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Endoscopic management of walled-off pancreatic necrosis

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ABSTRACT

Pancreatic necrosis, which can be associated with organ failure and infection, occurs in approximately 15% of patients with acute pancreatitis (AP). Indications for endoscopic or other interventions include infected necrosis or symptomatic sterile necrosis. Delayed intervention leads to improved outcomes, and it is generally recommended that interventions are performed at least 4 to 6 weeks after the onset of AP. It is also critical to accurately characterize the anatomical extent and level of organization of the necrosis and to preoperatively differentiate walled-off necrosis from pancreatic pseudocysts. Options for debridement include endoscopic transmural (transgastric or transduodenal) necrosectomy, percutaneous drainage alone, combined percutaneous and endoscopic drainage, and retroperitoneal, laparoscopic, or open surgical debridement. Most available data now support a "step-up" approach to the management of patients with severe AP complicated by infected or symptomatic walled-off pancreatic necrosis with more invasive options reserved for patients who do not respond to initial conservative management. Regardless of the approach to debridement used, patients with pancreatic necrosis, particularly those with infected necrosis, are best treated by an experienced multidisciplinary clinical team.

1. Introduction

Acute pancreatitis (AP) is the third most common gastrointestinal cause for hospitalizations in the United States; it is estimated that there are >243,000 hospital admissions because of AP each year, and approximately 4000 deaths annually are attributed to AP [1]. Among patients with AP, the vast majority of patients (85%) have interstitial pancreatitis but about 15% of patients have necrotizing pancreatitis [2,3]. Patients with necrotizing pancreatitis have an increased rate of multisystem organ failure and higher mortality (as high as 30% in infected necrosis), compared with patients with interstitial pancreatitis. Historically, the standard of care for infected necrosis, in addition to supportive intensive care, has been open surgical debridement. However, open surgery in these acutely ill patients is associated with substantial morbidity and mortality. Over the past 2 decades, several minimally invasive alternatives to open surgical debridement have gained acceptance including percutaneous, laparoscopic, endoscopic, or retroperitoneal drainage and debridement [3]. The objective of this review is to describe the general principles, current published techniques, and outcomes of endoscopic management of walled-off pancreatic necrosis (WOPN).

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2. Definitions and indications for intervention in pancreatic necrosis

The 1992 Atlanta Symposium defined pancreatic necrosis as diffuse or focal areas of nonviable pancreatic parenchyma typically associated with peripancreatic fat necrosis [4]. The initial phase (approximately 2 weeks) of necrotizing pancreatitis is usually characterized by a systemic inflammatory response syndrome and may be associated with multiorgan failure [2]. Mortality in this initial phase of AP is usually attributed to organ failure. Endoscopic or other interventions for pancreatic necrosis in this initial phase are relatively contraindicated because the necrosis is not organized and the outcomes are poor [5]. Over time, the systemic inflammation resolves and the necrotic collection evolves to become more defined and encapsulated. This defined collection has been described as organized or WOPN [6,7]. Approximately 30% of patients with pancreatic necrosis develop infected necrosis [5], which carries a substantially higher mortality rate and thus these patients require debridement, either through surgical, endoscopic, or other methods. Emerging data suggest that a small subset of patients with infected necrosis can be managed conservatively with antibiotics [5]. Asymptomatic sterile necrotic collections are usually managed conservatively. Debridement can be considered where the sterile necrotic collections result in anorexia, abdominal pain, or nausea and vomiting secondary to gastric outlet obstruction [2].

