14 Direct Endoscopic Necrosectomy

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Introduction

Clinically severe acute pancreatitis is almost always associated with necrotizing pancreatitis and/or necrosis of surrounding peripancreatic fat [1]. With early recognition and improvements in critical care, most patients survive the early phase of systemic inflammatory response syndrome (SIRS) and multisystem organ failure. Often these patients have a prolonged course of sterile necrosis while others develop delayed infection. Several weeks after onset of pancreatitis a defined entity referred to as walled-off necrosis (WON) develops (see Chap. 2) [2]. When indicated the approaches to drainage/debridement for WON can be surgical, percutaneous, endoscopic or a combination [3]. Early, open surgical necrosectomy has largely been supplanted by delayed minimally invasive approaches to WON [4–6] using flexible endoscopic, rigid endoscopic [7], percutaneous and laparoscopic approaches, alone or in combination [8]. Unfortunately, there is no definite consensus on optimal timing and type of intervention. Several endoscopic approaches are available to manage WON [9] (Table 14.1). One approach using flexible endoscopes is termed direct endoscopic necrosectomy (DEN), whereby the necrotic cavity is entered transmurally (via the stomach or duodenum, or both [10, 11]), or through percutaneously created tracts. In this chapter the use of DEN will be discussed.

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Brief History

The passage of peroral flexible endoscopes into WON (at that time termed organized pancreatic necrosis) was described in 1999 [12]. However, it was not until Siefert [13] and subsequently Seewald [14] introduced DEN as a method to remove necrotic tissue using mechanical methods that this technique was adopted in some centers. This led to studies showing that DEN may be superior to peroral endoscopic irrigation methods [15, 16].

Timing and Indications for DEN

The timing of and indications for intervention in patients with WON will be detailed in other chapters. Additionally, the types of interventions will be discussed in Chaps. 16, 17, and 18. Briefly, however, it is accepted that for patients with sterile necrosis any intervention should be delayed as long as possible and at a minimum 4 weeks after the onset of acute pancreatitis. Most patients with pancreatic necrosis can be managed with medical therapy until resolution. Endoscopic management using DEN cannot be undertaken

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Table 14.1 Flexible endoscopic approaches to organized (walled-off) pancreatic necrosis

Endoscopic approach	Advantages	Disadvantages
Single or multiple entry transmural entry with nasocystic irrigation	Technically easy	Discomfort of nasal tube
Single entry transmural with PEG-PEJ for irrigation	Avoids nasal tube	– Technically more difficult than nasocystic irrigation – External tube
Transmural entry with direct endoscopic necrosectomy (DEN)	Avoidance of external drains	– Technically difficult – Time-consuming – Labor intensive
Hybrid percutaneous irrigation-endoscopic transmural approach	Minimal endoscopic procedures	– Requires both interventional radiologist and gastroenterologist – External tube
Hybrid percutaneous-endoscopic direct necrosectomy using external/internal large diameter stents	Allows endoscopic access to areas not accessible translumenally	– Requires both interventional radiologist and gastroenterologist – External stent – Abdominal wall pain – Stent cost

until the necrotic process has become walled-off. This may occur as early as 2–3 weeks but often requires 4 weeks. For those with WON, intervention can be considered for patients who remain systemically ill and unable to resume normal life activities 4–6 weeks after the onset of pancreatitis, those with symptoms of gastric outlet obstruction, intractable pain, and inability to eat, especially when CT or MRI shows progressive enlargement. Less common indications include inability to wean from mechanical ventilation due to increased intra-abdominal pressure and documented large, high amylase level pleural effusions or ascites. Our approach is to offer DEN to patients with WON who have had a prolonged course of sterile necrosis, intractable pain, gastric outlet obstruction, inability to eat, or rapidly enlarging collections present at 4 or more weeks after onset of pancreatitis. It is believed that DEN will return the patient to a normal health status more rapidly than "watchful-waiting" (supportive care), though without clear-cut evidence.

The decision to intervene is easier in patients in whom there is a high suspicion for or known infected necrosis, and we have intervened as early as 3 weeks after the onset of acute pancreatitis and in septic patients with acute pancreatitis and WON (as determined by CT). DEN is often undertaken when patients have clinical deterioration unresponsive to medical therapy.

