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Position Paper

The i-EUS consensus on the management of pancreatic fluid collections – Part 1

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ABSTRACT

Pancreatic fluid collections (PFCs), including pancreatic pseudocysts (PPs) and walled-off pancreatic necrosis (WON), are common complications of pancreatitis and pancreatic surgery. Historically, the treatment of these conditions has relied on surgical and radiological approaches; however, it has later shifted toward an endoscopy-based approach. With the development of dedicated lumen-apposing metal stents (LAMS), interventional Endoscopic Ultrasound (EUS)-guided procedures have become the standard approach for PFC drainage. However, there is still limited consensus on several aspects of the multidisciplinary management of PFCs. The interventional endoscopy and ultrasound (i-EUS) group is an Italian network of clinicians and scientists with special interest in biliopancreatic interventional endoscopy, especially interventional EUS. This manuscript describes the first part of the results of a consensus conference organized by i-EUS with the aim of providing evidence-based guidance on aspects such as indications for treating PFCs, the timing of intervention, and different technical strategies for managing patients with PFCs.

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1. Background

The incidence of pancreatic disorders, including acute and chronic pancreatitis is increasing [1,2]. Complications of acute pancreatitis (AP) are a major cause of their unfavourable outcomes and of increased costs [3]. The most common local complications of pancreatitis are pancreatic fluid collections (PFCs), defined as either acute peripancreatic fluid collection (APFC), pancreatic pseudocysts (PPs), and their evolution into acute necrotic collection (ANC) or walled-off pancreatic necrosis (WON), respectively [4]. The treatment of these conditions has historically been based on surgical and radiological procedures; however, the advent of interventional Endoscopic Ultrasound (EUS) made endoscopy the cornerstone of the initial treatment of PFCs [5,6]. This rapid paradigm change corresponds to the need for clear evidence regarding the indication of such procedures, standardization of techniques, and use of devices that are rapidly evolving [7-9].

Enforcement of novel approaches in daily practice must be verified and standardized. The interventional Endoscopy and Ultrasound (i-EUS) group was created in 2017 as a community of advanced Italian biliopancreatic endoscopists to promote data sharing, continuous updating, and support education initiatives to optimize procedural outcomes and review execution methods, technical and clinical success, and long-term follow-up. Finally, to overcome the lack of guidelines on these topics, i-EUS was developed into a multidisciplinary stakeholder to organize consensus conferences regarding indications, techniques, clinical management, and follow-up of patients based on the available scientific evidence. The overall objective of this consensus guidelines is to provide evidence-based recommendations on endoscopic treatment of PFCs. The first part of the consensus document focuses on the indications for treating PFCs, the timing of intervention and the different technical strategies and is hereby presented.

2. Methods

2.1. Organization

Four working groups (WGs) were created, each composed of four experts in managing PFCs and a WG leader. The WGs met online and prepared a list of questions and statements based on systematic reviews and related evidence tables regarding the four main aspects (Supplementary Material 1). The first and second groups analyzed the indications for treating PFCs, pre-interventional essential examinations, timing of intervention, and different technical strategies for managing them. The consequent questions and statements were uploaded to a specific app to be read by all experts and were eventually presented in a plenary session in a face-to-face meeting. All statements with less than 80 % agreement were discussed again for possible amendments and excluded if the agreement level was not reached. The excluded questions and statements are provided in Supplementary Material 1. Those that reached agreement were checked and elaborated by the four WGs leaders. An updated literature review was conducted in January 2024; however, its content was only employed in the comments and voted statements. The target users of this document were clinicians involved in the care of patients with PFCs.

2.2. Grading of evidence

Based on the best available evidence, the four WGs provided the following for each clinical question, based on the use of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system for grading evidence levels and recommendation strengths (Supplementary table 1) [10,11].

1. Recommendation: the GRADE strength of recommendation (1 strong, 2 weak) and the quality of evidence (A high, B moderate, C low, D very low), together with the rate of agreement (Supplementary table 2) [10,11]
   In the absence of studies specifically addressing a particular question, this had to be stated, and the recommendation was based on related studies or expert opinions.
2. Comments: These remarks could discuss any relevant aspect regarding the recommendation, such as important exceptions/contraindications, availability, lack of evidence, risks, and costs. In addition, given the time between the consensus conference and the publication of the document, any important additional evidence that could not be considered at the time of document preparation is presented and discussed in the comments. Additional details of the methodology are provided in Supplementary Material 2.

3. Results

The topics examined in the first part were presented consecutively, incorporating 18 questions and 20 related statements (Table 1). The GRADE strength of recommendation and quality of evidence were accordingly provided for each of them, together with the rate of agreement. For each recommendation, comments from the reviewers and attendees at the meeting are summarized.

CHAPTER 1

Question 1.1

Should LAMS be preferred to plastic stents for the drainage of postoperative pancreatic fluid collections?

Statement 1.1

I-EUS suggests LAMS and DPPS equally for drainage of postoperative pancreatic fluid collections.

Quality of evidence: low; recommendation: weak; Agreement 92 %

Comment

With a reported incidence ranging 5 %–20 %, postoperative fluid leaks represent a well-recognized complication of pancreatic surgery, causing significant morbidity and mortality [12,13].

Leaking pancreatic fluid can cause bleeding from adjacent vessels, tissue necrosis, abscess, thus leading to complications, such as pancreatic fistula or PFC, the so-called postoperative pancreatic fluid collection (POPFC).

Percutaneous drainage (PCD) is the conventional approach for managing symptomatic POPFC; however, a meta-analysis showed that EUS has significantly better clinical outcomes in terms of clinical success and collection recurrence [14], avoiding the occurrence of local skin irritation, infections, fistula formation which compromise the patient's quality of life.

