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ORIGINAL SCIENTIFIC REPORT WITH VIDEO

Stent-Assisted Percutaneous Endoscopic Necrosectomy for Infected Pancreatic Necrosis: Technical Report and a Pilot Study

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Abstract

Background and aims A variety of minimally invasive techniques have been proposed to replace open surgery for the treatment of infected pancreatic necrosis (IPN). In this study, we evaluate the feasibility and safety of the stent-assisted percutaneous endoscopic necrosectomy (SAPEN) procedure.

Methods Data were collected on all patients who underwent the SAPEN procedure between October 2017 and March 2018. The demographic and clinical characteristics of the study patients were analyzed. A composite primary endpoint of major complications and/or death was used. Three different cases were selected to illustrate different technical aspects of the SAPEN procedure.

Results The placement of a percutaneous stent was successful in all of the 23 patients (17 males, six females). IPN was successfully managed in 16/23 (70%) patients, with the need for open surgery in seven patients (30%), with a median of two (range 1–5) SAPEN procedures. No significant procedure-related complications occurred. Overall 11/23 (48%) patients had a major complication and/or death.

Conclusions In conclusion, the SAPEN procedure was effective in treating IPN without adding extra procedural risk. The role and benefits of the SAPEN procedure now need to be demonstrated in larger controlled study.

Lu Ke, Wenjian Mao and Jing Zhou have contributed equally to this work.

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Introduction

The "step-up" approach to the management of infected pancreatic necrosis (IPN) has become the standard of care and is widely accepted around the world [1–3]. This involves initial endoscopic or percutaneous drainage of an acute necrotic collections (if before 4 weeks) or walled-off necrosis (if after 4 weeks) and is usually indicated for suspected or confirmed infection. Following drainage, and if clinically indicated, it is followed by debridement, using a very wide range of available techniques [4]. The most frequently performed minimally invasive debridement techniques include videoscopic-assisted retroperitoneal debridement (VARD) and minimal access retroperitoneal pancreatic necrosectomy (MARPN) [5, 6]. More recent evidence has shown that transgastric endoscopic debridement is probably superior to these minimally invasive retroperitoneal debridement techniques [7, 8].

There are a number of potential advantages to endoscopic transgastric approaches including being done without general anesthesia and being less invasive with fewer procedure-related complications [7, 8]. And while the PENGUIN randomized controlled trial [7] indicated the endoscopic approach was superior to the VARD procedure, the Dutch Pancreatitis Study Group have since published a large multicenter prospective series that did not confirm a better overall clinical outcome with the endoscopic approach, but did show a decreased rate of pancreatic fistula and a reduced length of stay [9]. A possible explanation for this difference could be the invasiveness of the VARD procedure, which requires a 5–7 cm flank incision for inserting the laparoscope, irrigation catheter and open surgical forceps [5]. In comparison, the MARPN procedure is less invasive as it requires a smaller incision for dilatation of the drain tract and insertion of the Amplatz sheath through which the rigid operating nephroscope is passed [10]. There are no data comparing the VARD and MARPN procedures. To reduce the risk of procedure-related complications associated with percutaneous radiological techniques and to take advantages of the flexible endoscopic techniques, we deployed a fully covered self-expanding metal stent (FCSEMs) to provide repeatable access for necrosectomy.

Two previous case series ($n = 5$ and $n = 9$) and other case reports have described the use of percutaneous stents in treating infect walled-off necrosis (WON) dating back to 2011 [11–13]. This meager evidence is insufficient to draw any meaningful conclusion about the pros and cons of this approach. The aim of this pilot study is to describe the stent-assisted percutaneous endoscopic necrosectomy (SAPEN) procedure in an initial series of patients, illustrating technical aspects with three cases and providing the clinical outcomes. This is considered a necessary step before embarking a larger definitive trial to evaluate SAPEN in the context of the step-up treatment for IPN.

