Endoscopic removal of lumen-apposing metal stents – risk factors for stent embedment, complex removals, and adverse events: analysis from a multicenter prospective case series

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ABSTRACT

Background Removing lumen-apposing metal stents (LAMSs) may be difficult and even harmful, but these features have seldom been analyzed. We aimed to generate a comprehensive assessment of the feasibility and safety of LAMS retrieval procedures.

Methods A prospective multicenter case series including all technically successfully deployed LAMSs between January 2019 and January 2020 that underwent endoscopic stent removal. All retrieval-related data were prospectively recorded using standardized telephone questionnaires as part of centralized follow-up that ended after stent removal

had been performed. Multivariable logistic regression models assessed the potential risk factors for complex removal.

Results For the 407 LAMSs included, removal was attempted in 158 (38.8 %) after an indwell time of 46.5 days (interquartile range [IQR] 31–70). The median (IQR) removal time was 2 (1–4) minutes. Removal was labelled as complex in 13 procedures (8.2 %), although advanced endoscopic maneuvers were required in only two (1.3 %). Complex removal risk factors were stent embedment (relative risk [RR] 5.84, 95 %CI 2.14–15.89; $P = 0.001$), over-the-wire deployment (RR 4.66, 95 %CI 1.60–13.56; $P = 0.01$), and longer indwell times (RR 1.14, 95 %CI 1.03–1.27; $P = 0.01$). Partial and complete embedment were observed in 14 (8.9 %) and five cases (3.2 %), respectively. The embedment rate during the first 6 weeks was 3.1 % (2/65), reaching 15.9 % (10/63) during the following 6 weeks ($P = 0.02$). The adverse event rate was 5.1 %, including seven gastrointestinal bleeds (5 mild, 2 moderate).

Conclusions LAMS removal is a safe procedure, mostly requiring basic endoscopic techniques attainable in conventional endoscopy rooms. Referral to advanced endoscopy units should be considered for stents with known embedment or long indwell times, which may require more technically demanding procedures.

Introduction

Lumen-apposing metal stents (LAMSs) are being increasingly used to treat pancreatic fluid collections (PFCs) [1–3]. LAMSs are also temporarily deployed to drain other intra-abdominal fluid collections [4] or to create temporary access to the duodenum and the biliary tree after Roux-en-Y gastric bypass surgery [5]. All these indications, along with others, usually require the removal of the stent at the end of the treatment.

While there are many published papers assessing LAMS-related adverse events (AEs) [6–9], data regarding the safety of their removal are scarce and mainly retrospective. A retrospective single center study including 104 stent retrievals reported an 8.7 % AE rate, all of which were moderate or mild events [10]; another retrospective multicenter study involving 93 stent retrievals reported a 5.4 % retrieval-related AE rate, with two severe AEs (SAEs): a hemorrhage treated by embolization and a perforation that required surgical treatment [11].

Follow-up after LAMS placement is not always easy. They are usually deployed in advanced endoscopy units but follow-up is often performed at the referring institutions. This entails two complex situations. First, removal might be attempted at institutions where advanced endoscopic procedures, which might be required, are not available. Second, follow-up techniques, such as necrosectomy, secondary procedures or, more importantly, stent removal itself might be delayed, as conventional care pathways between attending physicians and out-of-center endoscopists are frequently lacking. In this situation severe delayed bleeding, embedment, or other complications may occur, as these have been associated with longer indwell times [12]. These situations might also complicate removal of the stent.

We therefore aimed specifically to assess the safety and feasibility of LAMS removal. Additionally, we evaluated the risk factors for complex removal, which could be of use in identifying those patients who should be referred to advanced endoscopy units.

Methods

The multicenter, nationwide prospective registry (RNPAL) was established in 2019 and aimed to include all patients who received a transmural LAMS in the 30 participating centers. All outcomes and definitions included in this manuscript were aims stated in the project's original design. The study was approved by the institutional review board of all participating centers and reported following the STROBE Initiative Statement (**Table 1 s**, see online-only Supplementary material). All participants signed the informed consent form prior to inclusion in the study.

