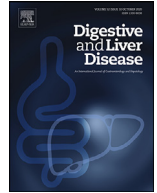




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Digestive Endoscopy

Endoscopic ultrasound-guided drainage of pancreatic collections with dedicated metal stents: A nationwide, multicenter, propensity score-matched comparison



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ABSTRACT

Background: The new dedicated stents for endoscopic ultrasound (EUS)-guided transluminal drainage of peri-pancreatic fluid collections (PFCs) demonstrated optimal efficacy and safety profiles.

Aims: This study aimed to evaluate the safety, technical and clinical success, and recurrence rate of PFCs drained with Lumen Apposing Metal Stent (LAMS) or Bi-Flanged Metal Stent (BFMS).

Methods: Data from a multicenter series of PFCs treated with LAMS or BFMS at 30 Italian centers during a 5-year period were retrieved. The rate of adverse events (AEs), technical success, clinical success, PFC recurrence were evaluated. To overcome biases, a 1-to-1 match was created using propensity score analysis.

Results: Out of 476 patients, 386 were treated with LAMS and 90 with BFMS, with a median follow-up of 290 days (95% CI 244 to 361). Using propensity score matching, 84 patients were assigned to each group. The incidence of AEs did not differ between the two stents (13.1% versus 15.5%, $p = 0.29$), mainly bleeding or recurrence rate (4.7% versus 3.5%, $p = 1$). Technical and clinical success in the BFMS and LAMS groups were 92% versus 95% ($p = 0.36$) and 91% versus 94% ($p = 0.64$), respectively.

Conclusion: Our study demonstrates that LAMS and BFMS have comparable safety profiles with similar technical and clinical success rates for EUS-guided PFC drainage.

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1. Introduction

Pancreatic fluid collections (PFCs) are frequent complications of acute pancreatitis (AP) and, less frequently, abdominal trauma or surgery. The updated Atlanta classification categorizes PFCs as acute PFC, pancreatic pseudocysts (PP), acute necrotic collections,

and walled-off necrosis (WON) according to the time onset (less than or greater than 4 weeks after AP) and the presence or absence of necrosis. Both PP and WON are surrounded by a detectable capsule on imaging [1].

Drainage of PFCs is indicated in case of documented or suspected infection, abdominal compartment syndrome, or symptoms related to organ compression [2]. Both European and American guidelines recommend endoscopic drainage of PFCs under endoscopic ultrasound (EUS) guidance as first-line therapy, utilizing either polyethylene stents (PS) or Lumen-Apposing Metal Stent (LAMS), with LAMS appearing to be superior to PS [2,3]. Surgery

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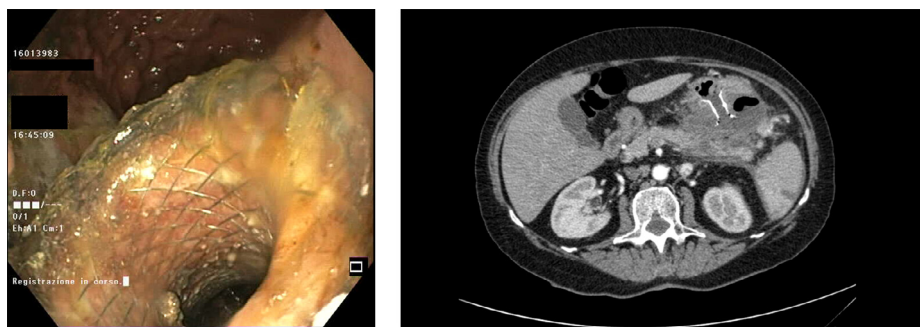


Fig. 1. a) endoscopic view of Niti-s NAGI™ (Taewoong Medical, Gyeonggi-do, Seoul, South Korea) through a pancreatic fluid collection; b) radiologic view of Niti-s NAGI™ (Taewoong Medical, Gyeonggi-do, Seoul, South Korea) through a pancreatic fluid collection.

