Surg Endosc (2016) 30:2592–2602
DOI 10.1007/s00464-015-4505-2

DYNAMIC MANUSCRIPT

Endoscopic necrosectomy of walled-off pancreatic necrosis using a lumen-apposing metal stent and irrigation technique

Joan B. Gornals[1] · Claudia F. Consiglieri[1] · Juli Busquets[2] · Silvia Salord[1] · Meritxell de-la-Hera[1] · Lluis Secanella[2] · Susana Redondo[3] · Nuria Pelaez[2] · Joan Fabregat[2]

Received: 26 December 2014 / Accepted: 3 August 2015 / Published online: 3 September 2015

Abstract
Background Endoscopic management of walled-off pancreatic necrosis (WOPN) is an area of great interest with many still unanswered questions, including the role of mechanical necrosectomy versus irrigation. The aim of this study was to evaluate a new method of endoscopic transmural necrosectomy.
Methods Patients with WOPN after necrotizing pancreatitis, who underwent endoscopic transmural necrosectomy using a lumen-apposing metal stent with vigorous irrigation sessions, were prospectively recruited between September 2011 and August 2014. Initial endoscopic session was performed by EUS-guided drainage and lavage sessions by flushing saline through the stent. Technical and clinical success rates, number of repeat interventions, and adverse events were analyzed.
Results Twelve patients with 13 WOPN collections (median size 12.4 ± 2.94 cm) underwent endoscopic treatment. Clinical success was achieved in 100 % of cases after a median of three sessions per patient (range 2–8). The median length of hospitalization was 15.9 days. Median procedure time of the access session was 31 ± 10.16 min. No adverse events (AE) were described during the procedures or 24 h after. There were four AE (two infections and two bleedings) between sessions, but only two were severe (16.6 %). There was no need for surgery, and no mortalities occurred. Mean time to stent retrieval was 9 ± 3.4 weeks. Mean follow-up was 13 months with only one recurrence at 12 months after stent removal.
Conclusions This new variant of irrigation endoscopic transmural necrosectomy without mechanical debridement helps to simplify the technique, is feasible, and has excellent outcomes in WOPN treatment.

Keywords Endoscopic necrosectomy · Necrotizing pancreatitis · Transmural drainage · Self-expanding metal stent · Walled-off pancreatic necrosis

According to the revised Atlanta criteria, walled-off pancreatic necrosis (WOPN) consists of collections derived from a necrotizing pancreatitis as the liquefied parenchyma matures into a contained collection [1]. Traditionally, interventions for WOPN have been surgical or percutaneous, and endoscopic management of these necrotic collections is a relative newcomer.

The first endoscopic transmural drainage of a WOPN was reported in 1996 by Baron et al. [2]. More recently, a limited number of large multicenter studies have demonstrated the efficacy and safety of endoscopic transmural necrosectomy for WOPN which now is accepted as first-line treatment for WOPN when indicated [3–5]. However, the indications and methodology described vary between

Electronic supplementary material The online version of this article (doi:10.1007/s00464-015-4505-2) contains supplementary material, which is available to authorized users.

✉ Joan B. Gornals
jgornals@bellvitgehospital.cat

[1] Endoscopy Unit, Department of Digestive Diseases, Hospital Universitari de Bellvitge-IDIBELL (Bellvitge Biomedical Research Institute), Feixa Llarga s/n, L'Hospitalet de Llobregat, 08907 Barcelona, Catalonia, Spain

[2] Department of Surgery, Hospital Universitari de Bellvitge-IDIBELL, Barcelona, Spain

[3] Department of Anesthesiology, Hospital Universitari de Bellvitge-IDIBELL, Barcelona, Spain

studies, and the endoscopic techniques are complex and continuously evolving [6].

For these reasons, management of WOPN is an area of great interest and current research with as yet many unanswered questions. For example, it is unclear how aggressive endoscopists should be in the debridement of the necrosis and when and how frequently the debridement should be performed. Other concerns include the roles of mechanical necrosectomy versus irrigation, and which type of stents should be used [7, 8].

Recently, some case series have reported the initial experience using a new type of self-expanding metal stent (SEMS), specifically designed for endoscopic ultrasound (EUS)-guided transmural drainage of collections, defined as lumen-apposing metal stents (LAMSs). Stents of this kind could be used as ports for repeated sessions of necrosectomy [9].

To our knowledge, no study has evaluated endoscopic drainage using LAMS combined with sessions of energic flushing of the cavity for debridement of the debris, as in irrigation necrosectomy, avoiding the direct manipulation of adherent necrotic material as a direct endoscopic transmural necrosectomy.

The aim of this study was to evaluate, in terms of feasibility and safety, the outcome of a new variant of the endoscopic treatment for WOPN, using a LAMS and irrigation sessions through this stent.

Materials and methods

The study took place at Hospital Universitari de Bellvitge, a tertiary-care public institution in the Barcelona area (Catalonia, Spain). Patients and procedural data from September 2011 to August 2014 were prospectively recruited and analyzed retrospectively from a specific database. The following information was collected: demographic data, procedure details, clinical outcomes, adverse events, and follow-up after endoscopic treatment. The study concept was investigator initiated, and no financial support or free devices were received. Written informed consent was obtained from all patients. Our institutional review board approved the technique, deeming it to be an extension and variant of existing procedures. All procedures were performed by one experienced endoscopist.