Subjects and methods

Study population

This retrospective cohort study was conducted at the Pancreatic Center of Jinling Hospital between October 2017 and March 2018. All patients with IPN who underwent the SAPEN procedure during the study period were included, and all the data were retrieved from a prospectively collected electronic database. The diagnosis of IPN was made in patients who had gas bubbles within (peri)pancreatic necrosis on CT scan or had a positive culture of (peri)-pancreatic necrosis obtained either by fine-needle aspiration or during the drainage procedure and/or necrosectomy [14]. An approval from the Acute Pancreatitis Database Management Committee was obtained, and all the analyses were performed in compliance with the committee's regulation. Informed consent regarding data storage and publication was obtained from each patient who was recorded in the database during their hospitalization.

Percutaneous drainage and stenting

All the study patients underwent our step-up approach after diagnosis of IPN with percutaneous catheter drainage (PCD) as the primary choice of drainage as previously described [15, 16]. The routes of PCD could be either retroperitoneal or transperitoneal depending on the location of the infected collection. Endoscopic necrosectomy was considered when clinical improvement cannot be achieved by PCD drainage alone, mean CT density of necrotic tissue $\geq$ 30Hu or gastrointestinal fistula was suspected or diagnosed. Stent would be applied when the site of the necrotic cavity was suitable based on its location, range to the skin and size. Briefly, a guide wire was inserted into the pancreatic collection through the PCD tube and the position checked by CT scan. The drain was then removed and the tract was dilated to 28F using an Amplatz renal dilator set to enable full expansion of a fully covered self-expanding metal esophageal stent (FCSEMS, 18 mm $\times$ 80 mm, 18 mm $\times$ 103 mm, or 18 mm $\times$ 123 mm, Zhiye, Changzhou, China). The stent has a ball-type distal end to avoid potential damage to the wall of the infected cavity and a cup-shape proximal end to facilitate easy endoscopic access (Fig. 1a). After placement of the stent, a double catheterization cannula was then inserted through the stent for continuous negative irrigation as we described in previous reports (Fig. 1b) [16]. After 24-hours of self-expansion and continuous irrigation, the stent was considered ready for endoscopic necrosectomy. The stent was removed when CT imaging confirmed resolution of the infection site, and a 12-14F silicone drainage tube was used to replace the stent and removed after drainage of pus stopped.

Endoscopic necrosectomy

Patients usually had SAPEN procedures under conscious sedation using dexmedetomidine (Xinchen, Lianyungang), either at the bedside or in the operating theater. Analgesia was provided with remifentanil (Renfu, Yichang). Through the previously placed stent, a flexible endoscope (9.8 mm, Olympus Medical Systems; Center Valley, Pa) or nephroscope (10 mm, Karl Storz) was inserted. Necrosectomy was performed with either polypectomy snare (with gastroscopy) or grasping forceps (with nephroscopy) (Fig. 1c, d). CO_2 was used for insufflation during the procedure. The

