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Original Article

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Analysis of Adverse Events of Endoscopic Ultrasound-Guided Lumen-Apposing Metal Stent Placement: Insights Across Various Indications and Techniques

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Abstract

Background: Endoscopic ultrasound (EUS)-guided lumen-apposing metal stent (LAMS) placement is increasingly being used *in lieu* of surgery for multiple procedures, including transmural fluid drainage. However, few studies have evaluated adverse events (AEs) associated with LAMS placement. Our aim was to characterize the rates of AEs associated with several LAMS placement strategies across different procedures and indications.

Methods: A single-center retrospective cross-sectional study was conducted on patients who underwent EUS-guided LAMS placement between 2015 and 2023 at a single institution. Technical and clinical success rates and rates of early and late AEs were analyzed. Comparisons of AE rates were determined for patients who had LAMS dilation versus those without dilation, patients who had plastic stent placement in addition to LAMS placement versus those with no plastic stents, and patients who had combined dilation and plastic stent procedures versus those with LAMS dilation only.

Results: A total of 243 patients underwent EUS-guided LAMS interventions: 110 (45.3%) women and 133 (54.7%) men (mean age 53.7 ± 15.9 years). There were 96 (39.5%) patients who had at least one AE. Abdominal pain was the most common early and late AE. Plastic stent placement alongside LAMS placement was associated with a significantly higher rate of overall AEs (48.3% vs 29.9%; P = 0.009), late AEs (33% vs 17.9%; P = 0.021), and stent occlusion (5.7% vs 0%; P = 0.046). LAMS dilation was associated with higher rates of late AEs (34.2% vs 20.6%; P = 0.022) and stent occlusion (6.2% vs 1.0%; P = 0.049).

Conclusions: LAMS placement showed high technical and clinical success rates across different indications with mostly mild AEs, suggesting that LAMSs may be safe and effective for pancreatic and biliary drainage.

Keywords: Endoscopic ultrasound; Lumen-apposing metal stent; Adverse events

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Introduction

Advances in interventional endoscopy, particularly in the area of endoscopic ultrasound (EUS)-guided approaches, have altered treatment protocols for gastrointestinal and pancreaticobiliary disorders. Device improvements along with advances in endoscopic techniques now allow minimally invasive therapeutic approaches for treating complex disorders affecting regions beyond the gastrointestinal system. For example, endoscopic transmural drainage has traditionally been carried out under endoscopic guidance alone, which requires a somewhat blind approach that has been associated with a higher risk of complications such as bleeding and perforation. But thanks to the development of the EUS, these endoscopic procedures are now carried out under imaging guidance, greatly improving accuracy and safety [1]. Currently, a variety of important procedures can be carried out with EUSs, including biliary tree and gallbladder drainage, endohepatology interventions, creation of gastrointestinal anastomoses, radiofrequency ablation of tumors, injection of medications for the treatment of tumors and cancer-related pain, and management of local complica-

tions of acute pancreatitis [2].

The first transmural EUS-guided biliary tree drainage was performed in 2001 in a patient with a pancreatic head mass [3]. Since then, the development of EUS-guidance has led to ongoing advances in endoscopic procedures and technologies for transmural drainage. In particular, one important development was the introduction of self-expanding metal stents and lumen-apposing metal stents (LAMSs) to be used during EUS-guided drainage procedures [2]. While LAMSs were first introduced in 2012, they were not widely available until 2015. The first reported application of LAMS in humans involved five patients with acute cholecystitis and 15 patients with symptomatic pancreatic pseudocysts, all of whom had contraindications to surgery and were treated successfully [4]. Notably, EUS-guided procedures that include LAMS placement incur similar adverse event (AE) risks as any other advanced endoscopic procedure. But importantly, timely identification of any complication that may be associated with an endoscopic procedure is crucial for mitigating morbidity and mortality. Also, complications associated with stent placement can vary in severity and timing, sometimes occurring immediately after stent deployment, yet often occurring well after the procedure. However, reports on the safety of LAMSs are limited and highly varied, and some studies have observed complication rates of up to 20% [5].

Therefore, considering our lack of understanding regarding the short-term and long-term complications associated with EUS-guided LAMS placement, we performed a single-center, retrospective cross-sectional study to explore the procedural features, clinical outcomes, and AE rates in patients who received this procedure. Furthermore, we specifically explored whether certain AEs were associated with specific procedural strategies, including the concomitant use of LAMSs with plastic stents, implementation of LAMS dilation, and the combined application of LAMS dilation with the use of plastic stents. Our comprehensive characterization of the procedural features and clinical outcomes for patients having EUS-guided LAMS placement will help to optimize therapeutic guidelines and risk stratification approaches for patients with biliary, pancreatic, and gastrointestinal conditions requiring stents for anastomosis and fluid drainage.