Patient data

All patients with symptomatic WOPN were considered eligible for this study. Criteria for drainage were as specified by the Working Group of IAP [10]. The exclusion criteria were: imaging findings suggesting a pseudocyst, collections extended into the lower abdomen/pelvis or endoscopically inaccessible from the gastric cavity or duodenum, severe coagulopathy (prothrombin time >1.5 or platelet count $<50 \times 10^9$/L), age younger than 18 years, and inability to give a written informed consent.

Material

All access sessions were performed under orotracheal intubation. For irrigation or removal stent sessions, only general anesthesia was used. Patients were placed on the left side or in a prone position. For access sessions, only seven procedures were carried out in a fluoroscopic room. The rest of the procedures were performed in the EUS room. In all access sessions of non-infection collections, prophylactic doses of intravenous antibiotics were administered before the procedure and 7 days following.

EUS-guided transmural drainage was performed with a therapeutic linear echoendoscope (GF-UCT140, Olympus Europa). Other sessions (irrigation, stent removal) were performed using a standard upper endoscope (GIF-Q145, Olympus). A fully covered LAMS was used in all cases (AXIOS or Hot AXIOS, 10 or 15 mm × 10 mm, Xlumena Inc., Mountain View, CA, USA). In six cases, double-pigtail plastic stent were placed through the LAMS (10F × 5 cm, Cook Endoscopy, NC, USA). In one case of massive bleeding inside the drained cavity, an 8.5F nasocystic catheter (Boston Sc., Natick, MA, USA) was placed within an LAMS and coaxial to a pigtail stent.

In four procedures, an LAMS was placed using a novel cautery-tipped stent delivery system called Hot AXIOS (Xlumena Inc.).

The irrigation endoscopic necrosectomy sessions were performed using an endoscopic flushing powerful pump (OFP, Olympus) that can irrigate saline via the instrumental channel of the endoscope.

Technique

Access session

Initial endoscopic access was obtained using EUS-guided transmural drainage. An LAMS was placed to create a wide stable access to the cavity.

- First, a linear echoendoscope was used to visualize the extent of the collection and necrosis.
- In nine cases, the cavity was punctured with a 19-gauge needle (Expect Flex, Boston Sc.), and an aspirate was obtained for analysis. A guidewire was inserted through the needle into the necrotic cavity under fluoroscopic or EUS guidance. The puncture site was dilated using a 6F

cystotome (EndoFlex, Voerde, Germany) and a biliary (6 or 8 mm, Boston Sc.) or CRE (10–12 mm, Boston Sc.) dilating balloon.
- In four cases, the puncture and ostomy were performed directly and at the same time using the Hot AXIOS cautery-tipped (as a cystotome) stent delivery system.
- In all procedures, an AXIOS stent was placed over the guidewire and deployed under EUS guidance.
- Then, one or more double pigtail stent(s) and/or a nasocystic drainage catheter were inserted. In a few cases, endoscopic necrosectomy was performed on the same day.

Irrigation sessions

- After the access session, irrigation necrosectomy sessions were planned at intervals of 2–5 days until most of the non-adherent necrotic material was pushed out, and there was clinical improvement of the patient.
- If necessary to gain a better view, a gastroscope was entered into the cavity, but in the majority of cases this was not necessary.
- These lavage sessions were performed by flushing SSF (500–1500 mL) through the LAMS using a water-jet system. All of the SSF flushed was totally aspirated by suction until the cavity was empty, removing all the non-adherent necrotic debris from the gastric cavity.
- As a final step, LAMS was removed after WOPN resolution and confirmed by imaging.
- Initially, the first session was restricted to insertion of the LAMS (±double plastic pigtail) aspirating all the fluid content of the cavity, but with increased experience, irrigation sessions were carried out during the first session.

Examples of the techniques applied in the access and irrigation sessions are shown in Figs. 1 and 2, respectively.

Post-procedure care and follow-up

- All patients were monitored and admitted to our center for observation after the procedure.
- WOPN resolution was assessed by MDCT (multidetector computed tomography) or EUS generally 4–8 weeks after initial transmural drainage. If complete resolution was achieved, all stents were removed.
- However, if the collection was not resolved, stent removal was deferred and new imaging procedure was scheduled for 2–4 weeks later.
- In patients with suspicion of possible pancreatic duct disruption, stent removal was deferred and a cholangiomagnetic resonance imaging (MRI) was proposed to evaluate the need for a therapeutic ERCP.
- After the removal of the stents, follow-up visits with an MDCT scan were scheduled for each case at between 2 and 6 months.

Outcome measures: definitions of events

Procedure time was calculated as the time from the insertion of the first scope to the withdrawal of the last.

The term WOPN is defined, according to the revision of the Atlanta classification, by the presence of necrotic tissue in the collections, based on a history of necrotizing pancreatitis [1].

Technical success was defined as the correct placement of the stent. Clinical success was defined as a decrease in the size of the collection by $\geq$50 % at 4- to 6-week follow-up imaging, together with resolution of symptoms.

