



## Interventions for walled off necrosis using an algorithm based endoscopic step-up approach: Outcomes in a large cohort of patients



Yukako Nemoto <sup>a, b, c</sup>, Rajeev Attam <sup>a, d</sup>, Mustafa A. Arain <sup>a</sup>, Guru Trikudanathan <sup>a</sup>, Shawn Mallery <sup>a</sup>, Gregory J. Beilman <sup>e</sup>, Martin L. Freeman <sup>a, \*</sup>

<sup>a</sup> Division of Gastroenterology, Hepatology and Nutrition, University of Minnesota, United States

<sup>b</sup> Division of Gastroenterology and Hepatology, Department of Internal Medicine, Toho University Ohashi Medical Center, Japan

<sup>c</sup> Department of Gastroenterology, Kohsei Chuo General Hospital, Japan

<sup>d</sup> Advanced Endoscopy, Southern California Permanente Medical Group, Kaiser Permanente Downey, United States

<sup>e</sup> Department of Surgery, University of Minnesota, United States

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### ABSTRACT

**Objectives:** The minimally invasive step-up approach for treatment of walled off necrosis (WON) involves drainage followed by later necrosectomy as needed, and is superior to primary surgical necrosectomy. Reported series of endoscopic transluminal necrosectomy include highly selected patients. We report outcomes of a large series of patients with WON managed by an algorithm based on an endoscopically centered step-up approach.

**Methods:** Consecutive patients with necrotizing pancreatitis from 2009 to 2014, with intervention only for infected or persistently symptomatic WON. The primary approach involved endoscopic transluminal drainage plus minus necrosectomy whenever feasible, with percutaneous catheter drainage (PCD) plus minus sinus tract endoscopy if not feasible or sufficient. Surgery was reserved for failures of the step up approach.

**Results:** Of 109 consecutive patients with necrotizing pancreatitis, intervention was required in 83, including endoscopic transluminal drainage in 73 (88%) (alone in 49 and combined with PCD in 24), and PCD alone in 10 (12%). 64 (77%) of the 83 patients required endoscopic transluminal and/or sinus tract necrosectomy. Adverse events occurred in 11 (13%). Three patients (4%) failed step up approach and required open surgical necrosectomy. All-cause mortality occurred in 6 (7%) of 83 patients after intervention, including 2 of 3 requiring surgery.

**Conclusions:** An algorithm based step-up approach for interventions in necrotizing pancreatitis using primarily endoscopic techniques with adjunctive percutaneous approaches as needed resulted in favorable outcomes with small numbers proceeding to open surgery, and with acceptable rates of major complications and mortality. A purely endoscopic transluminal approach was feasible in approximately 60% of patients requiring intervention in this series.

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### 1. Introduction

Walled off necrosis (WON) occurs in the context of necrotizing pancreatitis and can be intra-pancreatic, extra-pancreatic, or both. WON present as heterogeneous collections with varying degrees of liquid and solid material. WON evolve from acute necrotic

collections and typically occur 4 or more weeks after the onset of acute pancreatitis [1–3].

While open surgical necrosectomy was the mainstay of management in the past, several studies have demonstrated that a step-up approach based on minimally invasive techniques improves patient outcomes. Such an approach has been endorsed by a number of recent multi-disciplinary consensus statements [2–5]. Minimally invasive therapies fall into three broad categories: endoscopic transluminal drainage and necrosectomy, image-guided percutaneous approaches, and laparoscopic or retroperitoneal surgical techniques [2–14]. Such interventions, as

\* Corresponding author. University of Minnesota, 420 Delaware St SE, Minneapolis, MN 55455, United States

E-mail address: [freem020@umn.edu](mailto:freem020@umn.edu) (M.L. Freeman).

demonstrated in randomized controlled trials, can serve as alternative approaches resulting in improved patient outcomes [6–9]. The goal of these techniques is to provide minimal access drainage and necrosectomy equivalent to open necrosectomy.

While endoscopic transluminal drainage (ETD) and endoscopic transluminal necrosectomy (ETN) have become increasingly widespread, almost all of the published reports consist of cases series with patients carefully selected who were felt to be suitable for endoscopic management, and excluding those with anatomically unfeasible collections and those in whom transluminal approaches would be likely to fail [15–21]. The use of adjunctive techniques such as percutaneous catheter drainage has been highly variable. The main limitation of these series is the lack of a context for endoscopic, percutaneous and other forms of intervention, and lack of information about patients not requiring intervention.