Materials and Methods

Study design and patients

We performed a retrospective cross-sectional study of all adult patients (≥ 18 years old) who underwent EUS-guided LAMS placement interventions from January 2015 to December 2023 at Henry Ford Hospital (Detroit, MI). Only patients under 18 years of age were excluded from the study. Patients were identified from the Henry Ford Health endoscopic procedure database. All patients had a biliary-gastrointestinal connection or drainage created with LAMS placement per one of nine procedures and were followed for at least 30 days after the initial procedure. This study was approved by the Henry Ford Health Institutional Review Board, and the requirement for informed consent was waived. Patient confidentiality was maintained throughout the study. The study was conducted in compliance with the ethical standards of the responsible institution on human subjects as well as with the Helsinki Declaration.

Outcomes

The main outcomes were AEs associated with EUS-guided LAMS placement and defined per a modified version of the American Society for Gastrointestinal Endoscopy lexicon for endoscopic AEs [6]. AEs were further categorized as being early (within 48 h of the procedure) or delayed (between 48 h and 30 days after the procedure). Secondary outcomes included the following: technical success defined as successful placement of the LAMS; clinical success with no needed intervention defined as improvement in clinical outcomes; specific clinical outcomes (e.g., cholecystitis resolved); and multiple clinical consequences within three categories (i.e., hospital stay/admission, need for clinical intervention, serious outcomes including death and permanent disability).

Statistical approach

Baseline characteristics of the study population, EUS-guided procedures, technical details, and procedure outcomes were summarized as mean with standard deviation (SD) for continuous data and as frequencies and proportions for categorical data. To determine AEs associated with various EUS-guided LAMS placement strategies, patients were stratified via three schemes and compared: 1) LAMS placement with a concomitant plastic stent versus LAMS placement with no plastic stent used during the initial LAMS placement procedure, 2) LAMS dilation versus no LAMS dilation during the main LAMS placement procedure, 3) combination of LAMS dilation with a plastic stent versus LAMS dilation only with no plastic stent during the LAMS placement procedure. Chi-square test was used to determine the differences between groups in categorical variables. For continuous variables, *t*-tests or Wilcoxon rank sum tests were used depending on the data distributions. A P value of < 0.05 was considered statistically significant. Statistical analyses were performed using the Statistical Package for the Social Sciences (IBM v20.0, Armonk, NY) software.

Results

There were 243 patients who underwent EUS-guided LAMS interventions during the study period, including 133 (54.7%) men and 110 (45.3%) women. The mean age was 53.7 ± 15.9 years. Most patients were White (65.4%) or Black (18.1%) people. The mean body mass index (BMI) for the study population was 30.0 ± 9.5 kg/m^2, with more than half of the population being in the overweight range (n = 163, 67.1%). There were 108 (44.4%) patients who were active smokers, and the

Table 1. Sociodemographic and Health Behavior Characteristics of Patients Who Had EUS-Guided LAMS Placement

	Result (n = 243)
Age (years), mean ± SD	53.7 ± 15.9
Sex	
Female	110 (45.3)
Male	133 (54.7)
Race/ethnicity	
Arabic	2 (0.8)
Asian (from India)	1 (0.4)
Black	44 (18.1)
Hispanic	3 (1.2)
White	159 (65.4)
Other	17 (7.0)
Not specified	17 (7.0)
BMI (kg/m^2), mean ± SD	30.0 ± 9.5
Weight range by BMI	
Underweight (< 18.5 kg/m^2)	11 (4.5)
Normal weight (18.5 - 24.9 kg/m^2)	69 (28.4)
Overweight (≥ 25.0 kg/m^2)	163 (67.1)
Health behaviors	
Alcohol use	102 (42.0)
Illicit substance use	34 (14.0)
Smoking	108 (44.4)
Comorbidities	
Asthma or COPD	30 (12.3)
Cirrhosis	13 (5.3)
Coronary artery disease	20 (8.2)
Diabetes	89 (36.6)
Dyslipidemia	74 (30.5)
End-stage kidney disease	3 (1.2)
Hypertension	117 (48.1)
Myocardial infarction	10 (4.1)
Stroke	5 (2.1)
Ulcerative colitis	1 (0.4)

Data were shown as n (%) unless otherwise indicated. EUS: endoscopic ultrasound; LAMS: lumen-apposing metal stent; BMI: body mass index; COPD: chronic obstructive pulmonary disease; SD: standard deviation.

most common comorbidity was hypertension in 117 (48.1%) patients (Table 1).