Adverse events were defined and graded according to the standard lexicon for endoscopic adverse events.

Irrigation necrosectomy was defined as vigorous irrigation of the WOPN cavity with a large amount of SSF followed by aspiration of the saline, without using mechanical tools for the debridement.

Recurrence was defined as symptomatic collection diagnosed on imaging procedure following initial treatment success.

Results

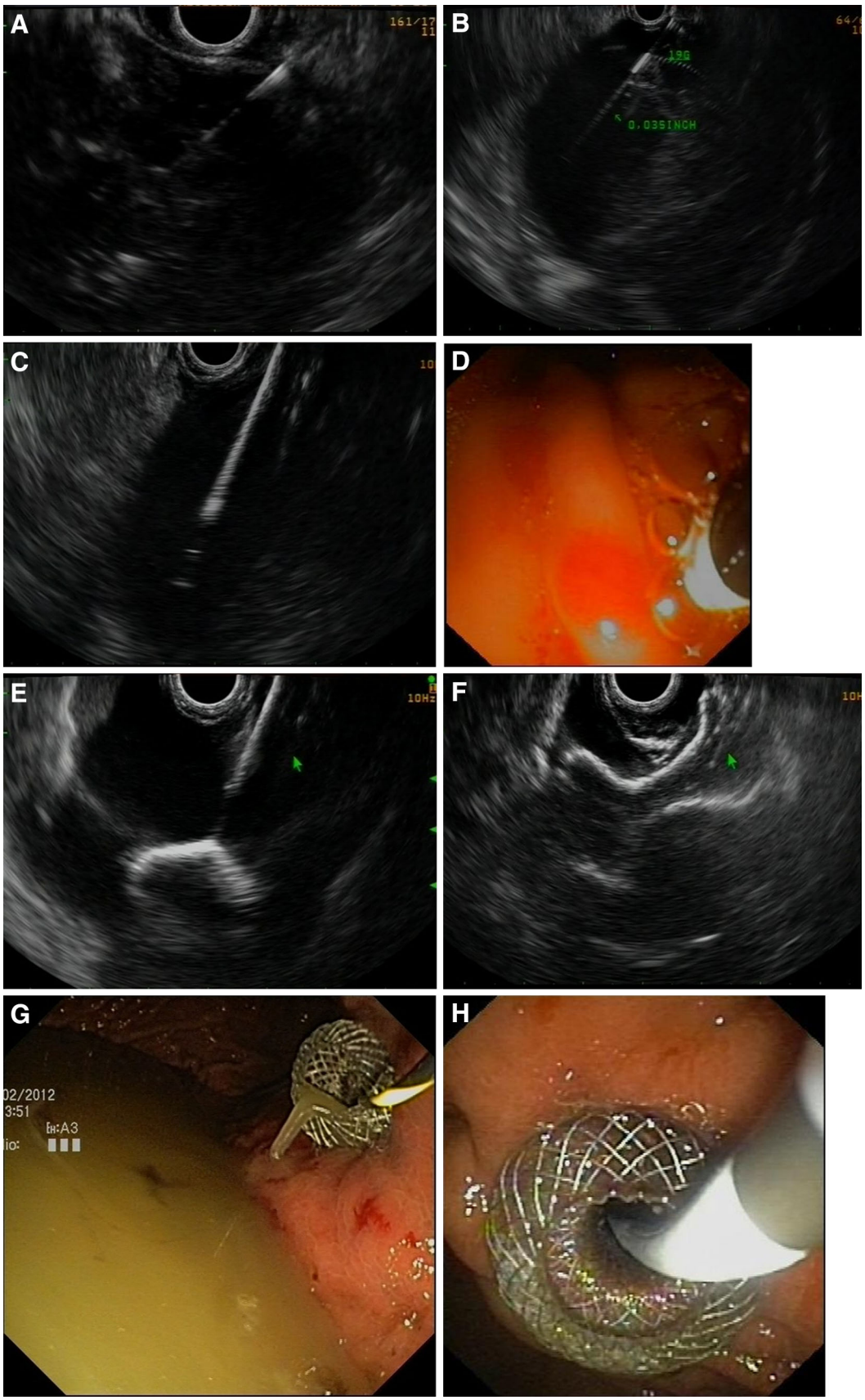
Patient characteristics

Twelve patients (52.6 ± 14.4 years) with 13 WOPN collections (median size 12.4 ± 2.94 cm; range 8–18 cm) underwent endoscopic treatment with the reported technique.

Of the 12 patients, one was in very poor health and five had severe systemic disease, according to the American Society of Anesthesiologists (ASA) physical status classification.

All patients had a previous acute necrotizing pancreatitis which, after 4 weeks, developed partially liquefied collections with necrotic debris. These collections were well identified by the imaging procedures (MDCT or MRI). Indications for endoscopic intervention (transmural drainage ad necrosectomy) in these necrotic collections were abdominal pain, infection, food or biliary obstruction, disconnected pancreatic duct syndrome, and severe stricture of splenic vessels with high risk of bleeding.

The baseline characteristics and demographics of each case with procedural outcomes are summarized in Table 1.