The aforementioned meta-analysis included studies mainly used double-pigtail plastic stents (DPPS) [14]; studies directly comparing lumen-apposing metal stents (LAMS) with DPPS for POPFCs are lacking.

Currently, eight studies have tested DPPS or tubular self-expandable metal stents (SEMS) in patients with POPFCs [15-22], whereas five studies used LAMS in the same setting [9,23-26]; the baseline characteristics of patients included are presented in Supplementary Table 3. Given the lack of a significant difference between DPPS and LAMS, both in terms of efficacy and safety (Supplementary Table 4), I-EUS suggests equal LAMS and DPPS for the drainage of the POPFC. However, given the easier procedure and possibility of achieving quick drainage of large collections, LAMS could represent a valuable option.

After the consensus conference, at the time of manuscript preparation, a further systematic review with meta-analysis [27] of three prospective studies [28,29,30] including 206 patients with

Table 1
Agreement to the proposed statements (first part).

Statement	*Agreement (%)*
Statement #1.1 I-EUS suggests LAMS and DPPS equally for drainage of postoperative pancreatic fluid collections. Quality of evidence: low; recommendation: weak;	92
Statement #1.2 In the case of LAMS placement, i-EUS suggests the use of DPPS after LAMS removal for the drainage of pancreatic fluid collections in patients with disconnected pancreatic duct syndrome *Very low quality evidence; Recommendation weak*	53 (not approved)
Statement #1.3 Considering safety, I-EUS does not suggest against the early EUS-guided drainage of infected pancreatic necrosis that does not respond to antibiotic therapy in critically ill patients. Quality of evidence: low; recommendation: weak	90
Statement #1.4 *I-EUS suggests LAMS removal within 4 weeks after EUS-guided drainage of pancreatic fluid collections. Late removal can be considered in specific clinical settings, providing no risk situation are present.* *Quality of evidence: low; recommendation: weak; Agreement 96 %*	96
Statement #1.5a *I-EUS does not recommend immediate catheter drainage over a postponed strategy, which involves waiting for full encapsulation, as no improvement in the patients' clinical outcomes was demonstrated.* *Quality of evidence: moderate; recommendation: strong*	89
Statement #1.5b In cases of failure of conservative treatment or in critical conditions, I-EUS does not suggest a tailored step-up approach for catheter drainage. Percutaneous image-guided catheter drainage is the best strategy for early intervention (within 2–4 weeks after symptom presentation) in critical patients with failed conservative strategies. *Moderate quality of evidence, weak recommendation*	96
Statement #1.6 I-EUS suggests contrast-enhanced CT (CE-CT) as the preferred imaging modality for evaluating local complications of pancreatitis. If contrast is contraindicated, non-enhanced magnetic resonance imaging (MRI) might be preferred over non-enhanced CT-scan for the initial evaluation of the disease and local complications. *Quality of evidence: very low; recommendation: weak*	95
Statement #1.7 I-EUS suggests embolization of a pseudoaneurysm in the peripancreatic collection to reduce the risk of bleeding. Thus, a multidisciplinary approach with shared decisions among experts is recommended. *Quality of evidence: very low; recommendation: weak*	95
Statement #2.1 I-EUS suggests the use of luminal apposing metal stents (LAMS) for the transmural drainage of WON. LAMS diameter should be 15 mm or larger. *Quality of evidence: low; recommendation: weak*	100
Statement #2.2 I-EUS suggests immediately after its placement, LAMS dilation with pneumatic balloon could reduce the risk of adverse events *Very low quality evidence; recommendation weak;*	53 (not approved)
Statement #2.3 I-EUS suggests placement of a coaxial double-pigtail stent after LAMS insertion to be evaluated on an individual basis. *Quality of evidence: very low; recommendation: weak*	91
Statement #2.4 I-EUS suggests considering dual-modality drainage (endoscopic and percutaneous) in patients with WON with extension to the paracolic gutter or > 10 cm and multiple or septate lesions. *Quality of evidence: low; recommendation: weak*	90
Statement #2.5 I-EUS suggests considering the multigate transluminal gateway technique (MTGT) with LAMSs in cases of multiple/septated collections or in cases of suboptimal response to single drainage. *Quality of evidence: low; recommendation: weak*	89
Statement #2.6 I-EUS suggests that Direct Endoscopic Necrosectomy (DEN) should be performed only if required by persistent clinical symptoms or biochemical signs when drainage alone is insufficient. *Quality of evidence: low; recommendation: weak*	94
Statement #2.7 I-EUS suggests that further necrosectomies after the first procedure are planned on-demand, based on clinical evaluation, rather than scheduled. Quality of evidence: low; recommendation: weak	93
Statement #2.8 I-EUS recommends that DEN is started using standard endoscopic devices to be chosen based on local expertise and availability (snares, rat-tooth forceps, Dormia baskets, and retrieval nets are among the most frequently adopted devices). *Quality of evidence: very low; recommendation: weak;*	98
Statement #2.9 I-EUS suggests performing follow-up imaging four weeks after the index procedure to assess the resolution of WON, prior to LAMS removal. I-EUS suggests that CE-MRI is the technique of choice to assess the resolution of WON prior to LAMS removal. If MRI is not available or not feasible, CE-CT is an alternative imaging modality. *Quality of evidence: very low; recommendation: weak*	81
Statement#2.10a I-EUS suggests performing necrosectomy on an inpatient basis under deep sedation or general anesthesia, depending on individual risk. *Quality of evidence: low; recommendation: weak*	93

(*continued on next page*)

Table 1 (*continued*)

Statement#2.10b I-EUS suggests performing necrosectomy in a dedicated radiology room. *Quality of evidence: very low; recommendation: weak*	80
Statement#2.11 I-EUS suggests that DEN is an invasive technique and serious AEs can occur, including death. Bleeding is the most common complication. Early removal of the LAMS, if the collection has resolved, identification of a vessel within the WON, use of CO2 insufflation, and experienced operators performing these procedures could reduce the risk of AEs. *Quality of evidence: low; recommendation: strong*	92

WON (104 LAMS vs. 102 plastic stent) analyzed several outcomes and found no superiority of one over another, as well as a recent multicenter randomized controlled trial (RCT) [31].