DEN Methods

Preprocedural Planning/Sedation

It is imperative that a cross-sectional imaging procedure (CT or MRI) be obtained within several days prior to planned intervention to best determine degree of demarcation and anticipated access points, and for evaluation for major vessels either within the cavity or between the cavity and gastric or duodenal wall. In addition, imaging can determine the degree of paracolic extension and any communication between multiple cavities. Such connections can often be appreciated on coronal CT images. One should be suspicious of a fistula between the lumen and collection when spontaneous air is present. This tract can be conveniently used for entry as described below.

A pre-procedural INR and platelet count should be obtained and corrected, as necessary.

Pre-procedural antibiotics should be administered in patients not already receiving them. Extended intravenous penicillin agents (piperacillin/tazobactam), quinolone agents (levofloxacin), or a carbapenem (meropenem) are recommended agents.

Sedation using anesthesia support is recommended as these patients are often ill, procedures are prolonged, aspiration risk is high, and intraprocedural adverse events (AEs) (bleeding, pneumoperitoneum) can occur.

Puncture and Access

DEN is performed using flexible endoscopes. One or more transmural access points are targeted for drainage depending on imaging, most often CT. For WON collections located in the mid-body and tail a transgastric route is usually undertaken. A transgastric approach is often a more direct approach to subsequently pass an endoscope directly into the cavity and into paracolic gutter extensions, if needed for DEN. A transduodenal approach is usually the only and best option for collections confined to the pancreatic head.

The initial transmural puncture can be performed in a variety of ways, with or without EUS guidance. Non-EUS-guided punctures can be performed using a side-viewing endoscope (therapeutic duodenoscope, ERCP endoscope) (Fig. 14.1). Advantages to using the duodenoscope are the ability to puncture at a perpendicular angle to the collection, the use of an elevator, and ability to enter collections in the cardia or fundus in a retroflexed position. The disadvantages are lack of dedicated large-caliber needles that allow passage of 0.035″ guidewires and lack of ultrasound guidance to detect underlying vessels. Using a duodenoscope the puncture is performed "blindly" using electrocautery with a biliary needle knife or Cystotome (Cook Endoscopy, Winston-Salem, NC). Alternatively, a sclerotherapy needle can be used that accepts a 0.018″ guidewire (Marcon-Haber, Cook Endoscopy). The needle, however, is short and not designed for guidewire passage; the wire often does not pass through the sheath after it is angled. Exchanges are difficult, and the small-diameter wire is not sufficiently robust to allow accessories to pass

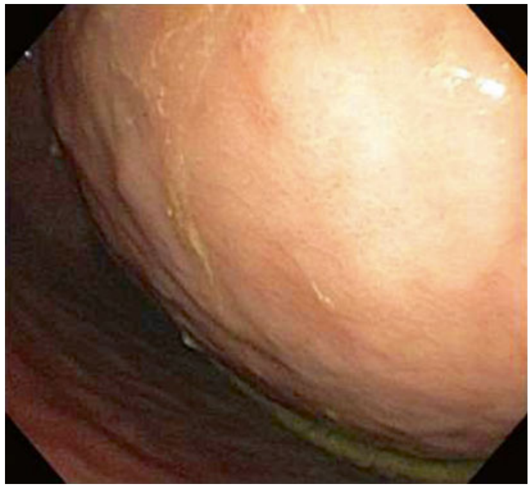

Fig. 14.1 Endoscopic image taken immediately prior to puncture of a large WON using a standard therapeutic duodenoscope

through the thicker gastric wall. In these cases, a triple-lumen needle knife or other cautery device is passed over the wire and into the cavity to allow entry and subsequent upsizing to a 0.035″ guidewire. Standard EUS needles are not long enough to pass through duodenoscopes.

Standard upper endoscopes can also be used to create the puncture, but a perpendicular approach to the posterior gastric wall may not be possible unless the collection is massively bulging into the gastric lumen so that an end-on view of the collection is feasible. However, a standard 19-gauge EUS needle will pass through a forward endoscope and obviates the need for changing endoscopes for subsequent DEN.

Most commonly, EUS-guided puncture is performed using an oblique endoscope. The advantages to EUS guidance are the ability to target the lesion, avoid large blood vessels, and assess the degree of underlying necrosis [17]. The disadvantages are the relative inflexibility, need to have a straight access due to stiffness of the needle, tangential nature of the puncture, and the tendency of the punctures to be more proximal both because of the access angle as well as the proximal location of the exit site relative to the transducer. While there are no data to show the more proximal locations are less effective, this author believes the angle into the cavity for DEN