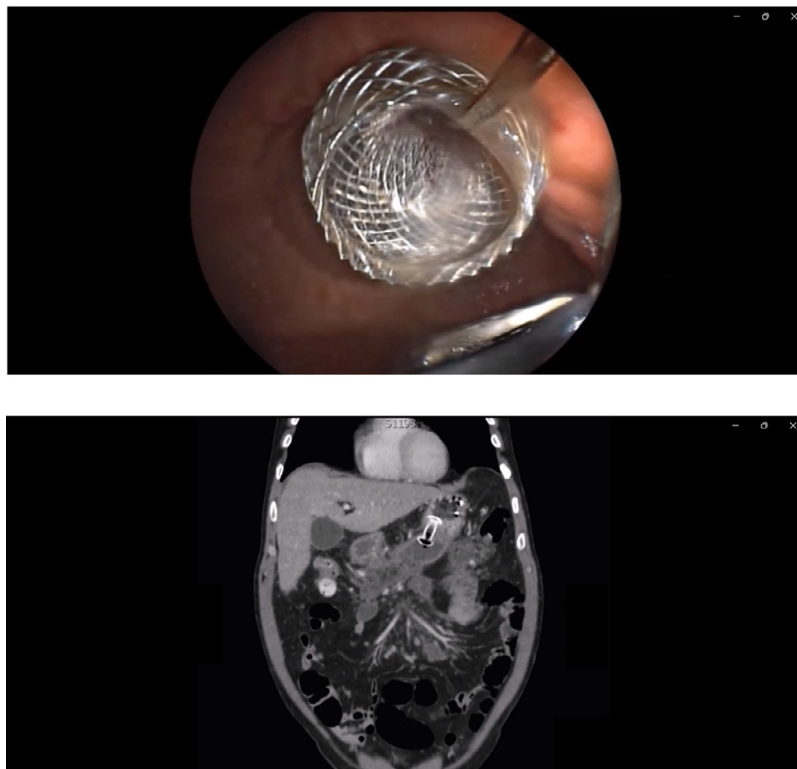


Fig. 2. a) endoscopic view of Hot Axios stent (Boston Scientific, Marlborough, Mass, USA) through a pancreatic fluid collection; b) radiologic view of Hot Axios stent (Boston Scientific, Marlborough, Mass, USA) through a pancreatic fluid collection.

is associated with high morbidity and mortality, whereas percutaneous treatment carries an increased risk of infection and fistula [4–6].

To date, there are several types of LAMS for EUS-guided drainage of PFCs are currently available on the market, but comparative efficacy studies are lacking. In 2013, a specially designed removable and bi-flanged metal stent (BFMS) called Niti-s NAGI™ stent (Taewoong Medical, Gyeonggi-do, Seoul, South Korea) became available, demonstrating good safety and efficacy with a lower rate of stent migration compared to traditional SEMS [7]. (Fig. 1a/b)

During the same time frame [8] a new barbell-shape LAMS (Axios™, Boston Scientific, Marlborough, Mass, USA) equipped with an electrocautery-enhanced (EC) delivery system (Hot-Axios™) was introduced (Fig. 2a/b). This added benefit allows endoscopists to access the target cavity in a single step and deliver stents without the need of fluoroscopy.

Due to their wide diameters, both stents allow the endoscope to be inserted through the stent for direct therapeutic interven-

tion and have high reported technical (89–100%) and clinical (93–100%) success rates for the management of PFCs [9–15]. However, to date, only one retrospective single-center study has compared NAGI™ and Hot-Axios™ for EUS-guided drainage of PFCs [16].

The primary aim of this multicenter study was to evaluate the safety of these two differently tailored stents in a large cohort of patients who underwent EUS-guided PFCs. The secondary aims were technical success, clinical success rate, and recurrence of collection.

2. Methods

2.1. Study design and population

Retrospective data on patients with PFCs treated with EUS-guided placement of LAMS and BFMS were retrieved from an Italian nationwide EUS registry involving 30 secondary and tertiary centers and including all consecutive patients with PFC, both PP and WON, with suspected or proven infection or causing abdomi-

nal symptoms due to compression during a 5-year period (January 2016–July 2020). Patients who underwent PFC drainage with PS or different metal stents were excluded. The Italian nationwide EUS registry included approximately 80% of centers performing these procedures at the time, thereby representing real-world settings. Endoscopists performed EUS-guided drainage with varying levels of expertise. The study was approved by the institutional review board of each participating center (NCT03903523) and performed in accordance with the Declaration of Helsinki.

2.2. Devices and procedures

EUS-guided procedures were performed with a therapeutic echoendoscope, using CO₂ insufflation with the patient under deep sedation or general anesthesia administered by an anesthesiologist in accordance with local sedation policies. The procedures were performed in a single session. Under EUS guidance, the fluid collections were examined and drained either trans-gastric or trans-duodenal. The selection of stent type and size was left to the endoscopist's discretion or dependent on the institution's availability. In this study, all LAMS were Hot-Axios™, and all BFMS were Niti-s NAGI™ stents. Different deployment techniques were utilized based on the stent and endoscopist preference, with or without fluoroscopic guidance. Details on the Nagi™ and Hot-Axios™ stents and technical procedures were reported in Supplementary material (S.1, S.2) [11,14,17–21].

2.3. Data collection

Data were compiled and extracted in a central database. For each procedure, patient-related data, demographics, etiology of pancreatitis causing PFC, size of the PFC, imaging appearance of pancreatic duct and vessels, type and location of PFC, and indications for drainage were collected. In addition, data were collected on the type and size of the used stent, deployment technique, site of approach, use of stent dilation, necrosectomy with hydrogen peroxide or antibiotic irrigation, nasocystic tube or pigtail use, procedural and deployment stent time. Postprocedural data were collected for percutaneous drainage, days to stent indwelling and AEs. In accordance with the discretion of the endoscopist in charge at each participating hospital, patients were observed with periodic laboratory tests and clinic visits.

2.4. Outcomes and definitions

The study's primary outcome was the AE rate, with severity graded according to the American Society for Gastrointestinal Endoscopy (ASGE) lexicon severity grading system [22].

Secondary outcomes included technical and clinical success rates and recurrence of fluid collections. Technical success was defined as completing EUS-guided drainage of PFC drainage with stent placement. Clinical success was defined as PFC size reduction to <2 cm on axial imaging between 2 weeks and 6 months after stent insertion without the need for additional radiologic, endoscopic, or surgical intervention [21].