3. Diagnosis of pancreatic necrosis and differentiation from pancreatic pseudocyst

In addition to clinical criteria that predict necrosis, cross-sectional imaging with contrast-enhanced computed tomography (CT) scan is sensitive for detection of pancreatic necrosis, which, in the initial stages, manifests as lack of or decreased enhancement of pancreatic tissue. The usually accepted definition of necrotizing pancreatitis is the lack of enhancement in >30% of the pancreatic parenchyma [4]. Subsequently, the imaging findings correlate with the evolution and the progressive liquefaction of the areas of necrosis. WOPN characteristically appears as a well-circumscribed low attenuation collection that replaces the area of initial pancreatic necrosis and usually extends into the peripancreatic areas and paracolic gutters [8,9]. The differentiation between WOPN and pancreatic pseudocyst by imaging is a difficult but crucial distinction to make because the therapeutic approach and outcomes vary substantially [10]. Patients with pancreatic pseudocysts can typically be managed by endoscopic, surgical, or percutaneous drainage alone, whereas those with infected WOPN require some form of debridement along with drainage. In a retrospective study of 73 patients (45 WOPN and 28 pseudocysts) who eventually underwent endoscopic therapy, Takahashi et al. [8] described that larger size, extension to the paracolic space, irregular wall definition, presence of fat attenuation debris in the collection, and pancreatic deformity or discontinuity were predictors of WOPN. Presence of pancreatic ductal dilation was associated with a pseudocyst. Magnetic resonance imaging can be helpful for detection of solid debris within the collection, which represents pancreatic and peripancreatic fat necrosis [9].

Differentiation between sterile and infected necrosis is also important from a therapeutic perspective; signs of infected necrosis include clinical deterioration, fever, leukocytosis, persistent organ failure, or the presence of gas bubbles within the necrotic collection on CT (Fig. 1). However, clinical determination of infected necrosis can be difficult and may require percutaneous, ultrasound- or CT-guided aspiration with gram stain and culture [2].

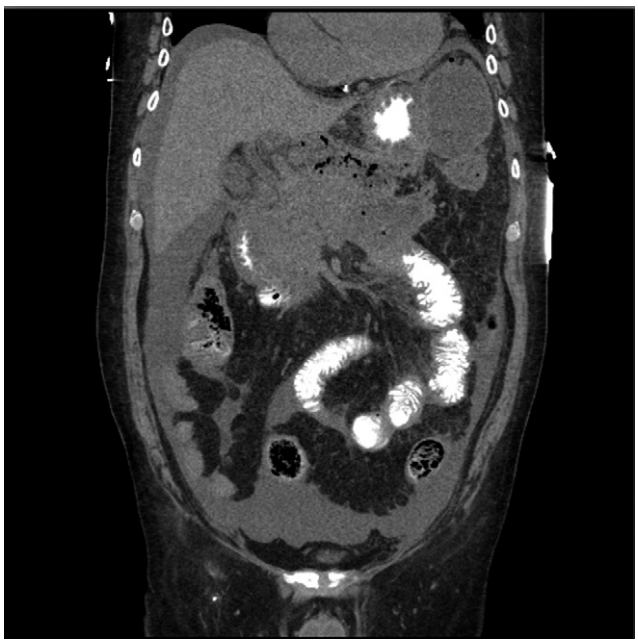

Fig. 1. Infected necrosis. Computed tomography scan demonstrating infected necrosis. Note the presence of air bubbles in the necrotic collection.

4. Timing of intervention

There is no clear consensus on the optimal timing of intervention in either infected or sterile pancreatic necrosis. Several studies suggest that early intervention (<2 weeks after onset) is associated with substantial morbidity and mortality and, therefore, is generally avoided [2,5,11]. Early surgical intervention is usually performed when there is suspicion of an abdominal catastrophe, and the mortality rate in these patients can be as high as 78% [5]. The timing of intervention in the late phase of AP varies substantially in the published series. In the initial report by Baron et al. [6] who pioneered endoscopic debridement, the mean time to intervention was 50 days (range 28-77 days). In a more recent multicenter United States study, the median time from the onset of pancreatitis to first endoscopic intervention was 46 days (range 6-510 days) [12]. Our group has previously reported a mean time to intervention of 44.5 ± 11.3 days among patients undergoing combined endoscopic and percutaneous drainage [13]. In a multicenter European series, the mean time to intervention was 41 days (4-158 days) [14]. In another large European cohort study, the median time from onset of symptoms to any intervention was 28 days (interquartile range (IQR) 22-41 days) [5]. However, the primary intervention in 63% of patients in this study was catheter drainage (endoscopic or percutaneous) followed later by endoscopic necrosectomy. Collectively, these studies suggest that drainage or debridement is generally performed around 4 to 6 weeks from the onset of AP. The timing of intervention in an individual patient is usually decided by the clinical status and indication (organ failure vs symptoms) and the degree of organization of the necrotic collection.