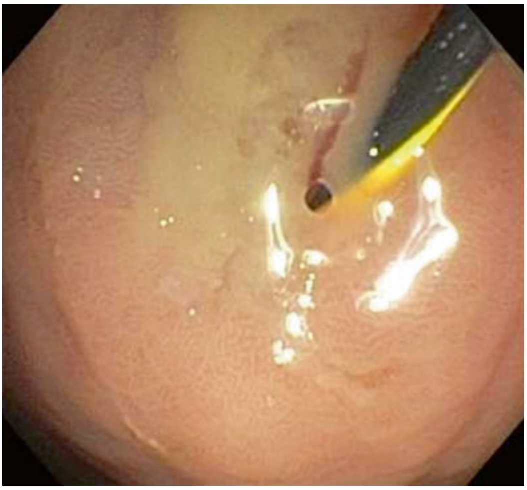

Fig. 14.2 Endoscopic image taken of gastric entry site immediately after puncture and guidewire placement into the cavity

Fig. 14.3 Endoscopic image taken during large-bore balloon dilation over the guidewire

may promote separation of the collection from the thinner, more proximal stomach when entered at a tangential angle and following large-diameter balloon dilation. Finally, the echoendoscope mechanics and optics are less favorable than ERCP endoscopes.

Recently, a forward-viewing echoendoscope has been used for the puncture and to perform DEN [18]. However, the forward view poses similar difficulties in entering 90° to the posterior gastric wall.

Another option for access is to use a spontaneous fistula tract in the stomach or duodenum [19]. A fistulous connection should be suspected in any patient with spontaneous air inside the cavity as this usually represents the fistula and not simply gas-producing organisms. These tracts are usually safe to dilate as lack of antecedent clinical bleeding suggests a vessel is not present along the tract.

Management of the Tract

Once the cavity has been successfully accessed (Fig. 14.2) the transmural tract is balloon-dilated (Fig. 14.3) to allow passage of a forward-viewing endoscope into the cavity. A minimum diameter of 15 mm is required. In some cases 20-mm dilation is performed at the time of initial puncture, though may be associated with higher risks of bleeding and perforation due to tearing of vessels and separation of the wall of the collection. At this point, some prefer to place one or more double pigtail stents prior to performing DEN. This is particularly useful when transgastric DEN is performed as it may be surprisingly difficult to identify the large puncture tract in the midst of gastric folds. It is less important to place plastic stents through the duodenum prior to DEN as it is usually not difficult to identify the dilated entry site.

Another option is to dilate the transmural site to a small diameter followed by placement of large bore (16–23 mm mid-body diameter) self-expandable metal stents (SEMS) across the gastric or duodenal wall for maintaining access for DEN (Fig. 14.4) [20–24]. In the U.S. the only large-diameter fully covered SEMS are esophageal with the shortest lengths being 6–7 cm. This is still relatively long compared to the distance between the lumenal site and the inside of the cavity and results in an excessive stent length inside the lumen or the cavity. Shorter-length devices (2 cm) with larger flanges are available outside of the U.S. and at least one is expected to receive FDA approval in the near future.

Fig. 14.4 Endoscopic image taken immediately after transgastric placement of a large-diameter fully covered self-expandable metal stent

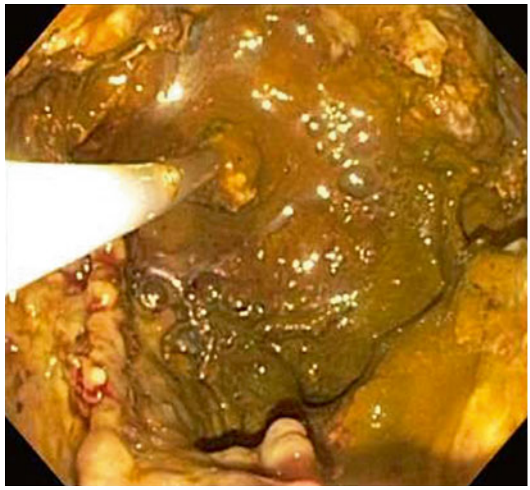

Fig. 14.5 Endoscopic image taken during DEN using a therapeutic upper endoscope. A snare can be seen grasping necrotic tissue

Necrosectomy

Once the access site is secured DEN is usually performed with a forward-viewing upper endoscope. Diagnostic channel scopes have the advantage of flexibility but the small working channel makes suctioning thick secretions difficult and also becomes filled with debris making it difficult to pass accessories for debridement. A therapeutic channel endoscope also has water jet capabilities to aid in loosening adherent necrosis. A jumbo channel endoscope with a 6-mm channel and dual suction designed for removal of clots during gastrointestinal bleeding can be used. This endoscope is rather inflexible but large fragments of necrotic debris can be suction once loosened into smaller fragments.