Study population

The RNPAL registry considered all attempted LAMS deployments between January 2019 and January 2020 to be eligible. Patients participating in randomized clinical trials and those who declined to participate were excluded. All LAMSs that were technically successfully placed that were later endoscopically removed, regardless of the clinical outcome, were included in this subanalysis.

Endoscopic procedures

All stent retrievals were performed under endoscopist- or anesthesiologist-directed sedation with propofol (with or without midazolam), as per each center's protocol. All procedures were performed with conventional or therapeutic gastroscopes. Most LAMSs were located under direct view. Fluoroscopy was employed to locate completely embedded stents. Removal procedures included:

a) proximal flange traction using forceps to pull the luminal flange of the stent
b) flange traction using a snare to pull the luminal flange of the stent
c) distal flange traction using forceps to pull from the distal flange of the stent
d) other methods, all of which were thoroughly described in the case report form.

Definitions and outcomes

Stent removal was defined as the complete extraction of the stent. Stent embedment was endoscopically assessed at stent removal. It was categorized as: "absent" if the whole proximal flange was free; "partial" embedment if the proximal flange was at least partially covered but the metal mesh could be identified; and "total" if the mesh could not be seen with conventional endoscopy (buried stents).

The time needed to remove the stent was prospectively recorded. It was measured from the insertion of the first instrument employed through the endoscope working channel until the LAMS was outside the patient's body. Endoscopists also subjectively rated the task difficulty using a 5-point Likert scale (very easy, easy, intermediate, hard, and very hard). Complex LAMS removals were defined as those procedures specifically described by the endoscopist as "hard" or "very hard," and/or those where removal times were above the 90th percentile of the whole cohort.

The presence of adhered tissue, the integrity of the silicone covering the metal mesh, and the preservation of the stent morphology were assessed after stent removal as dichotomous variables. AEs identified during removal and their severity were defined and graded according to the ASGE recommendations [13].

Study data and follow-up

The study design included scheduled centralized telephone contacts at 14 days, and then 3, 6, 9, and 12 months after stent deployment. Once the stent had been retrieved, centralized follow-up was terminated at the next scheduled contact, unless this contact took place within 2 weeks after stent removal, in which case it was extended until the next scheduled contact. Data were collected and managed using a Research Electronic Data Capture tool (REDCap), a secure web-based application created to support data capture for research studies, providing semiautomatic data quality control [14]. Patient-related and procedural data were included by the local investigators at stent deployment and retrieval.

Statistical analysis

Categorical variables were reported as percentages. Normally distributed continuous variables were reported as the mean and SD, while non-normally distributed variables were reported as the median and interquartile range (IQR); the range was also used in some cases. We used an uncorrected Pearson's chi-squared test or Fisher's exact test, as appropriate, to analyze categorical variables and Student's *t* test or Wilcoxon's rank tests to analyze continuous variables, as appropriate.

To identify the risk factors for complex removals, we used a multivariable logistic regression model. Potential factors for the model were chosen according to the results of previous studies assessing LAMS removal (embedment) [15, 16] and other gastrointestinal stent removals (overall stent indwell time [weeks] and LAMS diameter) [17, 18]. Other variables were included based on experts' opinion (location of transmural access, indication [each one employed as a dichotomous variable], deployment technique [freehand vs. over-the-wire], balloon dilation at deployment, deployment of a double-pigtail plastic stent, proton pump inhibitor or antiplatelet treatment during stent indwell time, and bleeding during follow-up).

Embedment was directly included in the multivariable model. Variables based on experts' opinion and those extrapolated from other procedures underwent a prescreening using univariable logistic regression models. Those reaching a significance threshold of $P<0.20$ in univariable analysis were then evaluated in multivariable logistic regression models. In an iterative process, covariates were removed from the model if they were nonsignificant (establishing a significance threshold of $P<0.10$) and not a confounder. Confounders were maintained if their removal caused a greater than 20 % change in any remaining parameter estimate compared with the full model. The relative risks (RRs) with 95 %CIs were reported. Analyses were performed with Stata (StataCorp. 2013; College Station, Texas, USA).

