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Evaluation of Advanced Endoscopic Stents for Pancreatic Pseudocyst Drainage: A 2-Year Study

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Abstract

Background: Endoscopic ultrasound (EUS)-guided drainage using lumen-apposing metal stents (LAMS) is the first line choice for treatment of pancreatic fluid collections (PFCs). This study evaluated the technical success, clinical success, and adverse events (AE) associated with the Hot AXIOS electrocautery-enhanced LAMS for pancreatic pseudocysts (PPs).

Methods: This retrospective cohort study included 45 patients with PPs undergoing Hot AXIOS stent placement between 2019 and 2021. Clinical and technical success were assessed. AEs were graded based on severity and timing. Survival analysis and the Kaplan-Meier curve were used in the study.

Results: Technical success was achieved in 97.78% (44/45) cases and clinical success in 95.56% (43/45). Patients with a previous history of PP intervention were significantly more likely to experience moderate to severe AE ($P = 0.009$). Removal time of stent was significantly longer in patients with moderate or severe AE (median 70 vs 34.5 days, $P = 0.005$). Transition of PP to walled-off necrosis was associated with moderate or severe AE in comparison with mild or no AE ($P < 0.001$).

Conclusion: Hot AXIOS stents demonstrated high clinical and technical success rates for PP drainage. Patients with a history of prior interventions for PPs were at significantly higher risk of AE. Closer monitoring is recommended in patients with delayed removal. Future studies should incorporate a multicenter design and control groups with standardized success rates and AE definitions.

Keywords: Pancreatic pseudocysts, Hot AXIOS, Lumen-apposing metal stents, Endoscopy

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Introduction

Pancreatic pseudocyst (PP) is a common complication of acute and chronic pancreatitis (1, 2). The incidence of PP after acute pancreatitis ranges from 5% to 16% (1, 3, 4). Pancreatic pseudocysts are fluid-filled collections that develop next to the pancreas due to the leakage of pancreatic fluids during pancreatitis (5). These pseudocysts are different from true pancreatic cysts, lacking an epithelial lining and no closed structures (6). Pancreatic pseudocysts can cause various symptoms, such as nausea, vomiting, abdominal pain, and a palpable abdominal mass (6). They

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↑What is "already known" in this topic:
Lumen-apposing metal stents (LAMS) are generally easier to place and provide better pseudocyst drainage than traditional plastic stents. They are equipped with an electrocautery-enhanced delivery system (ECE-LAMS) without any need for fluoroscopy, guidewire exchanges, or tract dilatation by passing the catheter and LAMS into the pancreatic fluid collections with a single endoscopic ultrasound-guided puncture. However, these stents have complications such as delayed bleeding and stent migration, which require careful monitoring and management.

→What this article adds:
Clinical and technical success was achieved in 97.78% and 95.56%, respectively. Patients with a previous history of pancreatic pseudocysts (PP) intervention were significantly more likely to experience moderate to severe adverse effects (AE) (P = 0.009). Removal time of the stent was significantly longer in patients with moderate or severe AE.

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can also lead to complications like gastric outlet obstruction, biliary obstruction, and infection (7). While some pseudocysts may resolve spontaneously, others may require intervention, such as drainage or surgical treatment, particularly if they are causing significant symptoms or increasing in size (7).

For small pseudocysts (<5 cm) without complications, the initial approach is often to observe and monitor them, as up to one-third of them may resolve spontaneously within 6 weeks (8, 9). However, the risk of complications increases over time; thus, this approach is limited to asymptomatic patients with small, uncomplicated pseudocysts (8, 9). Surgical treatment, such as internal drainage (cystogastrostomy or cystoenterostomy) or pseudocyst resection, has been a common approach for managing PPs (6, 9, 10). Surgery has high success rates but low morbidity and mortality, is more invasive, and carries the risks associated with major abdominal surgery (6, 9, 10). Percutaneous catheter drainage (PCD) is a less invasive approach where a needle is inserted through the skin to drain the fluid from the pseudocyst. PCD can be effective, but it is associated with a higher risk of secondary infection compared to other methods (6, 10). The limitations of these traditional approaches include the invasiveness of surgery, the risk of complications with PCD, and the limited success rates of observation, especially for larger or symptomatic pseudocysts (6, 9, 10). These factors have led to the development of newer, less invasive techniques, such as endoscopic drainage, which have often become the preferred treatment option (6, 9, 10).