More than 7 years ago, our center developed an algorithm for interventions in necrotizing pancreatitis based on a step up approach, beginning with drainage via a primarily endoscopic route, followed by endoscopic necrosectomy as needed, but with utilization of percutaneous catheter drainage and sinus tract endoscopic necrosectomy as adjunctive approaches for extensive collections and as the primary approach for collections which could not be approached via an endoscopic transluminal route [21] (Fig. 1). We report outcomes of a large consecutive series of patients with necrotizing pancreatitis managed via this algorithm.

## 2. Patients and methods

This was a retrospective, nonrandomized, observational study of consecutive patients managed between 2009 and 2014 at the University of Minnesota Medical Center, a tertiary pancreaticobiliary referral center in a metropolitan area of approximately 3 million population. All patients with severe acute pancreatitis were consulted by or managed by a pancreatic team consisting of interventional endoscopists, critical care surgeons,

interventional radiologists, and hospitalists. Decisions for intervention were made by this team, and reviewed on an ongoing basis at a weekly conference. Before the first intervention, all patients underwent abdominal and pelvic CT, with further imaging by MRI as clinically indicated. A prospective registry was maintained of all patients entering this facility with the diagnosis of necrotizing pancreatitis. Indications for intervention were according to published guidelines [2,3]. Included in the current study were patients undergoing intervention for persistently symptomatic or infected WON measuring over 5 cm in size. Infection was defined as any one of the following: 1) positive microbiological culture from fine-needle aspiration before necrosectomy, 2) positive culture from catheter drainage before necrosectomy, 3) positive culture from first necrosectomy. Excluded from the study were patients undergoing initial intervention at outside facilities prior to transfer, and those with follow-up of less than 60 days. The study was approved by the Institutional Review Board.

## 3. Interventional methods

### 3.1. Algorithm

A flow diagram for interventions in WON based on multidisciplinary management of necrotizing pancreatitis at our center which was focused on ETD/ETN when feasible is shown in Fig. 1.

Primary focus of endoscopic therapy was to provide transluminal drainage (ETD). Endoscopic transluminal necrosectomy (ETN) was performed on “as needed” basis at subsequent sessions. ETD was performed with endoscopic ultrasound guidance and fluoroscopy under general anesthesia in an advanced endoscopy interventional suite integrated into the main operating rooms. All initial drainage procedures were performed by one of 4 experts in interventional endoscopic ultrasound. Cross sectional imaging was reviewed prior to the endoscopic procedure. Appropriate site for ETD was chosen after excluding intervening blood vessels with

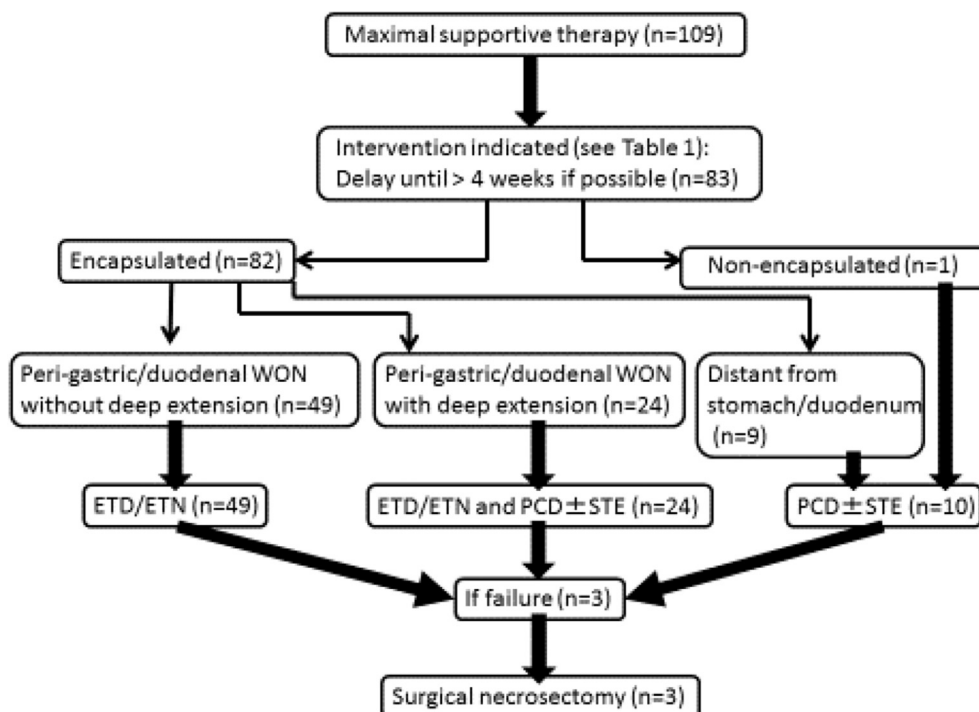


Fig. 1. Algorithm for interventions for collections associated with necrotizing pancreatitis based on a step-up approach.