Results

A total of 407 LAMS were included in the RNPAL study. The present study assessed all endoscopic removal attempts after a technically successful stent placement, which accounted for 158 cases (38.8 %). One technical failure was included, an endoscopic ultrasound-guided gallbladder drainage (EUS-GBD) where the distal flange placed in the cystic duct was removed 10 days after stent placement. Over 80 % of the 249 non-removed stents were EUS-GBDs (31.3 %), EUS-guided gastroenterostomies (EUS-GEs; 34.1 %), and choledochoduodenostomies (EUS-CDSs; 18.9 %), which were placed with the aim of being permanently indwelling.

The outcome of all included stents is shown in **Fig. 1 s**. Stents deployed to manage intra-abdominal collections were removed once resolution of the collection had been confirmed. Among the 17 EUS-GEs, nine removals were performed after the patient had undergone endoscopic ultrasound-directed transgastric endoscopic retrograde cholangiopancreatography (ERCP), six cases presented with benign gastric outlet obstruction, and one was a temporary EUS-GE in a localized periampullary tumor; a 15 × 10-mm stent replacement for a 20 × 10-mm stent in a patient with metastatic malignancy was also included.

A detailed description of the patients and their stent insertion procedures is presented in ▶ **Table 1**. Most cases were PFCs, including 76 walled-off necroses (WONs; 48.1 %) and 39 pseudocysts (24.7 %). Two patients (1.3 %) had received a coaxial LAMS placed to salvage a proximal flange misplacement: one in a 64-year-old woman undergoing an enteroanastomosis to gain access to the biliary tree in a gastric bypass required a second 15 × 10-mm LAMS and a 20 × 100-mm self-expandable metal stent (WallFlex; Boston Scientific); the other an 83-year-old man undergoing an EUS-CDS received a second 8 × 8-mm LAMS. A double-pigtail plastic stent was placed within the LAMS of 68 patients; at stent removal, 47 (69.1 %) were still in place, eight (11.8 %) had been previously removed, and 13 (19.1 %) had migrated prior to the removal.

▶ **Table 1** Baseline characteristics of the 158 patients who had a successfully placed lumen-apposing metal stent later removed endoscopically.

	Pancreatic fluid collection (n = 115)	Other procedures (n = 43)
Age, median (IQR), years	61.1 (50.6–69.5)	64.5 (52–74)
Sex, male, n (%)	84 (73)	21 (48.8)
Type of procedure, n (%)		
▪ Walled-off necrosis	76 (66.1)	
▪ Pseudocyst	39 (33.9)	
▪ Other fluid collections		19 (44.2)
▪ Enteroanastomoses		17 (39.5)
▪ EUS-guided gallbladder drainage		4 (9.3)
▪ EUS-guided choledo-choduodenostomy		2 (4.7)
▪ Postsurgical anastomotic dehiscence		1 (2.3)
Puncture site, n (%)		
▪ Esophagus	1 (0.9)	2 (4.7)
▪ Gastric fundus	7 (6.1)	2 (4.7)
▪ Gastric body	96 (83.5)	22 (51.2)
▪ Gastric antrum	5 (4.3)	6 (14.0)
▪ First or second part of duodenum	6 (5.2)	3 (7.0)
▪ Third part of duodenum or jejunum		6 (14.0)
▪ Colon		2 (4.7)
Stent diameter and length, n (%), mm		
▪ 20 × 10	9 (7.8)	9 (20.9)
▪ 15 × 10	81 (70.4)	19 (44.2)
▪ 10 × 10	25 (21.7)	13 (30.2)
▪ 8 × 8		1 (2.3)
▪ 6 × 8		1(2.3)
Insertion technique, n (%)		
▪ Freehand	101 (87.8)	38 (88.4)
▪ Over the wire	14 (12.2)	5 (11.6)
Balloon dilation after deployment, n (%)	29 (25.2)	23 (53.5)
Coaxial double-pigtail - plastic stent, n (%)	55 (47.8)	13 (30.2)

IQR, interquartile range.