2.5. Statistical analysis

Categorical variables were reported as the number of cases and percentage, and differences between groups were compared using the Chi-square and McNemar analysis before and after matching. Continuous variables were expressed as median and interquartile range (IQR), and the Mann-Whitney and Wilcoxon-rank test were used to examine differences between groups before and after matching. All analyses were conducted with a two-tailed test, and the significance threshold was assessed at <0.05.

Using propensity score analysis, a 1-to-1 match was generated to eliminate biases caused by the different distribution of covariates among patients treated with the two types of stent. 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 [23]. A multivariate logistic regression was constructed to predict the probability of each individual patient being assigned one of the two groups based on covariates that are known to be able to affect postoperative outcomes, including PFC type (whether pseudocyst or WON), imaging appearance of the pancreatic duct and vessels (leak versus no leak versus unknown), approach (transduodenal versus transgastric), the endoscopic appearance of the cavity (purulent fluid versus solid debris versus other), use of hydrogen peroxide irrigation, use of necrosectomy, 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) [24,25]. Thus, patients for whom the propensity score could not be matched because 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 [24].

The statistical analysis was performed using the R Statistical Software 3.0.2's MatchIt package (Foundation for Statistical Computing, Vienna, Austria).

3. Results

3.1. Study population

In total, 476 patients with PFCs underwent EUS-guided drainage with dedicated metal stents (386 treated with LAMS and 90 with BFMS). The characteristics of the study population prior to propensity score matching are summarized in Table 1.

84 patients were assigned to each group based on their propensity score (Fig. 3a/b). Table 2 details the baseline characteristics of the two groups after matching by propensity score. The two groups were comparable regarding age, gender, PFC type, size, and location. As anticipated, technical variations in stent deployment were observed (e.g., PFC access, use of fluoroscopy guide, and second flange deployment). In addition, the median time to stent removal was comparable between the two groups (45 days, 33.5–58.5 days for LAMS, and 43 days, 30–116 days for BFMS; $p = 0.94$). The median duration of follow-up was 290 days (95 percent CI 244 to 361).

3.2. Outcomes

A detailed list of the outcomes analyzed in this study is reported in Table 3. The two stents did not differ regarding the AE rate (13.1% in the LAMS versus 15.5% in the BFMS group, $p = 0.29$). Overall, 11 (13.1%) AEs were observed in the LAMS group, of which three (3.5%) were mild, four (4.7%) were moderate, three (3.5%) were severe, and one (1.1%) was fatal, whereas 13 AEs (15.5%) were registered in the BFMS group, of which three (3.5%), five (5.9%), three (3.5%), and two (2.3%) mild, moderate, severe, and fatal, respectively ($p = 0.63$). The most common AE was bleeding (5.9% in both groups), followed by infection (4.7% in both groups). Less frequent were stent occlusion (one case in the BFMS group), stent

Table 1
Baseline patients' characteristics and outcomes before propensity score matching.

