

# What is the Impact of the Proportion of Solid Necrotic Content on the Number of Necrosectomies during EUS-Guided Drainage using Lumen-Apposing Metallic Stents of Pancreatic Walled-off Necrosis ?

Andrada Seicean<sup>1,2</sup>, Cristina Pojoga<sup>2,3</sup>, Ofelia Moşteanu<sup>1,2</sup>, Sorana D. Bolboacă<sup>1,4</sup>, Mădălina Ilie<sup>5,6</sup>, Mihai Rimbaş<sup>5,7</sup>, Marcel Gheorghiu<sup>1</sup>, Laura Lucaciu<sup>1</sup>, Adrian Bartoş<sup>1,2</sup>, Nadim Al Hajjar<sup>1,2</sup>, Vasile Şandru<sup>5,6</sup>, Gabriel Constantinescu<sup>5,6</sup>, Radu Seicean<sup>1,8</sup>

1) Iuliu Haţieganu University of Medicine and Pharmacy

Cluj-Napoca;

2) Regional Institute of

Gastroenterology and Hepatology, Cluj-Napoca;

3) Clinical Psychology and Psychotherapy Department

Babes-Bolyai University Cluj-Napoca,

4) Department of Medical Informatics and Biostatistics;

5) Carol Davila University of Medicine and Pharmacy, Bucharest;

6) Floreasca Emergency Hospital, Bucharest;

7) Colentina Clinical Hospital, Bucharest;

8) First Surgical Clinic, Cluj-Napoca, Romania

## ABSTRACT

**Background & Aims:** The fully-covered, lumen apposing metal stents are designed for one step placement, facilitating the direct endoscopic necrosectomy into the walled-off pancreatic necrosis. However, the prediction of the number of necrosectomy sessions in these patients is not known. This study evaluated the association between the proportion of solid necrotic material inside walled-off necrosis, as assessed during the endosonography placement of a lumen apposing metal stent, and the number of necrosectomies subsequently required.

**Methods:** Patients from three tertiary medical centers with symptomatic walled off pancreatic necrosis (pain, infection, gastric/biliary obstruction) at more than 4 weeks after onset of acute pancreatitis were retrospectively analysed. Proportion of solid necrotic debris was estimated during endosonography procedure of lumen apposing metal stents placement. Necrosectomy was performed when obstruction or inflammation occurred subsequently. Lumen apposing metal stents were removed after clearance of necrotic content.

**Results:** In 46 patients with successful lumen apposing metal stents placement, necrosectomy was performed in 39 patients (72.78%). Performance of 3 or more necrosectomies was significantly associated with more than 50% pancreatic necrosis ( $p=0.032$ ), but not with walled-off pancreatic necrosis size or location. Necrotic infection during lumen apposing metal stents stenting was associated with hypoalbuminemia, but not with necrosectomy requirement. Clinical success after a median follow-up of 13.37 months was 87%.

**Conclusions:** Walled-off pancreatic necrosis with more than 50% solid necrotic content were associated with more necrosectomy procedures, requiring longer endoscopy time, intravenous sedations, and higher costs.

**Key words:** endosonography – drainage – pancreatic necrosis – metallic stent – acute pancreatitis.

**Abbreviations:** DEN: direct endoscopic necrosectomy; EUS: endoscopic ultrasound; IQR: interquartile range; LAMS: lumen-apposing metal stent; MRI: magnetic resonance imaging; MSOF: multisystem organ failure; WON: walled-off pancreatic necrosis.

## INTRODUCTION

Necrotizing pancreatitis represents roughly 20% of acute pancreatitis cases, with a mortality up to 15% [1, 2]. About 50% of acute necrotic collections develop into walled-off pancreatic necrosis (WON), while among WONs only 20%–63% require further intervention [3–5]. Cross-sectional imaging should be performed after four weeks from onset, for management planning [6]. Indications for drainage are

infected necrosis or symptoms: abdominal pain, vomiting, jaundice, recurrent acute pancreatitis, fistulas; or persistent systemic inflammatory response [7].

Differentiating WONs from pseudocysts is important for management, as residual necrotic debris after insufficient drainage may cause secondary infection [8], but how the amount of solid necrosis affects the patient course has been infrequently studied.

Drainage followed by necrosectomy can be surgical, endoscopic through metallic stents, or percutaneous [9]. Endoscopic ultrasound (EUS) is preferred over other techniques because it avoids creating a pancreaticocutaneous fistula [3]. Endoscopic ultrasound drainage using lumen-apposing metal stents (LAMSS) facilitates the insertion of an endoscope into the WON, allowing direct endoscopic necrosectomy (DEN). Lumen-apposing metal stents showed

*Address for correspondence:*

Andrada Seicean, M.D., Ph.D.