During endoscopic drainage, the goal is to connect the pseudocyst and the stomach or duodenum, allowing the fluid within the pseudocyst to drain and be expelled (6, 9, 11, 12). To perform drainage, the endoscopist uses endoscopic ultrasound (EUS) guidance to identify the pseudocyst and create a tract (6, 9, 11, 12). A stent is placed across this tract to maintain the connection and facilitate ongoing drainage (6, 9, 11, 12). Stents for EUS-guided drainage include double-pigtail plastic stents (DPPSs), fully covered self-expanding metal stents (FCSEMS), and lumen-apposing metal stents (LAMSs) (11-13). Comparad with other available stents, LAMS is designed with a wide diameter (10-15 mm) and flanges on each end that help secure the stent, preventing migration (11-13). The wide lumen of the LAMS also allows for direct endoscopic access to the pseudocyst cavity, enabling further debridement or necrosectomy, if needed (11, 12).

Compared with traditional plastic stents, LAMS is generally considered easier to place and provides better pseudocyst drainage (11, 12). In addition to being a fully covered self-expanding metal stent, the Hot AXIOS stents are equipped with an electrocautery-enhanced delivery system (ECE-LAMS). A further benefit of an ECE-LAMS is that the electrocautery-enhanced delivery system eliminates the need for fluoroscopy, guidewire exchanges, or tract dilatation by passing the catheter and LAMS into the PFC by a single EUS-guided puncture (14).

However, these stents have also been associated with unique complications, such as delayed bleeding and stent migration, which require careful monitoring and management (6, 9). The most commonly reported adverse events (AE) included hemorrhaging, perforations, pain, infections, and death (15). The main objective is to investigate the long-term efficacy and safety of using a Hot AXIOS stent for cyst gastrostomy in patients with PPs after acute pancreatitis. We followed these patients for 2 years to assess the procedure's success, the rate of pseudocyst resolution, and any associated complications. Understanding the long-term outcomes of using Hot AXIOS is crucial, as this technique has become increasingly adopted in managing PPs. By evaluating the efficacy and side effects over an extended follow-up period, we can better inform clinical decision-making and provide patients with a more comprehensive understanding of this treatment approach's potential benefits and risks.

Methods

Aim

This single-center, retrospective cohort study aimed to investigate patients with PPs who underwent pancreatic fluid drainage using EUS-guided Hot AXIOS stents. The study encompassed 45 patients treated at Firouzgar Hospital in Tehran, Iran, period between March 2019 and March 2021.

Participants

The definitive diagnosis of PP was established through ultrasound, computed tomography (CT) scan, or magnetic resonance imaging (MRI). The inclusion criteria comprised age over 18 years, nonpregnant female patients, symptomatic pseudocyst pancreatitis, pseudocyst size exceeding 5 cm with no morphological change after 6 weeks, cyst wall thickness exceeding 5 mm, and pseudocyst fluid volume ≥70%. The exclusion criteria included PPs resulting from chronic pancreatitis, patients requiring surgical intervention, patients with cystic neoplasms, patients with immature PPs, and patients with bleeding disorders or an INR of >1.5. Considering type 1 error equal to 0.05, using 1 proportion estimation formula, the minimum sample size of 24 was chosen based on the clinical success rate of 93% (mentioned by Li et al, (16) which employed a similar design and achieved adequate statistical power) and the precision around this percentage of success rate about 0.1%.

Procedure

Eligible patients underwent PFC drainage using a Hot AXIOS stent (AXIOS-EC, Boston Scientific), temporarily implanted for a maximum of 90 days, with removal determined by individual site or treating clinician preference.