Question 1.3

Is it safe to perform early EUS-guided drainage of pancreatic fluid collections using lumen-apposing metal stents in critically ill patients?

Statement 1.3

Considering safety, I-EUS does not suggest against the early EUS-guided drainage of infected pancreatic necrosis that does not respond to antibiotic therapy in critically ill patients.

Quality of evidence: low; recommendation: weak; Agreement 90 %

Comment

A case-control study by Oblizajek [32] retrospectively evaluated patients who underwent endoscopic PFC drainage (including LAMS) for <4 weeks after the onset of pancreatitis. Adverse events (AEs) occurred in 21 % and 32 % of early and late intervention cases, respectively (p=NS).

Trikudanathan [33] retrospectively analyzed 193 patients (76 early and 117 standard) with necrotizing pancreatitis who underwent drainage (main indication was infection) using LAMS among other stents. No significantly increased risk of complications was observed: stent occlusion and infection, bleeding, perforation, and fistulae occurred in 40 % and 33 %($p = 0.36$), 10.5 % and 10.3 %($p = 0.95$), 0 % and 6.0 %($p = 0.044$), and 32.9 % and 20.5 %($p = 0.054$) of patients, respectively. Significantly higher mortality (13% vs. 4 %) and need for rescue open surgery (7% vs. 1 %) were recorded in early drained patients, probably related to the greater severity of the cases. Two other studies explored this field (using LAMS), one retrospective by Chantarojanasiri [34] who compared safety and effectiveness of early vs. standard treatment, with AE rates of 25 and 13 %, respectively. The second study [35] prospectively enrolled 71 patients underwent endoscopic drainage of PFCs, and 25 (35.2 %) within the first 4 weeks; no statistical difference was observed in terms of the clinical success, even long-term, recurrence rate or AEs depending on the timing of treatment. Interestingly, also a multicenter, randomized superiority trial [36] confirmed this trend, with no superiority of immediate (within 24 h) over postponed drainage regarding complications. The characteristics of aforementioned studies are summarized in Supplementary Table 5.

After the consensus conference, at the time of manuscript preparation, two meta-analyses evaluated early vs. delayed EUS-guided drainage of POPFC [37] or WON [38], both concluding that there is no increase of AEs for early drainage (<4 weeks), suggesting no need to delay it.

Question 1.4

What is the safest timing for lumen-apposing metal stent removal after EUS-guided drainage of pancreatic fluid collections?

Statement 1.4

I-EUS suggests LAMS removal within 4 weeks after EUS-guided drainage of pancreatic fluid collections. Late removal can be considered in specific clinical settings, providing no risk situation are present.

Quality of evidence: low; recommendation: weak; Agreement 96 %

Comment

Walter [39] reported a low rate of self-limiting device-related bleeding in 61 patients with PFCs, in which 82 % of LAMS were removed after a median of 32 days. Conversely, a retrospective, international, nested case-control study [40] from 15 centers that evaluated the risk factors for LAMS-related AEs reported that less than half of all AEs occurred early. Bang [41] highlighted the high rate of AEs in patients with WON treated with LAMS, all occurring in the first 3 weeks after LAMS placement or at the 6-week follow-up; accordingly, the authors modified the study protocol by planning a scheduled early Computed Tomography (CT)-scan and removing stent in case of PFC resolution. Since then, early removal of LAMS (<4 weeks) has become an assumption considered by the major scientific societies to avoid stent-related AEs [42] such as delayed bleeding [43].

Although this major concern appears conflicting in other two large multicenter retrospective studies [44,45], I-EUS suggests LAMS removal within 4 weeks after EUS-guided drainage of PFCs, with considerable late removal in specific clinical settings, providing no risk (Supplementary Table 6). After the consensus conference, one retrospective study, including 108 consecutive patients undergoing LAMS drainage of PFCs, showed higher clinical success in cases of delayed LAMS removal (>4 weeks) (70% vs. 96.4 %, $p = 0.03$), with no differences in AEs occurrence compared with early removal (<4 weeks) [46].

Question 1.5

Which treatment strategy should be adopted in the early phase of the disease (within 4 weeks of symptom onset) in patients with infected pancreatic necrosis?

Statement 1.5a

I-EUS does not recommend immediate catheter drainage over a postponed strategy, which involves waiting for full encapsulation, as no improvement in the patients' clinical outcomes was demonstrated.

Quality of evidence: moderate; recommendation: strong; Agreement 89 %

Statement 1.5b

In cases of failure of conservative treatment or in critical conditions, I-EUS does not suggest a tailored step-up approach for catheter drainage. Percutaneous image-guided catheter drainage is the best strategy for early intervention (within 2–4 weeks after symptom presentation) in critical patients with failed conservative strategies.

