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

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► Additional supplemental material is published online only. To view, please visit the journal online (http://dx.doi.org/10.1136/gutjnl-2022-326880).

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Received 1 January 2022
Accepted 1 February 2022
Published Online First 22 February 2022

To cite: Amato A, Tarantino I, Facciorusso A, *et al*. *Gut* 2022;**71**:1050–1052.

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[1] and improved efficacy.[2] The improvement of endosonographic procedures and the introduction of dedicated LAMS have made endoscopic drainage relatively easier,[3] 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,[4–6] 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, 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

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.

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.

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.

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).[7]

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.

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

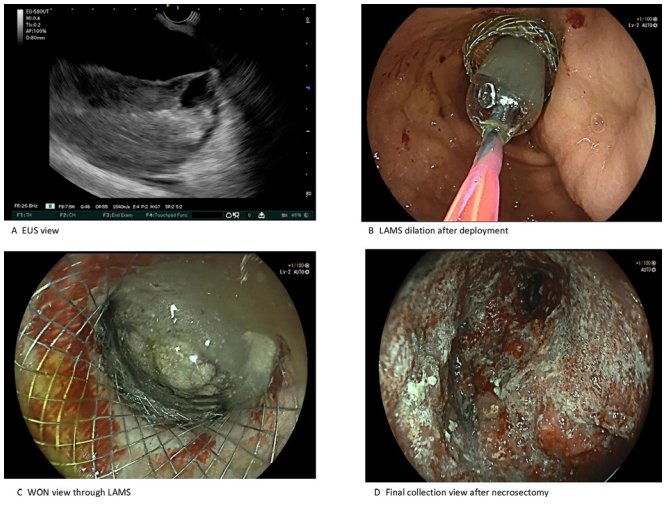

Figure 1 EUS-guided drainage of a pancreatic collection (walled-off necrosis, WON). EUS, endoscopic ultrasound; LAMS, lumen apposing metal stents.

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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Contributors Study concept and design: AA, AF and CF. Acquisition of data: AA and AF. Analysis and interpretation of data: AF, ES and MM. Drafting of the manuscript: AA and AF. Revision of the manuscript for important intellectual content: IT, AA and CF. Approval of the final manuscript: all the authors. Guarantor of the article: AA.

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests None declared.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; internally peer reviewed.

Data availability statement All data relevant to the study are included in the article or uploaded as supplementary information.

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SUPPLEMENTARY MATERIAL

Group Formation

As part of a nationwide educational initiative held in Italy in 2019 involving gastrointestinal endoscopists from about 80% of the centers performing EUS-guided drainage at the time, the Interventional Endoscopy and Ultrasound (i-EUS) group was formed. In order to collect clinical data in a real life setting on efficacy and safety of these procedures, we planned to conduct a multicenter retrospective analysis of all procedures involving EUS guided drainage with LAMS for the three approved indications (PFCs, gallbladder, biliary) (NCT03903523). A total of 850 cases for these 3 indications were collected into a database. In this paper, we included and analyzed all EUS-guided PFC drainage procedures using LAMS from January 2016 to June 2020, collected across 30 secondary and tertiary care centers.

Definitions

The primary outcome of the study was adverse events rate. Secondary outcomes included type and severity of AEs, collection recurrence, technical and clinical success rate. AEs were defined as all symptomatic events related to the use of LAMSs such as bleeding, infection, stent occlusion and stent migration resulting in prolongation of hospital stay, requiring medical therapy or further procedure or action to resolve the event or to treat the symptoms. Collection recurrence was defined as the new appearance of a necrotic cavity or pseudocyst requiring re-treatment. Technical success was defined as the ability to correctly perform an EUS-PFCs with LAMS placement. Clinical success was defined as WON or PP <2cm on axial imaging 1 to 6 months after LAMS insertion without need for further interventional radiologic, endoscopic, or surgical procedures. As reported in a recent publication of our group[8], the threshold for definition of the experience of the centers (high versus low experience) was settled at 15 procedures.

