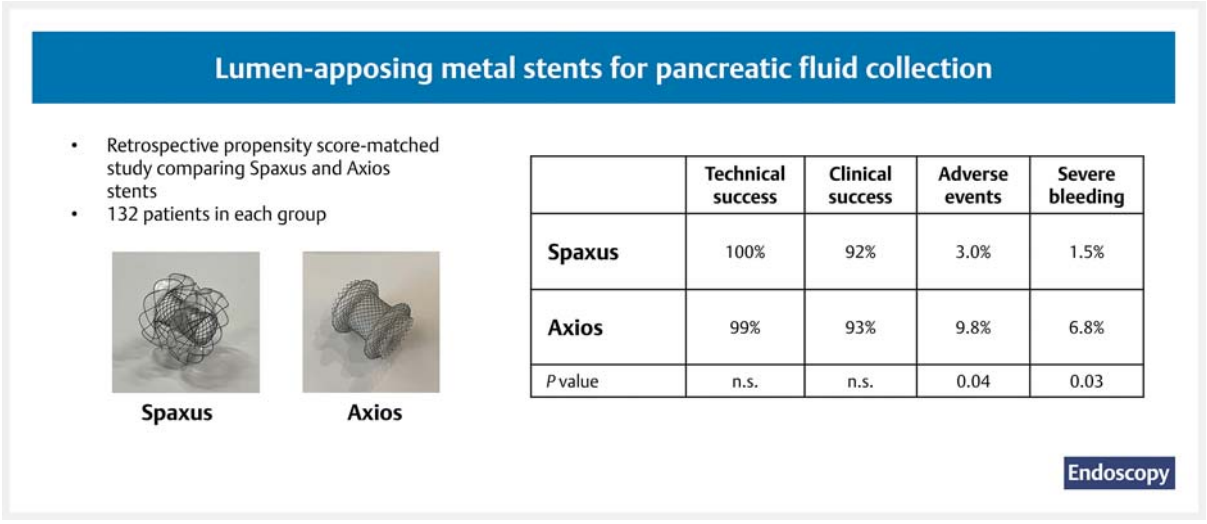
Lumen-apposing metal stents for the treatment of pancreatic and peripancreatic fluid collections and bleeding risk: a propensity matched study

GRAPHICAL ABSTRACT



	Technical success	Clinical success	Adverse events	Severe bleeding
Spaxus	100%	92%	3.0%	1.5%
Axios	99%	93%	9.8%	6.8%
P value	n.s.	n.s.	0.04	0.03

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ABSTRACT

Introduction Endoscopic ultrasound (EUS)-guided drainage of symptomatic pancreatic fluid collections (PFCs) using the Hot-Axios device has recently been associated with a significant risk of bleeding. This adverse event (AE) seems to occur less frequently with the use of a different device, the Spaxus stent. The aim of the current study was to compare the rates of bleeding between the two stents.

Methods Patients admitted for treatment of PFCs by EUS plus lumen-apposing metal stent in 18 endoscopy referral centers between 10 July 2019 and 28 February 2022 were identified and their outcomes compared using a propensity-matching analysis.

Results 363 patients were evaluated. After a 1-to-1 propensity score match, 264 patients were selected (132 per group). The technical and clinical success rates were comparable between the two groups. Significantly more bleeding requiring transfusion and/or intervention occurred in the Hot-Axios group than in the Spaxus group (6.8% vs. 1.5%; $P=0.03$); stent type was a significant predictor of bleeding in both univariate and multivariate regression analyses ($P=0.03$ and 0.04, respectively). Bleeding necessitating arterial embolization did not however differ significantly between the two groups (3.0% vs. 0%; $P=0.12$). In addition, the Hot-Axios was associated with a significantly higher rate of overall AEs compared with the Spaxus stent (9.8% vs. 3.0%; $P=0.04$).

Conclusion Our study showed that, in patients with PFCs, bleeding requiring transfusion and/or intervention occurred significantly more frequently with use of the Hot-Axios stent than with the Spaxus stent, although this was not the case for bleeding requiring embolization.

Introduction

Endoscopic ultrasound (EUS)-guided drainage has become the standard of care for the treatment of symptomatic pancreatic fluid collections (PFCs), including pancreatic pseudocysts (PPCs) and walled-off necrosis (WON). While PPCs are managed mainly by the placement of double-pigtail plastic stents (DPPSs), the introduction of lumen-apposing fully covered metal stents (LAMSs) has substantially increased the ability to treat necrotic collections [1]. Moreover LAMSs facilitate, when needed, direct endoscopic necrosectomy (DEN) [2, 3].