Variable	Total (n = 476)	LAMS (n = 386)	BFMS (n = 90)	p value
Age (years)	62 (52.1–74)	62 (49.5–73)	63 (50–74)	0.40
Gender M	321 (67%)	264 (68%)	57 (63%)	0.42
F	155 (33%)	122 (32%)	33 (37%)	
PFC type				<0.001
Pseudocyst	220 (46%)	162 (42%)	58 (64%)	
WON	256 (54%)	224 (58%)	32 (36%)	
Percentage of necrosis	46 (30–60)	48 (38–60)	42 (30–58)	0.09
Location				0.10
Body	320 (67%)	268 (69%)	52 (58%)	
Head	79 (17%)	59 (15%)	20 (22%)	
Tail	77 (16%)	59 (15%)	18 (20%)	
Collection width (mm)	90 (60–120)	95 (62–115)	88 (56–110)	0.21
Collection length (mm)	75 (52–100)	80 (59–100)	74 (52–96)	0.35
Collection				0.71
Multiloculated	110 (23%)	91 (24%)	19 (21%)	
Single	366 (77%)	295 (76%)	71 (79%)	
Extension to paracolic gutter				0.06
NR	15 (3%)	15 (4%)	0 (0%)	
No	336 (71%)	266 (69%)	70 (78%)	
Yes	125 (26%)	105 (27%)	20 (22%)	
Imaging appearance of PD				<0.001
Leak	32 (7%)	27 (7%)	5 (6%)	
No leak	294 (62%)	217 (56%)	77 (86%)	
Complete disruption	15 (3%)	15 (4%)	0 (0%)	
Unknown	135 (28%)	127 (33%)	8 (9%)	
Vessels appearance on imaging				0.04
No alterations	378 (79%)	296 (77%)	82 (91%)	
Perigastric varices	33 (7%)	31 (8%)	2 (2%)	
Pseudoaneurysm	9 (2%)	8 (2%)	1 (1%)	
Portal vein thrombosis	21 (4%)	20 (5%)	1 (1%)	
Splenic vein thrombosis	35 (7%)	31 (8%)	4 (4%)	
Indication				0.4
Abdominal pain	141 (30%)	114 (30%)	27 (30%)	
Early satiety	36 (8%)	26 (7%)	10 (11%)	
Infection	200 (42%)	162 (42%)	38 (42%)	
Outlet obstruction	58 (12%)	48 (12%)	10 (11%)	
Vessels thrombosis	8 (2%)	8 (2%)	0 (0%)	
Vomiting	15 (3%)	11 (3%)	4 (4%)	
Other	18 (4%)	17 (4%)	1 (1%)	
Etiology of pancreatitis				0.52
Alcohol	91 (19%)	74 (19%)	17 (19%)	
Biliary	236 (50%)	198 (51%)	38 (42%)	
Idiopathic	60 (13%)	45 (12%)	15 (17%)	
Post-ERCP	23 (5%)	17 (4%)	6 (7%)	
Post-operative	13 (3%)	11 (3%)	2 (2%)	
Trauma	39 (8%)	29 (8%)	10 (11%)	
Other	14 (3%)	12 (3%)	2 (2%)	
Access				<0.001
Needle/cystotome+guidewire	90 (20%)	0 (0)	90 (100%)	
Single stage	386 (80%)	386 (100%)	0 (0)	
Fluoroscopic guide				<0.001
Yes	163 (34%)	89 (23%)	74 (82%)	
No	313 (66%)	297 (77%)	16 (18%)	
Stent diameter (mm)				0.48
<15	339 (71%)	61 (16%)	26 (29%)	
15–16	87 (18%)	275 (71%)	64 (71%)	
>16	50 (11%)	50 (13%)	0 (0%)	
Number of stents				0.23
1	465 (98%)	375 (97%)	90 (100%)	
2	11 (2%)	11 (3%)	0 (0%)	
Second flange deployment				<0.001
Endoscopic view	135 (28%)	67 (17%)	68 (76%)	
Intrachannel	341 (72%)	319 (83%)	22 (24%)	
Approach				0.004
Transduodenal	37 (8%)	24 (6%)	13 (14%)	
Transgastric	428 (90%)	354 (92%)	74 (82%)	
Both	1 (0.2%)	1 (0.2%)	0 (0%)	
Other	8 (1.4%)	7 (1.8%)	1 (1.5%)	
Not reported	2 (0.4%)	0 (0%)	2 (2.5%)	
Stent dilation				<0.001
No	375 (79%)	290 (75%)	85 (94%)	
Yes	101 (21%)	96 (25%)	5 (6%)	

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Table 1 (continued)

Variable	Total (n = 476)	LAMS (n = 386)	BFMS (n = 90)	p value
Necrosectomy				<0.001
No	277 (57.6%)	201 (51.6%)	76 (84%)	
Yes	198 (42%)	184 (48%)	14 (16%)	
Not reported	1 (0.4%)	1 (0.4%)	0 (0%)	
Endoscopic appearance of cavity				<0.001
Purulent fluid	209 (44%)	169 (44%)	40 (44%)	
Solid debris	156 (33%)	140 (36%)	16 (18%)	
Vessels	11 (2.2%)	11 (3%)	0 (0%)	
Other	91 (19%)	57 (15%)	34 (38%)	
Not reported	9 (1.8%)	9 (2%)	0 (0%)	
Hydrogen peroxide irrigation				<0.001
No	329 (69%)	246 (64%)	83 (92%)	
Yes	136 (29%)	129 (33%)	7 (8%)	
Not reported	11 (2%)	11 (3%)	0 (0%)	
Antibiotic irrigation				0.08
No	446 (94%)	357 (92%)	89 (99%)	
Yes	19 (4%)	18 (5%)	1 (1%)	
Not reported	11 (2%)	11 (3%)	0 (0%)	
Nasocystic tube drainage				<0.001
No	402 (84%)	336 (87%)	66 (73%)	
Yes	63 (13%)	39 (10%)	24 (27%)	
Not reported	11 (2%)	11 (3%)	0 (0%)	
Pigtail use through stent				<0.001
No	411 (86%)	322 (83%)	89 (99%)	
Yes	65 (14%)	64 (17%)	1 (1%)	
Need of percutaneous drainage				0.54
No	457 (96%)	369 (96%)	88 (98%)	
Yes	19 (4%)	17 (4%)	2 (2%)	
Days to stent removal	30 (21–48)	30 (21–43)	45 (30–117)	<0.001
Procedural time	25 (16–40)	27 (17–40)	19 (15–38)	0.01
Technical success	464 (97%)	378 (98%)	86 (96%)	0.25
Clinical success	440 (92%)	355 (92%)	85 (94%)	0.56
Collection recurrence	30 (6%)	26 (7%)	4 (4%)	0.75
Adverse event rate	71 (15%)	56 (15%)	15 (17%)	0.72

Continuous variables were reported as median values and interquartile range. Comparisons were performed with Mann-Whitney U test for continuous variables and Fisher exact test for categorical ones.

Abbreviations: LAMS, Lumen Apposing Metal Stent; BFMS, Bi-Flanged Metal Stent; PD, pancreatic duct, PFC, pancreatic fluid collection; NR, not reported, WON, walled-off necrosis, ERCP, Endoscopic Retrograde Cholangio-Pancreatography.

Significances were reported in bold.

migration (one case in each group), and perforation (one case in the LAMS group and two cases in the BFMS group; $p = 0.18$).