Doppler examination. Access was achieved via cystotome electrocautery or needle puncture followed by guide wire placement and coiling within the collection under fluoroscopy. Subsequent, balloon dilation was performed to diameters ranging from 8 to 15 mm. Finally, transmural stents (7 or 10 French double pigtailed, 10–18 mm fully covered self-expanding metal stents or 26 mm uncovered self-expanding metal stents) were placed. Lumen apposing metallic stents were not available during this study. Nasocystic catheters were not placed in this series. ETN was performed only at repeat procedures as dictated by evolution of the cavity and clinical course after there had been time for decompression of purulent contents. For ETN, a forward- or side-viewing endoscope was inserted into the cavity. Under direct visualization, solid material was debrided by forceful irrigation-suction with normal saline, and the utilization of accessories such as baskets, caps, nets and snares. Decision to repeat ETN at subsequent sessions was based on clinical progress and evolution of the collection on serial imaging.

Percutaneous catheter drainage (PCD) was performed by the Interventional Radiology Service under CT guidance, and always via a retroperitoneal route if feasible. Catheters were exchanged and upsized to allow for more effective irrigation. Drain size ranged from 8 to 24 French. Vigorous catheter irrigation (100–200 cc sterile NS or water) was performed at the bedside in patients with combined endoscopic and percutaneous drainage, usually once every 8 hours.

Sinus tract endoscopy (STE) was performed in collections refractory to percutaneous catheter lavage and endoscopic necrosectomy, (Fig. 2). STE was performed by interventional endoscopists under general anesthesia in the operating room, often in conjunction with ETN, and utilizing the same equipment and techniques as ETN, via a flexible upper endoscope passed only through a retroperitoneal percutaneous catheter tract. STE was performed after upsizing to 24F or greater, with or without balloon dilatation of the percutaneous drain tract.