Indications and procedural features

The most common indication for LAMS placement was pancreatic fluid collections in 170 (70%) patients, followed by gastric outlet obstruction in 27 (11.1%) patients, and the most frequently performed biliary-gastrointestinal connection type was cystogastrostomy in 159 (65.4%) patients. The most common LAMS size was 20 × 10 mm in a little over half of the patients. Plastic stents were implemented in conjunction with the LAMS in 176 patients (72.4%), and 145 patients (59.7%) had the LAMS dilated during the initial procedure. For the patients who had LAMS dilation, the mean maximum diameter of dilation was 13.2 ± 2.7 mm. The mean procedure time was 62.9 ± 31.5 min, and the maximal cyst/fluid collection diameter prior to the LAMS placement was 97.2 ± 40.2 mm (Table 2).

Procedural success and outcome rates

Procedures for almost all patients were technically successful (n = 237, 97.5%), and the overall rate of clinical success was 93% (n = 226) across all interventions (Table 2). There were 219 (90.1%) patients who had no clinical post-procedural consequences; however, nine (3.7%) patients required intensive care unit admission for more than one night, eight (3.3%) patients required a blood transfusion, two (0.8%) patients developed a permanent disability, and mortality occurred in five (2.1%) patients (Table 2).

Table 3 outlines the success and AE rates in patients for the five most frequently performed procedures, with the most commonly employed procedure being cystogastrostomy in 158 patients and the least employed being cystoduodenostomy in 10 patients. Of note, across these five procedures, technical success rates were high, occurring at rates between 90% and 100%, and clinical success rates ranged from 88% to 95%. Cystoduodenostomy done in the 10 patients showed the lowest rate of early AEs (1/10, 10%) but the highest rate of late AEs (4/10, 40%). The highest rate of early AEs occurred in the 31 patients who had gastro-jejunostomy (8/31, 25%); whereas the lowest rate of late AEs was 19% in patients who underwent both gastrojejunostomy (6/31) and cholecystoduodenostomy (3/16).

Out of the six patients who did not achieve technical success, four patients had AEs, two patients had early AEs (stent migration and misdeployment), and two patients had both early and late AEs (i.e., perforation, abdominal pain and hypoxia, infection and abdominal pain).

Overall AEs

Of the 243 patients, 96 (39.5%) experienced at least one of 155 AEs, with 48 patients (19.7%) having at least one early AE and 70 patients (28.8%) having at least one late AE. The most common early AE was abdominal pain in 28 (11.5%) patients, followed by bleeding in nine (3.7%) patients, and infection in six (2.5%) patients. The most common late AE was abdominal pain in 25 (10.3%) patients, followed by infection in 13 (5.3%), bleeding in 10 (4.1%), and stent occlusion in 10 (4.1%). Of the total 96 patients who experienced AEs, most had mild AEs (75/96, 78.1%), whereas 16.6% (16/96) experienced moderate AEs, and 5.2% had severe AEs (5/96) (Table 4).

Table 2. Procedural Features, Success Rates and Outcomes, and Clinical Consequences and Serious Outcomes of Patients Who Had EUS-Guided LAMS Placement