5. Techniques for endoscopic management of WOPN

5.1. Endoscopic necrosectomy

The endoscopic approaches and techniques in the management of WOPN have evolved considerably since the initial report by Baron et al. in 1996 [6]. In the initial report, access, using a needle–knife sphincterotome, was gained into the necrotic collection through a transgastric or transduodenal approach using an endoscopic bulge as the point of entry. The tract was then dilated to 8 mm and 2 10F double-pigtail stents were placed. This technique was modified to include daily saline lavage through 7F nasobiliary pigtail drain placement adjacent to the stents after infections occurred in the patients undergoing transgastric stent placement alone. The technique further evolved to include larger balloon dilation (up to 20 mm) of the entry tract and passage of various devices including extraction balloons and baskets through the entry tract (Figs. 2 and 3).

Subsequently, direct endoscopic necrosectomy (DEN) was developed with the passage of the endoscope through the transmural entry tract and debridement performed using a variety of routinely used endoscopic accessories including snares, net, baskets, or forceps [7,12,15]. Specific tools for endoscopic debridement and transmural entry are being developed but are generally suboptimal compared with accessories available for laparoscopic or retroperitoneal debridement. Following reports of air embolism associated with the procedure [12,16], many centers now routinely use carbon dioxide instead of air. Whether DEN is performed at the time of initial endoscopy is variable as is the amount of debridement performed at each procedure. The eventual goal is the removal of the entire devitalized pancreatic tissue such that the pink granulation tissue lining the cavity is visualized [7,17].

5.2. Role of endoscopic ultrasound (EUS)

Increasingly, EUS with color Doppler is being used to gain initial access into the necrotic cavity and avoid vasculature within the wall of the cavity [17,18]. A prospective comparison of EUS-guided versus endoscopic puncture in patients with WOPN undergoing DEN has not

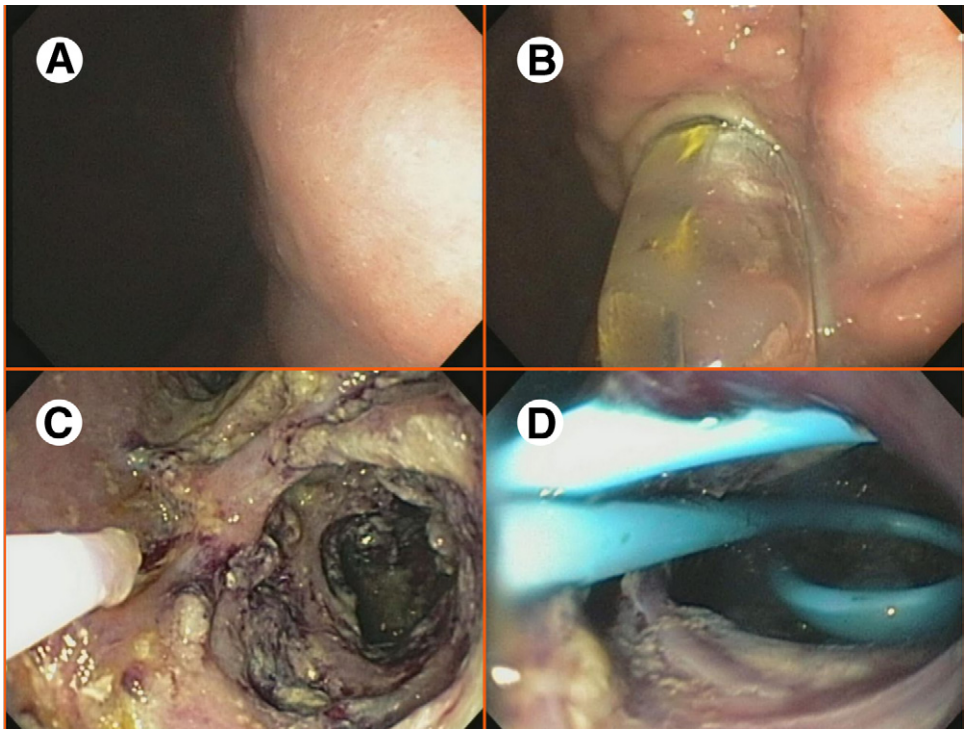

Fig. 2. Direct endoscopic necrosectomy. (A) Endoscopic bulge noted in the stomach, (B) balloon dilation of the transgastric entry point, (C) endoscopic view of the necrotic cavity, (D) placement of 2 double-pigtail stents after debridement.

been performed. In one case series, the incidence of bleeding complications, either at the time of initial entry or at the time of necrosectomy, was not lower with the use of EUS [19].