Procedure

All endoscopic ultrasound guided PFC drainage procedures were performed by advanced endoscopists with different experience in PFCs management. All EUS-PFC drainages were performed with a therapeutic echoendoscope, using CO2 insufflation, under deep sedation or under general anesthesia managed by the anesthesiologist, and in accordance with center-specific guidelines. Patients were given broad-spectrum antibiotics. The type, dosage and course of the antibiotic therapy were at the discretion of the endoscopist or in accordance with the local hospital policies.

The PFC was identified using a linear echoendoscope. Doppler flow was used to evaluate presence of blood vessels along the puncture trajectory. PFC was drained through either the stomach or duodenum wall. Selection of stent type and size and of deployment techniques were at the discretion of the endoscopist.

In case of necrosectomy, several devices (snares, standard biopsy forceps, rat-tooth forceps, Roth nets and biliary basket) have been used at endoscopist discretion. The timing and frequency of necrosectomy were based on several factors (such as symptoms, imaging-data and operator experience) until the emptying of cavity was obtained. Endoscopic retrograde cholangiopancreatography with pancreatic duct stent placement was performed when indicated.

In all cases, procedural time was calculated from echoendoscope insertion to removal.

Statistical analysis

Categorical variables were reported as number of cases and percentage, and differences between groups were compared using the Chi-square and McNemar analysis before and after matching, respectively.

Continuous variables were expressed as median and interquartile range (IQR) and differences between groups were explored by the Mann-Whitney and Wilkoxon-rank test before and after matching, respectively. All analyses were 2-tailed and the threshold of significance was assessed at ≤ 0.05.

To overcome biases owing to the different distribution of covariates among patients who were submitted to early or late removal of LAMS, a 1-to-1 match was created using propensity score analysis.

The propensity score represents the probability of each individual patient being assigned to a particular condition in a study given a set of known covariates. A multivariate logistic regression was built to predict the probability of each individual patient being submitted to the two groups on the basis of several demographic, technical and collection-related covariates, namely age, PFC Type, percentage of estimated necrosis on EUS in the case of WON, location of fluid collection, extension to paracolic gutter, indication for collection drainage, etiology of pancreatitis, stent type, access (whether single stage versus needle+guidewire), use of fluoroscopy, stent diameter, release of the second flange, stent dilation, use of necrosectomy, endoscopic appearance of cavity, hydrogen peroxide irrigation, use of nasocystic drainage tube, use of pigtail stents through the LAMS.

The predictive values were then used to obtain a 1-to-1 match by using the nearest neighbor matching within a specified caliper distance. Nearest neighbor matching within a specified caliper distance selects for matching an untreated subject whose propensity score is closest to that of the treated subject ("nearest neighbor matching" approach) with the further restriction that the absolute difference in the propensity scores of matched subjects must be below some pre-specified threshold (the caliper distance) . Thus, patients for whom the propensity score could not be matched because of a greater caliper distance were excluded from further analysis. As suggested by Austin, a caliper of width equal to 0.2 of the

standard deviation of the logit of the propensity score was used, as this value has been found to minimize the mean squared error of the estimated treatment effect.

Subgroup analysis according to the type of pancreatic collection (WON versus pseudocysts) was performed.

In order to define the eventual impact of the exact timing of stent removal on the final outcomes, a logistic regression considering the correlation between days to LAMS removal and the primary outcome (AE rate) was performed.

The statistical analysis was run using the *MatchIt* package in R Statistical Software 3.0.2 (Foundation for Statistical Computing, Vienna, Austria).