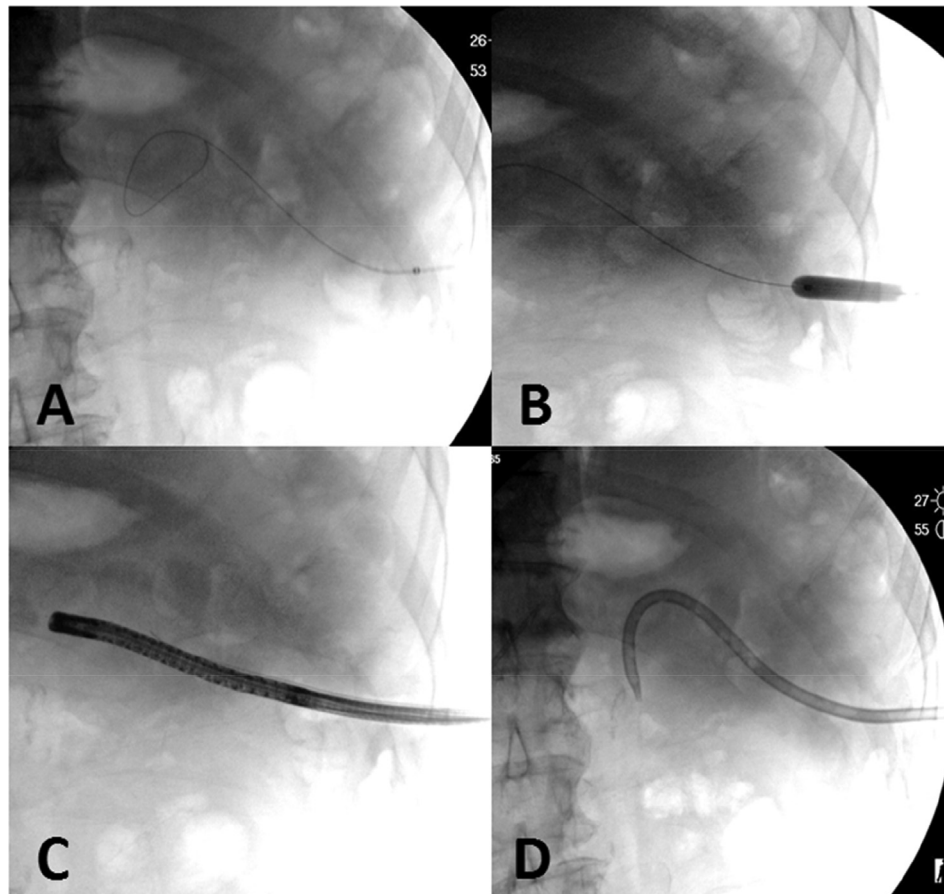
#### 4. Definitions

Treatment success was defined as reduction in WON size to 2 cm or decrease in size by 25%/2 weeks on follow-up abdominopelvic CT within 12 weeks, with symptom resolution. Treatment failure was defined as persistence of WON on follow-up CT within 12 weeks, need for surgical necrosectomy or disease-related death.

#### 5. Results

109 patients with necrotizing pancreatitis were managed between 2009 and 2014. Five patients were excluded from the data analysis because of interventions done prior to transfer to our institution.

Mean age of patients in this series was 49.4 years (range 11–87), and mean BMI was 29.3 kg/m<sup>2</sup> (range 16.6–51.1). The mean largest-



**Fig. 2.** Fluoroscopic images of sinus tract endoscopy (STE), elected for additional necrosectomy when endoscopic transluminal necrosectomy and percutaneous catheter drainage were insufficient.

A: Wire placed as PCD removed; B: Tract dilation with balloon dilator; C: STE performed using an endoscope; D: PCD replaced after endoscopic necrosectomy.

**Table 1**  
Patient demographics.

Demographic and clinical characteristics	Patients undergoing Intervention (n = 83)
Female/male	26/57
Age, mean (range), years	49.4 (11–87)
BMI, mean (range), kg/m <sup>2</sup>	29.3 (16.6–51.1)
Etiological factors, n (%)	
Gallstone	35 (42)
Alcohol	22 (27)
Others	26 (31)
DM, n (%)	22 (27)
APACHE-II score, mean (range)	5.8 (0–25)
CTSI, mean (range)	7.0 (3–10)
Size of collection, mean (range), cm	13.0 (5.0–30.3)
Indications for intervention, n (%)	
Persistent symptoms	36 (43)
Infection	33 (40)
Gastric outlet, intestinal or biliary obstruction	14 (17)

diameter of the collection was 13.0 cm (range 5.0–30.3). Gallstones and alcohol were the leading cause of pancreatitis.

Interventions were required in 83 (76%), including endoscopic in 73 (88%) (alone in 49, and combined with PCD in 24); incorporating dual duodenal + gastric cystenterostomy in 9 (11%) of 83. Self-expanding metal stents were placed in cystenterostomies in 26 (31%) and pancreatic duct stents were placed in 48 (58%) of 83. 64 patients (77%) of 83 required transluminal or STE necrosectomy. Mean number of endoscopic interventions was 3.8 (range 1–9). Mean duration between onsets of pancreatitis to first intervention was 61 days (range 10–336 days). Mean ICU length of stay was 2.3 days (range 1–6 days) and hospital length of stay was 22 days (range 0–147 days). Mean duration of hospital free days in the first 90 days was 70 days (range 5–90 days).

Patient demographics are shown in [Table 1](#).

Adverse events were seen in 11 (13%) during or after endoscopic interventions. Bleeding was seen from the margin or the tract of cystgastrostomy in 7 patients and was treated endoscopically; injection with a 1:10,000 solution of epinephrine, and superficial coagulation using bipolar probe, hemostatic clips, or placement of a fully covered metal stent for tamponade. Two patients had major hemorrhage in the WON and required angiographic intervention.