When EUS is used, a EUS-guided transgastric or duodenal puncture is made with a 19-gauge needle, and after sampling of the fluid for culture, a 0.035-inch guidewire is coiled into the cavity. Further dilation of the tract is gained by advancing a cystenterotome (Wilson Cook, Winston Salem, NC), a graduated-dilating catheter, or a cannula with subsequent dilation using an 8- to 10-mm controlled radial expansion balloon dilator [17,20,21]. In some cases, passage of the bal-

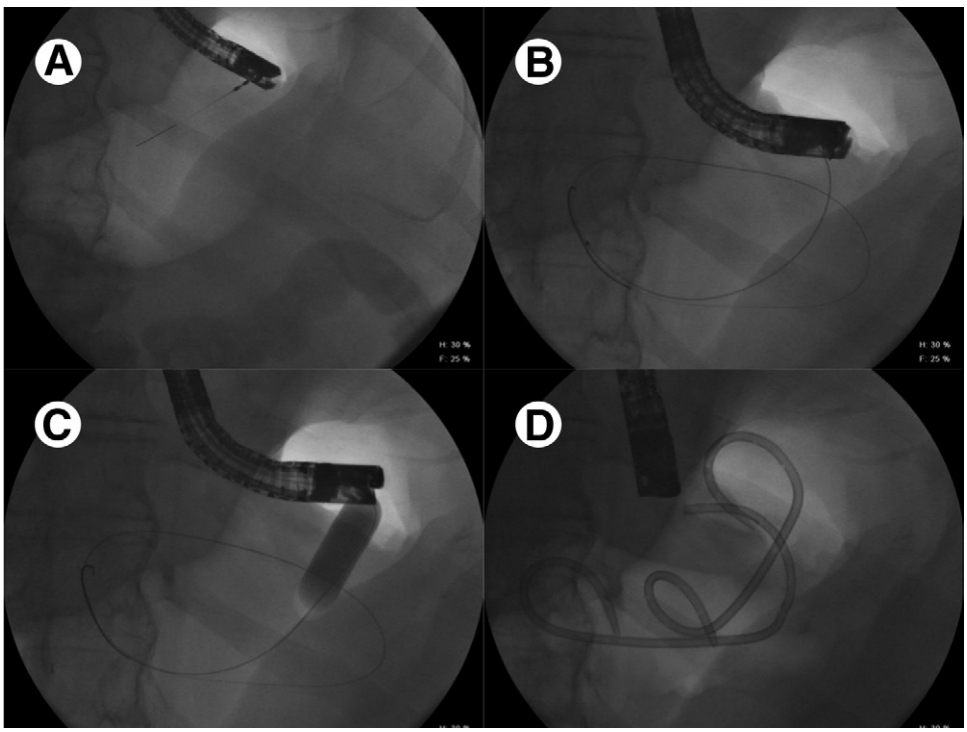

Fig. 3. Fluoroscopic view of necrosgastrostomy corresponding to procedure from Fig. 1. An initial transgastric approach is created (panel A), a 0.035-inch guidewire is placed into the collection (panel B), balloon dilation of the tract is performed (panel C), and double-pigtail stents are placed (panel D).

loon dilator may proceed directly without the need for initial dilation as described previously. Next, 2 or more double-pigtail stents (7F) are deployed through the echoendoscope. The site is usually accessed a few days later and the tract dilated to 15 to 20 mm followed by DEN. Dilation up to 20 mm and DEN at the time of the initial EUS-guided access has also been reported [12].

Varadarajulu et al. [20] recently reported a EUS-guided technique of multiple sites of transluminal drainage; double-pigtail stents and a nasocystic drain are placed into one of these sites and only double-pigtail stents are placed in the other sites. They reported treatment success in 91% of patients (n = 12) compared with 52% (n = 48) for conventional drainage (one site through which nasocystic drain and double-pigtail stents were placed).