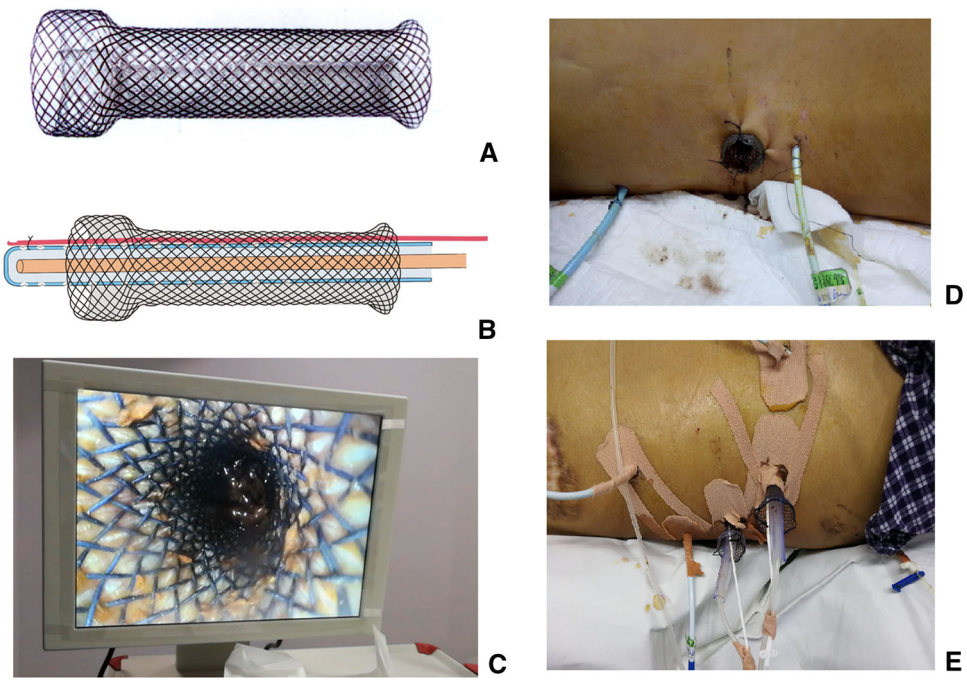

Fig. 1 **a** Sketch map for the fully covered metal esophageal stent; **b** sketch map for the metal stent with a double catheterization cannula inside; **c** endoscopic view of the sinus tract well protected by the metal stent; **d** metal stent that was sutured to the skin; and **e** multiple metal stents with double catheterization cannulas inside and other percutaneous drains

advantage of nephroscopy was high volume irrigation to facilitate visualization but was disadvantaged by the limitations imposed by the small forceps, which meant that necrosectomy was more tedious.

In patients with large volume of peripancreatic necrosis, a multi-port SAPEN procedure using both upper endoscope and nephroscope would be performed to facilitate more efficient necrosectomy (Fig. 1e). The multi-port approach requires two proceduralists. The SAPEN procedure does not preclude other interventions, including further PCDs or endoscopic transgastric procedures, usually with EUS guided.

Cases to illustrate the SAPEN technique

Three typical cases are used to demonstrate variations with technique, including the different access routes used. The VRP classification was applied for different procedures [4], and typical application scenarios are shown in Fig. 2.

Case 1: retroperitoneal route (V2R3P4)

A 37-year-old male with IPN presented to our center due to persistent fever and malnutrition. The onset of the disease was about 2 month ago and initial drains had been placed. A positive bacteriological culture of pancreatic or peripancreatic necrosis was obtained at the first drainage procedure, suggesting *klebsiella pneumonia*. Laboratory values revealed significant signs of infection evidenced by increased PCT and CRP levels.

His CT scan showed a large volume of pancreatic and peripancreatic necrosis extending to the paracolic gutter (Fig. 3a). A stent was placed two days after admission through the anterior renal space into the pancreatic bed (Fig. 3b). He underwent three procedures in the next 10 days, and full resolution was confirmed 2 weeks after admission (Fig. 3c).

Case 2 transperitoneal route (V2R4P4)

A 41-year-old male presented to our center for symptomatic wall-off necrosis 6 weeks after the onset of acute pancreatitis (Fig. 3d). Due to the location of the infected collection, the stent was placed transperitoneally through the gastrocolic ligament to reach the posterior gastric cavity two days after admission under CT guidance (Fig. 3e). In the next 3 days, he underwent two consecutive SAPEN procedures and clinical success was accomplished after the second procedure and he was soon discharged soon after a CT scan (Fig. 3f).

Case 3 multi-port procedure (V2R3P4)

A 42-year-old male presented to our center with a 2-day history of nausea, emesis and abdominal pain. Organ failure followed soon after admission, and artificial organ support and other medical treatments were applied according to the current guidelines [2]. His enhanced CT showed a large volume of pancreatic and peripancreatic necrosis (Fig. 3g). Drainage procedures started about 3 weeks after onset of the disease with percutaneous