The endoscope is passed into the cavity (Fig. 14.5) and necrotic material is removed using mechanical measures. Accessories used include standard polypectomy snares, polyp retrieval nets, and grasping forceps. The most effective forceps have large, long prongs (Pelican-alligator forceps) rather than shorter, traditional rat-toothed forceps, which tear small pieces of tissue. I prefer to use spiral snares (Olympus Corporation, Center Valley, PA) to grasp and remove tissue. Unfortunately, these snares deform after many uses and it is not uncommon to use several during the course of one procedure. Once the tissue is grasped, it is withdrawn from the cavity and deposited in the lumen.

It is important to realize that not all necrotic contents have the same consistency. Some are large adherent, smooth, solid pieces that can be difficult to grasp with any device, whereas others are looser and more easily grasped. High flow through the scope irrigation is helpful for breaking up some types of necrotic tissue. Hydrogen peroxide irrigation has been used and may be useful in breaking down necrotic tissue during DEN [25], though comparative trials are lacking.

DEN can be a time-consuming, labor-intensive process. Many passages of the endoscope into and out of the WON are necessary. However, there does appear to be a learning curve that allows more material to be removed in a shorter period of time as experience is gained. Nonetheless, one should allow at least 90 min for the first access/debridement and 60 min for subsequent debridement procedures. The amount of time is dependent on many factors, which I often refer to as patients, patience and patients. These include patient and physician tolerance to the procedure (patients and patience) and number of cases yet to be done (patients). The goal is to remove as much necrotic tissue as possible in one session. A complete necrosectomy in one session is usually not possible, particularly when there is a large necrotic burden.

If stents were not placed prior to DEN, they are placed at the end of the procedure. Commonly two or more 7- to 10-Fr double pigtail stents are placed. Placement of a nasocystic irrigation tube is sometimes performed between DEN sessions, though the necessity of their use is not clear when DEN is used [26].

Subsequent DEN Procedures

The timing of subsequent DEN procedures has not been standardized. One approach is to perform scheduled, protocolized repeat necrosectomies [27]. The duration between procedures can be as short as 24 h or as long as several weeks. Inpatients who are debilitated and who may not be discharged soon after their first intervention can return frequently. In contrast, outpatients who are relatively well may return as outpatients on a weekly or biweekly basis. Additional considerations include the residual amount of necrotic material as determined by prior endoscopy or imaging (CT, MRI). One should consider limiting the number of CT scans in younger patients so as to minimize radiation exposure. Some patients improve dramatically after removal of the fluid component and can tolerate a moderate amount of residual necrotic debris, while others remain symptomatic. If patients develop infectious symptoms, they should return for urgent repeat necrosectomy and/or cross-sectional imaging.

Post-procedural Care

Outpatients who undergo necrosectomy can be managed as outpatients as long as the procedure was performed uneventfully and the patient meets discharge criteria. Antibiotics are continued perorally for at least several weeks and in most cases until the necrosis completely resolves. The patient may resume (or initiate) oral intake the day of the procedure, assuming no AEs occurred and there is no nausea, vomiting, or pain. Acid secretory agents should be withheld, if possible (absence of severe reflux esophagitis), as the presence of acid may reduce infection due to bacteriostatic properties and acid entry into the necrotic cavity could break down necrotic debris.

Repeat cross-sectional imaging is done on a case-by-case basis. Antithrombotic medications can be re-initiated approximately 24–48 h later, based upon risk of bleeding and thrombosis.

Management of Paracolic Gutter Extensions

Paracolic gutter extensions can be difficult to treat, particularly when extending well into the pelvis. The central areas of necrosis in the pancreatic bed are accessible and communicate with the paracolic extensions and are thus potentially amenable to necrosectomy.

Percutaneous DEN

Navarrete [28] and others [29, 30] have placed large-bore fully covered SEMS through percutaneous tracts to allow access for DEN using flexible endoscopes. This latter approach is similar to video-assisted retroperitoneal debridement (VARD) as performed by surgeons who pass rigid endoscopes through percutaneous drain tracts after dilation and/or incision of the tract [7]. This method is useful to treat paracolic gutter extensions, areas that have already been accessed with percutaneous drains but with inadequate drainage, and those collections that cannot be accessed translumenally. The timing varies between percutaneous drain placement and SEMS placement, depending on local practice. The SEMS remains in place with an ostomy bag over the stent between procedures. The SEMS is removed when the WON is completely evacuated and the space has collapsed.