Moderate quality of evidence, weak recommendation Agreement 96 %

Comment

The standard approach for infected PFC is based on minimally invasive drainage performed until 4 weeks after pancreatitis onset, when complete encapsulation becomes evident. The safety and efficacy of earlier interventions (<4 weeks) have been evaluated in the above-mentioned RCT [36], not showing any superiority of immediate over delayed intervention in terms of mortality, complications, and AEs. Given the evidence of the non-superiority of immediate versus postponed interventions, together with the demon-

stration that a significant number of patients (up to 35 %) could be managed with conservative treatments, I-EUS suggests conservative and supportive treatment as a first-line approach for patients with infected pancreatic necrosis. A recent AGA clinical guideline recommends percutaneous drainage as a safe and effective alternative strategy for critically ill patients with infected WON when EUS-guided drainage is contraindicated, infeasible, or unavailable. Catheter drainage can allow local sepsis control through PFC drainage and irrigation, and evacuation of necrotic content is possible when large-caliber catheters are used [43]. Two RCTs and one multicenter observational study assessed the outcomes of critically ill patients treated with percutaneous catheter drainage alone, reporting a clinical success rate of 35–51 % [47-49]. The risk of pancreatocutaneous fistula was demonstrated to be significantly higher in patients treated with percutaneous versus endoscopic alone (32% vs. 5 %), while the combination of both approaches seems to abolish this risk [47]. After the consensus conference, a retrospective propensity score-matched study of 278 patients [50] showed similar clinical success (92.3% vs. 93.1 %, $p = 0.861$) and AE rates (23.1% vs. 27.6 %, $p = 0.565$) between early and late drainage. Another retrospective study [51] on 148 patients underwent percutaneous drainage, early one was associated with a higher complication rate (16% vs. 5.4 %, $p = 0.034$) and need for surgery (13 vs. 5 patients, $p = 0.031$).

Question 1.6

What is the best pre-interventional imaging modality for peri–pancreatic collections for planning potential endoscopic treatment?

Statement 1.6

I-EUS suggests contrast-enhanced CT (CE-CT) as the preferred imaging modality for evaluating local complications of pancreatitis. If contrast is contraindicated, non-enhanced magnetic resonance imaging (MRI) might be preferred over non-enhanced CT-scan for the initial evaluation of the disease and local complications.

Quality of evidence: very low; recommendation: weak; Agreement 95 %

Comment

CE-CT is usually the first-line imaging modality on admission for AP, and within the first week from onset/hospital admission [42]. CE-CT is easily available and has high reproducibility and accuracy for predicting severity and clinical outcomes [49,52-54], although it has some contraindications. Non-enhanced MRI (NE-MRI) is similar to CE-CT for the initial assessment of pancreatitis complications [55-57]. Pre-interventional imaging should clearly inform about presence or absence of a well-defined wall, intra-pancreatic or extra-pancreatic collections, communication with main pancreatic duct (MPD), MPD integrity, size and extension of PFCs, amount of solid debris, dangerous vessels or pseudoaneurysms, since these informations are related to drainage strategy and outcomes [58,59,60]. Moreover, the percentage of pancreatic necrosis (OR=0.4; $p = 0.01$) and heterogeneous collection on CT-scans (OR=0.19; $p = 0.005$) seem associated with a lower rate of success in patients treated with catheter drainage (percutaneous or endoscopic) [61]. In fact, no specific imaging modality covers all the needs; therefore, CE-CT and MRI are both adequate elective pre-interventional imaging modalities. MRI is slightly preferred to assess the drainability of WON in scheduled procedures because it detects non-liquefied material better than CT, with a higher interobserver agreement [62,63]. Moreover, CT-scan showed poor performance in assessing infected pancreatic necrosis (sensitivity 45.9 %; specificity 81.5 %; accuracy 50.5 %) [64], whereas MRI had a higher performance (specificity >90 %; accuracy 95 %) (Supplementary Table 7) [65,66]. After the consensus conference, a retrospective propensity score study [67] of 289 AP patients underwent CE-CT between 4 and 10 days after disease onset demonstrated that the identification of early encapsulation showed good intra- and inter-observer agreement (kappa statistics: 0.729 and 0.614, respectively) and that the early encapsulation group repoted a lower incidence of persistent organ failure (6.1% vs. 22.4 %, $p = 0.043$).

Question 1.7

Is pre-emptive embolization recommended prior to drainage of PFCs if pseudoaneurysms are detected?

Statement 1.7

I-EUS suggests embolization of a pseudoaneurysm in the peripancreatic collection to reduce the risk of bleeding. Thus, a multidisciplinary approach with shared decisions among experts is recommended.

Quality of evidence: very low; recommendation: weak; Agreement 95 %

Comment

Imaging for staging PFCs should include careful attempts to rule out pseudoaneurysms to prevent severe bleeding during or after drainage, which can be a life-threatening complication [68]. A recent single-center study retrospectively evaluated patients with necrotizing pancreatitis, with 39 of 607(6.4 %) patients showing pseudoaneurysm; 44 % of those with pseudoaneurysm were diagnosed after endoscopic LAMS placement. In this setting, CE-CT was diagnostic for pseudoaneurysm in 83.9 % of cases, with a false-negative rate of 16.1 % [69]. Therefore, preemptive treatment of arterial pseudoaneurysms is a rational option in patients requiring drainage because of the risk of spontaneous rupture. Angiography with arterial embolization using interventional radiology is the first-line treatment [58]. A few case series reported pre-emptive embolization of arterial pseudoaneurysms or vessels encased in the PCFs before EUS-guided drainage, showing a high rate of safety and efficacy in preventing bleeding (Supplementary Table 8) [70-72]. Some authors have suggested a multidisciplinary approach to indicate prophylactic embolization of high-risk vascular lesions before PFC drainage [73]. After the consensus conference, another case report [74] of rupture of a gastroduodenal artery pseudoaneurysm was successfully treated using interventional radiology. Moreover, a multicenter retrospective study of 516 patients showed that pseudoaneurysm was an independent predictor of AE occurrence (OR 2.99, $p = 0.002$) [75].