	Result (n = 243)
Indication for stent placement	
Abscess drainage	2 (0.8)
Acute cholecystitis	11 (4.5)
Cholangitis	2 (0.8)
First step of EDGE procedure	22 (9.1)
Gastric outlet obstruction	27 (11.1)
Pancreatic and bile duct obstruction from neoplasia	5 (2.1)
Pancreatic fluid collection (necrosis/pseudocyst)	170 (70.0)
Other	4 (1.6)
Biliary-gastrointestinal connection type	
Cholecystoduodenostomy	16 (6.6)
Cholecystogastrostomy	2 (0.8)
Choledochoduodenostomy	1 (0.4)
Colo-abscess	1 (0.4)
Cystduodenostomy	10 (4.1)
Cystgastrostomy	159 (65.4)
Duodenojejunostomy	1 (0.4)
Gastrogastrostomy	22 (9.1)
Gastrojejunostomy	31 (12.8)
Plastic stent also used	176 (72.4)
Stent size	
10 × 10 mm	28 (11.5)
10 × 15 mm	86 (35.4)
10 × 20 mm	127 (52.3)
22 × 90 mm	2 (0.8)
LAMS dilated during procedure	146 (60)
Maximum LAMS dilation diameter (mm), mean ± SD	13.2 ± 2.7
Procedure time (min), mean ± SD	62.9 ± 31.5
Maximal cyst/fluid collection diameter prior to LAMS placement (mm), mean ± SD	97.2 ± 40.2
Success rates and outcomes	
Technical success of LAMS placement	237 (97.5)
Clinical success with no needed intervention	226 (93.0)
Clinical outcome success	
Cholecystitis resolved (n = 11)	10/11 (90.9)
Pancreatic necrosis/pancreatic cyst resolved (n = 170)	170/170 (100)
Successful ERCP after EDGE procedure (n = 22)	22/22 (100)
Successful bypass of gastric outlet obstruction with oral intake ability (n = 27)	22/27 (81.4)
Clinical consequences	
No clinical consequences or need for further intervention	219 (90.1)
Unplanned hospital admission and stay requirements	
ICU admission > 1 night	9 (3.7)
Unplanned hospital admission/prolonged hospital stay ≤ 3 nights	7 (2.9)

Table 2. Procedural Features, Success Rates and Outcomes, and Clinical Consequences and Serious Outcomes of Patients Who Had EUS-Guided LAMS Placement - *(continued)*

	Result (n = 243)
Unplanned hospital admission/prolong hospital stay 4 - 10 nights	2 (0.8)
Need for clinical interventions	
Blood transfusion	8 (3.3)
Interventional radiology for AE	2 (0.8)
Repeat endoscopy for AE	6 (2.5)
Surgery for AE	2 (0.8)
Unplanned anesthesia/ventilation support	1 (0.4)
Serious outcomes	
Death	5 (2.1)
Permanent disability	2 (0.8)

Data were shown as n (%) unless otherwise indicated. ERCP: endoscopic retrograde cholangiopancreatography; EDGE: endoscopic ultrasound-directed transgastric ERCP; EUS: endoscopic ultrasound; LAMS: lumen-apposing metal stent; SD: standard deviation; ICU: intensive care unit; AE: adverse event.

Table 3. Procedural Success and Complication Rates by Anastomosis Procedural Approach for Patients Who Had EUS-Guided LAMS Placement

	EUS-guided LAMS placement anastomosis procedure				
	Cholecystoduodenostomy (n = 16)	Cystoduodenostomy (n = 10)	Cystogastrostomy (n = 158)	Gastrogastrostomy (n = 20)	Gastrojejunostomy (n = 31)
Technical success	16 (100%)	10 (100%)	156 (99%)	18 (90%)	29 (94%)
Clinical success	14 (88%)	9 (90%)	150 (95%)	19 (95%)	29 (94%)
Early AEs	3 (19%)	1 (10%)	28 (18%)	4 (20%)	8 (26%)
Late AEs	3 (19%)	4 (40%)	47 (30%)	4 (20%)	6 (19%)

Data were shown as n (%) unless otherwise indicated. EUS: endoscopic ultrasound; LAMS: lumen-apposing metal stent; AE: adverse event.

Table 4. AEs Experienced by Patients Who Had EUS-Guided LAMS Placement

Post-procedural AE[a]	Results (n = 243)
Total patients with at least one AE	96 (39.5)
Early AE (< 48 h from procedure) (n = 60 AE in 48 patients)	
Bleeding	9 (3.7)
Cardiac arrest	2 (0.8)
Deep vein thrombosis	1 (0.4)
Hypoxia (O_2 < 85%)	3 (1.2)
Infection (fever > 38 °C)	6 (2.5)
Misdeployment	1 (0.4)
Pain (abdominal)	28 (11.5)
Pain (non-abdominal)	1 (0.4)
Pancreatitis	1 (0.4)
Perforation	1 (0.4)
Pulmonary embolus	1 (0.4)
Stent migration	1 (0.4)
Stent occlusion	1 (0.4)
Other	4 (1.6)

Table 4. AEs Experienced by Patients Who Had EUS-Guided LAMS Placement - *(continued)*