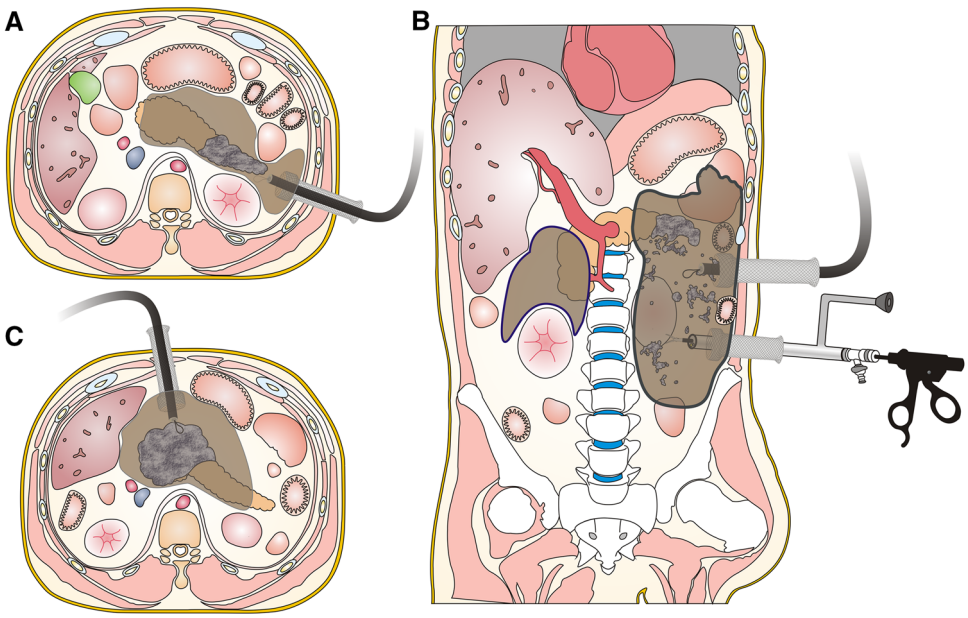

Fig. 2 Sketch map for the typical accesses used for stent-assisted percutaneous endoscopic necrosectomy procedure. **a** Left retroperitoneal access; **b** right transperitoneal access; and **c** multiple accesses for large necrotic collection

drainage, as he showed no signs of organ recovery and signs indicating infection of necrosis like persistently increased body temperature and PCT levels.

One week later, his organ function remained unchanged and CT showed clear evidence of infection with gas bubbles (Fig. 3g). Therefore, SAPEN was applied to facilitate necrosectomy with two stents placed simultaneously (one in the left anterior pararenal space and one down in the left paracolic gutter, Fig. 3h, i). The second day after stent placement, he received a multi-port SAPEN procedure with both gastroscope and nephroscope working together. The technical details can be checked in the supplemental video file (Supplement file). His organ function recovered gradually after necrosectomy, and full resolution was achieved after four SAPEN procedures (two multi-port and two single-port) due to the extent of necrosis.

Outcome measures

Patient characteristics such as age, sex, etiology of pancreatitis, organ function and APACHEII score were recorded. Procedural, periprocedural and follow-up data were collected for all patients. Data were expressed as the median (range) or median (interquartile range) unless mentioned otherwise. Categoric variables were described in absolute numbers and in percentages. The primary outcome was mortality, and major complications as a composite to enable comparison with previous large reports on treatment of IPN and the definition of major complications were defined accordingly including new-onset organ failure (cardiovascular, pulmonary and renal), major bleeding requiring intervention and gastrointestinal fistulas requiring intervention. Secondary outcomes included: time to removal of the stent, number of SAPEN and other endoscopic procedures, requirement of surgery and procedure-related adverse events. All patients who survived the disease were defined as clinical success no matter what kind of treatment was applied.

Results

Patient cohort

A total of 23 patients who underwent SAPEN procedures during the study period were included in this initial analysis. Table 1 shows the demographic and clinical characteristics of these patients at admission. Due to the tertiary nature of our hospital, most of the study patients were transferred from other hospitals, which leads to the variability of the intervals from symptom onset and admission to our center.

Management of IPN

All the patients received IPN treatment based on our own step-up approach with initial PCD followed by at least one SAPEN procedure. All patients underwent successful placement of the stent, and no significant procedure-related complication occurred. As shown in Table 2, the study subjects received a median of two (range 1-5) SAPEN procedures. Half of the patients (12 of 23) required additional other endoscopic interventions with a median of one (range 0–3) procedure.