CHAPTER 2

Question 2.1

What size/length/type of stent is the best option for patients with pancreatic necrosis?

***Statement* 2.1**

I-EUS suggests the use of luminal Apposing metal stents (LAMS) for the transmural drainage of WON. LAMS diameter should be 15 mm or larger.

Quality of evidence: low; recommendation: weak; Agreement 100 %

Comment

Both bi-flanged metal stents (BFMS) and LAMS can be used [76-79]. Early studies evaluated BMFS (NAGI stent; Taewoong Medical, Gyeonggi-do, Korea) for EUS-guided drainage of WON. Stents had an expanded diameter of 14 or 16 mm and lengths of 20- or 30-mm [76,77]. Recently, two different types of LAMS (Axios [Boston Scientific, Marlborough, Mass, USA] and Spaxus[Taewoong Medical Co, Gimpo, Korea]) were introduced. The first LAMS (Axios) had high reported technical (97.5 %−100 %) and treatment success rates (86.3 %- 88.2 %), and the migration rate ranged from 2.5 % to 5.6 % [78,79]. Multivariable analysis demonstrated that clinical success

was six times more likely with larger stents (15 mm vs. 10 mm) [78]. A recent prospective study confirmed the high technical success (100 %). The median procedure time was 14 min, the median stent indwelling time was 19 days, and clinical success was observed in 80 % of patients [80]. These high success rates were also observed with a novel LAMS, as shown in a recent prospective international multicenter study that evaluated the outcomes of Spaxus for the drainage of PFCs. Technical and clinical success rates were 100 % and 98.3 %, respectively. The stent-related AE rate was 6.8 % and none of the patients had stent migration or buried-stent syndrome [81]. Another study [82] reported similar success rates for LAMS and BFMS, but higher rates of stent dysfunction (10.2% vs. 5.9 %, $p = 0.04$) as well as higher rates of stent migration (7.3% vs. 1.6 %; $p < 0.001$) with BFSM compared with LAMS (Supplementary table 9). The 20-mm diameter has been shown to require fewer necrosectomy sessions than 15 mm [8,83]; thus, 20 mm LAMS should be considered in cases of large collections with extensive necrosis.

Question 2.3

Should double-pigtail plastic stents be placed through the LAMS after WON drainage?

***Statement* 2.3**

I-EUS suggests placement of a coaxial double-pigtail stent after LAMS insertion to be evaluated on an individual basis.

Quality of evidence: very low; recommendation: weak; Agreement 91 %

Comment

Some endoscopists place one or more double-pigtail plastic stents through the LAMS to reduce the risk of early occlusion and LAMS migration [43]. DPPS stent-in-stent seems to be associated with a lower bleeding risk; in 2019, Wundsam et al. reported that bleeding with metal stent treatment occurred in 14.3 % of patients. When LAMS was combined with DPPS, bleeding was observed in only 5.3 % [59]. These findings have been confirmed in two recent studies: Puga et al. [84] found that the LAMS alone had a significantly higher rate of AEs than the LAMS plus DPPS group (42.9% vs. 10.0 %; $P = 0.04$), and bleeding was the most frequently observed AE, followed by infection. Recently, a study confirmed a trend toward lower bleeding rates with DPPS, even if no significant differences were found [85]. Thus, it seems to increase the benefit associated to stent-related bleeding complications [59]. However, the number of patients treated with FCSEMSs/LAMSs and additional DPPS remains too low to allow for a profound statistical analysis and support this practice. After the consensus conference, at the time of manuscript preparation, four additional significant studies on this topic were published (Supplementary Table 10). Indeed, a RCT [86] investigated whether the insertion of a coaxial DPPS through LAMS can prevent LAMS-related AEs. Failure of the index method was lower in the LAMS+DPPS group (29.4% vs. 48.5 %, $p = 0.109$). This high failure rate is partly caused by the inclusion of endoscopic necrosectomy as a failure of the index treatment. The global AEs rate was significantly lower in the LAMS+DPPS group than in the LAMS group (20.7% vs. 51.5 %, respectively; $p = 0.008$). In addition, a retrospective study that included 83 patients with LAMS and 102 patients with LAMS/DPPS did not find any differences in the rates of AEs (15.7% vs. 15.7 %, $p = 0.825$) or clinical success (75.9% vs. 69.6 %, $p = 0.340$) [87]. Two more recent meta-analyses disproved the difference in AE rates between the two groups [88,89]. Specifically, lower trends of overall AE (RR:=0.64), stent occlusion (RR=0.63), infection (RR=0.50), and perforation (RR=0.42) were observed in the LAMS+DPPS group compared to the LAMS alone group [88]. Furthermore, no difference in bleeding rate was documented between LAMS alone and LAMS-DPPS (RR=1.80) [89].

Question 2.4

In which cases WON drainage should be initiated using a combined endoscopic/percutaneous approach (dual modality)?

***Statement* 2.4**

I-EUS suggests considering dual-modality drainage (endoscopic and percutaneous) in patients with WON with extension to the paracolic gutter or > 10 cm and multiple or septate lesions.