After general anesthesia using propofol and sterile preparation, the endoscopist inserted the EUS scope into the upper gastrointestinal tract. Using ultrasound guidance, the PP will be visualized and identified. A needle was passed through the endoscope and into the pseudocyst under real-time ultrasound visualization. Once proper needle placement within the pseudocyst is confirmed, a guidewire is inserted through the needle and into the cyst cavity. The Hot AXIOS stent delivery system was intro-

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duced over the guidewire. Using fluoroscopic guidance, the preloaded stent was deployed across the wall of the pseudocyst and into the stomach (transgastric approach) or duodenum (transduodenal approach), depending on the location of the pseudocyst, creating a drainage pathway for the pancreatic fluid. The Hot AXIOS stent system was placed in compliance with the manufacturer's instructions. Fluoroscopy and direct visualization through the endoscope will be used to confirm the appropriate stent position and patency of the drainage channel. The procedure will be concluded by removing the endoscope and monitoring the patient for immediate complications.

Follow-up Visits

In each patient, 30 days after cyst-gastrostomy, the condition of the pseudocyst was evaluated in terms of PFC size, fluid volume, and communication with the intestinal wall using endoscopic ultrasound. If the PFC was not resolved within 30 days, the evaluation was repeated 30 days later (60 days after the procedure). Patients were reevaluated on the 7th day, 3rd month, 6th month, 12th month, and 48th month post-stent removal for latent complications.

Outcomes

Clinical success, as the primary outcome, was defined as a minimum of 75% decrease in the size of PFC at the time of endoscopic HOT AXIOS removal. Failed cases were considered patients requiring surgical intervention for the management of their PFC after HOT AXIOS implementation. Secondary outcomes were technical success, early and late AE, successful stent removal, and AE after stent removal.

Successful deployment of the HOT AXIOS, causing drainage of PFC contents into the stomach/duodenal lumen, was considered a technical success. Timing and severity of AE were defined according to the American Society for Gastrointestinal Endoscopy (ASGE) lexicon (17). Any procedure-related AE occurring immediately or within the first 48 hours after HOT AXIOS implementation was considered an early AE. Late AE were defined as events occurring 48 hours after implementation. Major bleeding was defined as hematemesis and/or melena or a hemoglobin drop of more than 2 g. Any reformation of PFC needs further endoscopic management after initial resolution, and HOT AXIOS removal was defined as recurrence. When evaluating the adverse effects of stent removal, we excluded surgically removed stents.

Data Collection

For each patient, comprehensive pre- and post-cyst-gastrostomy evaluations were conducted by a gastroenterology specialist, and the findings were recorded in electronic checklists, which were searched retrospectively by the authors. Baseline variables collected for each patient included medical history, encompassing a history of diabetes mellitus, hypertension (HTN), cholecystectomy, gallbladder stone (GB stone), common bile duct stone (CBD stone), pancreatitis, previous interventions for PPs, and cigarette smoking status. Documented signs and symptoms before the procedure included abdominal pain, weight loss, jaundice, fever, vomiting, diarrhea, pruritus, nausea, constipation, weakness, and loss of appetite. The size of the pseudocyst was measured in millimeters using EUS.

Statistical Analysis

Upon data collection, it was entered into STATA 14 software (Stata Corp LLC). Descriptive indexes were employed to summarize patient demographics, clinical data, and outcomes. Continuous variables were reported as means with standard deviations (SDs) or medians with interquartile ranges (IQRs), based on the distribution. Categorical variables were presented as frequencies and percentages. The type and role of variables determined the application of appropriate statistical tests, including independent t-tests, Mann-Whitney tests, chi-square tests, and Kaplan-Meier survival curves. We compared the survival curves between the 2 groups using the log-rank test. Results with $P < 0.05$ were deemed significant.