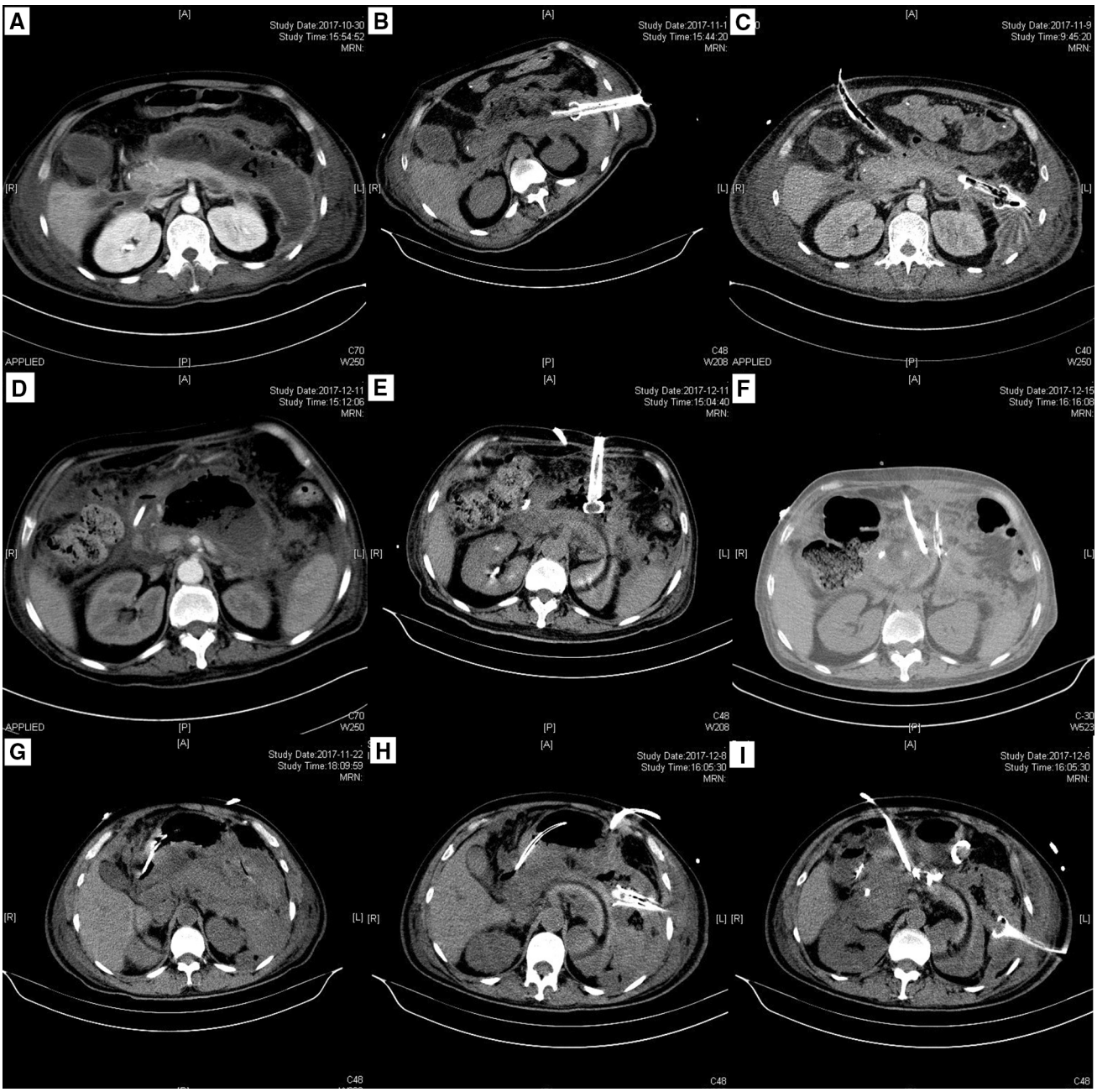

Fig. 3 CT imaging illustrating the evolution of the cases

In the study cohort, 16 patients did not receive open surgery and one of them died, while among the seven patients who had to receive open surgery, only one survived. The overall clinical success rate was 16 of the 23 patients (70%), and 15 of the study patients (65%) were successfully treated with minimally invasive interventions alone. One patient suffered minor bleeding requiring bedside packing after a SAPEN procedure, which was considered as procedure related. For the seven patients who needed open surgical treatment, five received surgery because of inadequate endoscopic debridement, one for intra-abdominal bleeding and one due to colonic fistula.