Post-procedural AE[a]	Results (n = 243)
Late AE (48 h to 30 days from procedure) (n = 95 AE in 70 patients)	
Bile leak	1 (0.4)
Bleeding	10 (4.1)
Deep vein thrombosis	2 (0.8)
Disconnected duct syndrome	1 (0.4)
Hypoxia (O_2 < 85%)	6 (2.5)
Infection (fever > 38 °C)	13 (5.3)
Pain (abdominal)	25 (10.3)
Pancreatitis	4 (1.6)
Perforation	2 (0.8)
Pneumonia	1 (0.4)
Pulmonary embolus	2 (0.8)
Stent migration	7 (2.9)
Stent occlusion	10 (4.1)
Other	11 (4.5)
AE severity[a] (at least one AE in n = 96 patients)	
Mild	75/96 (78.1)
Moderate	16/96 (16.6)
Severe	5/96 (5.2)

Data were shown as n (%) unless otherwise indicated. [a]Some patients experienced more than one AE in more than one time period. Each AE was considered an independent event, and overall AE rates were calculated per total study population. A total of 155 AEs were recorded. EUS: endoscopic ultrasound; LAMS: lumen-apposing metal stent; AE: adverse event.

AEs - LAMS placement with versus without concomitant plastic stent

We asked whether the addition of a plastic stent alongside a LAMS might be associated with certain AEs. A comparison between patients who had the added plastic stent versus those who had no plastic stent showed that of the 176 patients with plastic stents, 85 had at least one AE, while 20 of the 67 patients with no plastic stent had at least one AE, indicating a significantly higher rate of AEs in those with the addition of a plastic stent (48.3% vs. 29.9%; P = 0.009). A significantly higher proportion of patients who had plastic stents included in their procedure had a late AE (33.0% vs. 17.9%; P = 0.021), but groups did not differ in regard to early AEs (20.5% vs. 17.9%; P = 0.656). The most common late complication was abdominal pain in 22 (12.5%) patients who underwent plastic stent placement with a LAMS. Notably, perforation occurred at a significantly higher rate in those who had LAMS placement alone than in those who underwent LAMS and plastic stent placement (3.0% vs. 0%; P = 0.021), while stent occlusion occurred at a higher rate in the group with plastic stent inclusion (5.7% vs. 0%; P = 0.046) (Table 5).

AEs - LAMS dilation versus no LAMS dilation

We next asked whether having the LAMS dilated might be associated with certain AEs. Of the 146 patients who underwent LAMS dilation during the same procedure as the initial LAMS placement, 64 had an AE; whereas 41 of the 97 patients who did not have LAMS dilation had an AE (43.8% vs. 42.6%; P = 0.809). While the dilation group had a significantly higher rate of late AEs (34.2% vs. 20.6%; P = 0.022), the rate of early AEs did not differ between groups (17.1% vs. 23.7%; P = 0.207). Notably, the rate of stent occlusion was greater in the LAMS dilation group than in the non-dilation group (6.2% vs. 1.0%, P = 0.049) (Table 5).

AEs - LAMS dilation with a plastic stent versus LAMS dilation only

Lastly, we asked whether LAMS dilation in combination with a plastic stent was associated with different rates of AEs compared to LAMS dilation without an additional stent. Of the 146 patients who underwent LAMS dilation, 125 had an added plastic stent placed, and 21 had no added plastic stent. Of those with LAMS dilation and the added plastic stent, 56 experienced at least one AE, while five of the 21 patients with no added plastic stent had AEs. There was no statistically significant difference in the rates of AEs between the two groups (45.1% vs. 25%, P = 0.090) (Table 6). Furthermore, this analysis showed that there was no statistically significant difference between the two groups in the rates of early AEs (17.6% vs.

Table 5. A Comparison of AE Rates in Patients Who Had EUS-Guided LAMS Placement With or Without Concomitant Plastic Stents, and in Patients Who Had EUS-Guided LAMS Placement With or Without Dilation