5.3. Percutaneous drains

Percutaneous drainage catheters, placed by interventional radiology, are often used alone for the treatment of infected WOPN or as an adjunct to DEN when the necrotic collections extend widely into the paracolic gutters or into the pelvis and for loculated aspects, which are not accessible to DEN. In a large series of patients treated with percutaneous drainage alone, there was a high rate of clinical success with single-digit mortality [22]. The major drawback to this approach is a rate of pancreaticocutaneous fistula formation, which approaches 21%, occurring almost exclusively in patients with the disconnected pancreatic duct syndrome. In a series of 53 patients treated by DEN, Baron et al. [6] reported that adjuvant percutaneous drains were used in 40% of patients. In other series, about half of patients underwent initial percutaneous drainage and were then referred for endoscopic treatment when their clinical status did not improve [14,21].

5.4. Combined modality drainage

In an effort to decrease the incidence of pancreaticocutaneous fistulae seen in patients treated by percutaneous drainage alone, a hybrid approach that includes a combination of endoscopic and percutaneous drainage has been developed [23]. In this technique, initially a CT-guided percutaneous drain is placed by interventional radiology and a small sample (≤10 mL) is sent for gram stain and culture. The percutaneous drain is clamped and the patient is then transferred to the endoscopy suite and a necrogastrostomy or necroduodenostomy is performed similar to the technique described previously and 2 or more 7 to 10F double-pigtail stents are placed (Fig. 4). Unlike DEN, the endoscope is not passed into the necroma because the debridement is performed mechanically by flushing the large-caliber percutaneous drains. Subsequently, patients are followed clinically and with interval imaging in 1 to 2 weeks and as clinically indicated thereafter. The percutaneous drains are gradually upsized, as needed, to a maximum of 30F and may also require repositioning within the necrotic cavity. When there is radiologic resolution of the collection, the percutaneous drain is capped and CT scan repeated in 2 weeks. If there is no reaccumulation of fluid, the percutaneous drain is removed. Pancreatography, either endoscopic or by magnetic resonance cholangiopancreatography is performed to identify pancreatic leaks or a disconnected pancreatic duct. If there is a disconnected pancreatic duct, the endoscopic stents are left indefinitely.

5.5. Adjunct procedures

Placement of a percutaneous endoscopic gastrostomy tube with a jejunal extension placed into the necrotic cavity for irrigation has been described but is not commonly performed in clinical practice [24]. Several authors have reported the placement of fully or partially covered metal stents across the gastric wall to maintain patency of the necrogastrostomy, thus permitting larger diameter drainage compared with double-pigtail stents [25-27]. However, migration of the stent into the necrotic cavity, as well as embedding of the uncovered portion of the stent into the gastric wall, remains a concern.

6. Outcomes and complications of endoscopic management of WOPN

In the initial series of 11 patients reported by Baron et al. [6], endoscopic drainage was achieved in 9 (81%) patients. Procedure-related complications including procedure-induced infection of the necrosis, bleeding, and gastric perforation occurred in 5 patients. In a subsequent report, the same group reported successful transmural endoscopic debridement in 43/53 (81%) patients with infected and sterile necrosis [7]. Twelve patients (23%) required open surgical intervention after endoscopic intervention. Gardner et al. [12], in 2011, reported the results from a US multicenter series on DEN for the treatment of WOPN in 104 patients. They reported success, which they defined as complete or near-complete resolution of WOPN without surgical or percutaneous drainage, in 95/104 patients (91%). The mean time to resolution was 4.1 months after the first endoscopic intervention. They reported complications in 14% of patients; major complications included 1 periprocedural death from possible air embolism, 1 major bleed requiring operative intervention and 1 bleed requiring embolization as well as 5 retrogastric perforations, which were managed nonoperatively. In this series, approximately 60% of patients