Results

The study included 45 patients with PPs, with a mean age of 45.5 ± 14.85 years and 58% were women (Table 1). The majority of patients presented with abdominal pain (98.0%), nausea (73.3%), and vomiting (49%) (Table 1). The mean size of PP was 10661.1 ± 5772.3 mm^2. The medical history of the patients revealed that 20% had diabetes, 15.7% had hypertension, 28.9% had a history of cholecystectomy, and 22.2% had a history of gallbladder stones. Moreover, 4 patients (8.89%) had a previous

Table 1. Baseline Characteristics of Patients with Pancreatic Pseudocysts Undergoing Hot AXIOS Stent Placement (N=45)

Baseline variable	Index
Age (Year); Mean ±SD	45.55±14.85
Female; n (%)	26 (57.8)
Previous intervention for pancreatic pseudocyst; n (%)	4 (8.9)
Size of pancreatic pseudocyst (mm^2); Mean ±SD	10661.1 ± 5772.4
Pre-intervention signs and symptoms; n (%)	
Abdominal Pain	44 (97.8)
Nausea	33 (73.3)
Vomiting	22 (48.9)
Weight loss	17 (37.7)
Weakness	17 (37.7)
Loss of appetite	13 (28.9)
Jaundice	5 (11.1)
Fever	4 (8.9)
Constipation	4 (8.9)
Pruritus	2 (4.4)
Diarrhea	1 (2.2)
Medical history; n (%)	
Diabetes	9 (20.0)
Hypertension	7 (15.6)
Inflammatory bowel disease or ulcerative colitis	1 (2.2)
History of Cholecystectomy	13 (28.9)
History of Gall bladder stone	10 (22.2)
History of Common bile duct stone	1 (2.2)
History of Cancer	4 (8. 9)
Tobacco use	9 (20.0)
Opium use	4 (8. 9)

SD: Standard deviation

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history of pancreatic intervention (Table 1). Technical success was achieved in 97.78% (44/45) of cases, and clinical success was achieved in 95.56% (43/45) of cases (Table 2). Successful removal of the HOT AXIOS was reported in 100% (43/43) of cases where removal was attempted. Early AE were minor bleeding (2.22%, 1/45) and perforation (2.22%, 1/45). No major bleeding, deployment failures, or systemic inflammatory response syndrome (SIRS) were reported (Table 2).

The most common delayed AE were sepsis (6.67%, 3/45), need for endoscopic necrosectomy (6.67%, 3/45), need for surgical necrosectomy (4.44%, 2/45), and abdominal abscess (2.22%, 1/45). No major bleeding, stent migration, or deaths were reported. There were no reported cases of minor or major bleeding or buried LAMS syndrome during stent removal.

The overall rate of AE was 24.44% (11/45), with 8.89% (4/45) being mild, 8.89% (4/45) being moderate, and 6.67% (3/45) being severe (Table 2). Patients with AE are summarized in Table 3. Both cases of minor bleeding were managed without requiring a blood transfusion. Infectious disease consultation was done for patients with sepsis, and they were treated with intravenous antibiotics and fully recovered. In one of the patients with sepsis, an abdominal abscess was identified, which was drained using interventional radiology without further complications. Out of 5 patients who developed walled-off necrosis (WON), 3 (6.67%) required endoscopic necrosectomy,

Table 2. Procedural Outcomes and Adverse Events After Hot AXIOS Stent Placement for Pancreatic Pseudocysts (N=45)

Success rate	Number	Percent
Technical Success	44	97.78%
Clinical Success	43	95.56%
Successful Removal	43	95.56%
Early AE		
Minor Bleeding	1	2.22%
Perforation	1	2.22%
Major Bleeding	0	0.00%
Deployment Failure	0	0.00%
SIRS	0	0.00%
Delayed AE		
Minor Bleeding	1	2.22%
Sepsis	3	6.67%
Endoscopic Necrosectomy	3	6.67%
Surgical Necrosectomy	2	4.44%
Abdominal Abscess	1	2.22%
Major Bleeding	0	0.00%
Stent Migration	0	0.00%
Death	0	0.00%
Stent Removal AE		
Minor Bleeding	0	0.00%
Major Bleeding	0	0.00%
Buried LAMS	0	0.00%
Severity of AE		
Overall	11	24.44%
Mild	4	8.89%
Moderate	4	8.89%
Severe	3	6.67%
Recurrence	3	6.67%
Sustained PFC Resolution	42	93.33%
	Median	IQR
Time To Stent Removal (Days)	40	77.78

AE: Adverse events, LAMS: Lumen-apposing metal stents, PFC: Pancreatic fluid collection, SIRS: Systemic inflammatory response syndrome, IQR: Interquartile range