	Stent combination (n = 243)		P value
	LAMS + plastic stent (n = 176)	LAMS with no plastic stent (n = 67)	
All AEs	85 (48.3)	20 (29.9)	0.009*
Early AE (< 48 h)			
All	36 (20.5)	12 (17.9)	0.656
Bleeding	6 (3.4)	3 (4.5)	0.693
Cardiac arrest	1 (0.6)	1 (1.5)	0.476
Deep vein thrombosis	1 (0.6)	0 (0)	0.536
Hypoxia (O_2 < 85%)	2 (1.1)	1 (1.5)	0.822
Infection (fever > 38 °C)	5 (2.8)	1 (1.5)	0.545
Misdeployment	0 (0)	1 (1.5)	0.104
Pain (abdominal)	22 (12.5)	6 (9.0)	0.439
Pain (non-abdominal)	1 (0.6)	0 (0)	0.536
Pancreatitis	1 (0.6)	0 (0)	0.536
Perforation	0 (0)	1 (1.5)	0.104
Pulmonary embolus	1 (0.6)	0 (0)	0.536
Stent migration	0 (0)	1 (1.5)	0.104
Stent occlusion	1 (0.6)	0 (0)	0.536
Other	2 (1.1)	2 (3.0)	0.311
Late AE (48 h to 30 days)			
All	58 (33.0)	12 (17.9)	0.021*
Bile leak	0 (0)	1 (1.5)	0.104
Bleeding	8 (4.5)	2 (3.0)	0.584
Deep vein thrombosis	1 (0.6)	1 (1.5)	0.476
Disconnected duct syndrome	1 (0.6)	0 (0)	0.536
Hypoxia (O_2 < 85%)	4 (2.3)	2 (3.0)	0.749
Infection (fever > 38 °C)	10 (5.7)	3 (4.5)	0.709
Pain (abdominal)	22 (12.5)	3 (4.5)	0.066
Pancreatitis	3 (1.7)	1 (1.5)	0.908
Perforation	0 (0)	2 (3.0)	0.021*
Pneumonia	0 (0)	1 (1.5)	0.104
Pulmonary embolus	1 (0.6)	1 (1.5)	0.476
Stent migration	6 (3.4)	1 (1.5)	0.425
Stent occlusion	10 (5.7)	0 (0)	0.046*
Other	9 (5.1)	2 (3.0)	0.476

	Use of LAMS dilation (n = 243)		P value
	LAMS dilation (n = 146)	No LAMS dilation (n = 98)	
All AEs	64 (43.8)	41 (42.6)	0.809
Early AE (< 48 h)			
All	25 (17.1)	23 (23.7)	
Bleeding	6 (4.1)	3 (3.1)	0.207
Cardiac arrest	0 (0)	2 (2.1)	0.681

Table 5. A Comparison of AE Rates in Patients Who Had EUS-Guided LAMS Placement With or Without Concomitant Plastic Stents, and in Patients Who Had EUS-Guided LAMS Placement With or Without Dilation - *(continued)*

	Use of LAMS dilation (n = 243)		P value
	LAMS dilation (n = 146)	No LAMS dilation (n = 98)	
Deep vein thrombosis	1 (0.7)	0 (0)	0.081
Hypoxia (O_2 < 85%)	1 (0.7)	2 (2.1)	0.414
Infection (fever > 38 °C)	4 (2.7)	2 (2.1)	0.341
Misdeployment	0 (0)	1 (1.0)	0.739
Pain (abdominal)	14 (9.6)	14 (14.4)	0.219
Pain (non-abdominal)	1 (0.7)	0 (0)	0.247
Pancreatitis	0 (0)	1 (1.0)	0.414
Perforation	0 (0)	1 (1.0)	0.219
Pulmonary embolus	0 (0)	1 (1.0)	0.219
Stent migration	1 (0.7)	0 (0)	0.219
Stent occlusion	1 (0.7)	0 (0)	0.414
Other	1 (0.7)	3 (3.1)	0.414
Late AE (48 h to 30 days)			0.149
All	50 (34.2)	20 (20.6)	
Bile leak	0 (0)	1 (1.0)	0.022*
Bleeding	7 (4.8)	3 (3.1)	0.219
Deep vein thrombosis	1 (0.7)	1 (1.0)	0.513
Disconnected duct syndrome	0 (0)	1 (1.0)	0.770
Hypoxia (O_2 < 85%)	5 (3.4)	1 (1.0)	0.219
Infection (fever > 38 °C)	9 (6.2)	4 (4.1)	0.239
Pain (abdominal)	18 (12.3)	7 (7.2)	0.489
Pancreatitis	2 (1.4)	2 (2.1)	0.199
Perforation	0 (0)	2 (2.1)	0.678
Pneumonia	1 (0.7)	0 (0)	0.081
Pulmonary embolus	2 (1.4)	0 (0)	0.414
Stent migration	6 (4.1)	1 (1.0)	0.247
Stent occlusion	9 (6.2)	1 (1.0)	0.160
Other	8 (5.5)	3 (3.1)	0.049*
			0.381

Data were shown as n (%) unless otherwise indicated. *P value < 0.05. LAMS: lumen-apposing metal stent; AE: adverse event.