Clinical outcomes

The primary composite endpoint (major complication and/or mortality) occurred in 11 of 23 subjects (48%).The overall mortality of all the study patients was 30% (7/23 patients) (Table 3). Most patients died of progressive sepsis and accompanying multiple organ failure (5/7), and two died of major bleeding and subsequent shock (2/7). Ten of

Table 1 Demographic and clinical variables at admission (n = 23)

Age (years)	43 (37 to 54)
Gender	17 males/6 females
Etiology	Biliary origin (9, 39%)
	Hyperlipidemia (12, 52%)
	Others (2, 9%)
Interval from onset to admission (day)	26 (interquartile range,14 to 66)
APACHE II* score at admission	13 (interquartile range, 9 to 16)
Severity of the disease**	
Moderately severe	7 (30%)
Severe	16 (70%)
Organ dysfunction	
Pulmonary	12 (52%)
Cardiovascular	4 (17%)
Renal	11 (48%)
MODS(%)***	10 (43%)

*APACHE, Acute Physiology and Chronic Health Evaluation; **the severity of the disease was based on the Revised Atlanta Classification; ***multiple organ dysfunction syndrome

Table 2 IPN management-related measures (n = 23)

Clinical success with endoscopic debridement only	15 (65%)
Requirement of open surgery	7 (30%)
Requirement of reoperation	2 (9%)
Number of SAPEN procedures	2 (range 1–5)
Number of patients requiring other minimally invasive debridement procedures	12 (52%)
Number of other minimally invasive debridement procedures*	1 (range 0–3)
Interval between the initial PCD and stent placement (day)	4 (range 1–17)
Days between stent placement and first SAPEN procedure (day)	2 (range 1–4)
Days between initial SAPEN procedure to removal of the stent (day)	7 (range 3–22)

*Other minimally invasive procedures include percutaneous or transgastric endoscopic debridement

the study patients (43%) had major bleeding requiring radiological or surgical intervention, but none of these bleeding events was considered as procedure related. New-onset gastrointestinal fistula was found in five patients including four duodenal fistulas and one colonic fistula. Direct erosion and compromised blood supply resulted from infected pancreatic necrosis rather than interventions were considered as the cause of these fistulas. Moreover, only two patients developed pancreatic fistula and symptomatic splanchnic venous thrombosis.

Discussion

In this pilot study, we describe the SAPEN procedure in detail and evaluate its feasibility and safety in 23 patients. It is important to note that these patients were only those in whom prior catheter drainage had failed [6, 9, 15]. Of these 23 patients, none had any significant procedure-related complications and clinical success was achieved without additional open surgery in 15 (65%) and 11 (48%) had either a major complication and/or died.

In the present study, we used this SAPEN procedure as the mainstay of our drainage strategy for IPN rather than a supplement to other drainage procedures as reported in previous studies [11, 13]. The overall outcomes of the study patients were comparable to previous large IPN reports [1, 9] considering the study population, which were also similar to our previous study using percutaneous endoscopic debridement without stent [15, 16]. These data suggest that the SAPEN procedure did not increase the risk of mortality and morbidity in IPN patients, but the potential benefits of this novel procedure like faster debridement and reduced invasiveness need more data to address.

In recent years, a variety of minimally invasive procedures have been proposed to facilitate debridement and reduce complications in the treatment of IPN [17–19]. The most commonly performed percutaneous debridement techniques in the literature are MARPN and VARD, which were described in detail by Connor et al. in 2003 and van Santvoort et al. in 2007 [5, 10]. Both techniques are performed through direct retroperitoneal direct routes and most often between the upper pole of the left kidney, lower pole of the spleen and the splenic flexure of the colon. The selection of the route is constrained by the use of a rigid scope with these techniques, namely nephroscope and laparoscope, respectively). In contrast, the flexibility of the endoscope used with the SAPEN technique does not require the prior guiding percutaneous catheter to be inserted along the long axis of the pancreatic body and tail. With the MARPN and VARD techniques, a right-sided transperitoneal route would rarely be considered only when the favored left-sided retroperitoneal route is not possible because of there being no safe window or the location of the necrotic lesion is not extending to the left flank [20]. We have demonstrated with the aid of FCSEMS that it is possible to establish a reliable and optimal retroperitoneal or transperitoneal route for repeated use, according to the location and extent of the necrosis. And in contrast to the MARPN and VARD procedures, the wound is protected by the FCSEMS reducing possible site infection, although a larger study will be required to demonstrated a reduction of wound-related complications, including infection and incisional hernia (in the case of VARD). The other