▶ **Table 2** Details of the stent removal procedures.

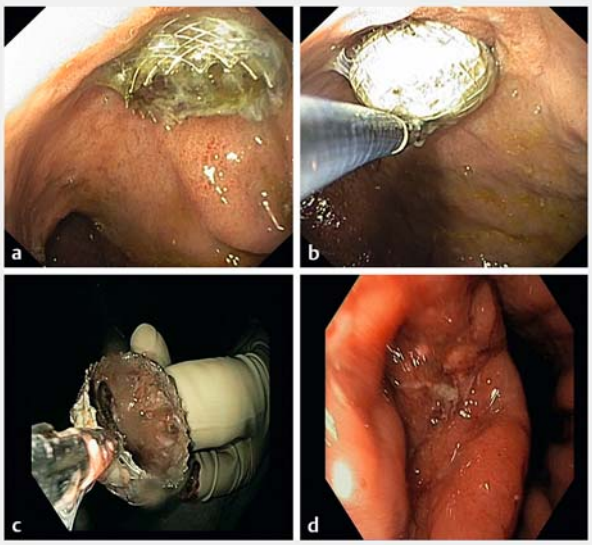
	Pancreatic fluid collection (n = 115)	Other procedures (n = 43)
Stent indwell time, median (IQR), days	46 (31–65)	52 (28–115)
Removal technique, n (%)		
▪ Proximal end forceps traction	97 (84.3)	38 (88.4)
▪ Proximal end snare traction	10 (8.7)	4 (9.3)
▪ Distal end forceps traction	6 (5.2)	1 (2.3)
▪ Other	2 (1.7)	
Time taken for removal, median (IQR), minutes	2 (1–5)	1 (1–2)
Endoscopist's subjective assessment, n (%)		
▪ Very easy	44 (38.3)	23 (53.5)
▪ Easy	58 (50.4)	15 (34.9)
▪ Intermediate	8 (7.0)	4 (9.3)
▪ Difficult	3 (2.6)	1 (2.3)
▪ Very difficult	2 (1.7)	
Stent embedment, n (%)		
▪ Absent	99 (86.1)	40 (93.0)
▪ Partial	11 (9.6)	3 (7.0)
▪ Complete	5 (4.3)	
Presence of adhered tissue after removal, n (%)	19 (16.5)	6 (14.0)
Intact silicone stent covering, n (%)	105 (91.3)	40 (93.0)

IQR, interquartile range.

Removal description

All the 158 stents were successfully removed. This was possible at the first attempt in 156 (98.7 %), while two required a second procedure. Stents were removed after a median indwell time of 46.5 days (IQR 31–70, range 7–303). A detailed description of the retrievals is presented in ▶ **Table 2**.

Most LAMS removals were straightforward procedures (▶ **Fig. 1**), with a median (IQR) removal time of 2 (1–4) minutes. The vast majority (149; 94.3 %) were removed by pulling from the proximal flange using conventional foreign body forceps (84.8 %) or polypectomy snares (9.5 %). Traction from the distal flange was used as a rescue technique for partially embedded stents in 2/14 cases (14.3 %), while the remaining stents could be retrieved with proximal flange traction.



▶ **Fig. 1** Step-by-step images of a lumen-apposing metal stent (LAMS) removal procedure showing: **a** the proximal flange of a correctly placed transmural stent; **b** traction being applied to the proximal flange with a forceps to remove the LAMS; **c** the integrity of the stent coating; **d** inspection of the fistula after stent removal.