Adverse Events

AEs can occur intra-procedurally or post-procedurally. Intra-procedural events include sedation, bleeding, and perforation.

Bleeding most often occurs at the entry site. Fortunately, it is usually self-limited and ceases by the end of the procedure. Uncontrolled or persistent bleeding can be managed by dilute epinephrine injection, balloon tamponade, clips, or electrocautery. Refractory or massive bleeding can be managed by placement of a large-diameter fully covered esophageal SEMS [31, 32]. Intra-cavitary bleeding is also usually self-limited. Severe intra-cavitary bleeding can be the most life-threatening and angst-producing for the physician. Hemostatic measures are similar to those for other bleeding including cautery and clip placement. If the bleeding is arterial, emergent embolization can be undertaken. Venous bleeding cannot be treated with interventional embolization techniques and may require surgery.

Perforation can also be at the entry site or at an intra-cavitary site. Intra-procedural perforation can result in tension pneumoperitoneum, a life-threatening emergency that requires prompt needle catheter decompression [33]. Similar to bleeding, perforation may occur at the entry site and may be managed with clips, diversion (in addition to internal pigtail stent placement), and placement of a large caliber SEMS [34]. Large intra-cavity perforations often require surgical or percutaneous management.

Air embolism can be silent, but often produces significant morbidity (stroke or spinal cord infarction) and can even result in procedural-related death [35]. It is believed to be preventable by the use of carbon dioxide for insufflation rather air, which should be utilized in all centers performing this procedure.

Introduction of organisms (bacteria and fungi) inevitably occurs during endoscopic intervention and may result in infectious complications. Thus, the need for removal of fluid and solid debris and administration of antibiotics are essential.

Outcomes

There are now many series demonstrating the efficacy of DEN [14–16, 36, 37]. However, one must be careful in interpreting the literature. For example, successful resolution can be defined as complete nonsurgical resolution, including the use of adjuvant percutaneous therapy or successful when only flexible endoscopic measures are used [15]. In addition, patients with WON are a heterogeneous group of patients based upon size of collection, total necrotic burden, paracolic gutter extension, nutritional status, comorbid medical illnesses, and time from onset of necrosis to intervention. This makes comparison of outcomes between centers and between disciplines difficult.

In a systematic review of more than 1,100 endoscopic necrosectomies in 260 patients the overall mortality was 5 % with a procedure-related morbidity of 27 %. Complete resolution of pancreatic necrosis using endoscopy alone was 76 %. However, these studies include all types of endoscopic interventions. Two large series of DEN [15, 16] showed successful resolution in approximately 90 % of patients with an adverse event rate of approximately 14 %. The median number of DEN procedures was 3.

Future Directions

Unanswered questions remain. Where does DEN fit into the management strategy of pancreatic necrosis? Is it the optimal type of endoscopic therapy? Where should DEN be performed—only in tertiary care centers or in high-level community care centers [38]? Should DEN be offered for otherwise healthy patients with sterile pancreatic necrosis who meet criteria for intervention and, if so, what is the optimal timing? Finally, can we predict which patients will fail endoscopic drainage? Unfortunately, an evidence-based approach to answer these questions is not possible at the present time.

DEN is a time-consuming, labor-intensive process not for the uncommitted [39] or faint of heart, since AEs occur more commonly than in any other pancreaticobiliary intervention and have the potential to be fatal [35]. Therefore, even more important, perhaps, is the need for support from a team of intensivists, endoscopists, surgeons, and interventional radiologists to manage these complicated patients (see Chap. 18).

Evidence in favor of endotherapy is evolving with work done by the Dutch Pancreatitis Group [8, 40] and others [26, 35, 41]. However, patients with pancreatic necrosis remain a heterogeneous group with regard to severity of illness and comorbid medical conditions at the time of intervention, because of surrounding inflammatory changes, location and extent of necrosis, and degree of underlying solid debris (necrotic tissue burden). These factors, coupled with variability in inter-center expertise of the various disciplines, means that the approach to these patients will never be standardized. Perhaps all we can hope for is the ability to tailor the best approach to the individual patient. We do believe, however, there will be unforeseen breakthroughs in endoscopic intervention as technology continues to evolve. The latter include new methods and devices to facilitate debridement, keep tracts into the necrotic cavity open to allow reintervention, and to preclude the long-term consequences of necrosis and a disconnected pancreatic duct to include recurrent fluid collections or attacks of relapsing pancreatitis.

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