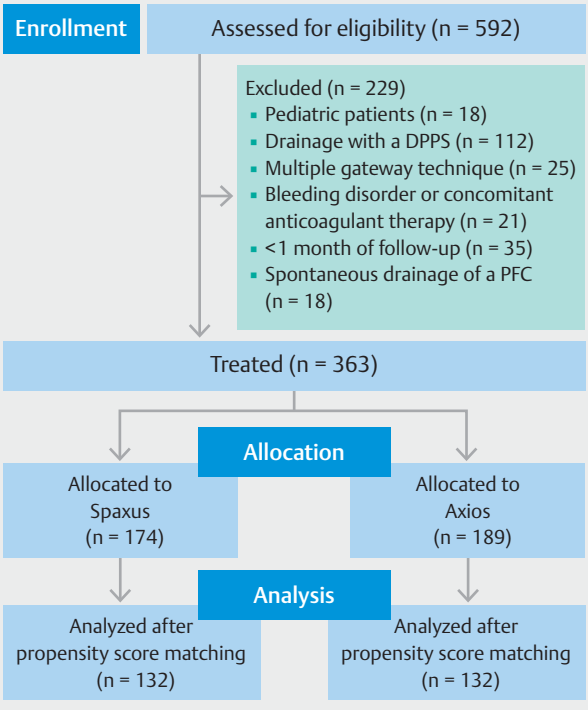
In 2017 Bang et al., reporting an interim analysis of an ongoing randomized controlled trial of WON treatment comparing DPPSs with the only LAMS available at that time (electrocautery-enhanced Hot-Axios; Boston Scientific Corp., Marlborough, Massachusetts, USA), reported a 25% rate of delayed bleeding requiring coil embolization, which occurred at 3 and 5 weeks after stent implantation [4]. No further bleeding episodes were observed after a modification of the protocol involving LAMS removal within 4 weeks [5].

Two subsequent retrospective studies confirmed the increased risk of bleeding, observed in 13.4% and 19% after Hot-Axios placement [6, 7]. The concern around bleeding-related adverse events (AEs) after Hot-Axios placement has been reinforced by data from post-marketing surveillance from the Food and Drug Administration (FDA) Manufacturer and User Facility

Device Experience (MAUDE), which highlighted the high frequency of AEs relating to use of the Hot-Axios for the treatment of PFCs, with a bleeding rate of 32.4% [8]. Bleeding occurs as the PFC is resolving and the pseudoaneurysms in the contralateral collection wall, previously compressed by the pressure of the cavity, come into contact with the rigid spikes of the terminal end of the intracavitary flange, causing wall erosion and consequent bleeding [9].

A second LAMS (Spaxus; Taewoong Medical Co., Gimpo, Republic of Korea) became available in 2016 and was recently incorporated into a device with electrocautery capabilities at its tip (Hot-Spaxus; Taewoong Medical Co.). The Spaxus stent has rounded edges and foldable flanges, allowing accommodative apposition between the stent and the cavity wall, which should theoretically reduce intracavity bleeding [10,11]. Available data on PFC drainage have reported bleeding rates of 5.1%, with one case requiring angiographic embolization; however, the number of treated patients in the publication by Teoh et al. [12] and in other small reports [13,14] is insufficient to draw any definitive conclusions.

To fill this gap, we performed a retrospective propensity study to compare the occurrence of bleeding between the Hot-Axios stent and the Spaxus stent, in both its cold and hot versions. In addition, the technical and clinical success, and overall AE rates of the two stents were also analyzed.



▶ **Fig. 1** Flowchart of patients included in the study.

Methods

Study population

This was a retrospective study conducted on patients who presented with symptomatic PFCs and were treated using cold or hot LAMSs (Hot-Axios or Spaxus/Hot-Spaxus) from 10 July 2019 to 28 February 2022 at one of 18 high volume endoscopy referral centers. All of the endoscopists had performed more than 30 LAMS placements before the start of the study period.