Regional Institute of

Gastroenterology and

Hepatology, Cluj-Napoca,

Romania

19-23 Croitorilor street,

400192, Cluj-Napoca,

Romania

[andradaseicean@gmail.com](mailto:andradaseicean@gmail.com)

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better clinical success than plastic stents [odds ratio (OR) 3.37], with similar side effects [10]. However, the factors affecting the required number of DEN procedures, their optimal timing (at index EUS procedure/as needed), and the interval between sessions remain unclear. The present study evaluated the association between the proportion of solid necrotic material inside WON, as assessed during EUS placement of LAMS, and the number of necrosectomies subsequently required and outcomes of EUS drainage of WONs using LAMs.

## METHODS

The research complied with the ethical standards of the responsible institutional committee and the revised 2000 Helsinki Declaration.

Medical charts from October 2016 to October 2019 from three Romanian tertiary centers, the Regional Institute of Gastroenterology and Hepatology Cluj-Napoca, the Floreasca Emergency Hospital Bucharest, and the Colentina Clinical Hospital, Bucharest, were retrospectively reviewed. Patients with symptomatic WON (abdominal pain, gastric/biliary obstruction or infected collections) at more than 4 weeks after the onset of acute pancreatitis were included in the analysis.

All patients underwent computed tomography (CT) evaluation before the drainage decision for assessing the size, the location, the content, the wall of WON and the presence of collateral circulation. Size of WON did not represent an inclusion criteria. Exclusion criteria were: platelets  $<50\,000/\text{mm}^3$  or international normalized ratio  $>1.5$ ; suspicion of cystic neoplasm; multiloculated WON or WON extension into the lower abdomen;  $>1\text{ cm}$  distance between WON and gut wall; and collateral circulation not avoidable during the procedure.

EUS drainage was done with the patient under general anesthesia and receiving broad-spectrum antibiotic prophylaxis. A therapeutic linear array echoendoscope, Olympus UCT 180, was used in combination with an Aloka F75 ultrasound device or EU-ME2 Premier Plus processor. Walled-off pancreatic necrosis were assessed for location, size, presence and amount of necrotic debris and collateral circulation. The size of WON was considered the largest diameter of the fluid collection. The presence of echogenic material in the WON cavity was suggestive of solid debris. As part of routine real-time EUS assessment, the amount of solid necrotic debris was measured by the endoscopist in mm (long axis and depth) and divided by the total size of the WON and the result represented the proportion of solid debris ( $<30\%$ ,  $30\%–50\%$ , or  $>50\%$ ). All four endosonographers (A.S., O.M., M.I., M.R.) experienced in EUS procedure (over 3000 procedures each) quantified the proportion of solid debris (Figs. 1 and 2) based on intra-procedural measurements or by reviewing the real-time EUS movie.

The LAMS (15 mm diameter, AXIOS; Boston Scientific, Europe) was deployed as previously described [11]. The incoming fluid was suctioned to prevent lung aspiration. To avoid early obstruction of the LAMS by necrotic tissue, an additional plastic stent or nasocystic catheter (in case of pus inside WON, followed by 24 h continuous saline flushing) was placed through the LAMS, when considered necessary. A transpapillary stent was placed when imaging raised suspicion of a disconnected pancreatic duct.



**Fig. 1.** Walled-off pancreatic necrosis visualized during endoscopic ultrasound with over 50% necrosis.



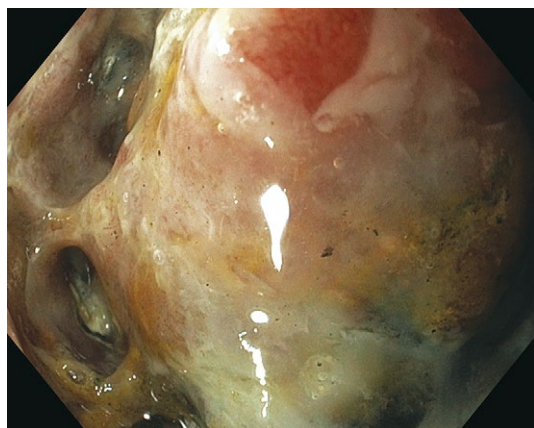
**Fig. 2.** Walled-off pancreatic necrosis visualized during endoscopic ultrasound with less than 30% necrosis.