Table 3S. Univariate/Multivariate logistic regression analysis for prediction of adverse events

	Univariate Analysis		**Multivariate Analysis**	
Variables	**Odds Ratio (CI 95%)**	**p-value**	**Odds Ratio (CI 95%)**	**p-value**
Age	1.31 (0.90-1.90)	0.15		
Gender (reference Female)	1.06 (0.78-2.3)	0.55		
Collection type (reference WON)	0.80 (0.49-1.31)	0.38		
Percentage of necrosis	0.99 (0.78-1.43)	0.89		
Location (reference body)	Head: 1.23 (0.65-2.3) Tail: 0.74 (0.35-1.57)	0.51 0.44		
Collection width (<70 mm)	1.16 (0.71-1.92)	0.53		
Collection length (<70 mm)	0.86 (0.55-1.73)	0.25		
Collection appearance (reference single)	1.14 (0.64-2.03)	0.65		
Extension to paracolic gutter (reference no)	1.01 (0.58-1.77)	0.92		
PD appearance on EUS (reference no leak)	Leak: 2.51 (1.06-5.97) Complete disruption: 2.61 (1.53-4.45) Unknown: 1.08 (0.67-2.31)	0.03 0.01 0.34	Leak: 2.29 (1.04-5.5) Complete disruption: 1.44 (1.14-5.61)	0.05 0.03
Vessels appearance on EUS (reference no alterations)	Perigastric varices: 2.90 (1.31-6.42) Pseudoaneurysm: 2.99 (1.75-11.93) Portal vein thrombosis: 1.64 (0.53-5.07) Splenic vein thrombosis:1.68 (0.70-4.04)	0.008 0.002 0.38 0.24	Perigastric varices: 2.15 (1.11-3.75) Pseudoaneurysm: 2.41 (1.45-6.22)	0.04 0.002
Indication (reference infection)	Abdominal pain: 0.97 (0.52-1.79) Early satiety: 1.50 (0.60-3.75) Other: 1.90 (0.58-6.21) Outlet obstruction: 1.84 (0.88-3.84) Vessels thrombosis:	0.34 0.36 0.27 0.10 0.33		

	2.22 (0.42-11.54) Vomiting: 0.74 (0.16-3.72)	0.72		
Etiology of pancreatitis (reference biliary)	1.94 (0.78-2.22)	0.14		
Type of stent (reference Hot Axios)	Nagi: 1.17 (0.63-2.19) Spaxus: 0.84 (0.55-2.1) Other: 0.50 (0.19-1.04)	0.60 0.76 0.91		
Access (reference single stage)	1.15 (0.67-1.94)	0.60		
Use of fluoroscopy (reference yes)	0.89 (0.54-1.47)	0.67		
Stent diameter (reference 15x10)	10x10: 1.07 (0.47-2.45) 20x10: 1.59 (0.73-3.74) 8x8: 3.35 (0.29-11.1) Other: 1.33 (0.74-2.37)	0.86 0.44 0.37 0.63		
Number of stents (reference 1)	3 (1.28-5.24)	0.05	2.33 (1.15-8.39)	0.02
Second flange release (reference intrachannel)	1.08 (0.65-1.80)	0.74		
Approach (reference transgastric)	0.70 (0.24-2.03)	0.23		
Stent dilation (reference no)	1.55 (0.88-2.74)	0.12		
Necrosectomy (reference no)	1.58 (0.97-2.58)	0.06		
Endoscopic appearance of cavity (reference purulent fluid)	Solid debris: 1.57 (0.89-2.76) Vessels: 3.64 (0.86-5.15) Other: 1.19 (0.61-2.31)	0.40 0.13 0.60		
Hydrogen peroxide irrigation (reference no)	0.71 (0.40-1.27)	0.26		
Antibiotic irrigation (reference no)	1.12 (0.45-2.13)	0.4		
Nasocystic drainage (reference no)	0.67 (0.31-1.47)	0.32		
Pigtail use through the stent (reference no)	0.90 (0.42-1.90)	0.78		
Need of percutaneous drainage (reference no)	2.81 (1.03-7.65)	0.04	2.82 (1.44-8)	0.009
Days to removal (reference <30)	1.32 (0.78-3.21)	0.19		
Experience of the center (reference high)	1.40 (0.75-2.12)	0.29		