Hospitalized patients were clinically evaluated the day after the procedure and daily until discharge. After hospital discharge, patients were followed up with outpatient clinic visits or by phone calls. The protocol was approved by the institutional review board of Humanitas Mater Domini (no.37/22 HMD). The inclusion criteria were: (i) adult patients undergoing EUS-guided drainage for a PFC with a LAMS; (ii) PFCs requiring drainage because of symptoms. Exclusion criteria were: (i) drainage with DPPSs; (ii) use of the multiple gateway technique; (iii) bleeding disorders or concomitant anticoagulant therapy (not discontinued); (iv) less than 1 month of follow-up. ▶ **Fig. 1** represents the flowchart of patients included in the study.

Study device

Electrocautery-enhanced Hot-Axios stent

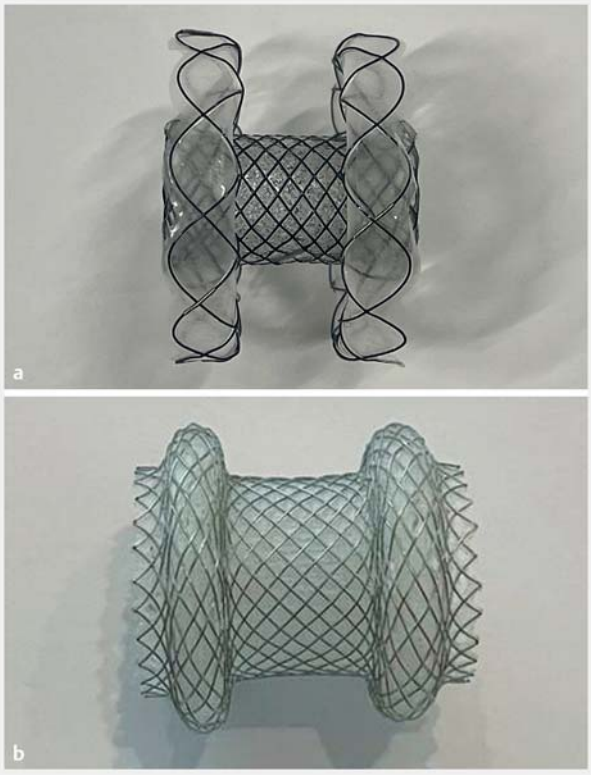
The Hot-Axios stent and delivery system (Boston Scientific) has the Conformité Européenne (CE) mark for drainage of PFCs with necrotic content of < 30%. The self-expanding Hot-Axios stent is made of braided medical-grade nickel titanium, fully covered with silicone (▶ **Fig. 2b**). The largest stents, used to drain PFCs, (saddle part measuring 10–20 mm) are released through a 10.5-Fr delivery system. The design incorporates flanges on both the distal and proximal ends to anchor the stent to the luminal walls, and a tip with electrocautery capabilities. The stent delivery system is Luer-locked onto the endoscope instrumentation channel inlet port. The dimensions and lengths of the body and flanges are listed in **Table 1 s**, see online-only Supplementary material.

Spaxus and Hot-Spaxus stents

This LAMS is a through-the-scope LAMS delivery device that is CE-approved for PPC drainage. The "cold" version lacks an electrocautery tip that was recently incorporated into the "hot" version (▶ **Fig. 2a**). The stent is comprised of braided nitinol, fully covered with silicone, with large flexible flanges on each end, with a saddle part length of 20 mm for PFC drainage. The flanges offer accommodative apposition regardless of the wall thickness, and the stent has a channel in which a 0.035-inch guidewire can be preloaded. The two available stents for PFC drainage, with body diameters and lengths of 10 × 20 mm and 16 × 20 mm (flange diameters of 25 and 31 mm, respectively), are delivered using a 10-Fr delivery catheter.

Procedures

Informed consent was obtained from all of the patients before they underwent treatment of their PFC. A therapeutic linear echoendoscope was used in all cases, and procedures were performed by an experienced ultrasonographer in a room with fluoroscopic capabilities, using carbon dioxide insufflation.



▶ **Fig. 2** A comparison of the features of: **a** the Hot-Spaxus stent; and **b** the Hot-Axios stent, which has metal spikes at the distal extremities of the stent.

All procedures were performed according to local policies, with deep sedation using propofol with anesthesiology assistance or with the patient under general anesthesia. The technique used for LAMS placement – either the freehand technique or 19G fine needle aspiration (FNA) needle puncture of the target PFC, followed by guidewire placement, cystotome use, and LAMS placement – was left to the discretion of each endosonographer. Similarly, the choice of stent diameter was left to endosonographer discretion. Patients were treated according to their respective local protocols in the event of a procedural or technical failure.