A
B
19G
0.035INCH
C
D
E
10Hz
F
G
02/2012
3:51
H:A3
H

◀**Fig. 1** Different images showing transluminal endoscopic ultrasound (EUS)-guided drainage of walled-off pancreatic necrosis (WOPN) with a lumen-apposing metal stent (LAMS). **A** Endosonography view showing a WOPN with abundant solid parts. A guidewire is seen as a hyperechogenic line through the gastric wall into the cavity. **B** Puncture of the collection using a 19G needle and a guidewire inserted into the cavity. **C** Access into the lesion with the insertion of cautery-tipped stent delivery system under EUS guidance. **D** Endoscopic view of the Hot AXIOS cautery tip. **E** Images of AXIOS stent deployment under EUS guidance. **F** EUS image of an AXIOS stent delivered. **G** Endoscopic view of the AXIOS stent deployed and well positioned, with abundant thick fluid drained into the stomach. **H** A pigtail inserted through the LAMS

Outcomes

All stents were successfully positioned in all cases, which means a technical success rate of 100 % was achieved. Resolution of the lesions was achieved in 100 % of cases after a median of three endoscopy sessions per patient (range 2–8).

The median length of hospital stay was 15.9 days. All patients experienced immediate symptom relief after endoscopic treatment.

General outcomes are given in Table 2.

Endoscopic procedures: observations

Median procedure time of the access session was 31 ± 10.16 min. The duration of irrigation sessions was usually limited to 30 min. A minimum of 48 endoscopic procedures was performed. In the case of Hot AXIOS, the median procedure time was 21.7 min ± 9.3 (9–28) versus 35.4 min ± 8.2 (20–47) in cases with device changes ($p < 0.05$).

All stents removed were easily retrievable after the resolution of the lesions. Mean time to stent retrieval was 9 ± 3.4 weeks.

A summary of all sessions done is presented in Table 3.

Follow-up: recurrence

Patients were followed up prospectively after stent retrieval for a mean time of 13 ± 11.4 months. Only one patient presented a recurrence 12 months after stent removal, with a suspected disrupted pancreatic duct.

Adverse events

No adverse events (AE) were described during the procedures or 24 h after. But four patients experienced adverse events between the procedures. Two patients had a severe AE; in both cases, there were bleeding requiring transfusion, therapeutic arteriography, and endoscopic treatment, thereby increasing the number of irrigation sessions. Two cases had infection successfully treated with antibiotics and with endoscopy, and both were deemed to be moderate AE. No late AE occurred when observing all patients a minimum of 40 days after the initial procedure.

There was no procedure-related mortality.

Discussion

The present study offers the results of a new variant of endoscopic transmural necrosectomy in 12 consecutive patients with carefully selected WOPN lesions with a technical and clinical success rate of 100 % and faster sessions of transmural drainage. Furthermore, this methodology was found to be safe without need for surgery and with no mortalities. The technique is a combination of irrigation technique (without mechanical devices) and the use of specifically designed stents for transmural drainage guided by endosonography.

First of all, it is important to clarify that correct categorization of pancreatic fluid collection is the first step in its management. In some cases, MDCT cannot reliably detect necrotic debris within a pancreatic collection and many WOPN can be referred as pseudocysts. This is important, because endoscopic treatment outcomes are directly related to the type of pancreatic fluid collection being treated (90 % for pseudocyst, 65 % WOPN). For these reasons, it has become increasingly apparent that WOPN has been erroneously misclassified as a pseudocyst and inappropriately treated with transmural plastic stenting alone [11]. These necrotic collections contain highly dense solid debris and require a larger fistulous opening, or more than one tract, for effective drainage. In addition to an endoscopic transmural drainage, these collections often require an endoscopic transmural necrosectomy for debridement of solid debris, and they represent a true natural orifice transluminal endoscopic procedure.

Baron et al. in their initial experience with endoscopic treatment of WOPN used a mixed technique of transmural drainage with irrigation through a nasocystic drain [2], but later made recourse to more aggressive treatment, mechanical endoscopic necrosectomy. Today this is accepted as the most frequently indicated endoscopic option for WOPN.

The available case series and recent multicenter studies show that direct mechanical endoscopic necrosectomy is associated with high morbidity (15–30 %) and mortality (2–11 %), is labor intensive, is resource- and time-consuming, and is lacking in technique-specific devices [3–6]. In a recent systematic review that included 283 cases of pancreatic necrosis treated with EUS-guided necrosectomy, a median of five (1–35) sessions was required to achieve total resolution. A mean clinical success rate of 88 % and