Technical and clinical successes were 91.7% and 90.5% versus 95.2% and 94.0%, $p = 0.36$ and $p = 0.64$, respectively, in the LAMS and BFMS stent groups. Recurrence of the fluid collection was observed in four cases after LAMS (4.7%) and three cases (3.5%) after BFMS stent placement ($p = 1.0$).

4. Discussion

Historically, PFCs have been drained utilizing double pigtail PS. Recent studies have demonstrated that the use of large-bore, fully-covered metal stents can improve patient outcomes and permit direct endoscopic necrosectomy, particularly in cases of WON (DEN). Bapaye et al. [26] retrospectively compared 133 patients who underwent WON drainage with multiple PS or BFMS (20 mm long, 16 mm diameter NagiTM stent). BFMS appeared superior to multiple PS in terms of clinical success, the number of sessions for necrosectomy, AEs, the need for salvage surgery, and hospital stay. This finding was also supported by a recent meta-analysis [27] which demonstrated that using LAMS/BFMS resulted in superior clinical outcomes compared to PS in patients with WON, with comparable AEs and technical failure.

Nonetheless, a recent single-center, randomized, controlled trial published by Karstensen et al. [28] showed that LAMS was not superior to double pigtail PS for treatment of large WON (>15 cm), considering a comparable need for DEN and hospital stay, with no apparent difference in AEs, thus suggesting that further evidence

are required to definitively establish the superiority of large-bore metal stents over double pigtail PS.

In recent years, LAMS has evolved and changed shape, and efforts have been made to simplify and make the drainage procedure safer. A significant breakthrough was the development of electrocautery delivery systems that allow fluoro-less deployment [17,29–31]. Indeed, EC-LAMS are widely perceived as technically easier to deploy than FCSEMS or PS, which require multiple procedure steps. However, some concerns remain regarding their routine use, including costs, AEs, and, sometimes, unsatisfactory resolution rates [10,32]. Moreover, the superiority of EC-LAMS over BFMS has not been demonstrated.

On the other hand, using BFMS could be theoretically associated with an increased risk of stent displacement during necrosectomy and stent ingrowth precluding removal. The presumed higher risk of displacement of BFMS compared to EC-LAMS has also been raised by a recent study [33] that compared the anchoring force of different LAMS, with Nagi demonstrating the lowest anchoring force and the Axios the highest. However, a large study evaluating the use of Nagi stents in 205 WOPN reported a technical success of 99% and a clinical success of 74.6%, with a low rate of AEs (3.9%) [34].

To demonstrate the superiority of LAMS over BFMS, we conducted a multicenter study including a large number of PFCs. To reduce the risk of selection bias, we employed the propensity score analysis to obtain well-balanced groups for many variables that could influence technical and clinical success and the risk of AEs. In the current study, there were no statistically

Table 2
Baseline patients' characteristics and outcomes after propensity score matching.

Variable	Total (n = 168)	LAMS (n = 84)	BFMS (n = 84)	p value
Age (years)	62 (52.1–74)	62 (49.5–73)	63 (50–74)	0.40
Gender				0.59
M	110 (65.4%)	59 (70%)	51 (61%)	
F	58 (34.6%)	25 (30%)	33 (39%)	
PFC type				0.70
Pseudocyst	108 (64%)	51 (61%)	57 (68%)	
WON	60 (36%)	33 (39%)	27 (32%)	
Percentage of necrosis	46 (30–60)	48 (38–60)	45 (30–58)	0.29
Location				0.62
Body	94 (56%)	43 (52%)	51 (61%)	
Head	43 (25.5%)	25 (30%)	18 (21%)	
Tail	31 (18.5%)	16 (17%)	15 (18%)	
Collection width (mm)	90 (60–120)	92 (61–120)	88 (56–110)	0.25
Collection length (mm)	75 (52–100)	78 (55–100)	74 (52–96)	0.37
Collection				0.80
Multiloculated	33 (19.6%)	17 (20%)	16 (19%)	
Single	135 (80.4%)	67 (80%)	68 (81%)	
Extension to paracolic gutter	133 (79%)	66 (78%)	67 (80%)	1.0
No	35 (21%)	18 (22%)	17 (20%)	
Yes				
Imaging appearance of PD	10 (6%)	6 (7%)	4 (5%)	0.19
Leak	142 (84.5%)	69 (83%)	73 (87%)	
No leak	16 (9.5%)	9 (10%)	7 (8%)	
Unknown				
Vessels appearance on imaging	156 (93%)	76 (90%)	80 (94.5%)	0.29
No alterations	3 (1.5%)	2 (2.5%)	1 (1%)	
Perigastric varices	3 (1.5%)	2 (2.5%)	1 (1%)	
Portal vein thrombosis	6 (4%)	4 (5%)	2 (2.5%)	
Splenic vein thrombosis				
Indication				0.26
Abdominal pain	47 (28%)	22 (26%)	27 (32%)	
Early satiety	17 (10%)	7 (9%)	10 (12%)	
Infection	64 (38%)	30 (35%)	34 (40%)	
Outlet obstruction	12 (7%)	3 (4%)	9 (11%)	
Vessels thrombosis	16 (9.5%)	16 (17%)	0 (0%)	
Vomiting	7 (6%)	3 (4%)	4 (5%)	
Other	3 (1.5%)	3 (4%)	0 (0%)	
Etiology of pancreatitis				0.42
Alcohol	31 (18%)	16 (19%)	15 (18%)	
Biliary	76 (45%)	40 (47%)	36 (43%)	
Idiopathic	25 (15%)	10 (12%)	15 (18%)	
Post-ERCP	9 (5%)	3 (4%)	6 (7%)	
Post-operative	6 (4%)	5 (5.5%)	1 (1%)	
Trauma	15 (9%)	6 (8%)	9 (11%)	
Other	6 (4%)	4 (4.5%)	2 (2%)	
Access				<0.0001
Needle+guidewire	84 (50%)	0 (0)	84 (100%)	
Single stage	84 (50%)	84 (100%)	0 (0)	
Fluoroscopic guide				<0.0001
Yes	96 (57%)	12 (14%)	84 (100%)	
No	72 (43%)	72 (86%)	0 (0)	
Stent diameter (mm)				0.25
<15	55 (33%)	29 (35%)	26 (31%)	
15–16	106 (63%)	48 (57%)	58 (69%)	
>16	7 (4%)	7 (8%)	0 (0%)	
Number of stents				0.53
1	167 (99.5%)	83 (98.5%)	84 (100%)	
2	1 (0.5%)	1 (1.5%)	0 (0%)	
Second flange deployment	83 (49%)	18 (22%)	65 (77%)	<0.001
Endoscopic view	85 (51%)	66 (78%)	19 (23%)	
Intrachannel				
Approach				0.13
Transduodenal	33 (20%)	22 (26%)	11 (13%)	
Transgastric	131 (78%)	59 (70%)	72 (86%)	
Other	4 (2%)	3 (4%)	1 (1.5%)	
Stent dilation				0.16
No	153 (91%)	73 (87%)	80 (95%)	
Yes	15 (9%)	11 (13%)	4 (5%)	