Distal flange release was performed under EUS control in all cases, whereas the proximal flange was delivered using the "intrachannel release" technique or under endoscopic/fluoroscopic view.

Study parameters/end points

The severity of bleeding was classified according to the American Society for Gastrointestinal Endoscopy (ASGE) lexicon [15]. Technical success was defined as adequate access and successful placement of the stent through the walls of the gastrointestinal tract into the PFC, with drainage of the intracollection fluids/necrotic material into the stomach/duodenum. Clinical success was defined as radiological resolution of the fluid collection at 3-month follow-up, without clinical symptoms attributable to the PFC.

Statistical analysis

Categorical variables were reported as the number of cases and percentage, and differences between groups were compared using Fisher's exact test. Continuous variables were expressed as the median and interquartile range (IQR), and differences between groups were explored by the Mann–Whitney and Wilcoxon rank tests before and after matching, respectively. All analyses were two-tailed, and the significance level was set at ≤ 0.05.

To overcome biases owing to the different distribution of covariates among patients assigned to Hot-Axios or Spaxus placement, a 1-to-1 match was created using propensity score analysis. The propensity score represents the probability of each patient being assigned to a particular condition or treatment in a study given a set of known covariates [16].

Multivariate logistic regression was performed to predict the probability of each patient being submitted to the two groups based on several demographic and collection-related covariates, including age, sex, collection size, type of collection, use of DEN, and approach for LAMS placement (transgastric or transduodenal). The predictive values were then used to obtain a 1-to-1 match using nearest neighbor matching within a predetermined caliper distance. Nearest neighbor matching within a specified caliper distance selects as a match 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 prespecified threshold (the caliper distance) [17]. Therefore, patients whose 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 SD 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 [18]. Subgroup analysis based on LAMS size was performed.

A univariate/multivariate logistic regression analysis was also performed to assess the correlation between baseline parameters and the bleeding rate. Results were reported as the odds ratio (OR) and 95 %CI. Significant factors in univariate analysis were then entered into the multivariate model.

In order to account for eventual center-effects in the analysis, the effect of the kind of stent used on the occurrence of the primary outcome (bleeding requiring transfusion and/or intervention) was analyzed through a random-effects analysis fitting a logistic regression model performed according to the formula

$$log\ it\ (\pi ij) = \alpha + \beta treat Xij + uj$$

where πij is the probability of an event for the *ith* patient in the *jth* center, $\beta treat$ indicates the log odds ratio for treatment, *Xij* indicates whether the patient received the treatment or control, and *uj* is the effect of the *jth* center [19].

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

▶ **Table 1** Baseline characteristics of the 363 patients who were treated with a Hot-Axios or Spaxus stent (both cold and hot) and whose data were retrospectively retrieved at one of 18 centers.

Variable	Overall (n = 363)	Spaxus (n = 174)	Axios (n = 189)	*P* value
Age, median (IQR), years	55 (39–65)	52.5 (37–61)	56 (41–68)	0.01
Sex, male, n (%)	251 (69.1 %)	123 (70.7 %)	128 (67.7 %)	0.61
Collection, n (%)				0.12
▪ Pseudocyst	123 (33.9 %)	68 (39.1 %)	55 (29.1 %)	
▪ WON	236 (65.0 %)	104 (59.8 %)	132 (69.8 %)	
▪ Pancreatic abscess	4 (1.1 %)	2 (1.1 %)	2 (1.1 %)	
Collection maximum diameter, median (IQR), cm	10.0 (7.0–13.0)	9.7 (7.0–12.6)	10.0 (7.0–13.8)	0.50
> 30 % necrosis, n (%)	128 (35.2 %)	43 (24.7 %)	85 (44.9 %)	< 0.001
Rate of infection, n (%)	193 (53.1 %)	95 (54.6 %)	98 (51.8 %)	0.67
Approach, n (%)				0.90
▪ Transgastric	348 (95.7 %)	168 (96.6 %)	180 (95.2 %)	
▪ Transduodenal	12 (3.3 %)	5 (2.9 %)	7 (3.7 %)	
▪ Combined	3 (0.8 %)	1 (0.6 %)	2 (1.1 %)	
Access type				< 0.001
▪ Freehand cystotome, guidewire placement, and cold LAMS	22 (6.1 %)	22 (12.6 %)	0	
▪ 19G needle, guidewire, cystotome, and cold LAMS	93 (25.6 %)	89 (51.1 %)	4 (2.1 %)	
▪ 19G needle, guidewire, hot LAMS	19 (5.2 %)	14 (8.0 %)	5 (2.6 %)	
▪ Freehand hot LAMS	229 (63.2 %)	49 (27.9 %)	180 (95.2 %)	
Plastic stent inside the LAMS, n (%)	168 (46.3 %)	90 (51.7 %)	78 (41.3 %)	0.02
Necrosectomy, n (%)	140 (38.5 %)	47 (27.0 %)	93 (49.2 %)	< 0.001

IQR, interquartile range; WON, walled-off necrosis; LAMS, lumen-apposing metal stent.