Direct endoscopic necrosectomy was performed after the index procedure, "on-demand" if obstruction by necrotic tissue or inflammation (fever, leucocytosis, high C-reactive protein) occurred. Solid non-adherent necrotic debris was removed using rat-tooth forceps, small snare, or Dormia basket (Fig. 3 and 4) through a gastroscope inserted into the WON, followed by lavage with saline and half-strength hydrogen peroxide at endoscopist discretion (minor bleeding in the WON cavity).

Clinical success was defined as symptom resolution and WON resolution ( $<3\text{ cm}$  diameter), without mortality or adverse events requiring surgery, without the recurrence of fluid collection or symptoms during follow-up [12]. Need for surgery was defined as surgical intervention (minimally invasive or open) for management of unresolved WON or related complications (multisystem organ failure [MSOF], stent dislodgement with symptomatic pneumoperitoneum,



**Fig. 3.** Endoscopic view of necrosis inside the walled-off pancreatic necrosis during necrosectomy.



**Fig. 4.** Endoscopic aspect of the walled-off pancreatic necrosis after partial cleaning of walled-off pancreatic necrosis cavity. Some debris are still visible on the pink granular tissue.

untreatable infection, or intraabdominal bleeding). Recurrence was defined as recurrent symptomatic WON with a diameter more than 3 cm [12].

Patients were discharged after clinical resolution (without pain, jaundice, emesis, fever), normal leucocytes and CRP; they were readmitted if fever or abdominal pain developed. The management of complications was multidisciplinary.

Lumen-apposing metal stents were removed when CT showed a remnant cavity less than 3 cm without solid content. This was usually about 30 days from the index procedure but earlier if collateral circulation was present or later if the nutritional status was low. The patients without at least 6 months of follow-up after LAMS removal were considered as lost from follow-up and were not considered for long-term analysis.

Clinical examination and transabdominal ultrasound were done every 4–6 months afterwards, and a control CT scan was performed in the first year of follow-up for assessing recurrence.

Qualitative data were reported as number and percentage and quantitative as mean ( $\pm$ standard deviation) or median (interquartile range [IQR]). The Mann–Whitney test was used for quantitative data differences and the Fisher's Exact for group differences (chi-square test assumptions not being met). Spearman's rho was used to test for association between number of DEN procedures and estimated necrosis, and also WON size. Logistic regression was used to investigate independent predictors of successful drainage. Adjustments were made for gender and age as potential confounders. Tests were two-tailed and  $p < 0.05$  was considered significant. The Statistica program (v.13; StatSoft, USA) was used.

## RESULTS

While 51 patients were eligible for EUS drainage, 4 were excluded (collateral circulation,  $n=3$ ; WON  $>1$  cm from gastric wall,  $n=1$ ), leaving 47. Men were younger than women (median [IQR] 52 years [47–61] vs. 65 [60–69];  $p=0.003$ ) and more frequently had pericollection collateral circulation (71.88% vs. 40%,  $p=0.036$ ) (Table I).

**Table I.** Characteristics of patients and pancreatic fluid collections.

Patients	
Age, mean $\pm$ SD (range), years	56.94 $\pm$ 11.44 (33–83)
Men/Women, n (%)	32/15 (68.08/31.92)
Etiology, n (%)	
Alcoholic	27 (57.45)
Biliary	15 (31.91)
Hypertriglyceridemia	1 (2.13)
Episodes of acute pancreatitis, n (%)	
One	44 (93.62)
Recurrent	3 (6.38)
Indication for drainage, n (%)	
Gastric obstruction and pain	29 (61.7)
Infection	17 (36.17)
Biliary compression	1 (2.13)
Previous drainage attempts, n (%)	
Surgical	3 (6.38)
ERCP	1 (2.12)
Percutaneous ultrasound-guided	1 (2.12)
Walled-off pancreatic necrosis	
Location, n (%)	
Head	9 (19.15)
Body/Tail	29 (61.70)
Whole pancreas	9 (19.15)
Dimensions, mean $\pm$ SD (range), mm	
Long axis	116 $\pm$ 36 (60 to 210)
Depth	83 $\pm$ 25 (50 to 179)
Collateral circulation, n (%)	
Yes	29 (61.70)
No	15 (38.30)
Percentages of solid necrotic content, n (%)	
<30%	16 (34.04)
30–50%	16 (34.04)
>50%	15 (31.91)

ERCP: endoscopic retrograde cholangiopancreatography; SD: standard deviation.

Technical success was noted in 46 of 47 patients (97.87%) (Table II). In the remaining patient a highly fibrotic wall impeded LAMS passage. Therefore two plastic stents were placed instead, which provided a successful outcome. This patient, with less than 30% solid necrosis, was excluded from analysis.