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Table 2 (continued)

Variable	Total (n = 168)	LAMS (n = 84)	BFMS (n = 84)	p value
Necrosectomy				0.23
No	133 (79%)	62 (74%)	71 (85%)	
Yes	35 (21%)	22 (26%)	13 (15%)	
Endoscopic appearance of cavity				0.78
Purulent fluid	72 (43%)	34 (39%)	38 (45%)	
Solid debris	37 (22%)	21 (26%)	16 (19%)	
Other	59 (35%)	29 (35%)	30 (36%)	
Hydrogen peroxide irrigation				0.44
No	150 (89%)	73 (87%)	77 (92%)	
Yes	18 (11%)	11 (13%)	7 (8%)	
Antibiotic irrigation				1.0
No	167 (99.5%)	84 (100%)	83 (99%)	
Yes	1 (0.5%)	0 (0%)	1 (1%)	
Nasocystic tube drainage				0.86
No	127 (75.5%)	65 (78%)	62 (74%)	
Yes	41 (24.5%)	19 (22%)	22 (26%)	
Pigtail uses through stent				0.17
No	160 (95%)	77 (92%)	83 (99%)	
Yes	8 (5%)	7 (8%)	1 (1%)	
Need of percutaneous drainage				0.52
No	162 (96%)	80 (96%)	82 (98%)	
Yes	6 (4%)	4 (4%)	2 (2%)	
Days to stent removal	44 (30–97.5)	45 (33.5–58.5)	43 (30–116)	0.94

Continuous variables were reported as median values and interquartile range. Comparisons were performed with Wilcoxon test for continuous variables and McNemar test for categorical ones.

The following demographic, technical and collection-related variables were selected for propensity score calculation:

PFC Type, imaging appearance of pancreatic duct and vessels, approach, endoscopic appearance of cavity, hydrogen peroxide irrigation, use of necrosectomy, use of nasocystic drainage tube, use of pigtail stents through the LAMS.

Abbreviations: LAMS, Lumen Apposing Metal Stent; BFMS, Bi-Flanged Metal Stent; PD, pancreatic duct, PFC, pancreatic fluid collection; NR, not reported, WON, walled-off necrosis, ERCP, Endoscopic Retrograde Cholangio-Pancreatography.

Significances were reported in bold.

Table 3

Outcomes.

	Total (168 pts)	LAMS (84 pts)	BFMS (84 pts)	p value
Adverse event rate	24 (14.2%)	11 (13.1%)	13 (15.5%)	0.29
Type of adverse event	10 (5.9%)	5 (5.9%)	5 (5.9%)	0.18
Bleeding	8 (4.7%)	4 (4.7%)	4 (4.7%)	
Infection	1 (0.5%)	0 (0%)	1 (1.1%)	
Stent occlusion	2 (1.1%)	1 (1.1%)	1 (1.1%)	
Stent migration	3 (1.7%)	1 (1.1%)	2 (2.3%)	
Perforation				
Severity adverse event				0.63
Mild	6 (3.4%)	3 (3.5%)	3 (3.5%)	
Moderate	9 (5.1%)	4 (4.7%)	5 (5.9%)	
Severe	6 (3.4%)	3 (3.5%)	3 (3.5%)	
Fatal	3 (1.7%)	1 (1.1%)	2 (2.3%)	
Technical success				0.36
	157 (93.4%)	77 (91.7%)	80 (95.2%)	
Clinical success				0.64
	155 (92.2%)	76 (90.5%)	79 (94.0%)	
Collection recurrence				1.0
	7 (4.1%)	4 (4.7%)	3 (3.5%)	

Values are expressed as number (percentage).