Results

Patients

Out of 592 patients initially assessed for eligibility, 363 were retrospectively retrieved from the databases of the 18 participating centers after excluding patients who did not fulfil the inclusion criteria (▶ **Fig. 1**). In the Spaxus group, 111 (64 %) and 63 (36 %) patients underwent cold and Hot-Spaxus placement, respectively, whereas the Hot-Axios was placed in 185 patients (98 %) (▶ **Table 1**). The number of procedures performed in the participating centers are detailed in **Table 2 s**.

The use of coaxial DPPSs inside the LAMSs was significantly more frequent for Spaxus stents compared with Hot-Axios stents (52 % vs. 41 %; $P = 0.02$), whereas necrosectomy was performed significantly more frequently in the Hot-Axios group than in the Spaxus group (49 % vs. 27 %; $P < 0.001$). All the other variables/parameters were similar between the two groups.

After 1-to-1 propensity score matching, 264 patients were selected for comparison: 132 were treated with the Spaxus stent (71 [54 %] with the cold Spaxus; 61 [46 %] with the Hot-Spaxus) and 132 with the Hot-Axios stent. Details of the propensity score matching are shown in **Fig. 1 s**. The characteristics of the 264 propensity score-matched patients are reported in ▶ **Table 2**.

The median age of the selected patients was 55 years (IQR 40–63.4), with equal sex distribution and no difference in any variable between the two groups ($P = 0.42$). WON was the most common type of treated collection (64.3 % and 62.8 % in the Spaxus and Hot-Axios groups, respectively; $P = 0.79$), with no difference in lesion size (9.7 cm [range 7.0–12.5] in the Spaxus group vs. 10.0 cm [range 7.0–13.5] in the Hot-Axios group; $P = 0.88$). Drainage was achieved through the stomach in almost all cases (97.0 % vs. 96.3 % in the Spaxus and Hot-Axios groups, respectively; $P = 0.73$), with coaxial DPPSs placed in 56.8 % of the Spaxus and 50.0 % of the Hot-Axios groups, respectively ($P = 0.26$). Unlike in the overall cohort, the use of DEN was not different between the two groups (35.6 % vs. 39.4 %; $P = 0.52$). More than 30 % of necrosis in the PFC was detected in 31.8 % of patients in the Spaxus group and 36.3 % of patients in the Hot-Axios group ($P = 0.51$), whereas the rate of

▶ **Table 2** Baseline characteristics of the 264 patients who were selected after 1-to-1 propensity score matching.

Variable	Overall (n = 264)	Spaxus (n = 132)	Axios (n = 132)	*P* value
Age, median (IQR), years	55 (40–63)	54 (39–61)	55 (40–65)	0.42
Sex, male, n (%)	184 (69.6 %)	92 (69.6 %)	92 (69.6 %)	> 0.99
Collection				0.79
▪ Pseudocyst	96 (36.4 %)	47 (35.7 %)	49 (37.2 %)	
▪ WON	168 (63.6 %)	85 (64.3 %)	83 (62.8 %)	
Collection maximum diameter, median (IQR), cm	10.0 (7.0–13.0)	9.7 (7.0–12.5)	10.0 (7.0–13.5)	0.88
> 30 % necrosis, n (%)	90 (34.1 %)	42 (31.8 %)	48 (36.3 %)	0.51
Rate of infection, n (%)	144 (54.5 %)	73 (55.3 %)	71 (53.7 %)	0.90
Approach, n (%)				0.73
▪ Transgastric	255 (93.3 %)	128 (97.0 %)	127 (96.3 %)	
▪ Transduodenal	9 (6.7 %)	4 (3.0 %)	5 (3.7 %)	
Access type, n (%)				< 0.001
▪ Freehand cystotome, wire placement, and cold LAMS	21 (7.9 %)	21 (9.8 %)	0	
▪ 19G needle, guidewire, cystotome, and cold LAMS	52 (19.6 %)	50 (44 %)	2 (1.5 %)	
▪ 19G needle, guidewire, and hot LAMS	17 (6.4 %)	14 (10.6 %)	3 (2.8 %)	
▪ Freehand hot LAMS	174 (66.1 %)	47 (35.6 %)	127 (95.7 %)	
Plastic stent inside the LAMS, n (%)	141 (53.4 %)	75 (56.8 %)	66 (50.0 %)	0.26
Necrosectomy, n (%)	99 (37.5 %)	47 (35.6 %)	52 (39.4 %)	0.52