A large proportion ( $>50\%$ ) of solid necrotic tissue and DEN requirement were significantly associated:  $p=0.45$ ,  $p=0.0019$ . No association was found between WON size and number of DENs ( $p=0.57$ ).

No immediate complications occurred after LAMS placement.

Severe complications considered failure of EUS drainage occurred in six patients (13.04%). Of these, five underwent surgery, namely: two patients with gastroduodenal pseudoaneurysms (who both died before 30-day follow-up); two dislodgements during necrosectomy with symptomatic pneumoperitoneum (operated with good outcomes); and one with unresponsive MSOF (who died 2 months later) (Table II). The sixth patient, had remnant WON after spontaneous dislodgement with elimination of LAMS, and underwent plastic stent drainage with a good outcome.

Lumen-apposing metal stents remained in situ for a median IQR: 21–42 days, range 2–104). Clinical success after LAMS removal was 40/46 (87%).



**Table II.** Drainage procedure characteristics and outcome

Procedure characteristics	
Technical success, n (%)	46/47 (97)
Transgastric approach, n (%)	46 (100)
Direct endoscopic necrosectomies (DENs)	
Patients and procedures, n (%)	
Total	39 (84.78)
1	13 (33.33)
2	13 (33.33)
≥3	13 (33.33)
Median, IQR (range)	2, 1–3, (0–6)
Additional plastic stent, n (%)	9 (19.56)
Additional nasocystic drain, n (%)	5 (10.86)
Additional transpapillary drainage, n (%)	2 (4.34)
Duration of LAMS stenting, median (IQR){range}, days	30 (21–42) {2–104}
Outcome	
Immediate complications, n (%)	0 (0)
Complications <30 days	
Gastroduodenal artery pseudoaneurysm, n (%)*	2 (4.34)
LAMS dislodgements during necrosectomy with symptomatic pneumoperitoneum, n (%)	2 (4.34)
Spontaneous dislodgements with elimination of LAMS, n (%)	1 (2.17)
Infection, n (%)**	9 (19.56)
Surgery	5 (10.86)
Indications for surgery	
Bleedings, n (%)	2 (4.34)
Pneumoperitoneum, n (%)	2 (4.34)
MSOF, n (%)	1 (2.17)
Mortality <30 days, n (%)	2 (4.34)
Mortality long-term, n (%)	3 (6.51)
Clinical success, <30 days, n (%)	40/46 (86.96)
Clinical success, long-term, n (%)	37/43 (86.04)

IQR: interquartile range; LAMS: lumen-apposing metal stent; MSOF: multisystem organ failure. \*Day 5 and 20 after LAMS placement. \*\*8 patients responded to conservative therapy (antibiotics and direct endoscopic necrosectomy [DEN]).

Mean follow-up was 13.37±9.88 months (range 0–36). Three patients were lost to follow-up, thus 43 patients were

analyzed. Clinical success was therefore obtained in 37/43 patients (86.04%). Recurrence of fluid collection less than 6 cm in diameter without necrosis after LAMSs removal was noted in six patients (13.9%); five were asymptomatic and in one case, fluid extended into the lower abdomen producing pain which was drained percutaneously.

The large WON size was associated with unsuccessful drainage ( $p=0.032$ ) (Suppl Table I), but when adjusted for age and gender, OR=1.022, 95%CI: 1.001–1.044;  $p=0.043$ ; Nagelkerke  $R^2=0.369$ .

In univariate analysis, number of DENs was significantly associated with >50% solid necrosis ( $p=0.032$ ), but not with WON size or location, or necrotic infection between DEN (Table III).

Hypoalbuminemia at index procedure was more frequently encountered in patients with infected necrosis during LAMS stenting (4/9, 44.44%) vs. those without (4/37, 10.81%) ( $p=0.036$ ).

## DISCUSSION

This multicenter retrospective study supports the hypothesis that DEN requirement after EUS-guided placement of a LAMS for WON drainage is associated with the proportion of solid necrotic material estimated preprocedurally. Also, the development of necrotic infection between DEN procedures could be related to the patient's nutritional status, as indicated by hypoalbuminemia, but did not affect DEN requirement.

The necrotic component negatively impacts the clinical success of plastic stent drainage of WONs compared to pseudocysts (63.2–72% vs. 92–93.5%) [13]. Computed tomography visualizes WON as fat globules, but their absence does not exclude necrosis. In detecting solid necrotic debris, CT is inferior to magnetic resonance imaging (MRI) [14, 15] and EUS (32% vs. 92%) [16]. Hence MRI is preferred to CT in WON management [6], EUS is comparable to MRI in diagnosing necrosis [17]. Walled-off pancreatic necrosis with more than 30% solid necrotic content were encountered in two-thirds of our patients, and in over half of 85 patients with WONs more than 10 cm [18]. Solid content more than 50% was noted in 31% (15/47) in our study, and in 43% of 102 WONs elsewhere [12].