Table 3. Characteristics of Patients Experiencing Adverse Events After Hot AXIOS Stent Placement (N=45)

	Adverse Event	Severity	Timing	Management	Technical	Clinical	Removal
Patient 1	Latent Bleeding	Mild	Delayed	IV Fluids, Vital Sign Monitoring	Success	Success	Success
Patient 2	Immediate Bleeding	Mild	Early	IV Fluids, Vital Sign Monitoring	Success	Success	Success
Patient 3	Sepsis	Mild	Delayed	ID Consult + IV Antibiotic	Success	Success	Success
Patient 4	Sepsis	Mild	Delayed	ID Consult + IV Antibiotic	Success	Success	Success
Patient 5	Sepsis + Abdominal Abscess	Moderate	Delayed	ID Consult + IV Antibiotic + Abscess Drained Via Interventional Radiology	Success	Success	Success
Patient 6	WON	Moderate	Delayed	Endoscopic Necrosectomy	Success	Success	Success
Patient 7	WON	Moderate	Delayed	Endoscopic Necrosectomy	Success	Success	Success
Patient 8	WON	Moderate	Delayed	Endoscopic Necrosectomy	Success	Success	Success
Patient 9	Perforation	Severe	Early	Surgery For Gastric Repair	Failure	Success	Success
Patient 10	WON	Severe	Delayed	Surgical Necrosectomy	Success	Failure	-
Patient 11	WON	Severe	Delayed	Surgical Necrosectomy	Success	Failure	-
Patients 12-45	-	No AE	-	-	Success	Success	Success

WON: Walled-off pancreatic necrosis, AE: Adverse events, IV: Intra-venous, ID: Infectious diseases.

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Table 4. Comparison of Patient Characteristics by Severity of Adverse Events After Hot AXIOS Stent Placement (N=45)

Variable	Adverse events				*P*-value
	Moderate or severe AE (n=7)		Mild or No AE (n=38)		
Age (Years); Median (IQR)	58	(28)	44.5	(25)	0.061
Sex, N (%)					
Male	5	71.43%	14	36.84%	0.114
Female	2	28.57%	24	63.16%	
Size of PP (cm^2), Median (IQR)	8.92	(9.76)	8.90	(6.92)	0.570
Previous intervention for PP, N (%)					
Yes	3	42.86%	1	2.63%	0.009
No	4	57.14%	37	97.37%	
History of Cholecystectomy, N (%)					
Yes	2	28.57%	11	28.95%	1
No	5	71.43%	27	71.05%	
History of Diabetes, N (%)					
Yes	0	0.00%	9	23.68%	0.315
No	7	100%	29	76.32%	
Time to stent removal (Days), Median (IQR)	70	(43)	34.5	(25)	0.005
WON formation, N (%)					
Yes	5	100%	0	0%	<0.001
No	2	5.0%	38	95%	

AE: Adverse events, PP: Pancreatic pseudocyst, IQR: Interquartile range, N: Number of affected patients ,%: Percent, WON: Walled-off pancreatic necrosis.