IQR, interquartile range; WON, walled-off necrosis; LAMS, lumen-apposing metal stent.

infected collections was 55.3 % and 53.7 %, respectively (*P* = 0.90).

Outcomes

Study outcomes were reported in ▶ **Table 3**. The technical and clinical success rates were similar between the two groups. Bleeding, the primary outcome, occurred in two patients (1.5 %) who had a Spaxus stent compared with nine patients (6.8 %) who had a Hot-Axios stent placed (*P* = 0.03) (**Fig. 2 s**).

In both of the patients who bled in the Spaxus group, a 16 × 20-mm stent was used, with two severe bleeding episodes occurring 4 and 8 days post-procedure, at the level of the site of stent placement in one and an intracavity bleed in the other. The first patient was treated by stent removal, local epinephrine injection, and application of argon plasma coagulation, followed by placement of a second Spaxus stent when the bleeding stopped. In the second case, the intracavitary bleeding was stopped using an epinephrine injection and hemostatic powder. Both patients were hospitalized for 12 days; in neither case was a blood transfusion required.

Nine bleeds requiring transfusion and/or intervention were recorded in the Hot-Axios group. The stents placed among the patients who experienced bleeding requiring transfusion and/or intervention in the Hot-Axios group were a 10 × 10-mm stent (n = 1), a 15 × 10-mm (n = 5), and a 20 × 10-mm (n = 3) (**Table 3 s**). Bleeding occurred early (within 24 hours) in two patients, while two others bled at 48 hours; the remaining five patients bled late at 12, 16, 18, 21, and 23 days.

Five episodes of bleeding occurred at the site of LAMS placement and were treated endoscopically, while in four patients (3.0 %), bleeding occurred inside the cavity and required embolization by an interventional radiologist. In all four of these patients, a two unit blood transfusion was required; two presented with hematemesis and two with hypovolemic shock and melena, and their mean (SD) hemoglobin drop was of 4.8 (1.2) g/dL. For all four of them, bleeding resulted in admission to the intensive care unit for 2 nights, and their length of hospitalization ranged from 10 to 22 days. There was however no statistical difference in the number of patients who required embolization between the two groups (*P* = 0.12). Interestingly in two of these patients, coaxial DPPSs had been placed to prevent bleeding. Finally, one case of moderate bleeding during Hot-Axios stent placement (0.7 %) was also observed.

There were three additional AEs, so the overall, AEs were also significantly higher in the Hot-Axios group than the Spaxus group (9.8 % vs. 3.0 %; *P* = 0.04). One procedural perforation was successfully closed by an over-the-scope clip (Ovesco, Tübingen, Germany) and two migrated stents were not replaced at 32 and 45 days because of a healing sign. There were two

▶ **Table 3** Comparison of outcomes for endoscopic ultrasound-guided pancreatic fluid collection drainage between the 264 propensity score-matched patients selected for comparison.

	Overall (n = 264)	Spaxus (n = 132)	Axios (n = 132)	*P* value
Technical success, n (%)	263 (99.6 %)	132 (100 %)	131 (99.2 %)	> 0.99
Clinical success, n (%)	245 (92.8 %)	122 (92.4 %)	123 (93.1 %)	> 0.99
Adverse event rate, n (%)				
Overall	17 (6.4 %)	4 (3.0 %)	13 (9.8 %)	0.04
▪ Bleeding	12 (4.5 %)	2 (1.5 %)	10 (7.5 %)	0.03
▪ Severe bleeding	11 (4.1 %)	2 (1.5 %)	9 (6.8 %)	0.03
▪ Perforation	1 (0.3 %)	0	1 (0.7 %)	> 0.99
▪ Stent migration	2 (0.7 %)	0	2 (1.5 %)	0.49
▪ Stent misdeployment	2 (0.7 %)	2 (1.5 %)	0	0.49
LAMS occlusion	39 (14.7 %)	19 (14.3 %)	20 (15.1 %)	0.86

LAMS, lumen-apposing metal stent.

cases of stent misdeployment (1.5 %) observed in the Spaxus group.