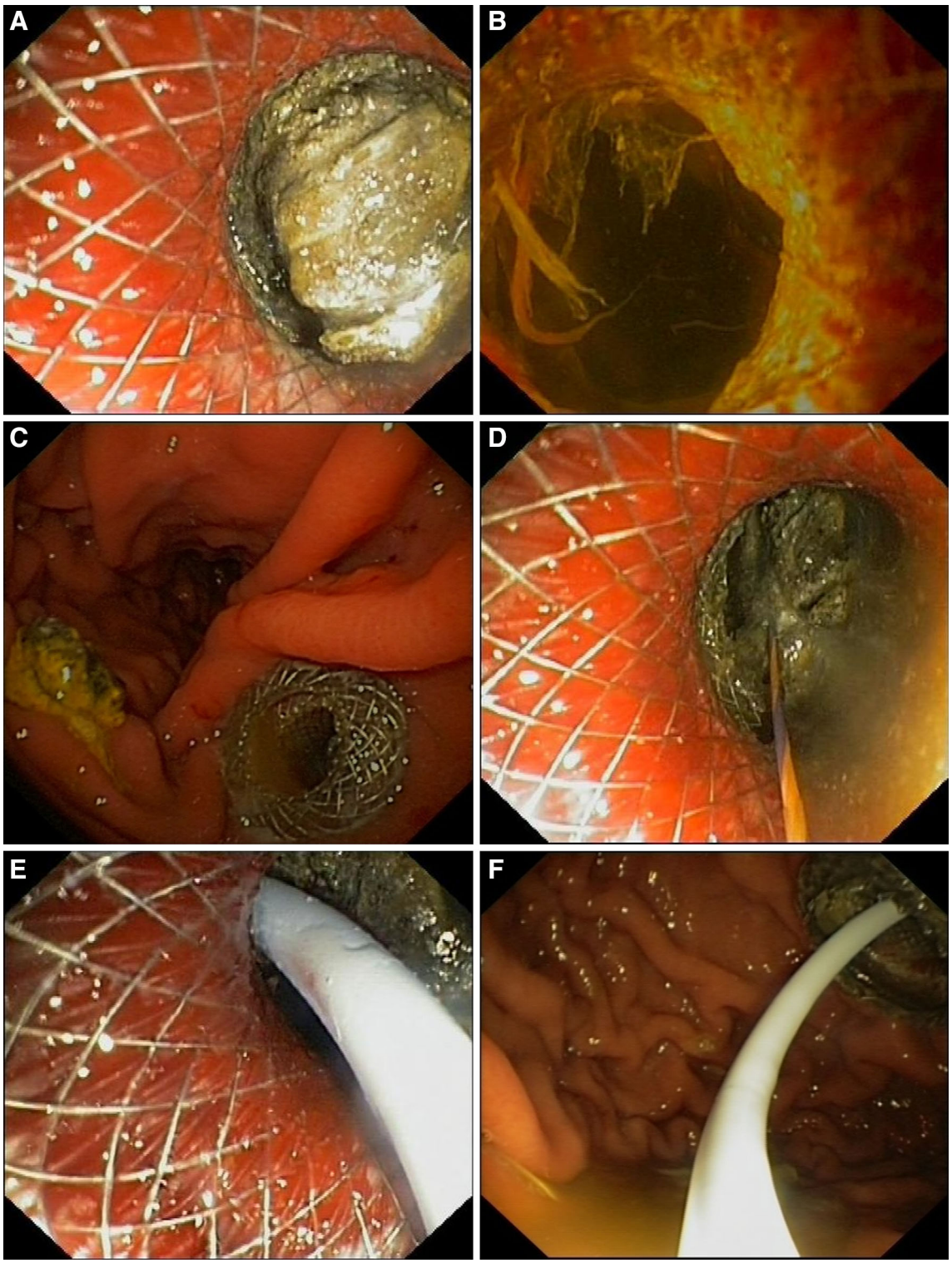


Fig. 2 Sequence of endoscopic images showing an endoscopic necrosectomy session with irrigation technique using a high-flow water-jet system. **A** Endoscopic view across an occluded AXIOS stent with necrotic debris. **B** AXIOS lumen submerged underwater. **C** Necrotic fragments lie in the gastric cavity after being dragged in the necrosectomy session by irrigation. **D** A guidewire is inserted through the AXIOS stent. **E** A double-pigtail plastic stent within the AXIOS stent creating space between necrotic fragments and lumen stent, to avoid self-occlusion. **F** Endoscopic view of the 10F double pigtail placed within the AXIOS stent

Table 1 Patient demographics and procedural outcomes

Patients	Age in years, sex	Etiology	Infection Y/N	Size in cm	Form	LAM type and size, ±double pigtail stent	Access session duration in min	Adverse events Y/N (treatment)	Outcome	Recurrence (treatment)
1	52/M	Alcohol	Y	10	Single	AXS 10 × 10 mm 10F double pigtail	40	N	Resolution	N
2	36/M	Alcohol	Y	18	Single	AXS 15 × 10 mm	35	N	Resolution	N
3	44/M	Alcohol	N	13	Single	AXS 15 × 10 mm	20	N	Resolution	N
4	33/M	Lithiasis	Y	17	Single	AXS 15 × 10 mm	42	Bleeding (arteriography plus endos. tr.)	Resolution	N
5	32/M	Alcohol	N	10	Single	HXS 15 × 10 mm	9	N	Resolution	N
6	69/M	Idiopathic	Y	11	Single	AXS 10 × 10 mm, 10F double pigtail 8.5F nasocystic catheter	38	Bleeding (arteriography plus endos. tr.)	Resolution	N
7	69/M	Lithiasis	Y	8	Single	AXS 10 × 10 mm	25	N	Resolution	Y[d] EUS-guided drainage
8	46/M	Lithiasis	Y	12	Single	AXS 15 × 10 mm[a] AXS 10 × 10 mm + 10F double pigtail	34 38	Infection–stent migration (antibiotics, new LAMS)	Resolution	N
9	57/M	Alcohol	Y	13	Double	AXS 15 × 10 mm[b] 10F double pigtail HXS 10 × 10 mm + 10F double pigtail	35 26	Infection–stent occlusion (antibiotics, 10F double pigtail)[c]	Resolution	N
10	71/F	Idiopathic	N	12	Single	AXS 10 × 10 mm	47	N	Resolution	N
11	56/F	Lithiasis	N	13	Single	HXS 10 × 10 mm + 10F double pigtail	24	N	Resolution	N
12	65/F	Lithiasis	N	12	Single	HXS 15 × 10 mm + 10F double pigtail	28	N	Resolution	N