Abbreviations: LAMS, Lumen Apposing Metal Stent; BFMS, Bi-Flanged Metal Stent.

significant differences in technical or clinical success between LAMS and BFMS for EUS-guided drainage of PFC (both PP and WON); moreover, the safety profile of the two devices was also comparable.

Overall, a similar rate of AEs was reported in the two groups (13% for LAMS whereas 15% for BFMS, $p = 0.63$), with bleeding representing the most common AE (5.9% in both groups), followed by infection (4.7% in both groups). The predominance of bleeding among AEs is consistent with the findings of the international

multicenter analysis by Fugazza et al. [21] on AEs associated with LAMS for PFC drainage. Their study reported bleeding in 27.8% of cases and stent migration in 25.3%. Even in the retrospective study by Chandran et al. [10], stent migration associated with BFMS was not negligible (8.5% in the early phase, 12.8% in the late phase). In contrast, in our results, only 1 case was in each group. Other AEs observed in our series were perforation (1 case in the LAMS group and 2 cases in the BFMS group; $p = 0.18$), stent migration (1 case in each group), and stent occlusion (1 case in the BFMS group), col-

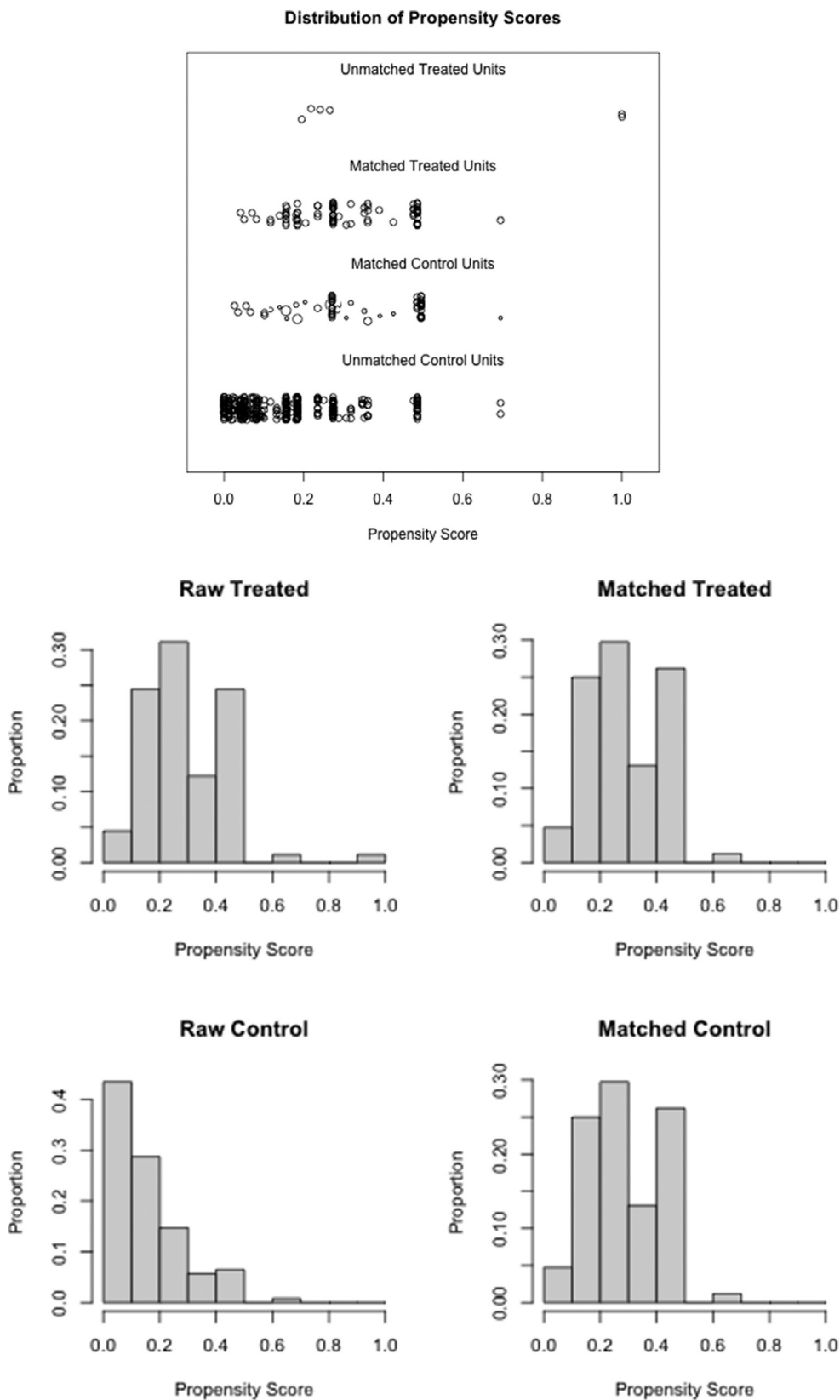


Fig. 3. Propensity score matching. Out of 476 patients with pancreatic fluid collection drained with EUS-guided lumen-apposing metal stent, of which 386 were treated with Hot-Axios, and 90 with Nagi stent after propensity score matching two groups were compared: 84 subjects who underwent EUS-drainage with Hot-Axios and 84 treated with Nagi stent. A. Propensity score matching jitter plot. B Propensity score matching histogram.

lection recurrence was observed in 4 cases after LAMS (4.7%) and 3 cases (3.5%) after BFMS ($p = 1.0$).