Quality of evidence: low; recommendation: weak; Agreement 90 %

Comment

Percutaneous drainage is a safe tool for WON treatment. A systematic review of 384 patients concluded that no additional surgical necrosectomy was required in 55.7 % of the patients [90]. In 2018, the ESGE guidelines suggested considering concurrent endoscopic transmural drainage and percutaneous drainage in patients with WON with extension to the pelvic paracolic gutters [42]. This recommendation was based on three retrospective studies describing the procedure and reporting favorable outcomes compared with percutaneous drainage alone [91-93]. Moreover, in a retrospective series of 53 patients, a larger WON, extension to the paracolic gutter, and pre-existing diabetes were associated with the need for surgery [94]. Recently, in a retrospective study including 136 patients, the authors investigated factors associated with additional treatments, including DEN, additional drainage (both endoscopic or percutaneous), and surgical debridement. Sixty-nine patients required step-up therapy (65 DEN, nine additional sites of endoscopic drainage, 17 percutaneous drainage, and one operative intervention). Independent predictors of step-up therapy included collection size measuring >10 cm (OR=8.91), paracolic extension of the PFC (OR=4.04), and >30 % solid necrosis (OR=4.24) [95]. Another large retrospective study included 291 patients. Patients with evidence of disconnected pancreatic duct syndrome (DPDS) required hybrid treatment in 31.1 % of cases compared to only 4.8 % without DPDS ($p < 0.001$). Hybrid interventions included drainage by MTGT in 46 patients, dual-modality treatment in 18 patients, and percutaneous transluminal necrosectomy in 14 patients. Moreover, a significantly larger number of patients with DPDS required rescue surgery (13.2% vs. 4.8 %, $p = 0.017$). The presence of DPDS, WON, PFC size ≥ 100 mm, and multiple PFCs was associated with the need for hybrid treatment (Supplementary Table 11) [96].

Question 2.5

When and how should endoscopic drainage be performed using the multigate transluminal gateway technique (MTGT)?

Statement 2.5

I-EUS suggests considering the multigate transluminal gateway technique (MTGT) with LAMSs in cases of multiple/septate collections or in cases of suboptimal response to single drainage.

Quality of evidence: low; recommendation: weak; Agreement 89 %

Comment

The MTGT consists of more than one endoscopic drainage procedure. The procedure was initially described using a step-up algorithm where the MTGT was performed for WON >12 cm in size and for unilocular WON ≤12 cm that responded suboptimally to a single transluminal drainage [97]. Then, ESGE guidelines suggested considering it in patients with either multiple or large (>12 cm) WON, or in cases of suboptimal response to single transluminal gateway drainage [42]. In another retrospective study from same authors including 291 patients, hybrid interventions were more frequently represented by the MTGT [96]. The same group developed a treatment protocol in which single unilocular collections were treated with a single LAMS, and multiple collections were managed with multiple LAMS. In the case of DPDS, collections

<10 cm were drained with a single LAMS, and collections >10 cm were drained using a modified MTGT (i.e., LAMS + plastic stent for long-term drainage). Finally, in cases of lower abdominal extension, dual-modality drainage was used [98]. However, a recent RCT demonstrated no advantage of LAMS with DPPS after LAMS removal in patients with DPDS (Supplementary Table 12) [99]. After the consensus conference at the time of manuscript preparation, a multicenter retrospective study identified the multigate technique as an independent predictor of AE occurrence (OR 3.00, $p = 0.05$) [75].

Question 2.6

Should the first necrosectomy be performed at the index procedure or postponed?

***Statement* 2.6**

I-EUS suggests that Direct Endoscopic Necrosectomy (DEN) should be performed only if required by persistent clinical symptoms or biochemical signs when drainage alone is insufficient.

Quality of evidence: low; recommendation: weak; Agreement 94 %

Comment

Drainage itself, especially with large-caliber LAMS, can resolve symptoms and/or superinfection of WON without any additional maneuvers. Failed resolution of symptoms, organ failure, or persistently elevated inflammatory markers requires additional procedures. Factors associated with the need for a step-up approach with additional interventions include $a \geq 30$ % extent of solid necrosis, a large volume (≥10 cm) of the WON, and paracolic extension [78,95,100-102].

European and American guidelines suggest that DEN should be performed only in the absence of improvement following endoscopic transmural drainage [42,43]. In almost half of the patients, drainage alone is sufficient [95,103,104], paired with the potential adverse events of DEN (air embolism, bleeding, and perforation), discouraging DEN during the first procedure. Although this has been uneventfully reported in a large proportion of patients in a retrospective series [83], DEN has been performed on demand in major RCTs on endoscopic treatment of necrotizing pancreatitis [47,105]. In one retrospective multicenter study including only WONs requiring DEN, those undergoing necrosectomy during the first drainage session ($N = 69$) required fewer sessions for WON resolution [106], despite no differences in overall clinical success and additional interventions. Furthermore, in three cases (4.3 %) LAMS had to be repositioned due to intraprocedural dislodgement. Criteria for improvement deserve further definitions, as some studies assessed an amelioration based on clinical improvement, whereas others relied on early imaging repetition (even as soon as 72 h after the procedure) to discriminate the need for additional interventions [107]. Regarding timing, the literature ranges from an early aggressive reintervention strategy within 72 h from drainage to repeated imaging with eventual reintervention within 4 weeks. Despite scheduled 72-hours CT-scan [107] or endoscopy [108] have been described to assess the clinical success of primary drainage, there is no evidence that this provides better outcomes than relying on clinical evolution. In a meta-analysis, the mean time from drainage to necrosectomy was seven days [109]. The same timeframe was suggested by a worldwide multi-institutional survey of experts, 85 % of whom discouraged DEN during the index procedure [110]. After the consensus conference, at the time of manuscript preparation, a multicenter RCT [104] was published comparing upfront necrosectomy with a step-up approach in cases of infected necrotizing pancreatitis, showing a lower median number of reinterventions for upfront necrosectomy ($p = 0.0027$), while no differences were observed in mortality, disease-related AEs, or procedure-related AEs.