Fluoroscopy was needed to locate all completely embedded (buried) LAMSs (five cases), three of which could be retrieved with proximal flange traction. Advanced endoscopic maneuvers were needed in two cases, with the indication for the LAMS being drainage of an infected pseudocyst in both cases, and the same removal technique being employed, as follows. The LAMS was located by endosonographic and fluoroscopic vision, and a 19G needle (Expect; Boston Scientific) puncture directed to the stent lumen was performed, followed by the advancement of a 0.035-inch guidewire (Jagwire; Boston Scientific) through the LAMS under fluoroscopic guidance. Serial dilation of the puncture tract was then performed using a 6-Fr cystotome (Cystotome; Endo-Flex) and an 8-mm biliary balloon (Hurricane RX Biliary Balloon Dilatation Catheter; Boston Scientific). Finally, the stent was extracted using rat-toothed forceps.

Complex removal

Overall, 140 LAMS removals (88.6%) were described as easy or very easy by the endoscopist, while only six (3.8%) were defined as difficult or very difficult; 90% of removals were performed in ≤10 minutes. Therefore, we identified 13 complex removals (8.2%), with three (1.9%) defined by the endoscopists, seven (4.4%) because of the prolonged procedure time (median 14 minutes, range 11–60), and three (1.9%) fulfilling both criteria.

Patients with coaxial double-pigtail plastic stents did not have significantly lower rates of embedment (8.6% vs. 13.8%; $P=0.30$) or complex removals (5.9% vs. 10.0%; $P=0.40$).

Multivariable logistic regression analysis identified stent embedment (RR 5.84, 95%CI 2.14–15.89; $P=0.001$) and over-the-wire deployment (RR 4.66, 95%CI 1.60–13.56; $P=0.01$) as independent risk factors for complex removals, and longer indwell times (RR 1.14, 95%CI 1.03–1.27; $P=0.01$) as a confounding factor (▶ **Table 3**).

▶ **Table 3** Univariable and multivariable analysis of risk factors for complex retrieval.

	Relative risk (95%CI)	*P* value
Univariable analysis[1]		
▪ Stent indwell time, weeks	1.16 (1.05–1.28)	0.003
▪ Over-the-wire technique	3.25 (1.11–9.57)	0.03
▪ Bleeding during follow-up	1.76 (1.03–3.01)	0.04
Multivariable analysis		
▪ Stent embedment[2]	5.84 (2.14–15.89)	0.001
▪ Over-the-wire technique	4.66 (1.60–13.56)	0.01
▪ Stent indwell time, weeks	1.14 (1.03–1.27)	0.01

[1] Other variables included in univariable analysis (results shown only if $P \leq 0.20$) were proton pump inhibitor or antiplatelet treatment during stent indwell time, bleeding during follow-up, overall stent indwell time, location of transmural access, indication (each one employed as a dichotomous variable), LAMS diameter, deployment technique (freehand vs. over the wire), balloon dilation, and coaxial double-pigtail plastic stent.
[2] Stent embedment was directly included in the multivariable analysis.

Stent embedment

A partial embedment was observed in 14 cases (8.9%), while a complete embedment was found in five cases (3.2%). A detailed description of patients with and without an embedded stent is shown in ▶ **Table 4**. Among PFCs, embedment was observed in 18% of pseudocysts and 11.8% of walled-off necroses. Cases where the LAMS was partially embedded required a median (IQR) of 4.5 (2–7) minutes for its removal and the five cases presenting with complete embedment required a median (range) of 16 (5–60) minutes, while non-embedded stents required a median (IQR) of only 2 (1–3) minutes. Overall, embedded stents required longer removal times ($P=0.01$).

The risk of embedment was strongly related to the indwell time, as shown in ▶ **Fig. 2**. Embedment was observed in 3.1% (2/65) of LAMSs removed during the first 6 weeks and in 15.9% (10/63) of those removed between the 7th and 12th weeks ($P=0.02$). Furthermore, in the remaining 30 stents removed after the first 12 weeks, the embedment rate was 23.3%.