Siddiqui et al. [14] in 2016 conducted a large retrospective, multicenter U.S. study to evaluate clinical outcomes and safety of EUS-guided drainage of PFC using LAMS (Axios™) on 82 patients. Results demonstrated high technical and clinical success rates (resolution of pseudocysts and WON of 100% and 88%, respectively). The results of this study appear to be superior to those observed in a case series by Chandran et al. [10], in which BFMS stents were used to drain 47 PFC, with a resolution rate of 76.6% and a notable rate of AEs (in particular 4 early and 6 late stent migrations). In the study by Chandran et al., a larger subgroup of WON (infected or uninfected) was included, which may account for these differences.

Although LAMS and BFMS stents have a similar design, their minor differences may account for the higher migration rate reported for BFMS, which was not confirmed by our study.

More recently, the same American group [35] conducted an international, multicenter retrospective trial to compare the efficacy and safety of BFMS versus LAMS for endoscopic drainage of WON. No statistically significant differences were found in technical and clinical success or AEs among 387 pts (205 using BFMS with a “step-up approach” and 182 using LAMS with scheduled necrosectomy). The migration rate was higher in the BFMS group than in the LAMS group (15 [7.3%] vs. 3 [1.6%]; $P < 0.001$); however, there was no difference between the BFMS and LAMS groups in the clinically significant migration (2.4% vs. 1.6%, respectively; $P = 0.73$). It is essential to note that only the cold version of Axios™ was used in this study. This could have impacted the results, particularly the technical success rate and AEs. Moreover, this represents the main difference with our study (where only EC-LAMS were used), in addition to the significant heterogeneity between the two groups, which was mitigated in our study by propensity score analysis.

To our knowledge, only one study published in 2017 by Bekkali et al. [16] has compared the efficacy of EC-LAMS and BFMS for EUS-guided drainage of PFCs. They demonstrated that, in a retrospective series of 72 patients (40 treated with BFMS, 32 with EC-LAMS), the use of a single-device LAMS is associated with a statistically significant shorter procedure time compared with BFMS, but with overall total procedure costs and technical and clinical outcomes similar for both systems, without significant differences in the rate of AEs, which is supported by our findings. Nevertheless, there are substantial differences between our study and this one: i) the number of patients included was significantly lower than our sample size even after matching; ii) the two groups were not comparable in terms of the different variables, whereas in our study we used a propensity score analysis; iii) a selected population affected only by WON was included, while in our series WON accounted for only one-third of collections.

Our study has a few limitations: first, the retrospective design with non-randomized stent selection poses a risk of selection bias due to the preference/availability of one stent over the other. However, we attempted to limit this bias by employing the propensity score analysis, which assists in overcoming biases caused by the different distribution of covariates among the included patients, thereby adjusting the sample. Second, the multicenter setting, with the participation of several endoscopists with diverse expertise and the different experience of the centers and their facilities of other disciplines, may have resulted in substantial variation in patient management or techniques, which may have negatively impacted certain outcomes. However, it is difficult to standardize these procedures, and the participation of multiple centers makes our results more representative of daily clinical practice nationwide.

Indeed, most previously published studies on this topic originate from single referral centers or involve a small number of expert endoscopists [15,19,36], certainly ensuring better outcomes

but presenting a less reproducible picture of real-world conditions. Third, in our study, the majority of stents used had a diameter of 15–16 mm or less, with only 7 cases (8%) using wider LAMS (20 mm Hot-Axios™), despite recent evidence [37–40] supporting the use of larger diameters to favor WON resolution, due to a significant increase in the cross-sectional area for PFC drainage, allowing a quicker resolution of WON as well as enable necrosectomy. The use of these sizes of stents could have slightly influenced our reported outcomes and could account for some discrepancies between them and more recently published series.

On the other hand, this study has notable strengths. The significant number of patients involved, the standardized definition of AEs, and the clear distinction between LAMS and BFMS, which are considered two distinct groups, should not be underestimated. Indeed, several studies group the two types of stents together, despite their slight differences; as a result, the distribution imbalance or the size of each group (which is not always homogenous) might influence the statistical comparison.

In conclusion, although the data is inconclusive regarding which type of stent provides the best outcome for EUS-guided PFC drainage, our study demonstrates that, among dedicated metal stents, EC-LAMS and BFMS have comparable safety profiles with similar technical and clinical success rates, suggesting that the choice of one stent over another should be based on clinical and technical aspects and/or personal expertise, rather than efficacy rate alone.

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Conflict of interest

There is no financial support to this study.

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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.2023.07.012](https://doi.org/10.1016/j.dld.2023.07.012).

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