**Table 2**  
Demographic and clinical characteristics according to treatment approach.

	ETD/ETN (n = 49)	ETD/ETN and PCD (n = 24)	PCD (n = 10)
Female/male	12/37	10/14	4/6
Age, mean (range), years	49.8 (11–87)	50.6 (12–84)	45.1 (23–60)
BMI, mean (range), kg/m <sup>2</sup>	27.7 (16.6–38.9)	32.1 (20.4–51.1)	30.0 (23.6–36.3)
Etiological factors, n (%)			
Gallstone	22 (45)	9 (38)	4 (40)
Alcohol	15 (31)	6 (26)	1 (10)
Others	12 (24)	9 (38)	5 (50)
DM, n (%)	14 (29)	7 (29)	1 (10)
APACHE-II score, mean (range)	4.3 (0–14)	7.9 (0–25)	8.2 (0–17)
CTSI, mean (range)	7.0 (3–10)	6.6 (3–10)	7.7 (3–10)
Size, mean (range), cm	12.1 (5.0–22.7)	14.1 (6.0–30.3)	14.8 (7.4–23.1)
Necrosectomy required (ETN or STE) n (%)	44 (90%)	18 (75%)	2 (20%)
Indications for intervention, n (%)			
Persistent symptoms	27 (55)	7 (29)	2 (20)
Infection	10 (20)	15 (63)	8 (80)
Gastric outlet obstruction	12 (25)	2 (8)	0
Duration between onset to intervention (days)	65 (20–336)	48 (10–133)	68 (18–144)
Hospital length of stay (days)	17 (0–147)	31 (0–108)	24 (4–82)
Hospital free days in the first 90 days	76 (9–90)	59 (5–89)	65 (8–86)
Follow up duration (days)	260 (60–938)	244 (60–942)	166 (67–279)
Treatment success, n (%)	42 (86)	14 (58)	7 (70)

Symptomatic perforation occurred after ETN in one patient. In this patient, CT demonstrated a very large amount of peritoneal free air, and exploratory laparotomy demonstrated septic peritonitis from a posterior gastric perforation. Air embolism occurred in one patient prior to introduction of CO<sub>2</sub> insufflation, and resulted in fatality.

Successful resolution of walled off necrosis was achieved in 61 patients (73%) following a mean of 3.8 (range 1–9) endoscopic necrosectomy sessions.

PCD was used primarily or in adjunct to ETN in 20 (24%), 10 (12%) had PCD alone and 24 had ETN/ETD + PCD (29%). The percutaneous catheters were left in place for an average of 3 months (range 14–353 days). Persistent external fistula occurred in 2 patients after PCD. Enterocutaneous fistula in one patient was treated with temporary wound closure with a split thickness skin graft followed by eventual surgical takedown of enterocutaneous fistula. Others were managed by graded withdrawal of PCD catheter drains and wound care.

In 24 (29%) of patients the cystenterostomy stents were left in place indefinitely. Recurrent cavity formation was seen in 8 (6%) cases; 7 cases without transmural stents and in one case with transmural stents during a mean follow-up period of 10 months. Five of these patients needed no further intervention. One patient without transmural stent developed a fistula and a recurrent left lower abdominal abscess. He was treated with EUS guided pancreatic duct reconnection. Another patient subsequently developed a collection in the tail and body of the pancreas 5 months after the first ETN and was treated with EUS guided cystgastrostomy. The patient who developed recurrence of a collection in spite of retained transmural stents failed EUS guided retreatment and was subsequently managed with distal pancreatectomy.

Technical success rate was 96% (80/83). Treatment success was 73% (61/83). Three (4%) of 83 patients failed the step-up approach with persistent or worsening organ failure and sepsis and required open surgical necrosectomy. [Table 2](#) shows demographic and clinical characteristics according to treatment approach.

All-cause mortality occurred in 6 (7%) of the 83 patients undergoing intervention, including 2 of those requiring surgery. Causes of mortality were multiple organ failure secondary to sepsis from pancreatic infection in 3 cases, air embolism in 1 case, and not clearly defined in 2 cases.

## 6. Discussion

When intervention is indicated for necrotic collections, a step-up approach utilizing percutaneous or endoscopic transluminal drainage followed by minimally invasive retroperitoneal or endoscopic necrosectomy is now recommended [2–8], with traditional open necrosectomy reserved for patients who fail minimally invasive approaches. Endoscopic management is increasingly adopted as a first line approach to WON [2,4,8,9,17]. It is clear that endoscopic approaches may have significant limitations with respect to types and locations of collections that can be approached.

Previous series have almost entirely consisted of selected patients felt suitable for this technique, rather than representing a true cohort [15,17,18,22]. A recent study showed comparable clinical outcomes of patients with WON treated by two different endoscopic approaches [8]. It showed that outcomes improved in algorithmic approach based on size and extent of the WON, but only included patients undergoing endoscopic therapy. The treatment success rate was 91% in the algorithmic treatment, and endoscopic treatment failed in 5 of 53 patients. Another recent study suggested that clinical outcomes of endoscopic transluminal necrosectomy at the initial drainage might be superior to subsequent on-demand necrosectomy via a step-up approach [9].