F female, *M* mascle, *LAMS* lumen-apposing metal stent, *AXS* AXIOS stent, *HXS* Hot AXIOS stent, *endos tr* endoscopic treatment, *N* no, *Y* yes

[a] New access session due to external migration of the AXIOS stent

[b] Double lesion that required transmural drainage in two different sites of the gastric cavity

[c] Fever due to stent occlusion that required new stent management session. A double pigtail was placed through the AXIOS stent

[d] Recurrence in a patient with pancreatic duct disruption

Table 2 General outcomes

	n	%
Number of patients/collections	12/13	–
ASA classification, *n*[a]	–	–
Grade II	6	50
Grade III	5	41.6
Grade IV	1	8.3
Technical and clinical success	13	100
Number of stents:		
(LAMS/double pigtail/nasocystic)	15/8	–
LAMS migration	1	6.6
Adverse events:	4	
During procedure/between sessions	0/4	33.3
Fatal/severe/moderate/mild	0/2/2/0	16.6/16.6
Median hospitalization (d)	15.9	–
Time from pancreatitis to initial drainage (w)	35.6 ± 24.7	
Mean follow-up period, m (range)	13.3 ± 11.4(2-36)	–
Mean time to stent removal, w	9 ± 3.4(4-16)	–
Recurrence, n/N	1/12	8.3
Need for surgery	0	0
Mortality	0	0

d days, *LAMS* lumen-apposing metal stent, *m* months, *w* weeks

[a] *ASA* American Society of Anesthesiologists physical status classification From: http://www.asahq.org/Home/For-Members/Clinical-Information/ASA-Physical-Status Classification-System

Table 3 Endoscopy sessions per patient

	n	%
Access ± irrigation	14[a]	31
Specific irrigation session	22	48
Median of sessions to achieve complete treatment	3	NA
Stent retrieval procedures	11	20
Total	47	100

NA not applicable

[a] One case of lumen-apposing metal stent migration, and another case with double lesion. Both patients needed one additional access session

mean complication rate of 28 % were reported [12]. These aspects limit the practicability of direct endoscopic necrosectomy and point up the need for simplification.

Most studies of peroral endoscopic necrosectomy use plastic stents. It is well known that these stents have several limitations in the drainage of WOPN: a limited diameter, a high migration rate, and high occlusion rate. Placement of multiple stents can be tedious, and it is labor intensive and time-consuming. And there is no anchorage force in cases of non-adherent collections, with a high risk of leakage.

In the last 5 years, fully covered SEMS have been adopted for the drainage of pancreatic collections and, more recently, for the endoscopic treatment of WOPN [13, 14]. At the same time, new stents such as LAMS designed specifically for EUS-guided transluminal drainage have appeared, and they can be used as an access port for necrosectomy [15, 16]. As in our previous published report, in the present study we used the same type of stent with an anchoring design that offered a low stent migration rate, with only one migration of 36 of access and irrigation sessions [16].

Our cohort consisted of patients with WOPN (58 % infected), candidates for endoscopic treatment, in whom we planned to perform an initial transmural drainage plus vigorous irrigation sessions using specific transmural stents. This initial experience suggests that mechanical endoscopic necrosectomy can be avoided and be replaced to irrigation endoscopic necrosectomy, which is faster (30 min per session, 20 min using special devices such as Hot AXIOS), with fewer sessions (median of three instead of 5–7), and less prone to severe AEs (16 %) such as air embolism, severe bleeding, and perforation during the sessions, yet with comparable outcomes [6]. With increasing experience, we noted that it was better to directly insert a double pigtail within the LAMS during the first access session, in order to avoid external migration, occlusion of LAMS lumen with necrotic fragments (after an initial endoscopic necrosectomy, all fluid is evacuated and the cavity lumen is collapsed), or bleeding between the sessions due to trauma caused by the internal stent end.

Our group is a multidisciplinary team. In recent years, we have been working toward improvement of the management of local complications secondary to severe acute pancreatitis. After a critical review of 143 patients, we realized that aggressive surgical management was associated with a high mortality rate (postoperative mortality of 25 %), and minimally invasive options such as endoscopic treatments began to seem more attractive [17]. In seeking to improve our results, we compared data from our last consecutive patients, treated with direct mechanical endoscopic necrosectomy and conventional lumen stents (plastic pigtail alone or biliary SEMS), with the results of the present study. In doing so, we detected better clinical success, less time-consuming procedure, less number of sessions, and greater safety with less severe complications and no mortalities (Table 4).