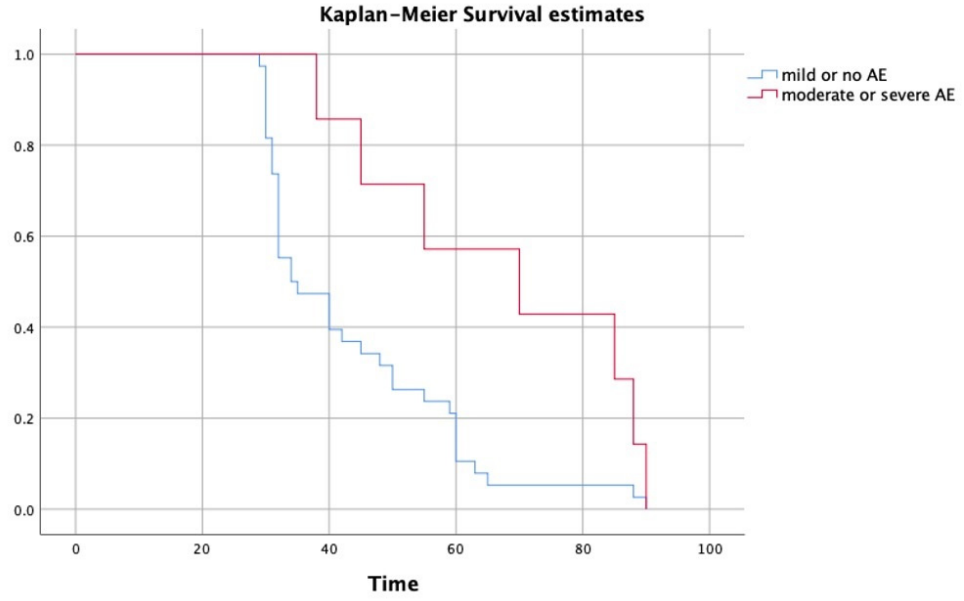

Figure 1. Kaplan-Meier curve for time to successful stent removal in patients with a Hot AXIOS stent replacement for pancreatic pseudocyst

and 2 (4.44%) required surgical necrosectomy (Table 3). The median time to stent removal was 40 days (IQR, 77.78 days). The recurrence rate was 6.67% (3/45), and sustained PFC resolution was achieved in 93.33% (42/45) of cases (Table 2). The earliest recurrence was at 4 months post-stent removal, and the latest was at 15 months post-stent removal.

We compared patients with moderate and severe AE (n = 7) with patients with mild or no AE (n = 38) based on the definitions of severity by ASGE (17) (Table 4). Bivariate analysis revealed that patients with a previous history of PP intervention were significantly more likely to experience moderate to severe AE ($P = 0.009$). Time to stent removal differed significantly between the groups. The median time for stent removal was twice as long (70 days) for patients experiencing moderate or severe AE compared with the other group (34.5 days) ($P = 0.005$).

Additionally, the transition of PP to WON was significantly associated with moderate or severe AE in comparison with mild or no AE ($P < 0.001$). Patients with mild or no AE had a lower median age (44.5 vs 58); however, the difference was not significant ($P = 0.061$). Other variables

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such as sex (P = 0.114), size of PP (P = 0.570), history of cholecystectomy (*P* = 0.999), and history of diabetes (*P* = 0.315) were not significantly different between the 2 groups.

Figure 1 shows the Kaplan-Meier survival curves for the 2 groups. The Kaplan-Meier analysis estimated the median time to stent removal to be 34 (95% CI = 25.9-42) days in the group with moderate or severe AE and 70 (95% CI = 31.5-108.5) days in the group with mild or no AE. Our findings suggested that the failure group had a significantly longer time for stent removal (*P* = 0.020).

Discussion

EUS–guided drainage for pancreatic collections was introduced in 1996 (18). This method, as the first-line treatment, has several advantages in comparison with surgical or percutaneous procedures, such as determining the characteristics of the PFC and potentially decreasing patient discomfort (19, 20). Lumen-apposing metal stents are specially designed for EUS-guided drainage and have higher diameters that allow endoscopists to perform direct endoscopic necrosectomy. We aimed to investigate the long-term efficacy and safety of using a Hot AXIOS stent for cyst gastrostomy in patients with PP.

On the one hand, LAMSs have shown significantly higher clinical success (odds ratio [OR], 2.86; 95% CI = 1.25-6.54) and a lower rate of recurrence (OR, 0.30; 95% CI = 0.12-0.80) compared to DDPS for management of PP (21). On the other hand, the technical challenges of LAMS deployment, compared to DPPS, resulted in a slight superiority of DPPS in terms of technical success for PP drainage (OR, 0.14; 95% CI = 0.02-0.86) (21). Willems et al observed that most LAMS technical failures occur during the first 50 attempted procedures (22). Thus, operator experience may somewhat compensate for the lower technical success. Furthermore, the cost of LAMS stents is significantly higher than that of DPPS (23, 24), making them less affordable. However, in a cost-effectiveness analysis by Chen et al, although costly, LAMS had a higher probability of being cost-effective than the DPPS (23). Therefore, when LAMSs are deployed by experienced physicians, they serve as a practical approach.