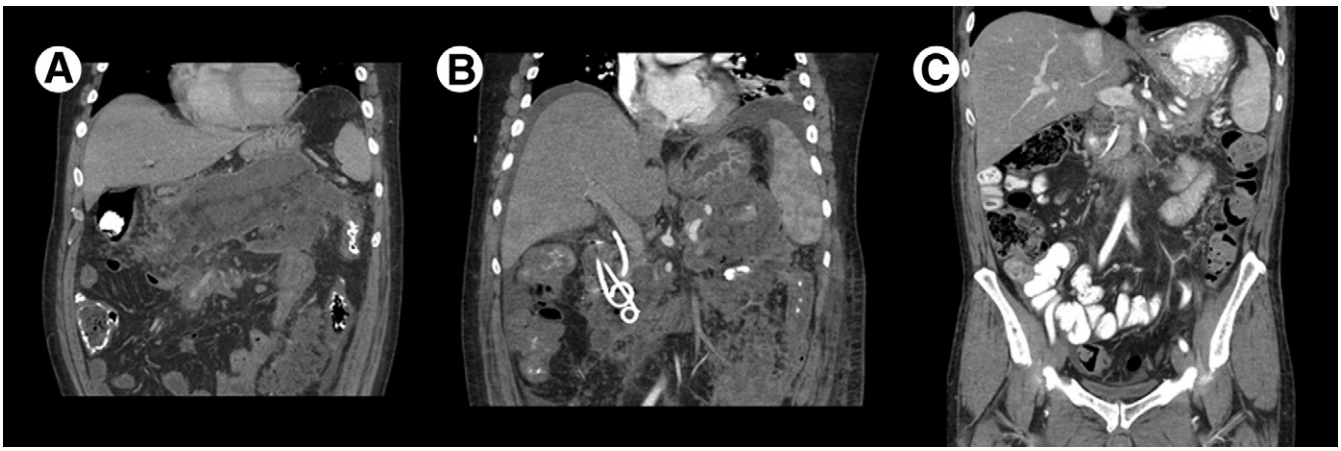

Fig. 4. Combined modality drainage, which includes percutaneous drainage combined with endoscopic necrogastrostomy or duodenostomy. Computed tomography scans showing walled-off pancreatic necrosis (panel A), placement of transgastric stents and percutaneous drainage catheter (panel B), and resolution of the necrotic collection (panel C).

were suspected clinically to have infected necrosis and 38% had infection documented with culture.

Several large European series have also been published on the outcomes of endoscopic therapy for WOPN. In 2007, in a report of 25 patients on whom DEN and nasocystic drainage were performed, Voermans et al. [17] noted resolution of the collection in 93% of patients for a median follow-up of 16 months. Seifert et al. [14], reported long-term data on 93 patients from 6 centers; initial clinical success was achieved in 80% and at a mean follow-up of 43 months, 84% of these patients had sustained clinical improvement. Seewald et al. [16] reported a long-term success rate of 72% for a mean follow-up of 31 months (n = 80) in a retrospective series that included pseudocysts and necrosis. In a systematic review of endoscopic necrosectomy in 260 patients from 10 studies, the overall success rate was 76%, mortality was 5%, and morbidity was 27% [28].

In the only comparative randomized trial of endoscopic versus surgical necrosectomy (n = 22), patients who underwent endoscopic necrosectomy had lower postprocedural inflammatory response as measured by interleukin 6 levels and lower risk of major complications including new organ failure, bleeding, fistulae, and death [21].

In the largest series on necrotizing pancreatitis published to date, the Dutch Acute Pancreatitis Group reported data on 639 consecutive patients [5]. Conservative management was successful in majority of patients (62%). Overall, mortality in the conservatively treated group was 7%. Conversely, 33% of patients had an intervention for infected necrosis with a mortality rate of 19%. Of note, percutaneous catheter drainage was the most frequently performed initial intervention and subsequent debridement was primarily surgical with only a few patients undergoing endoscopic necrosectomy. This study does highlight that the majority of patients with necrotizing pancreatitis can be managed conservatively without any intervention and, where required, a "step-up" approach to management should be considered.

One drawback of DEN has been the number of endoscopic procedures required to achieve complete resolution. In the United States multicenter series, the median number of necrosectomies was 2 (range 1-13), and overall, a median of 3 endoscopic procedures (range 1-14) were needed [12]. In the randomized trial comparing endoscopic versus surgical necrosectomy, the median number of endoscopic procedures was also 3 (IQR 2-6) compared with 1 (IQR 1-2) [21]. Other series have reported a mean of 6.2 procedures (range 1-35) [14]. In a systematic review of 10 studies, the median number of procedures was 4 (range 1-35) [28]. The need for multiple procedures may partly be related to the lack of dedicated accessories for endoscopic necrosectomy such that debridement is carried out by an assortment of currently available endoscopic tools that have been developed for other purposes.