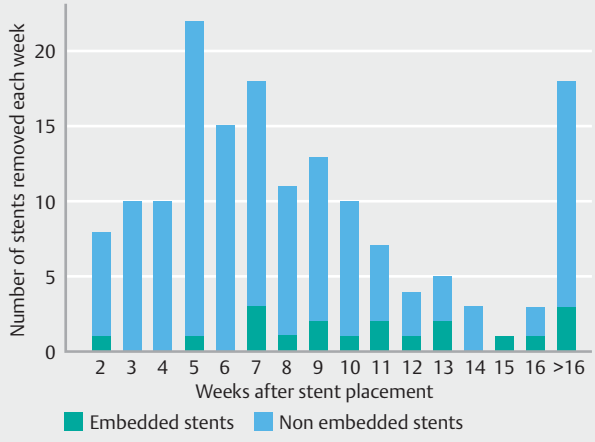
Retrieval-related adverse events

We did not identify any SAEs associated with LAMS removal. A total of seven gastrointestinal bleeds (4.4%) were observed: five mild cases where the patient could be discharged after stent removal and two moderate cases requiring a short hospital admission after endoscopic treatment (adrenaline injection in one case and hemostatic powder in another) for a second-look endoscopy to be performed. Moreover, one patient developed moderate acute cholecystitis 5 days after undergoing scheduled removal of a LAMS placed for gallbladder drainage.

▶ **Table 4** Characteristics of patients with and without an embedded lumen-apposing metal stent (LAMS).

	Embedded LAMS (n = 19)	Non-embedded LAMS (n = 139)	*P* value
Age, median (IQR), years	63.3 (53.3–69.5)	61.3 (50.6–71)	0.90
Sex, male, n (%)	14 (73.7)	91 (65.5)	0.50
Type of procedure, n (%)			0.23
▪ Pancreatic fluid collections	16 (13.9)	99 (86.1)	
▪ Other procedures	3 (7.0)	40 (93.0)	
Puncture site, n (%)			0.85
▪ Gastric fundus	1 (11.1)	8 (88.9)	
▪ Gastric body	15 (12.7)	103 (87.3)	
▪ Gastric antrum	2 (18.2)	9 (81.8)	
▪ Duodenum or jejunum	1 (6.7)	14 (93.3)	
Stent diameter and length, n (%), mm			0.87
▪ 10 × 10	5 (13.2)	33 (86.8)	
▪ 15 × 10	13 (13.0)	87 (87.0)	
▪ 20 × 10	1 (5.6)	17 (94.4)	
Insertion technique, n (%)			> 0.99
▪ Freehand	17 (89.5)	122 (87.8)	
▪ Over-the-wire	2 (10.5)	17 (12.2)	
Balloon dilation after deployment, n (%)	3 (15.8)	49 (35.3)	0.09
Coaxial double-pigtail plastic stent, n (%)	6 (31.6)	62 (44.6)	0.28
Stent indwell time, median (IQR), days	73 (46–99)	44 (29–66)	0.01

IQR, interquartile range.



▶ **Fig. 2** Bar graph showing the number of stents removed each week and whether they were embedded or not.

Discussion

Our study, the largest prospective case series specifically assessing LAMS withdrawals, reveals that most stent removals are technically simple and straightforward procedures, with an excellent safety profile. A small proportion may however be more technically demanding and some of these may require advanced endoscopic techniques, mainly if embedment is present.

Our case series, with over 150 procedures, confirms LAMS removal is a simple procedure, with nearly 95 % of removals performed by simple proximal flange traction. Furthermore, we identified a low AE rate (5.1 %) and, more importantly, no SAEs. It is interesting to highlight the multiple case reports that have been published describing different advanced maneuvers to retrieve embedded LAMSs [15, 19, 20]. This large body of literature might lead to a misconception about the relative frequency with which such maneuvers are needed. In fact, 98.7 % of LAMSs in our series were retrieved with a snare or a foreign body forceps.