Success rates for Hot AXIOS

Nowadays, 2 types of LAMSs are more commonly used: AXIOS stents (AXIOS-EC) and Spaxus stents (Taewoong Medical). Both types of stents can be combined with electrocautery-enhanced delivery systems (Hot AXIOS or Hot Spaxus). The main benefit of applying ECE-LAMS (Hot LAMS) is that it streamlines the entire process without requiring guide wire expansion. ECE-LAMS also makes fluoroscopy simpler during PFC drainage, which decreases the operation time (25, 26).

In our study, successful stent deployment was achieved in 97.78% of patients, which is close to the findings of a systematic review in 2023 by Armellini et al, who reported 98.1% technical success for ECE-LAMS (27). Bleeding, perforation, and LAMS misdeployment are the most common early AE, with incidence rates of 0.9 to 6.2, 2.2 to 3.4, and 0.5 to 8, respectively (28). Among these technical errors, LAMS misdeployment can be the most challenging. Armellini suggests that only 3.2% of misdetections require surgical rescue, and the rest of them can be managed through endoscopy by an experienced operator with an appropriate technique (27). Highlighting the significance of operator expertise, this study involved experienced endoscopists with at least 5 years of experience.

There is no consensus available for reporting clinical success, and there is heterogeneity among studies, making the reported rates less comparable. However, most of the definitions are consistent with the alleviation of symptoms and a 50% to 75% reduction in PFC or a decrease in the PFC size to $\leq$ 2 cm^2 just before stent removal. We observed 95.6% clinical success for >75% drainage of PFC companied by symptom relief, which is in line with the 90% to 97% clinical success range reported by recent cohort studies (14, 16, 29-32) and slightly >94% clinical success reported by a meta-analysis in 2021 by Lyu et al (21).

Adverse Events

Although ECE-LAMSs are widely used, and in the short and medium terms, the results were satisfactory, delayed AE has been reported (33-35), and several serious AE, like latent bleeding and LAMS syndrome, have raised concerns (24). Similar to success rates, definitions of AE are different among studies. Thus, we reported the severity and timing of our AE in accordance with the ASGE lexicon (17) (Table 2).

While most studies agree that LAMSs have a higher chance of bleeding than other stents (FCSEMS or DDPS), there is debate on the significance of this elevated risk (21, 36, 37). In our study, we had 2 cases of bleeding, but none met the criteria of major bleeding (hematemesis and/or melena or hemoglobin drop <2 g), and neither was managed conservatively. It is proposed that the Hot-AXIOS stent's internal flange might be the culprit of bleeding (38). This flange has sharp points at the end that could scratch or tear the opposite cavity wall as it shrinks. This wall damage could lead to bleeding from broken blood vessels. A recent propensity-matched study in 2023 suggests that while Spaxus and AXIOS have the same clinical and technical success, major bleeding is significantly more common when using AXIOS stents (32). This implies that improving the AXIOS stent structure can reduce the bleeding rate. Furthermore, a study by Gopakumar et al suggests that Hot AXIOS stents, with their built-in cauterization feature, may lead to less bleeding during LAMS procedures (39).

Studies agree that the chance of clinical success when managing WON is lower than PP (14, 30, 40). Additionally, She et al showed a higher rate of drainage problems when treating WON when LAMS is placed with the ECE technique (41). This is because ECE skips the guidewire expansion step, which usually helps the stent open up quickly and allows drainage of necrotic debris (41).

Because of the difference in the contents of WON and

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PP, stent occlusion is more common in patients with WON (42), and it has been demonstrated that necrotic/solid cyst contents contribute to a higher failure rate (22). Although LAMS stents provide the possibility of additional endoscopic necrosectomy, some cases of WON may require surgical necrosectomy. In a study by Khan et al, 17.5% of patients with PP and 60% of patients with WON required endoscopic necrosectomy, while surgical necrosectomy was needed in 2.1% of patients with PP and 2.7% of patients with WON (14). Of all patients with PP, there were 5 cases of WON development, from which 3 were managed endoscopically. At the same time, 2 of them required surgical necrosectomy and, therefore, were classified as clinical failure (2/45). Moreover, our results showed an association between WON formation and the occurrence of AE ($P < 0.001$).