**Table III.** Demographic and clinical factors associated with the number of necrosectomies and acquisition of infection after lumen-apposing metal stent (LAMS) placement

Parameters	No. of necrosectomies		p	Infection of necrosis		p
	1-2 (n=33)	3 or more (n=13)		Yes (n=9)	No (n=37)	
Gender, n (%) <sup>a</sup>						
Male	23 (69.70)	8 (61.54)	0.72	7 (77.78)	24 (64.86)	0.40
Female	10 (30.30)	5 (38.46)		2 (22.22)	13 (35.14)	
Age, years <sup>b</sup>	59 (50–68)	53 (49–61)	0.17	56 (47–61)	58 (50–67)	0.44
Location, n (%) <sup>a</sup>						
Head	5 (15.15)	4 (30.77)	0.25	2 (22.22)	7 (18.92)	>0.99
Body/tail	28 (84.85)	9 (69.23)		7 (77.78)	30 (81.08)	
Size, median (IQR), mm <sup>b</sup>	108 (93–140)	108 (82–130)	0.66	120 (90–140)	108 (93–130)	0.59
Percentage of necrosis, n (%) <sup>a</sup>						
<30%	12 (36.36)	3 (23.08)		4 (44.44)	11 (29.73)	0.26
30%–50%	14 (42.42)	2 (15.38)		1 (11.11)	15 (40.54)	
>50%	7 (21.21)	8 (61.54)	0.032	4 (44.44)	11 (29.73)	

a: Fisher exact test; b: Mann-Whitney test

We performed DEN in 39/46 patients (84%), with 1–2 procedures for 26/31 patients with less than 50% solid necrosis, and 3 or more for 8/15 patients with more than 50% solid necrosis (Table III), the DEN requirement being significantly associated with the percentage of solid content. Recognition is needed because a higher proportion of solid necrosis will entail more endoscopist effort, more intravenous sedations, risks in elderly patients with co-morbidities, higher costs and prolonged hospitalizations. Another retrospective study found that in 85 patients with WON (61 drained with plastic stents and 21 with metallic stents) those with more than 30% solid necrosis had significantly more DENs compared to those without (43.5% vs. 17.9%) [18]. A retrospective analysis of 43 patients (plastic stent drainage), reported that more than 40% of solid debris dictated more aggressive treatment [19]. Kumta et al. found that a higher proportion of solid debris increased the need for DEN and the adverse events rate [20].

Walled-off pancreatic necrosis drainage with LAMS, with a large diameter [21] and enabling of DEN, is preferred over plastic stenting [22, 23]. Our 86% clinical success with LAMS is comparable to the reported rates of 80–97% [12, 22–24]. They were better with interventional radiology support for pseudoaneurysm bleedings, although our rate of 4.34% (2/46) was below the reported range (5.1–15%) [12, 25–27]. The higher need for surgery (10.8%), compared to other studies [22, 23], was related to bleeding and loss of LAMS apposition during DEN, although we performed DEN only when necessary (obstruction/infection), avoiding immediate DEN during the index procedure. An ongoing prospective randomized study is investigating immediate DEN [28], as a retrospective study supported this approach [29].

This retrospective study has several limitations. First, there was no common drainage protocol relating to the timing for DEN or additional stenting, which could affect patient outcomes. Second, visual estimation of necrosis during EUS was operator-dependent. Third, the application of DEN depends on endoscopist experience and on local protocols that vary regarding optimal initiation [30], and procedure intervals [31, 32]. Also, lack of facilities such as interventional angiography worsens patient outcomes.

## CONCLUSIONS

The use of LAMS in WONs allows complete drainage and necrosectomy with good clinical success. Higher proportions of solid necrotic content dictate more DEN procedures. Necrotic infection during LAMS stenting is higher in patients with hypoalbuminemia, but is not associated with greater DEN requirement. Further prospective studies are necessary to support our findings.

**Conflicts of interest:** None to declare.

**Authors contribution:** A.S. conceived and drafted the study. A.S., S.B., M.I., M.R., G.C. and R.S. wrote the manuscript. A.S., O.M., C.P., M.I., V.S., G.C. and M.R. selected the data. A.S., C.P., O.M., M.I., G.C., M.R., M.G., L.L., A.B., N.A.H., and R.S. managed the patients. S.B. performed the statistical analysis. All the authors reviewed and approved the final form of the paper.

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