


# Real-life multicentre study of lumen-apposing metal stent for EUS-guided drainage of pancreatic fluid collections

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## MESSAGE

In a retrospective analysis involving 30 secondary and tertiary centres during a 5-year period (until July 2020), 516 pancreatic fluid collections (PFCs) (47.9% pseudocysts, 52.1% walled-off necroses) were drained by endoscopists with different levels of experience. High technical and clinical success rates (96.9% and 91.7%, respectively) and a good safety profile (adverse events (AEs) 14.7%, of which bleeding 5.6%) were confirmed also in a real-life setting. The timing for luminal apposing metal stents (LAMS) removal might be less relevant than currently considered.

## IN MORE DETAIL

Management of PFCs has moved from a surgical method to a 'step-up' endoscopic approach with reduction of negative outcomes<sup>1</sup> and improved efficacy.<sup>2</sup> The improvement of endosonographic procedures and the introduction of dedicated LAMS have made endoscopic drainage relatively easier,<sup>3</sup> making the treatment accessible not only to experienced endoscopists from third-level centres (figure 1). Having already proven its efficacy, safety, mainly the risk of delayed bleeding,<sup>4,6</sup> represents the main area for improvement.

To confirm the good safety and efficacy profile in a real-life setting, an Italian nationwide endoscopic ultrasound (EUS) registry, involving 30 secondary and tertiary centres during a 5-year period (January 2016–July 2020), collected data on 516 PFCs (47.9% pseudocyst, 52.1% walled-off necrosis (WON)) drained by advanced endoscopists with different levels of experience. The primary outcome of the study was the AEs rate. Secondary outcomes included type and severity of AEs, collection recurrence, technical and clinical success rate (definitions in online supplemental materials).

The baseline characteristics of the study population (516 patients) were reported in table 1. Median follow-up was 290 days (95% CI 244 to 361). Indication for drainage was mainly infection (40.1%). Biliary aetiology was the most frequent cause of pancreatitis (17.8%) and Hot-Axios was the main stent used (70.8%). The evaluated outcomes are reported in table 2. Technical and clinical success rates were 96.9% and 91.7%, respectively. Overall,

## Significance of this study

### What is already known about this topic?

► The use of lumen apposing metal stents (LAMS) is currently the most common choice for endoscopic ultrasound (EUS)-guided drainage of pancreatic fluid collections (PFCs). Early removal of LAMS from PFCs is considered key factor in reducing adverse events.

### What this study adds?

► The efficacy and safety of EUS-guided drainage of PFCs are confirmed in a real-life setting.  
► The timing for LAMS removal has not been confirmed to impact safety and efficacy of EUS-guided PFCs drainage, probably being less crucial than currently considered.

### How this study might affect research, practice or policy?

► The good outcomes of EUS-guided drainage also in a real-life setting and the possibility of leaving the LAMS longer in the PFCs, without incurring a greater risk of adverse events, might enable to better planning their management.

76 AEs were observed (14.7%), of which bleeding (5.6%), infection (1.9%), stent migration (1.4%) and dislodgement (1.3%) were the most frequent.

Management of AEs was conservative in 17 subjects (3.3%), whereas an intervention was needed in 41 patients (11 treated by embolisation and 30 endoscopically). Surgery was needed in two patients (0.4%). AEs were severe in 2.6%. Recurrence of the pancreatic collection occurred in 6.8% of the cases. At univariate logistic regression, the appearance of main pancreatic duct (MPD) at preprocedural imaging/EUS (OR in the case of leak 2.51, 95% CI 1.06 to 5.97,  $p=0.03$ ; OR in the case of complete disruption 2.61, 95% CI 1.53 to 4.45,  $p=0.01$ ), presence of abnormal vessels (OR in the case of peri-gastric varices 2.90, 95% CI 1.31 to 6.42,  $p=0.008$ ; OR in the case of pseudoaneurysm 2.99, 95% CI 1.75 to 11.93,  $p=0.002$ ), number



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**Table 1** Baseline patients' characteristics (extended version in online supplemental table S1)

Variable	Total (n=516)
Age (years)	61.64±15.16
Gender: male	351 (68%)
PFC type	
Pseudocyst	247 (47.9%)
Walled-off necrosis	269 (52.1%)
Indication	
Abdominal pain	165 (32%)
Early satiety	38 (7.4%)
Infection	207 (40.1%)
Outlet obstruction	60 (11.6%)
Vessels thrombosis	8 (1.6%)
Vomiting	20 (3.9%)
Other	18 (3.5%)
Collection width (mm)	89.03±61.9
Collection length (mm)	77.52±45.68
Necrosectomy	
No	307 (59.5%)
Yes	208 (40.3%)
Not reported	1 (0.2%)
Need of percutaneous drainage	
No	497 (96.3%)
Yes	19 (3.7%)
Days to stent removal	50.3±64.92

Variables were reported as absolute numbers (percentage) or mean (SD) when appropriate  
PFC, pancreatic fluid collection.

of stents used (OR 3, 95% CI 1.28 to 5.24;  $p=0.05$ ), need of combined percutaneous drainage (OR 2.81, 95% CI 1.03 to 7.65,  $p=0.04$ ) and experience of the centre (OR 2.95, 95% CI 1.48 to 5.90,  $p=0.002$ ) resulted as significant predictors of AE occurrence. All of these variables were confirmed as significant predictors of AEs in multivariate analysis (online supplemental table S3).