Furthermore, comparing our results with the major multicenter studies ($n > 55$) reporting endoscopic transmural necrosectomy which only included necrotic collections, we found a higher rate of clinical success, a lower median number of sessions, lower rates of severe AE, and no mortalities (Table 5) [4, 18, 19].

As noted in the literature, the most common complications associated with endoscopic necrosectomy are bleeding, perforation, infection, stent migration, and air embolisms. Bleeding usually occurs during balloon dilation

Table 4 Comparison data from our unit with recent previous cases using mechanical devices and non-specifically designed stents

Data	Previous methodology ($n - 9$)	Current methodology ($n - 12$)
Average procedure duration, (EUS-guided drainage, access session)	47 min	31 min 21 min (Hot AXIOS)
Stent type(s)	Plastic pigtail alone (>1) Biliary FCSEMS	LAMS alone LAMS + pigtail
Average number of sessions to achieve complete treatment	4.5	3
Severe adverse events (%)	33	16
Mortality (%)	11	0
Success (%)	88	100

FCSEMS fully covered self-expanding metal stent, *LAMS* lumen-apposing metal stent

Table 5 Major studies reporting endoscopic transmural necrosectomy of WOPN

Author, year (ref) study data	*n*	Infected	Days in hospital (mean days)	EUS-guided drainage in all cases	Modality	Sessions (mean days)	Overall success	AE	Mortality
Seifert et al. [18] Multicenter, GEPARD study, Germany	93	50 (54 %)	46	No	ETN	6.2	75 (81 %)	24 (26 %) Including: Perforation-5 Air embolism-2 Bleeding-13	7 (7.5 %)
Gardner et al. [19] Multicenter, USA	104	40 (39 %)	12	No	ETN	3	95 (91 %)	14 (14 %) Perforation-5 Air embolism-1 Bleeding-2	2 (1.9 %)
Yasuda et al. [4] Multicenter, JENIPaN study, Japan	57	57 (100 %)	21	Yes	ETN + nasocystic lavage	5	43 (75 %)	19 (33 %) Perforation-3 Air embolism-1 Bleeding-5	6 (11 %)
Gornals et al. (present study)	12	7 (58 %)	16	Yes	IEN + LAMS	3	12 (100 %)	2 (16 %) Perforation-0 Air embolism-0 Bleeding-2[a]	0

Comparison of data in the literature and our results

AE adverse events, *ETN* endoscopic transmural necrosectomy, *IEN* irrigation endoscopic transmural necrosectomy, *LAMS* lumen-apposing metal stent

[a] Bleeding occurred in cases in which LAMSs were used without pigtail stent within

of the transluminal tract or during the removal of necrotic material [6]. In our study, two serious AEs were described (16 %). Both were bleeding occurring between endoscopic necrosectomy sessions and not during stent placement. Curiously, these AEs occurred in two cases of LAMS stent alone (without plastic pigtail within). This suggests that the cause of the bleeding might be a vessel injury from the inner stent end. For this reason, all subsequent cases received an LAMS plus a pigtail stent, and no more bleeding events occurred. Nor were air embolisms or perforation described, perhaps as a result of having avoided exploration or manipulation of the cavity with the scope.

Limitations

Our study has some limitations that require further comment. The sample size was relatively small, although the number of total procedures was high ($n = 47$). As the study was carried out in a tertiary center with experienced interventional endoscopists, this might limit its generalizability to some extent. More importantly, this study was not randomized. A study comparing a mechanical endoscopic necrosectomy with this irrigation necrosectomy through an LAMS would require more patients and ideally would be a multicenter study. Additionally, we did not have long-term patient follow-up of all the cases, and a cost analysis was not carried out.

However, the good results from this technique have encouraged us to do a longer follow-up including more patients. We believe that the validity of our results is supported by a rigorous methodology; the data were prospectively collected, and the material used was standardized.

Conclusions

In conclusion, as shown by this pilot study, irrigation endoscopic necrosectomy by only flushing large amounts of saline through the LAMS, without any mechanical debridement, helps to simplify the technique, is faster and more effective, and yields excellent outcomes, without the need for surgery. Nevertheless, even though these clinical results are promising, larger prospective and randomized studies to validate and confirm these findings are in order.

Acknowledgments The authors wish to thank Dr. C Loras, Hospital Universitari Mutua de Terrassa, for critical reading of the manuscript.

Compliance with ethical standards

Disclosures Drs. Joan B Gornals, Claudia F Consiglieri, Juli Busquets MD, Silvia Salord, Meritxell de-la-Hera, Lluis Secanella, Susana Redondo, Nuria Pelaez, and Joan Fabregat have no conflicts of interest or financial ties to disclose.