As reported in ▶ **Table 4**, age (OR 1.16, 95 %CI 1.08–1.34; *P* = 0.02) and type of stent used (center-effect adjusted OR 0.25, 95 %CI 0.08–0.96; *P* = 0.04) were significant predictors of bleeding on multivariate analysis, and also on univariate analysis (*P* = 0.04) and (*P* = 0.03), respectively.

Discussion

Bleeding is a reported significant AE of Hot-Axios stents when used in patients with peripancreatic fluid collections and PFCs [6]. Driven by the low rate of bleeding episodes reported so far in patients with PFCs treated with the Spaxus stents [10], we performed a retrospective propensity score-matched study with the primary aim of comparing the occurrence of bleeding requiring transfusion and/or intervention between the Hot-Axios and the Spaxus stents in this patient population. Globally, we found the Spaxus stent to be associated with significantly lower rates of bleeding requiring transfusion and/or intervention episodes, and of overall AEs compared with the Hot-Axios stent, with similar technical and clinical success rates.

The "cold" Axios and the Hot-Axios were introduced into clinical practice in 2011 and 2013, respectively, with PFC drainage being the first and more common indication. Initial studies reported negligible rates of bleeding requiring transfusion and/or intervention [20], defined in our studies as endoscopic, radiological, or surgical intervention. Conversely, in more recent years, rates of bleeding requiring transfusion and/or intervention of 13.4 %–25 % have been observed [21, 22], reaching 32.4 % in post-marketing surveillance from the FDA-MAUDE [8]. It is plausible to hypothesize that this risk is related to the conformation of the intracavitary flange of the Hot-Axios stent, which presents at its terminal portion rigid spikes that can scrape and/or perforate the surface of the contralateral wall of the cavity when it shrinks, creating erosion of vessels and subsequent bleeding [23].

The advent of another LAMS in 2016, the Spaxus stent, which has a different terminal end design, with rounded edges and flanges that fold back and conform to the surface of the intracavity wall of the PFC, could theoretically reduce the risk of intracavity bleeding [10, 11]. To test this hypothesis, we collected data from 18 tertiary referral high volume endoscopy centers on a large number of patients with PFCs who underwent drainage with the Hot-Axios and Spaxus stents. Data were collected on an overall total of 363 patients, 99 of whom were excluded after 1-to-1 propensity score matching, with 132 patients allocated to each of the two study groups.

Our findings proved that bleeding requiring transfusion and/or intervention occurred significantly more frequently in the Hot-Axios group than in the Spaxus group (6.8 % vs. 1.5 %; *P* = 0.03). The relationship between the occurrence of bleeding requiring transfusion and/or intervention and the type of stent used was further confirmed by univariate regression analyses, which revealed that use of the Hot-Axios stent was a significant predictor of bleeding requiring transfusion and/or intervention (*P* = 0.03). However, although bleeding requiring arterial embolization was only observed in patients treated with the Hot-Axios stent, this AE did not reach a statistically significant difference compared with the Spaxus stents (3.0 % vs. 0 %; *P* = 0.12).

Caution should therefore be applied in interpreting our results, which do not allow us to conclude that the less aggressive design of the terminal end of the Spaxus stent, compared with the Hot-Axios stent, is associated with a decrease in the number of intracavitary bleeds necessitating interventional radiology. Although there was not a significant difference, we did however observe that this serious AE never occurred after Spaxus placement and the four cases registered in patients who were treated with Hot-Axios stent pose a note of caution that requires fur-

▶ **Table 4** Logistic regression analysis for the rates of bleeding requiring transfusion and/or intervention.

	Univariate analysis		Multivariate analysis	
	Odds ratio (95 %CI)	*P* value	Odds ratio (95 %CI)	*P* value
Age	1.13 (1.04–1.21)	0.04	1.16 (1.08–1.34)	0.02
Sex (reference male)	0.88 (0.73–1.83)	0.78		
Type of collection (reference pseudocyst)	1.81 (0.75–4.60)	0.18		
Diameter (reference < 10 cm)	1.33 (0.89–1.58)	0.15		
Approach (reference transgastric)	0.86 (0.61–1.48)	0.80		
Stent used (reference Axios)[1]	0.20 (0.04–0.95)	0.03	0.25 (0.08–0.96)	0.04
Necrosectomy (reference no necrosectomy)	0.64 (0.35–1.48)	0.62		
Use of DPPS inside the LAMS (reference no DPPS)	1.11 (0.36–4.03)	0.60		

LAMS, lumen-apposing metal stent; DPPS, double-pigtail plastic stent.
[1] Results adjusted for eventual center-effects using random-effects logistic regression.

ther studies with a larger sample size to draw definitive assumptions on this regard.