9.5%; P = 0.975) or late AEs (36.81% vs. 19.0%; P = 0.905). No other clinically relevant differences were seen between groups for specific AEs (Table 6).

Discussion

In this retrospective cross-sectional study of patients who had EUS-guided LAMS placement for a range of indications and through a variety of procedural strategies, we observed that EUS-guided LAMS placement procedures had high technical and clinical success rates ranging over 93%. The rate of AEs was 39.5%, which is comparable to previous studies [5]. LAMS dilation was associated with a higher risk of late AEs and stent occlusion, and plastic stent placement alongside a LAMS was associated with higher rates of overall AEs, late AEs, and stent occlusion. Most AEs were mild to moderate, and the mortality rate was 2.1%.

Endoscopic transmural drainage is a commonly used technique for gallbladder drainage and is also the standard practice for managing symptomatic pancreatic fluid collections, for which LAMSs were first authorized. Thus, most studies on the usage of LAMSs concern these indications [7-12]. In this study, we sought to determine the rate of AEs associated with LAMS placement across a wide range of indications and interventions. To the best of our knowledge, no previous stud-

Table 6. A Comparison of AE Rates in Patients Who Had EUS-Guided LAMS With Dilation, With or Without Concomitant Plastic Stent Placement

	Underwent both operations		Underwent LAMS dilation only		Significance	
	N	%	N	%	χ^2	P value
Overall complications						
No	69	54.8	16	75		
Yes	56	45.1	5	25	2.8671	0.090
Early AE	22	17.6	2	9.5	0.0010	0.975
Hypoxia (O_2 < 85%)	1	0.8	0	0.0	0.0949	0.758
Deep vein thrombosis	1	0.8	0	0.0	0.0949	0.758
Stent occlusion	1	0.8	0	0.0	0.0949	0.758
Bleeding	5	4	1	8.3	0.7273	0.394
Infection (fever > 38 °C)	4	3.2	0	0.0	0.4364	0.509
Pain (abdominal)	13	10.4	1	8.3	0.0623	0.803
Pain (non-abdominal)	1	0.8	0	0.0	0.0949	0.758
Other	1	0.8	0	0.0	0.0949	0.758
Late AE	46	36.8	4	19.0	0.0143	0.905
Hypoxia (O_2 < 85%)	4	3.2	1	8.3	1.087	0.297
Pneumonia	0	0.0	1	8.3	11.734	0.001
Deep vein thrombosis	1	0.8	0	0.0	0.0887	0.766
Pulmonary embolus	1	0.8	1	8.3	4.993	0.025
Stent occlusion	9	7.2	0	0.0	0.954	0.329
Bleeding	6	4.8	1	8.3	0.4369	0.509
Infection (fever > 38 °C)	9	7.8	0	0.0	0.954	0.329
Pain (abdominal)	18	14.4	0	0.0	2.445	0.118
Pancreatitis	2	1.6	0	0.0	0.1812	0.670
Stent migration	5	4	1	8.3	0.695	0.404
Other	8	6.4	1	8.3	0.1443	0.704

LAMS: lumen-apposing metal stent; EUS: endoscopic ultrasound; AE: adverse event.

ies have looked at the types of AEs associated with LAMSs across various procedures. The technical and clinical success rates we observed are in line with previous studies and suggest a high level of utility for the LAMS approach [8-10, 13]. Also, several of our more detailed observations align with what has been seen before. For example, the most common indication for LAMS placement in our cohort was pancreatic fluid collection [8], and the rates of early and late AEs ranged between 20% to 30% [5]. Importantly, the specific procedural complications of stent occlusion and migration occurred late in approximately 3% to 4% of patients, which has also been reported previously [8].

However, misdeployment was encountered in one patient in our study, whereas previous studies have reported it at a rate of up to 5.8% [2].

Notably, of the AEs that did occur, most were mild to moderate, although one patient remained intubated after the procedure due to worsening respiratory status and had a cardiac arrest 4 days later. However, we did observe a 2% post-procedural mortality rate, highlighting the fact that even though EUS-guided procedures are typically safe and successful, they are not without some serious risks. It is important to note that the mortality rate might be underestimated due to the retrospective nature of the study.