Combined modality drainage with endoscopic transmural stent placement and percutaneous drainage also appears to be an effective and minimally invasive approach to the management of WOPN [13,23,29]. In a retrospective analyses of patients treated with standard percutaneous drainage (n = 46) compared with patients treated with combined modality drainage (n = 49), Gluck et al. [29] reported that the latter group had shorter length of hospitalization (54 ± 41 vs 24 ± 23 days, $P < 0.01$) and time to drain removal (183 ± 161 vs 79 ± 44 days, $P < 0.01$) and fewer CT scans, drain studies, and endoscopic retrograde cholangiopancreatographies. The rate of resolution of WOPN was also higher in the combined modality group (80% vs 96%). The authors reported 12 complications in the combined modality group, primarily abscess formation in the noncommunicating aspects of the collections, which were treated with new drain placement. Of note, there were no major procedure-related complications reported. Three patients in the standard percutaneous drainage group required surgery for persistent fistulae compared with none in the combined modality group.

7. Surgical management of endoscopic complications and failures

Surgical backup by an experienced pancreatic surgeon is critical to optimal multidisciplinary management of patients with WOPN. Surgical intervention may be needed for management of endoscopic complications, such as major bleeding or perforation, and for persistence of WOPN despite endoscopic debridement. In the United States multicenter series, 1 of 104 patients required surgical control of bleeding that occurred at the time of balloon dilation of the entry site [12]. Retrogastric perforations in this series were treated successfully with bowel rest and antibiotics and did not require surgical intervention. Papachristou et al. [7] reported that surgical intervention was required in 23% of patients after endoscopic drainage or debridement because of persistence of WOPN, pancreaticocutaneous fistulae, and recurrent collections not amenable to endoscopic drainage. In the GEPARD study [14] of long-term follow-up of 93 patients with WOPN, 18/93 (19%) failed endoscopic therapy; 12 of these 18 patients had surgery and majority (73%) were successfully treated. In addition, 4 patients required emergency surgery for management of bleeding or perforation. In the subset of patients with successful endoscopic drainage, 4% required subsequent surgery for recurrence of their collections.

In an analysis of surgical intervention after endoscopic management of all pancreatic fluid collections including WOPN (n = 88), Evans et al. [30] reported that the major indications for surgery were persistent symptoms (28%), anatomy not feasible for further endoscopic drainage (26%), common bile duct or pancreatic duct strictures (18%), and clinical deterioration or infection (16%). However, surgery in this group of patients was associated with a 56% complication rate including 3 deaths.

In sum, these data suggest that surgical intervention may be required in a small subset of patients in the initial stages where either endoscopic debridement is not technically possible, is associated with major complications (bleeding and perforation), or is unsuccessful. Persistent or recurrent collections may also require surgical debridement in the later stages of the disease. Surgery in patients with WOPN is associated with substantial morbidity, and minimally invasive approaches may have better outcomes compared with open necrosectomy.

8. Conclusions

Our understanding of the various phases and manifestations of necrotizing pancreatitis and associated complications and the best approaches to managing these issues has evolved considerably over the past 2 decades. The recognition of WOPN as a different entity from other pancreatic fluid collections has changed our approach substantially. Indications for debridement, by any modality, are infected necrosis or symptomatic sterile necrosis. However, it is being increasingly recognized that patients should be managed in a "step-up" approach starting with conservative management and moving progressively to more aggressive interventions—percutaneous drainage, endoscopic necrosectomy, combined modality drainage, or surgery—as clinically indicated. In addition, the data are clear that intervention should be delayed as long as possible because early intervention is associated with increased mortality. The treatment strategy and approach to an individual patient with WOPN depend on the expertise available at each center and can include either endoscopic necrosectomy, percutaneous drainage, combined modality drainage, laparoscopic or retroperitoneal debridement, or open surgical necrosectomy. Regardless of the technique used, a multidisciplinary approach to management of these extremely ill and clinically complex patients is essential to achieving the best possible outcomes.

Acknowledgments

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