Table 1S. Baseline patients' characteristics

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%)
Percentage of necrosis	45.04 ± 20.56
Location	
Body	348 (67.4%)
Head	87 (16.9%)
Tail	81 (15.7%)
Collection appearance	
Single	404 (78.3%)
Multiloculated	112 (21.7%)
Collection width (mm)	89.03 ± 61.9
Collection length (mm)	77.52 ± 45.68
Extension to paracolic gutter	
Not reported	15 (2.9%)
No	367 (71.1%)
Yes	134 (26%)
EUS appearance of pancreatic duct	
Leak	36 (7%)
No leak	324 (62.8%)
Complete disruption	16 (3.1%)
Unknown	140 (27.1%)
Vessels appearance on EUS	
No alterations	415 (80.4%)
Perigastric varices	34 (6.6%)
Pseudoaneurysm	10 (1.9%)
Portal vein thrombosis	21 (4.1%)
Splenic vein thrombosis	36 (7%)
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%)
Etiology of pancreatitis	
Alcohol	92 (17.8%)
Autoimmune	1 (0.2%)
Biliary	254 (49.2%)
Idiopathic	68 (13.2%)
Post-ERCP	14 (2.7%)
Post-operative	46 (8.9%)
Trauma	18 (3.5%)
Other	23 (4.5%)
Type of stent	
Hot Axios™	386 (74.8%)
NAGI™	90 (17.4%)
Spaxus™	7 (1.4%)
Other	33 (6.4%)
Access	
Needle + guidewire	150 (29.1%)
Single stage	366 (70.9%)
Fluoroscopic guide	
Yes	294 (57%)
No	222 (43%)
Stent diameter	
10x10	58 (11.2%)
15x10	270 (52.3%)
20x10	52 (10.1%)
8x8	3 (0.6%)
Other	133 (25.8%)
Number of stents	
1	504 (97.7%)
2	12 (2.3%)
Second flange deployment	

Endoscopic view	175 (33.9%)
Intrachannel	341 (66.1%)
Approach	
Transduodenal	38 (7.4%)
Transgastric	466 (90.3%)
Both	9 (1.7%)
Other	2 (0.4%)
Not reported	1 (0.2%)
Stent dilation	
No	414 (80.2%)
Yes	102 (19.8%)
Necrosectomy	
No	307 (59.5%)
Yes	208 (40.3%)
Not reported	1 (0.2%)
Necrosectomy in the same session	102 (19.8%)
Endoscopic appearance of cavity	
Purulent fluid	224 (43.4%)
Solid debris	169 (32.8%)
Vessels	9 (1.7%)
Other	103 (20%)
Not reported	11 (2.1%)
Hydrogen peroxide irrigation	
No	362 (70.2%)
Yes	143 (27.7%)
Not reported	11 (2.1%)
Antibiotic irrigation	
No	486 (94.2%)
Yes	19 (3.7%)
Not reported	11 (2.1%)
Nasocystic tube drainage	
No	432 (83.7%)
Yes	73 (14.1%)
Not reported	11 (2.1%)
Pigtail use through stent	
No	450 (87.2%)
Yes	66 (12.8%)
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 (standard deviation) when appropriate	