In the current paper we report our approach based on an algorithm adopted more than 7 years ago. Our step up approach was based primarily on endoscopic therapy when feasible with adjunctive percutaneous techniques as needed. Utilizing this approach, success was substantial, with resolution of the cavity in 73% of patients, and with minimal need for open surgical necrosectomy, and a low all cause mortality (7%) for patients undergoing intervention. Adverse events after endoscopic necrosectomy occurred in 11 (13%). Bleeding (related to intervention and/or disease) occurred in 11% of patients in our study, but only 2% were severe enough to require angiography. Incidence of external fistulae in our cohort was similar to reported rates in other studies [6,23].

Reported clinical success of endoscopic necrosectomy ranges from 70 to 95%, requiring typically three to six sessions for completion, with surgery required in anywhere from 2 to 25% of cases, a morbidity of 11–70% and a mortality from 0 to 15% [21,22]. On the other hand, open necrosectomy is associated with relatively high morbidity (34%–95%) and mortality [6%–25%], depending on the series, the severity of illness at the time of surgery and other factors [2,21]. In a multicenter randomized controlled trial, short-term and long-term outcomes using a minimally invasive step-up approach have been shown to be superior to immediate open surgery for patients with infected necrosis [6].

Sixty one (73%) of 83 patients treated in our series using the step-up approach achieved clinical success. Notably, 42 (86%) of 49 patients treated endoscopically alone achieved treatment success. 77% of patients required endoscopic transluminal or sinus tract necrosectomy because drainage alone failed. Mean number of interventions was fewer than 4. Only patients (4%) of 83 failed step up approach and required open necrosectomy. We believe our high clinical success rate with a low rate of adverse events may be related to our emphasis on providing endoscopic drainage and using endoscopic necrosectomy only as needed. Our endoscopic treatment approach utilized multiple or larger bore stents to provide a bigger egress window to the necrotic collection. Larger egress windows may allow necrotic material to fall out spontaneously, thereby leading to fewer sessions of endoscopic necrosectomy. We chose to perform endoscopic necrosectomy on “as needed” basis rather than as per a fixed schedule. Reducing the number of endoscopic necrosectomy sessions may improve

outcomes and reduce mishaps. In our series more adverse events were associated with tract dilation and endoscopic necrosectomy than endoscopic drainage alone. When suitable, we also chose to provide dual drainage, combining cystgastrostomy and cystenterostomy. Approximately 3 in 5 patients requiring intervention could be treated by a purely endoscopic route, while the remainder required adjunctive percutaneous drainage with or without sinus tract endoscopy because of poorly demarcated or endoscopically inaccessible collections. The limitations of a purely endoscopic transluminal approach, even at a highly experienced center, should be kept in mind by endoscopists tackling collections in necrotizing pancreatitis.

Disconnected pancreatic duct syndrome occurs in up to 40% of patients with necrotizing pancreatitis. Methods to prevent external fistula after PCD consist of providing internal endoscopic drainage and leaving the stents in place indefinitely which may reduce risk of recurrence of fluid collections [19]. In our study, 48 patients (58%) had disconnected pancreatic duct.

There are several limitations to the current study. First, the results may not be generalizable as all procedures were performed at a highly specialized center with expert support services that may not be available at smaller institutions. Secondly, although the patient registry was prospective, data collection was retrospective, potentially leading to selection bias, favoring the results of the intervention. However, sicker patients are generally referred for minimally invasive endoscopy rather than being subjected to surgery as the first-line treatment approach.

In conclusion, a step-up approach for interventions in necrotizing pancreatitis using primarily endoscopic techniques resulted in favorable outcomes with acceptably low morbidity and mortality. The relative role of percutaneous and endoscopic methods requires further study. Also, newer types of stents, particular lumen apposing metallic stents, have been developed for drainage of WON that may improve outcomes. Regardless of the exact approach used, management of necrotizing pancreatitis requires a high degree of specialization including a well-coordinated multidisciplinary team with extensive familiarity and expertise at managing necrotizing pancreatitis.

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M.L.F. has served as a consultant for Boston Scientific and XLu-mena, has received speaking honoraria from Cook Endoscopy, and has been an unpaid consultant to Hobbs Medical Inc. S.K.A serves as consultant for Boston Scientific and Merit Endoscopy R.A. has served as consultant for Boston Scientific and Cook Endoscopy. Preliminary results of the study were presented at an American Pancreatic Association annual meeting.

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