References

1. Banks PA, Bollen TL, Dervenis C, Gooszen HG, Johnson CD, Sarr MG, Tsiotos GG, Vege SS (2013) Acute Pancreatitis Classification Working Group. Classification of acute pancreatitis—2012: revision of the Atlanta classification and definitions by international consensus. Gut 62:102–111
2. Baron TH, Thaggard WG, Morgan DE, Stanley RJ (1996) Endoscopic therapy for organized pancreatic necrosis. Gastroenterology 111:755–764
3. Jürgensen C, Neser F, Boese-Landgraf J, Schuppan D, Stölzel U, Fritscher-Ravens A (2012) Endoscopic ultrasound-guided endoscopic necrosectomy of the pancreas: is irrigation necessary? Surg Endosc 26:1359–1363
4. Yasuda I, Nakashima M, Iwai T, Isayama H, Itoi T, Hisai H, Inoue H, Kato H, Kanno A, Kubota K, Irisawa A, Igarashi H, Okabe Y, Kitano M, Kawakami H, Hayashi T, Mukai T, Sata N, Kida M, Shimosegawa T (2013) Japanese multicenter experience of endoscopic necrosectomy for infected walled-off pancreatic necrosis: the JENIPaN study. Endoscopy 45:627–634
5. Smoczynski M, Marek I, Dubowik M, Rompa G, Kobiela J, Studniarek M, Pieńkowska J, Adrych K (2014) Endoscopic drainage/debridement of walled-off pancreatic necrosis—single center experience of 112 cases. Pancreatology 14:137–142
6. Trikudanathan G, Attam R, Arain MA, Mallery S, Freeman ML (2014) Endoscopic interventions for necrotizing pancreatitis. Am J Gastroenterol 109:969–981
7. Mouli VP, Sreenivas V, Garg PK (2013) Efficacy of conservative treatment, without necrosectomy, for infected pancreatic necrosis: a systematic review and meta-analysis. Gastroenterology 144(333–340):e2
8. Hritz I, Fejes R, Székely A, Székely I, Horváth L, Sárkány A, Altorjay A, Madácsy L (2013) Endoscopic transluminal pancreatic necrosectomy using a self-expanding metal stent and high-flow water-jet system. World J Gastroenterol 19:3685–3692
9. Binmoeller KF (2013) EUS-guided drainage of pancreatic fluid collections using fully covered self-expandable metal stents. Gastroenterol Hepatol (NY) 9:442–444
10. Working Group IAP/APA acute pancreatitis guidelines (2013) IAP/APA evidence-based guidelines for the management of acute pancreatitis. Pancreatology 13(4Suppl2):e1–e15
11. Bang JY, Varadarajulu S (2013) Metal versus plastic stent for transmural drainage of pancreatic fluid collections. Clin Endosc 46:500–502
12. Fabbri C, Luigiano C, Lisotti A, Cennamo V, Virgilio C, Caletti G, Fusaroli P (2014) Endoscopic ultrasound-guided treatments: are we getting evidence based—a systematic review. World J Gastroenterol 20:8424–8448
13. Chandran S, Efthymiou M, Kaffes A, Chen JW, Kwan V, Murray M, Williams D, Nguyen NQ, Tam W, Welch C, Chong A, Gupta S, Devereaux B, Tagkalidis P, Parker F, Vaughan R (2015) Management of pancreatic collections with a novel endoscopically placed fully covered self-expandable metal stent: a national experience (with videos). Gastrointest Endosc 81:127–135
14. Saxena P, Singh VK, Messallam A, Kamal A, Zaheer A, Kumbhari V, Lennon AM, Canto MI, Kalloo AN, Baron TH, Khashab MA (2014) Resolution of walled-off pancreatic necrosis by EUS-guided drainage when using a fully covered through-the-

scope self-expandable metal stent in a single procedure (with video). Gastrointest Endosc 80:319–324
15. Itoi T, Binmoeller KF, Shah J, Sofuni A, Itokawa F, Kurihara T, Tsuchiya T, Ishii K, Tsuji S, Ikeuchi N, Moriyasu F (2012) Clinical evaluation of a novel lumen-apposing metal stent for endosonography-guided pancreatic pseudocyst and gallbladder drainage (with videos). Gastrointest Endosc 75:870–876
16. Gornals JB, De la Serna-Higuera C, Sánchez-Yague A, Loras C, Sánchez-Cantos AM, Pérez-Miranda M (2013) Endosonography-guided drainage of pancreatic fluid collections with a novel lumen-apposing stent. Surg Endosc 27:1428–1434
17. Busquets J, Peláez N, Secanella L, Darriba M, Bravo A, Santafosta E, Valls C, Gornals J, Peña C, Fabregat J (2014) Evolution and results of the surgical management of 143 cases of severe acute pancreatitis in a referral centre. Cir Esp 92:595–603
18. Seifert H, Biermer M, Schmitt W, Jürgensen C, Will U, Gerlach R, Kreitmair C, Meining A, Wehrmann T, Rösch T (2009) Transluminal endoscopic necrosectomy after acute pancreatitis: a multicentre study with long-term follow-up (the GEPARD Study). Gut 58:1260–1266
19. Gardner TB, Coelho-Prabhu N, Gordon SR, Gelrud A, Maple JT, Papachristou G, Freeman ML, Topazian MD, Attam R, Mackenzie T, Baron TH (2011) Direct endoscopic necrosectomy for the treatment of walled-off pancreatic necrosis: results from a multicenter U.S.series. Gastrointes Endosc 73:718–726