Table 3 Composite clinical outcome measures (n = 23)

Primary endpoint	
Major complication or death	11 (48%)
Secondary endpoints	
New-onset organ failure	
Pulmonary	6 (26%)
Cardiovascular	10 (43%)
Renal	2 (9%)
Multi-organ failure	5 (22%)
Bleeding required intervention	10 (43%)
New-onset gastrointestinal fistulas	5 (22%)
Death	7 (30%)
Length of ICU stay	30 (interquartile range,15 to 41)
Length of hospital stay	35 (interquartile range, 20 to 47)

advantage of the SAPEN procedure is that no patient required general anesthesia, which makes repeated bedside performance feasible. In contrast, the MARPN and VARD require transfer to the operating theater for necrosectomy by surgeons under anesthesia [9], and the cost and inconvenience of this are significant when repeated procedures are required. Another advantage of the SAPEN technique as described is the double-channel catheter which easily facilitates continuous irrigation between debridement procedures, although this could be used with other minimally invasive techniques[15].

There have been several previous reports of the use of an esophageal stent for pancreatic necrosectomy. Cerecedo-Rodriguez et al. [12] reported use of an esophageal self-expandable metallic stent in a patient who refused surgical treatment. Another study conducted by Saumoy et al. [11] reported a case series of nine patients with walled-off collections in the paracolic gutter who had percutaneous necrosectomy with esophageal metal stent. More recently, Thorsen et al. reported five patients underwent treatment with FCSEMs placement and reached a clinical success rate of 80% [13]. Bleeding and perforation were not reported in these publications. A potential problem of bleeding, secondary to erosion of the end of the FCSEMS into adjacent structures, has not been reported.

Recent evidence suggests that there are advantages of endoscopic transgastric necrosectomy over minimally invasive retroperitoneal necrosectomy [7, 21, 22], but there are limitations that can be addressed by SAPEN. Transgastric access is limited to where the WON abuts the stomach, and yet necrotic collections can be multiple, complex and extend in different directions including to the paracolic gutters, diaphragm and pelvis. The SAPEN technique, with the flexibility of access route and with the use of a flexible endoscope, is likely to be able provide effective treatment in more settings. Further, and in contrast to the SAPEN technique, transgastric stents can be complicated by migration and it can get worse even with the new versions of the wall-opposing stents specifically designed for transgastric application [23]. There were also studies showing transgastric procedures with the aid of stents that could debride the necrosis more effectively than traditional technique, but stent-related complication remains a major concern and oral diet would surely be delayed [24, 25]. In contrast, our SAPEN procedure has no limitation in terms of the extent and location of the necrotic collection and as the stent is fixed to the skin after placement and partially external, stent migration is impossible. Therefore, despite that transgastric drainage or debridement was applied occasionally in our center, the SAPEN procedure was used as the mainstay of our management approach for IPN. In addition, similar to other percutaneous debridement procedures, the SAPEN could debride the necrosis efficiently with surgical forceps as evidenced by that only a median of two procedures were required in our study.

In comparison with these reports, our use of the flexible endoscope and FCSEMS appears to have a number of advantages including being less invasive than MARPN and VARD and more effective and widely feasible than transgastric procedures. Besides, with multiple stent-secured accesses, different types of endoscopes could work collaboratively during the procedure, which could not only enhance the visualization of the infected collection but also improve the efficiency of debridement. Considering its flexibility in access routes and debridement tools, the SAPEN is essentially a combination of different minimally invasive necrosectomy techniques, which enables extensively application of this procedure in almost all infected or sterile pancreatic collections.

This retrospective pilot cohort study was not designed to provide definitive evidence of the superiority of the SAPEN technique compared with other minimally invasive approaches to necrosectomy. Like these, the SAPEN is indicated when initial drainage fails, as in the step-up approach. The intention has been to provide a detailed description of our technique, demonstrate its feasibility and flexibility, report on its safety profile and to describe our early experience. As such, we have demonstrate that this is an effective treatment of IPN that does not add an additional procedural risk to the patients. Confirmation of its potential clinical benefits will require a larger, controlled study.

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