Subgroup analysis according to the type of collection (WON vs pseudocyst) showed similar results in the two different subsets of patients.

After performing a 1:1 propensity score matching in order to balance the differences related to the heterogeneity of the included population, we performed subgroup analysis according to the LAMS removal time (early <4 weeks and late >4 weeks), highlighting no significant differences in terms of AEs (5% and 10% in early and late groups, respectively;  $p=0.19$ ) and recurrence rates (8% and 3% in early and late groups, respectively;  $p=0.17$ ) (online supplemental table S4, figure S1 and S2).

## COMMENTS

This multicentric study shows that EUS-guided drainage of PFC by positioning LAMS is a safe and effective procedure also in a real practice setting. In fact, we report very high technical and clinical success rates for both the type of collection, confirming improved outcomes in higher hospital volume (>15 procedures performed).<sup>7</sup>

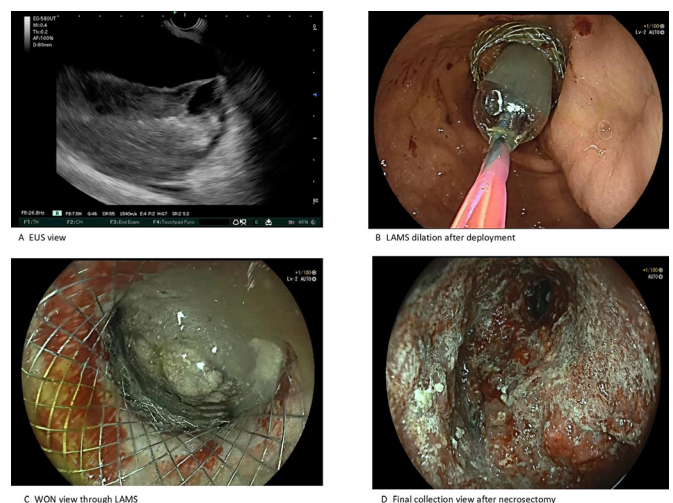
Overall, our study, which at the moment is the largest series, shows the appearance of MPD, presence of abnormal vessels, number of stents used and need of combined percutaneous drainage as significant predictors of AEs.

**Table 2** Outcomes (extended version in online supplementary table S2)

	Total (516 pts)	Pseudocysts (247 pts)	WON (269 pts)	P value
Technical success	500 (96.9%)	239 (97%)	261 (97%)	1.0
Clinical success	473 (91.7%)	230 (93%)	243 (90%)	0.32
Adverse event rate	76 (14.7%)	32 (13%)	44 (16%)	0.33
Type of adverse event				0.67
Bleeding	29 (5.6%)	13 (5.3%)	16 (6.0%)	
Infection	10 (1.9%)	3 (1.2%)	7 (2.6%)	
Stent occlusion	4 (0.7%)	1 (0.4%)	3 (1.1%)	
Stent migration	8 (1.4%)	3 (1.2%)	5 (1.8%)	
Stent dislodgement	7 (1.3%)	3 (1.2%)	4 (1.5%)	
Perforation	3 (0.5%)	0 (0%)	3 (1.1%)	
Capnoperitoneum	1 (0.2%)	1 (.4%)	0 (0%)	
Other	14 (2.7%)	8 (3.2%)	6 (2.2%)	
Severity adverse event				0.96
Mild	24 (4.7%)	10 (4%)	14 (5.2%)	
Moderate	33 (6.3%)	13 (5.3%)	20 (7.4%)	
Severe	13 (2.6%)	6 (2.4%)	7 (2.6%)	
Fatal	6 (1.1%)	3 (1.2%)	3 (1.1%)	
Collection recurrence	35 (6.8%)	12 (4.8%)	23 (9%)	0.11
Death	56 (10.9%)	22 (9%)	34 (13%)	0.13

WON, walled-off necrosis.

An interesting result of this paper is that the timing for LAMS removal might have less impact than previously thought. Indeed, although the number of events recorded is low, no statistically significant difference has been observed in terms of AEs between early and late removal time. Therefore, if confirmed by larger studies, our results could be relevant for several reasons. First of all, the heterogeneity of the PFCs requires flexibility of treatment according to several factors. Moreover, PFCs treatment can be particularly complex, constraining the difficulty of allocating these procedures in busy endoscopy schedules. Therefore, the possibility of leaving the LAMS longer in the PFCs, without incurring a greater risk of AEs, makes it easier to properly plan the procedure. We acknowledge several limitations of our study. First, the retrospective design and the involvement of several



**Figure 1** EUS-guided drainage of a pancreatic collection (walled-off necrosis, WON). EUS, endoscopic ultrasound; LAMS, lumen apposing metal stents.

centres and endoscopists might have determined heterogeneity in the procedure outcomes. However, this type of procedures are difficult to standardise and the participation of several centres better represents reality. The most of papers on this topic comes from referral centres, certainly ensuring better outcomes, but at the same time presenting a less reproducible picture of real life.

In conclusion, our study contributes to the definition of an important topic such as the management of PFCs, showing good results in terms of safety and efficacy in a real-life setting, pointing out some predictive factors of AEs and assuming that the removal time of LAMS may not have to be considered as a rigid assumption. Further studies are needed to adequately define the right protocols for the best endoscopic treatment of PFCs drainage.

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## Correction: *Real-life multicentre study of lumen-apposing metal stent for EUS-guided drainage of pancreatic fluid collections*

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There are errors in two of the affiliations.

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