given the high costs of SEMS the issue of cost-effectiveness will need to be addressed. In addition, patients may have underlying pancreatic duct disruption such that once the SEMS is removed the collection may recur, necessitating repeat drainage and reinsertion of plastic stents. In contrast, if EUS-guided drainage is performed using plastic stents, then an all in one solution would have been provided at the start, in that the initial plastic stent drained the fluid collection, and then its long term placement prevents recurrence of the pseudocyst [19].

Adjunctive measures

After placement of transmural stents and drainage catheters, further adjunctive measures may be necessary. These measures are the same whether or not EUS guidance was used to obtain initial access of the collection. In the context of an infected pancreatic fluid collection, continuous saline irrigation and drainage with a nasocystic catheter is important until sepsis has resolved.

In the presence of infected pancreatic necrosis, adjunctive endoscopic necrosectomy (Figures 27.7 and 27.8) is essential to improving the treatment success rates [20–25]. This approach is recognized by the updated International Association of Pancreatology (IAP) guidelines, which were published as the summary report of a consensus conference recently. The guidelines also acknowledge the role of minimally invasive techniques for treatment [26]. Since the technique was first reported in 2000, first as a case report [20], then as a case series detailing an aggressive endoscopic approach [21], outcome data from large multicenter case series have become available. The key data are summarized in Table 27.2 [22–25].

Figure 27.6 X-ray view after insertion of NAGI SEMS.

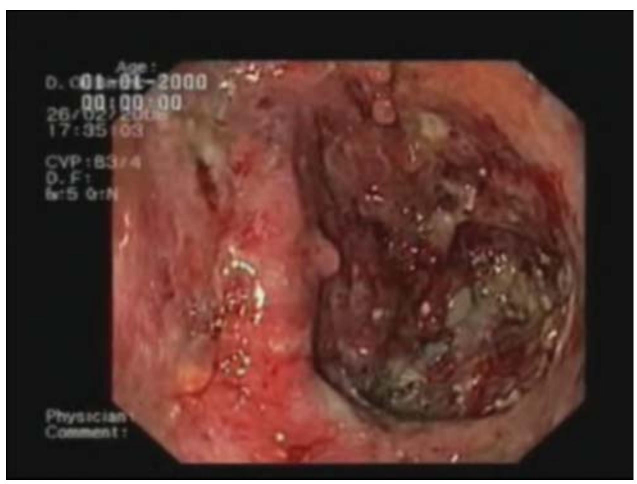

Figure 27.8 Appearance of the cavity of the walled-off necrosis after endoscopic necrosectomy.

Table 27.2 Clinical outcomes after endoscopic necrosectomy.

Reference	n	Success rate (%)	Morbidity (%)	Mortality (%)
Seifert et al. [22]	93	80	26	7.5
Yasuda et al. [23]	57	75	33	11
Seewald et al. [24]	80	83.8	26	0
Gardner et al. [25]	104	91	14	5.8

Although the technique has been proven to be effective, there is a risk of significant morbidity, and mortality has also been reported. Hence, the extent and aggressiveness of necrosectomy will need to be individualized and weighed against the risks of complications. In fact, complete necrosectomy may not be required in all instances, and flushing and irrigation may be adequate. A multicenter, randomized study compared a minimally invasive step-up approach with open necrosectomy, and found that the former reduced the rate of the composite end point of major complications or death among patients with infected necrosis. In fact, in 35% of cases, percutaneous irrigation and drainage alone was sufficient [27].

Another issue that must be addressed is the presence of pancreatic duct disruption. A good-quality magnetic resonance cholangiopancreatography (MRCP), especially with secretin use, may be able to fully visualize the ductal anatomy. ERCP is not required in most instances. Therapeutic ERCP may be needed in the context of pancreatic duct stricture or stones. Duct disruption can be treated by pancreatic duct stenting. If the fistula does not resolve after a prolonged period of pancreatic duct stenting, endoscopic sealing with Histoacryl can be considered [28]. As an alternative to ERCP, long-term transmural stenting has also been reported for treatment of pancreatic duct disruption, in order to prevent recurrence of pseudocysts [19].

Clinical outcomes

Technical success means successfully achieving access to and drainage of the fluid collection. Clinical success pertains to complete resolution and recovery. This concept is important, because technically one can be successful in terms of placing transmural stents for an infected walled-off necrosis, but this will not lead to resolution of the collection, since additional steps such as endoscopic necrosectomy are needed. When a collection is suitable and accessible, technical success can inevitably be achieved in expert hands. Another point is that when one compares EUS-guided with non-EUS-guided drainage, the difference exists only at the initial stage of attempting to puncture and access the fluid collection. All subsequent steps are similar in both approaches.

Pseudocysts and infected pseudocysts

Very high treatment success rates, >91% [29–31] and even reaching 100% [32], have been achieved. The term “pancreatic abscess” is no longer recommended based on the new terminology [1], although prior publications used this term. It should be regarded as equivalent to an infected pseudocyst. High treatment success rates >90% [30, 33] have been reported.