Question 2.7

Should repeated necrosectomy after the first procedure be scheduled or planned on demand?

***Statement* 2.7**

I-EUS suggests that further necrosectomies after the first one are planned on-demand, based on clinical evaluation, rather than scheduled.

Quality of evidence: low; recommendation: weak; Agreement 93 %

Comment

Although some authors have claimed that after the first necrosectomy, DEN should be repeated almost every seven days until collection resolution [108-111], no high-quality evidences have proven the clinical benefit of scheduling subsequent necrosectomies versus basing it on clinical status. Heterogeneous behaviors have been reported in assessing the subsequent need for necrosectomy, either relying on clinical symptoms versus aggressive radiological [80,112] or endoscopic follow-up, with even a 72-hours and every-7-days endoscopic evaluation proposed by one series [108]. In meta-analyses, an average of four interventions per patient has been reported, and the mean time from drainage to necrosectomy was 7 days, with almost 85 % of patients managed by endoscopy alone, the others requiring step-up with additional percutaneous or surgical interventions [109,113]. Some authors suggested a reduced number of DEN sessions when WONs were treated with a 20-mm versus 15-mm LAMS [83], corroborating the idea that large-caliber cystogastrostomy can facilitate spontaneous drainage of necrotic material regardless of DEN. In a multicenter retrospective evaluation of pre-drainage CE-scan features, a larger collection diameter, a subtotal/total pattern of pancreatic necrotic involvement, hemorrhage, and DPDS were associated with a higher likelihood of undergoing >2 necrosectomies. However, in multivariate analysis, none of these morphological factors predicted the need for a higher number of necrosectomies, whereas the use of an on-demand versus scheduled DEN reduced this risk [114]. Based on an RCT demonstrating a higher rate of LAMS-related AEs (mainly bleeding) three weeks after placement [28], retrieval of LAMS is currently recommended within four weeks [42]. This should be regarded as a fixed and scheduled appointment to re-evaluate the effectiveness of drainage with second-level imaging and for direct endoscopic evaluation of the cavity, preliminary to stent removal versus its replacement with one or more double-pigtail stents. This time interval has also been advocated as a therapeutic window for repeated DENs, when needed [80].

Question 2.8

Is there a preferred tool for necrosectomy?

***Statement* 2.8**

I-EUS recommends that DEN is started using standard endoscopic devices to be chosen based on local expertise and availability (snares, rat-tooth forceps, Dormia baskets, and retrieval nets are among the most frequently adopted devices).

Quality of evidence: very low; recommendation: weak; Agreement 98 %

Comment

DEN involves irrigation and aspiration, necrosis fragmentation and debris removal [42,105]. However, the LAMS can be accidentally displaced during maneuvers or impede the extraction of large pieces of necrosis. In such cases, the LAMS can be replaced with DPPS to maintain the fistula. One study described successful and uneventful replacement of the same LAMS during necrosectomies in 40 patients, repeated at each subsequent necrosectomy until resolution after a mean of two redeployments per patient, advocating the benefit of fewer passes and reduced duration

of each session [115]. Different devices have been adapted such as foreign body removal or stone extraction. In different studies, snares, retrieval nets, retrieval baskets, tripod retrieval forceps, grasping forceps, and balloons have been used [42]. No device has been specifically developed for this purpose. However, initial evidence has been published regarding Endorotor®(Interscope Medical, Worcester, MA, United States), an endoscopic through-the-scope device consisting of an outer cannula with hollow inner cannulas with rotable blades, resulting in tissue resection and subsequent negative-pressure aspiration. The larger prospective evaluation of this device regarding 30 patients and 64 necrosectomies sessions reported a 96 % clinical success within a median of 1.5 sessions, and AEs were registered in 33 % of patients, of which 3 serious AEs (2 bleedings and 1 pneumoperitoneum) were classified as potentially related to the DEN procedure but not caused by the device [116]. Currently, Endorotor® should be reserved for clinical studies or selected cases. Based on a live-voting survey among experts participating in the discussion, the tools more frequently adopted during necrosectomy were polypectomy snares (77 %), rat-tooth forceps (10 %), Dormia baskets, and retrieval nets (7 % each).

Question 2.9

When and how should follow-up imaging be performed to assess WON resolution prior to LAMS removal?

***Statement* 2.9**

I-EUS suggests performing follow-up imaging four weeks after the index procedure to assess the resolution of WON prior to LAMS removal.

I-EUS suggests that CE-MRI is the technique of choice to assess the resolution of WON prior to LAMS removal. If MRI is not available or not feasible, CE-CT is an alternative imaging modality.

Quality of evidence: very low; recommendation: weak; Agreement 81 %

Comment

Evidences regarding the optimal timing of follow-up after invasive WON procedures are lacking. Imaging should be performed at four weeks to assess the resolution of the WON prior to LAMS removal. CE-MRI is the imaging modality of choice due to its higher contrast resolution, higher sensitivity, and specificity for the detection of necrosis and allows better visualization of the pancreatic parenchyma and MPD [100,117]. Moreover, it is less invasive, because it is free of ionizing radiation [118]. In the absence of CE-MRI, CE-CT may be considered an alternative imaging modality.

Question 2.10

What is the ideal hospital setting and sedation regimen for a necrosectomy?