Table 2S. Outcomes

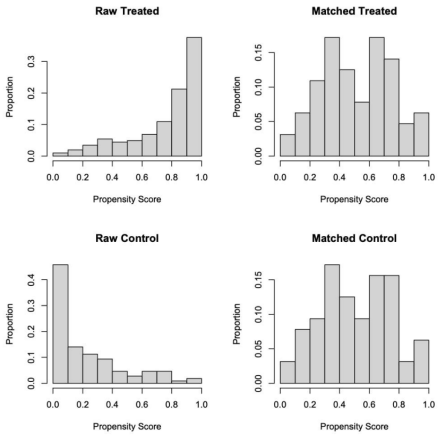
	Total (516 pts)	**Pseudocysts (247 pts)**	**WON (269 pts)**	**P value**
Technical success				
	500 (96.9%)	239 (97%)	261 (97%)	**1.0**
Clinical success				
	473 (91.7%)	230 (93%)	243 (90%)	**0.32**
Adverse event rate				
	76 (14.7%)	32 (13%)	44 (16%)	**0.33**
Type of adverse event				**0.67**
Bleeding	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				**0.11**
	35 (6.8%)	12 (4.8%)	23 (9%)	
Death				
	56 (10.9%)	22 (9%)	34 (13%)	**0.13**
Management of adverse events				**094**
Endo stent cleaning	**6 (1.2%)**	**2 (0.8%)**	**4 (1.5%)**	
Endoscopic hemostasis	**8 (1.6%)**	**4 (1.6%)**	**4 (1.5%)**	
Endoscopic stent removal	**8 (1.6%)**	**3 (1.2%)**	**5 (1.8%)**	
Endoscopic stent replacement	**8 (1.6%)**	**3 (1.2%)**	**5 (1.8%)**	
Additional stent insertion	**2 (0.4%)**	**0 (0%)**	**2 (0.7%)**	
Radiology percutaneous drainage	**1 (0.2%)**	**1 (0.4%)**	**0 (0%)**	
Interventional radiology embolization	**11 (2.1%)**	**5 (2.0%)**	**6 (2.2%)**	
Surgery	**2 (0.4%)**	**0 (0%)**	**2 (0.7%)**	
Conservative	**17 (3.3%)**	**7 (2.8%)**	**10 (3.7)**	
Autoresolution with LAMS placement	**1 (0.2%)**	**1 (0.4%)**	**0 (0%)**	
Resolved after plastic biliary stent				
Other	**1 (0.2%)**	**1 (0.4%)**	**0 (0%)**	
	10 (1.9%)	**5 (2.0%)**	**5 (1.8%)**	

Table 4S Subgroup analysis according to the timing of stent removal (early within 4 weeks versus late), after propensity score matching

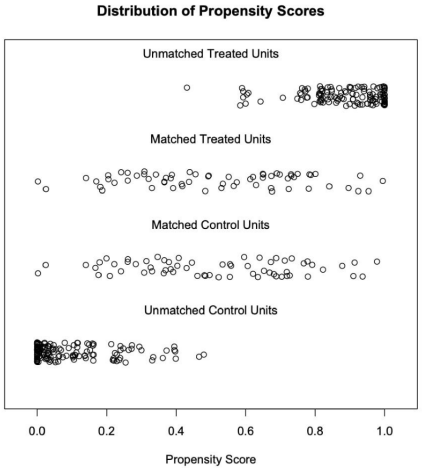
	Total (296 pts)	Early removal (148 pts)	Late removal (148 pts)	p value
Technical success				**0.28**
	288 (97%)	146 (99%)	142 (96%)	
Clinical success				**1.0**
	279 (94%)	140 (95%)	139 (94%)	
Adverse event				**0.19**
	23 (8%)	8 (5%)	15 (10%)	
Type of adverse event				**0.32**
Bleeding	7 (2.3%)	4 (2.7%)	3 (2.1%)	
Infection	5 (1.7%)	0 (0%)	5 (3.4%)	
Stent occlusion	2 (0.7%)	1 (0.7%)	1 (0.7%)	
Stent migration	2 (0.7%)	1 (0.7%)	1 (0.7%)	
Stent dislodgement	1 (0.3%)	0 (0%)	1 (0.7%)	
Perforation	1 (0.3%)	0 (0%)	1 (0.7%)	
Capnoperitoneum	2 (0.7%)	0 (0%)	2 (1.4%)	
Other	3 (0.9%)	2 (1.4%)	1 (0.7%)	
Severity adverse event				**0.804**
Mild	10 (2.9%)	3 (2.1%)	7 (4.8%)	
Moderate	9 (2.7%)	3 (2.1%)	6 (4.1%)	
Severe	1 (0.3%)	0 (0%)	1 (0.7%)	
Fatal	3 (0.9%)	2 (1.4%)	1 (0.7%)	
Collection recurrence				**0.07**
	17 (6%)	12 (8%)	5 (3%)	
Death				**0.05**
	25 (8%)	17 (11%)	8 (5%)	

Values are expressed as number (percentage)