Infected walled-off pancreatic necrosis

The results for clinical resolution are generally poorer than those for pseudocyst drainage, due to the need to remove necrotic debris. In a comparative study, it was reported that the success rate of pseudocyst drainage was 92%, compared to 72% in patients with necrosis [34]. Another study reported the success rate of simple drainage to be as low as 25% [30]. If an aggressive endoscopic approach using endoscopic necrosectomy is adopted, success rates ranging from 75 [23] to 84% [22], and even up to 91% [25], can be achieved based on reported data from large series. Adjunctive surgical and percutaneous drainage may be needed. A recently published randomized control trial (RCT) showed that in patients with infected necrotizing pancreatitis, endoscopic necrosectomy reduced the proinflammatory response as well as the composite clinical end point of major complications compared with surgical necrosectomy [35]. The enthusiasm for endoscopic necrosectomy must, however, be tempered by a realization of the procedural risks, as well as the fact that an aggressive approach toward necrosectomy may not be needed in the majority of patients [27, 36], such that even if endoscopic necrosectomy is performed, clinical resolution may be achieved with less extensive debridement.

Technical proficiency

Currently, in most parts of North America and Asia, dedicated devices for the performance of EUS-guided drainage are not commercially available. There are no predetermined threshold number of procedures that need to be performed under supervision before competency can be assessed. In the opinion of the authors, an endoscopist skilled in EUS FNA and ERCP should be able to perform the procedure competently. Endoscopists who want to perform pseudocyst drainage but who do not perform ERCPs need to be proficient with the use of accessories such as guidewires, needle-knife catheters, balloon dilators, and double-pigtail stents. In a study that evaluated the performance of a single endosonographer, the technical proficiency for performing pseudocyst drainages improved significantly after 25 procedures, while the median procedural duration after performing 25 cases decreased from 70 to 25 minutes [10].

Technical limitations

It is clear that EUS-guided drainage offers several advantages over traditional drainage techniques. However, the EUS procedure has limitations related to the echoendoscope design that result in technical difficulties during endoscopic drainage. An important limitation is that the size of the working channel of a therapeutic linear echoendoscope is 3.7 or 3.8 mm – smaller than that of a therapeutic duodenoscope (4.2 mm). This size limits the suction ability, which is important when copious fluid is draining from the pseudocyst cavity after the initial puncture. Additionally, although placing a 10 Fr stent is not an issue with a linear echoendoscope, one may need to place multiple stents or a nasocystic catheter for irrigation. In these situations, it may be faster and easier to use a double-wire technique. However, the smaller working channels of echoendoscopes limit the use of double-wire techniques, in that the size of the first transmural stent inserted must be 8.5 Fr or lower, as there is excessive resistance within a 3.7 mm working channel when two guidewires are in place. The first stent that is placed cannot be the preferred, larger 10 Fr size.

Another limitation is the oblique view of current echoendoscopes. This configuration limits the endoscopic view and results in a tangential puncture axis. Puncturing at an angle may hamper successful completion of the procedure, because the force that is applied when accessories are introduced through the working channel cannot be fully directed toward the puncture site. The tangential axis also makes subsequent cannulation of the pseudocyst cavity difficult, unless there was prior balloon dilatation of the puncture site or a double-wire technique was used.

A prototype forward-viewing therapeutic echoendoscope developed by Olympus allows a forward axis of needle puncture and insertion of accessories parallel to the scanning axis. This facilitates forward transmission of force when inserting accessories, stents, and catheters. In a pilot study, all pseudocysts were successfully drained without complications, and some pseudocysts could be punctured only with the forward-viewing scope [15]. The forward-viewing echoendoscope is limited by a 3.7 mm working channel, a lack of elevator, and an ultrasonic view of only 90°.

Endoscopic drainage is feasible only for pseudocysts located around the stomach and duodenum. When pseudocysts involve more distal locations, such as the paracolic regions, they are not accessible endoscopically, and other adjunctive measures, such as percutaneous or surgical drainage, need to be considered.

Complications

The main potential complications of concern are severe bleeding and perforation. To minimize risk, only fluid collections with a mature wall and within 1 cm of the gastrointestinal lumen should undergo endoscopic drainage. Any coagulopathy, if present, should be corrected. Patients with pseudocysts undergoing drainage should receive prophylactic antibiotics in order to prevent secondary infection of a sterile collection. A review showed that complication rates were higher for surgical (28–34%, with 1.0–8.5% mortality) and percutaneous drainage (18%, with 2% mortality) than for non-EUS-guided (15%, with 0% mortality) and EUS-guided (1.5%, with 0% mortality) transmural drainage [32]. A recent publication specifically examined the frequency of complications during EUS-guided drainage of pancreatic fluid collections in 148 consecutive patients over a 7-year period. Perforation was encountered at the site of transmural stenting in 2 patients (1.3%). Other complications included bleeding in 1 (0.67%), stent migration in 1 (0.67%), and infection in 4 patients (2.7%). These could all be managed endoscopically, except for the perforations, which required surgery [37]. Perforation rates of 3–4% have been reported in the context of endoscopic necrosectomy [4]. This risk can be reduced by adhering to key principles, such as only draining a collection with a mature wall, performing stepwise balloon dilatation of the cystogastrostoma, using carbon dioxide for insufflation, and performing gentle debridement using saline lavage and aspiration, baskets, soft snares, and retrieval nets.

Conclusion

EUS-guided drainage is an effective and safe technique for the treatment of symptomatic pancreatic fluid collections. To minimize risk and increase efficacy, key principles should be adhered to. It can also provide an all-in-one solution for patients with pseudocysts due to disconnected pancreatic duct syndrome, by first draining the collection at initial stent insertion, then preventing recurrence with continued long-term stent placement.

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