Moreover, all stents in the Hot-Axios group were placed using an electrocautery delivery system, whereas this system was used in only 46 % of the patients in the Spaxus group. In this regard, we observed that 5/9 cases of bleeding in the Hot-Axios group occurred at the entry site and not in the cavity, and we cannot be sure that the current used to place the stent did not have a role in the onset of bleeding. However, the cold Spaxus stents were placed using a cystotome with the same cutting current applied as is used for Hot-Axios deployment, thereby suggesting a minor role for the entry current. Only a prospective multicenter randomized study specifically designed to answer this question will be able to draw a definitive conclusion.

In our study, the rates of overall bleeding requiring transfusion and/or intervention were substantially lower than those reported in previous studies. Technical and clinical success were comparable between the two groups. Notably, in addition to bleeding requiring transfusion and/or intervention, in the Hot-Axios group, there were three additional AEs (one perforation and two stent migrations), meaning overall AEs occurred significantly more frequently in the Hot-Axios group (9.8 % vs. 3.0 %; $P = 0.04$).

We acknowledge several limitations in our study. First, because of the retrospective design, we cannot exclude selection bias, which we attempted to minimize by using the propensity score analysis and balancing the two groups for a number of factors associated with AEs. Our findings do however need to be further validated in a properly designed multicenter randomized controlled trial before any definitive conclusion can be drawn.

Second, our data are derived from experienced centers and operators, and might not be replicable in other settings. Third, some procedural aspects were not standardized, and heterogeneity of technical aspects could be found. This however is consistent with the real world, in which decision-making processes, particularly technical ones, are subject to operator preference and experience, and vary widely between institutions. Furthermore, these technical aspects have been shown to impact on technical success rather than on bleeding rate, which was the primary outcome in our study.

As a further limitation, the etiology of the bleeding episodes could not always be properly identified. In fact, it is very hard to differentiate between bleeding due to the natural course of disease (pseudoaneurysm) and direct stent-induced bleeding for at least two reasons: first, not all pseudoaneurysms are clearly detected on a computed tomography scan before a subsequent interventional radiology procedure; second, the two etiologies could coexist and both contribute to the onset of bleeding. It could be argued that the bleeding episodes observed in our study were detected beyond the usual timeframe described in the guidelines. However, this axiom has been questioned in recent large nationwide studies [22, 23], hence our results are in line with the recent literature in this field.

In conclusion, our study showed that, in patients with PFCs, bleeding requiring transfusion and/or intervention occurred significantly more frequently when the Hot-Axios stent was used than when the Spaxus stent was used, although this was not the case for bleeding requiring embolization. This higher risk of bleeding has been postulated to be related to the design of the end of the stent flange. A randomized controlled trial is warranted to obtain a proper comparison and draw a definitive conclusion.

Conflict of Interest

Benedetto Mangiavillano received a fee for a speech from Taewoong; Khanh Do-Kong Pham is consultant for Taewoong, MITech and Cook medical; Stefano Francesco Crinò received a grant from Steris Endoscop Anthony Teoh is s a consultant for Boston Scientific, Cook, Taewoong, Microtech and MI Tech Medical Corporations. Mark Anthony De Lusong is consultant for Boston Scientific, Fujifilm and Olympus; Alessandro Repici is consultant for Boston Scientific, Fujifilm and

Medtronic; Alberto Larghi is consultant for Boston Scientific, Pentax and MITech. The other Authors have no conflict of interest to declare.

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CORRECTION

Correction: Lumen-apposing metal stents for the treatment of pancreatic and peripancreatic fluid collections and bleeding risk: a propensity matched study

Benedetto Mangiavillano, Sundeep Lakhtakia, Jayanta Samanta et al. Lumen-apposing metal stents for the treatment of pancreatic and peripancreatic fluid collections and bleeding risk: a propensity matched study
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In the above-mentioned article the references in the text for Fig. 2a and 2b have been corrected. This was corrected in the online version on March 28, 2024.