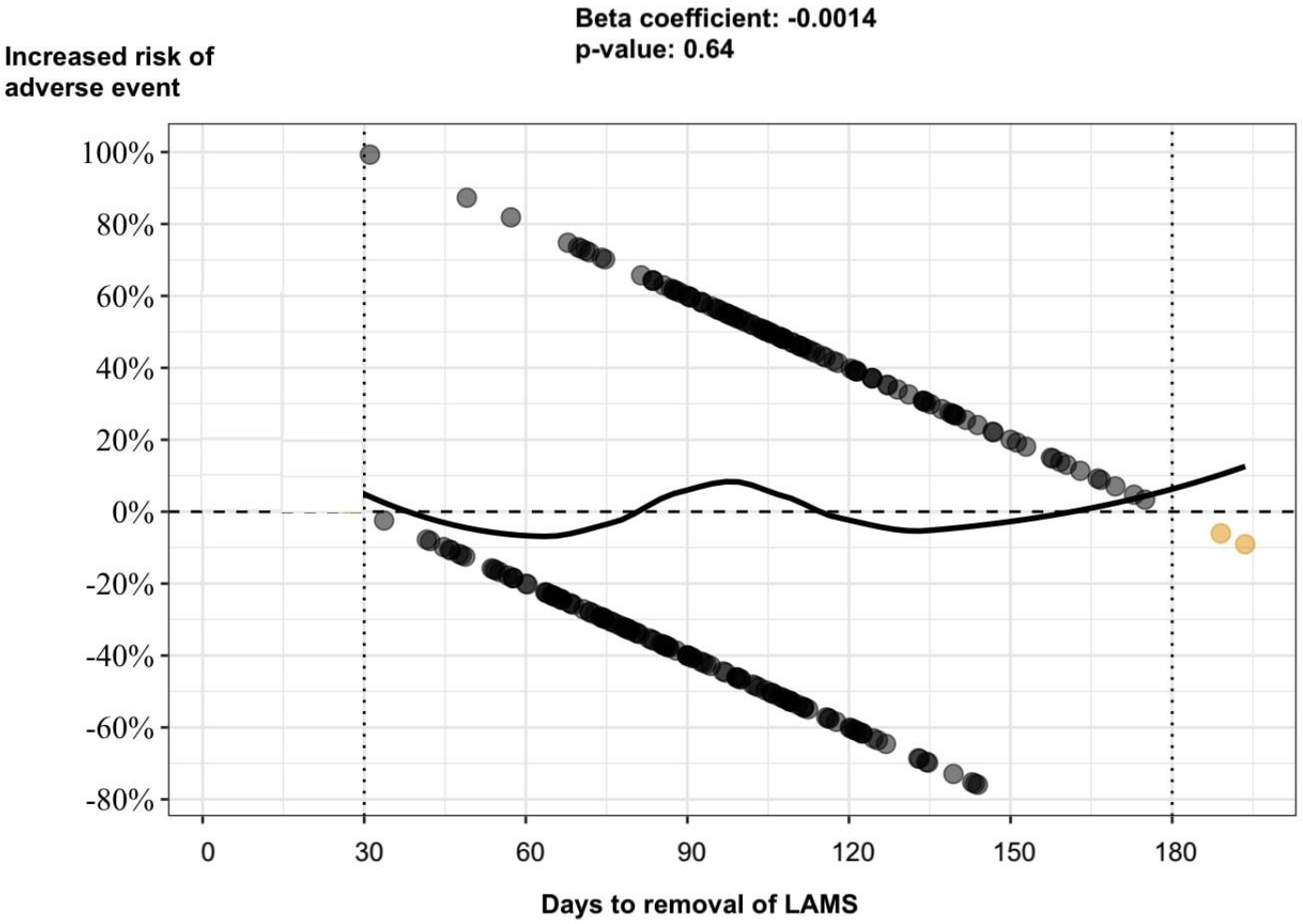
Figure 1S. Propensity score matching



1S A. Propensity score matching histogram.



1S B. Propensity score matching jitter plot.


Beta coefficient: -0.0014
p-value: 0.64
Increased risk of adverse event
100%
80%
60%
40%
20%
0%
-20%
-40%
-60%
-80%
0
30
60
90
120
150
180
Days to removal of LAMS