LAMS embedment was the strongest risk factor for complex removals. The actual prevalence of stent embedment is unknown. Retrospective studies have reported low rates. Chan-

dran et al. identified a 6% rate among 54 PFCs [21], and two other retrospective multicenter studies reported meagre embedment rates: 0.9% (1/116 patients) among PFCs with a median indwell time of 7 weeks; 1.1% (1/93) in a Spanish case series including different procedures with a median indwell time of 8.3 weeks [11, 22]. However, a randomized trial comparing LAMSs and plastic stents in WONs reported a significantly higher rate of buried stents (6.5% [2/31]), all of which required complex withdrawal maneuvers [9]. The 12% rate found in our study therefore represents the highest embedment rate published. This is probably related to the prospective design of the study, as partial embedment does not usually make stent removal difficult and consequently it is seldom reported unless it causes an AE or requires advanced techniques. In our study, more than 85% of the partially embedded LAMSs were removed with the standard pull technique. In contrast, the 3.2% complete embedment rate closely resembles data from previous studies.

Longer indwell times have been previously reported as a risk factor for embedment, using a 4-week threshold [12, 23]. We identified a slightly longer threshold, with a 3.1% embedment rate in the first 6 weeks and a 15.9% risk in the following 6 weeks.

An interesting and previously unreported finding of our study was the association of over-the-wire stent placement with complex removal of LAMSs. This could be explained by a protective effect caused by the electrocautery used in the free-hand technique. This hypothesis has been previously postulated for other endoscopic techniques. Endoscopic balloon dilation (EBD) is currently the treatment of choice for postsurgical colorectal anastomotic strictures [24, 25], but stricture relapse is relatively frequent [26] and has been related to traumatic injury leading to the formation of scar tissue in the deeper muscle layer [27]. In contrast, an electrocautery incision technique has been reported as an alternative treatment for anastomotic colorectal strictures [28–30] with a lower relapse rate, theoretically by avoiding the scar tissue formation. Furthermore, the use of electrocautery reduces the formation of adhesions in surgical colonic anastomoses [31].

Our study presents a series of strengths. It is the largest prospective case series specifically addressing LAMS removals published to date. A pre-established definition of all outcomes was used, and the complementary centralized follow-up diminished the risk of under-reporting AEs. In addition, the large number of participating centers allowed the inclusion of operators with different levels of experience. On the other hand, it also has some drawbacks. The definition of complex withdrawals was based on the subjective assessment of the endoscopist, which can cause interobserver variability and lead to bias, although we tried to diminish this by including an objective variable: stent retrieval time. Additionally, other possible risk factors for complex removal, such as through-the-stent procedures or local infection (infected WONs, cholecystitis) were not registered or included in the multivariable models.

In summary, our study shows that LAMS withdrawal is a safe procedure, requiring basic endoscopic techniques, and is therefore attainable in conventional endoscopy rooms; however, experienced operators are still needed if advanced endoscopic techniques are required and to assess cases where the initial proximal traction maneuvers fail. Therefore, the removal of embedded LAMSs and those with an indwell time over 6 weeks or placed using an over-the-wire technique should be scheduled in advanced endoscopy units.

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Competing Interests

M. Perez-Miranda is a consultant for Boston Scientific, Olympus, Medtronic, and M.I.Tech. The remaining authors declare that they have no conflict of interest.

Clinical trial

Trial Registration: EU Clinical Trials Register (https://www.clinicaltrialsregister.eu) | Registration number (trial ID): NCT04059926 | Type of study: Prospective multicenter study

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CORRECTION

Correction: Endoscopic removal of lumen-apposing metal stents – risk factors for stent embedment, complex removals, and adverse events: analysis from a multicenter prospective case series

Bazaga S, García-Alonso FJ, Aparicio Tormo JR et al. Endoscopic removal of lumen-apposing metal stents – risk factors for stent embedment, complex removals, and adverse events: analysis from a multicenter prospective case series.
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In the above-mentioned article, the institution affiliations for Sergio Bazaga and Carlos Guarner-Argente have been been corrected. Correct is:

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