Almost two-thirds of our patients had plastic stent placement along with LAMS, and of these, almost half showed complications. The rate of overall AEs and late AEs in this group was higher than what was previously reported [8]; this may be due to the fact that previous studies have investigated AEs associated predominantly with pancreatic fluid collections, whereas our study looked at a wider range of indications. Notably, we observed that the rate of stent occlusion was higher in patients who had plastic stent placement, which contradicts the theoretical benefit of placing coaxial plastic stents in the inner channel of the LAMS to prevent occlusion [14]. The higher rate of stent occlusion in patients with plastic stent placement inside the LAMS may be attributed to several factors. Mechanically, the addition of a coaxial plastic stent reduces the effec-

tive diameter of the LAMS, potentially increasing the risk of clogging with debris or necrotic material. Furthermore, plastic stents are more prone to biofilm formation, which, combined with debris, may accelerate occlusion compared to the LAMS alone [15]. The design mismatch between the coaxial plastic stent and the LAMS could create irregularities that trap debris, while the narrowed inner channel may disrupt the laminar flow of secretions, contributing to stasis. Additionally, the theoretical benefit of the plastic stent in preventing tissue in-growth or excessive debris accumulation might be offset by its tendency to act as a bottleneck, particularly at the interface with the LAMS. These factors could explain why the anticipated reduction in occlusion risk was not observed in practice. Therefore, when plastic stents are employed, physicians should be aware that occlusion may still occur, and signs and symptoms of occlusion should not be ignored.

Rates of late AEs were significantly higher in patients who had LAMS dilation than in patients with no LAMS dilation, most notably stent occlusion, while dilation was not associated with an increased risk of early AEs. We hypothesize that this finding may be due to tissue edema resulting from manipulation during LAMS dilation and subsequent tissue regeneration, which could lead to stent obstruction that would not be apparent soon after the procedure. This suggests that patients who have LAMS dilation during the procedure should be monitored specifically for occlusion and other complications that may arise from the healing process.

To further explore the role of LAMS dilation on AE rates, we asked whether patients who had LAMS dilation with concomitant plastic stent placement had different rates of AEs compared to those with LAMS dilation alone, wondering if the combination of procedural effects might have a greater influence on AEs. However, we found no difference in the rates of AEs between patients who had plastic stent placement along with LAMS dilation versus those who only had LAMS dilation, highlighting no synergistic influences associated with these combined procedural features.

Our study had some limitations. It was a retrospective study that was performed in a single, high-volume, quaternary-care center, which may have introduced potential bias in patient selection. The follow-up care was not standardized, resulting in varying symptom assessments. Another limitation of this study is the follow-up period of at least 30 days, which may be too brief to capture late AEs. Longer follow-up is needed to better assess long-term outcomes. Despite being the largest single-center study reporting on this topic, the study may still lack sufficient power to detect small differences in outcomes. Although this was a retrospective study, all data were complete, and no records were missing data.

Conclusions

In summary, the use of LAMSs led to high technical and clinical success rates across different indications and interventions. The rate of overall AEs was 39%, and most AEs were mild and moderate. Although plastic stent placement alongside a LAMS is done to avoid stent occlusion, the rate of stent occlusion was higher in patients who had plastic stents placed in addition to the LAMS. Notably, LAMS dilation was also associated with a higher risk of stent occlusion. Our findings suggest that EUS-guided LAMS placement may be a safe and effective technique for pancreatic and biliary drainage, and other indications. More studies are needed to investigate the full safety profile of LAMS use for various biliary and gastrointestinal indications.

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Conflict of Interest

The authors declare that they have no conflict of interest.

Informed Consent

Not applicable. Hospital database was used to pull data retrospectively.

Author Contributions

Mohammed Abusuliman contributed to manuscript writing, drafting, designing and critical revision of the manuscript. Taher Jamali contributed to data collection, and the conception and design of the manuscript. Faisal Nimri, Ammad Javaid Chaudhary, Khaled Elfert, Abdulmalik Saleem, Ahmad Alomari, Muhammad Saad Faisal, Omar Shamaa, Mark Obri, Ahmed E. Salem, Amr Abusuliman, Andrew Watson, Robert Pompa, Duyen Dang, Cyrus Piraka, Mazen Elatrache, Sumit Singla and Tobias Zuchelli contributed to the conception and design of the manuscript.

Data Availability

The data supporting the findings of this study are available from the corresponding author upon reasonable request.

Abbreviations

AE: adverse event; EUS: endoscopic ultrasound; LAMS: lumen-apposing metal stent; SD: standard deviation; COPD: chronic obstructive pulmonary disease; ERCP: endoscopic retrograde cholangiopancreatography; EDGE: endoscopic ultrasound-directed transgastric ERCP; BMI: body mass index; ICU: intensive care unit

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