Should necrosectomy always occur in a radiological room?

Statement 2.10a

I-EUS suggests performing necrosectomy on an inpatient basis under deep sedation or general anesthesia, depending on individual risk.

Quality of evidence: low; recommendation: weak; Agreement 93 %

Statement 2.10b

I-EUS suggests performing necrosectomy in a dedicated radiology room.

Quality of evidence: very low; recommendation: weak; Agreement 80 %

Comment

Prospective studies comparing in- and out-patient settings for LAMS placement and necrosectomy are lacking. A retrospective multicenter study showed that LAMS placement and subsequent DEN can be safely performed on an outpatient basis [119]. The mean number of procedures required after the initial stent placement was significantly lower in the inpatient group than in the outpatients (2.3 vs 3.1, respectively, $P = 0.025$). There were no significant differences in the complete resolution of PFCs between the inpatient and outpatient groups (91% vs. 87 %, respectively; $p = 1$), and no recurrence of WON or PP was observed after stent removal in either group. Nevertheless, procedure-related AEs were significantly lower in the inpatient group than in the outpatient group ($p < 0.01$), in the absence of significant differences in terms of AEs requiring endoscopic reintervention within 30 days ($p = 0.69$) [119]. Despite these initial results, further studies are needed before universally extending this recommendation. In the meantime, we suggest performing the procedure preferably after hospital admission, especially in symptomatic or septic patients.

In the absence of data comparing different sedation regimens, it is suggested that the procedure should be performed under deep sedation or general anesthesia, depending on individual risks [42]. Similarly, no studies have evaluated the optimal environmental setting for performing necrosectomy. In the absence of data, we suggest performing the procedure preferably in a dedicated radiology room because it allows for better management of complications.

Question 2.11

What are the possible Adverse Events (AEs) associated with endoscopic necrosectomy? Type, management, and prevention

Statement 2.11

I-EUS suggests that DEN is an invasive technique and serious AEs can occur, including death. Bleeding is the most common complication. Early removal of the LAMS, if the collection has resolved, identification of a vessel within the WON, use of CO2 insufflation, and experienced operators performing these procedures could reduce the risk of AEs.

Quality of evidence: low; recommendation: strong; Agreement 92 %

Comment

Data on the overall DEN-related AEs rate are sparse and range from 7.2 % to 36 %, graded from mild to serious complications, including death [106,109]. The timing of the DEN did not seem to affect the AEs rate. In a comparative study of immediate and delayed DEN, no significant difference in overall procedural AEs between the two groups was reported (7.2% vs. 9.4 %; $p = 0.81$) [106].

The most common AEs associated with DEN are bleeding, stent dislodgment, infection, perforation, and air embolism.

Bleeding

In a systematic review of 455 patients who had undergone DEN [109], bleeding was the most common AE, with an overall incidence of 18 %. After WON drainage with collapse of necrotic cavities, LAMS remains in situ, and the resultant friction against the collection wall can disrupt small capillaries and injure larger blood vessels. Therefore, performing a CT-scan within 3 weeks after WON drainage, followed by removal of the LAMS if the collection has resolved, has been a widely recommended practice to avoid AEs [41,42,58,108,120]. Moreover, bleeding can occur during DEN or at any moment after LAMS placement from crossing vessels, aneurysms, or pseudoaneurysms. The splenic and gastroduodenal arteries are the most common arteries involved in pseudoaneurysm formation, with an incidence ranging 4.3 %–6.4 % in patients with necrotizing pancreatitis [69,121]. The predictive factors for bleeding in patients with WON drainage remain unknown. Moreover, the identification of a vessel within the WON cavity during DEN was found to be highly predictive of bleeding. Therefore, pneumatic dilation of the stent could be performed after stent placement to check the content of the collection for evaluating the presence of any vessels. This technique has been shown to be effective in reducing the risk of AEs [40]. Hemostasis during mild bleeding events can be achieved endoscopically us-

ing epinephrine injections, clips, coagulation graspers, or glue injections [109,122,123]. However, severe bleedings require interventional radiology embolization [121].

Stent dislodgement

Dislodgement of the LAMS is a possible complication of DEN. There is a lack of dedicated devices for DEN, and the most common devices used are adapted, depending on availability and endoscopist preference. Therefore, unintentional capture of the LAMS with consequent dislodgment of the stent could occur. However, a successful technique for its replacement after stent dislodgement has been described [124,125].

Perforation

Perforation after WON drainage can occur in up to 4 % of the cases [109]. Usually, it is caused by the separation of the stomach or duodenum from the collection wall during the procedure. Most cases occurred after dilation of the LAMS, leading to the presence of abdominal free air on fluoroscopy during the procedure [126]. In the absence of any signs of peritonitis in a patient in stable condition, conservative treatment can be safely performed. In contrast, in cases of accidental collection wall perforation with leakage of necrotic content or liquid into the abdomen, surgery should be indicated.

Air embolism

Air embolism is a rare but severe AE of DEN resulting from direct communication between a gas source and the bloodstream [127-129]. A venous air embolism can be limited to the portal venous system or evolve into a systemic air embolism. Mobilization of inflammatory necrotic tissues during DEN could cause the rupture of a blood vessel, allowing the passage of air into the bloodstream. Gas embolism should be considered promptly if cardiovascular or respiratory symptoms develop abruptly during the procedure. Using CO2 for insufflation instead of air can eliminate the risk of air embolism because CO2 is easily absorbed [130]. However, fatal gas embolisms after DEN with CO_2 have also been described [131].

Conflict of Interest

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.dld.2024.06.030.

Appendix

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