To provide a better evacuation of PFC, an interesting method has been proposed by Gornals et al in 2015. They suggested inserting a coaxial DPPS through the LAMS to improve patency and anchoring while limiting contact with adjacent vessels (43). The efficacy of this method in reducing AE while maintaining similar clinical and technical success rates was further validated by meta-analysis (39, 44). Gopakumar et al mentioned that concurrent use of DPPS significantly reduced stent occlusion (13% vs 6.5%), with an OR of 2.36 (39). Considering the similar technical success when adding a coaxial DPPS, and the reduced chance of occlusion, this additional step is a reasonable variation to the original manufacturer's instructions.

Removal Strategy

To prevent delayed complications, the LAMS should be removed immediately after complete improvement in the necrotic parts of the WON and resolution of PP (31). However, studies have recommended different removal strategies. Preliminary data by Bang et al suggested that LAMS, if left for more than 4 weeks, is significantly associated with AE (12). Conversely, in patients with removal time of <4 weeks, Willems et al reported significantly lower clinical success (OR, 25.5; 95% CI = 4.9-202.7) and similar incidence of AE (OR, 2.4; 95% CI = 0.4-11.6) (22). Moreover, in an extensive multi-center retrospective study of 1018 patients in the UK, the timing of removal (4-8 weeks vs >8 weeks) did not correlate with AE (45). Herein, we observed that a higher time to stent removal is associated with significant AE (Figures 1). Therefore, the cause of this heterogeneity among cohorts can be the 4-week cutoff for categorizing time to removal, which has been used in studies later than the study by Bang et al. Based on our observations, we can add this to the existing literature that even though stent removal must be done as soon as possible (PFC <50%-75%), in patients without desirable resolution, removal can be delayed for more than 4 weeks, but additional monitoring for complications is necessary.

To our knowledge, none of the previous studies have included or assessed Hot-AXIOS as a secondary intervention for patients with a prior history of intervention for PP. Our results suggested an elevated incidence of AE in this population. Therefore, closer monitoring and shorter follow-ups are needed for timely prevention and/or management of the complications in these patients.

Strengths and Limitations

One strength of this study is that it is one of the first to assess the 2-year performance of the Hot AXIOS stent, especially in patients with prior PP interventions. Studying this patient population is important because of the previous knowledge gap in this population. These unique aspects offer valuable insights, even though there are some limitations. The study was conducted at a single center with highly skilled endoscopists. While this expertise ensured procedural quality, it may limit the generalizability of findings to routine clinical practice, where endoscopist experience might vary. Additionally, the absence of a control group or comparisons with other stents/drainage methods hinders definitive conclusions on the performance of Hot AXIOS stents.

Conclusion

Using Hot AXIOS stents for PPs had a clinical success of 95.6% and a technical success rate of 97.8%. Significantly longer times for stent removal were observed in patients experiencing moderate or severe AE. Patients with a history of prior interventions for PPs were at substantially higher risk of AE. Closer monitoring is recommended in patients with delayed stent removal. Future studies incorporating a multicenter design and control groups with standardized success rates and AE definitions could address these limitations.

Authors' Contributions

Concept, proposal preparation: M.N., A.F., H.A., and M.K; Data collection: E.H., F.Z., A.F., M.K., A.F., H.A., E.S., R.S., S.D., M.S.P., and F.S.T; Data analysis: M.N. and E.H; First drafting: E.H. and M.N; Critical revision: F.Z., A.F., M.K., A.F., H.A., E.S., R.S., S.D., M.S.P., and F.S.T; Final approval: E.H., F.Z., M.K., A.F., H.A., E.S., R.S., S.D., M.S.P., and F.S.T and Approving the final version of the study: E.H., F.Z., M.K., A.F., H.A., E.S., R.S., S.D., M.S.P., and F.S.T.

Ethical Considerations

This study received approval from the Ethics Committee of the Iran University of Medical Sciences (IUMS) (IR.IUMS.FMD.REC.1401.125). This observational study adhered to strict patient confidentiality and privacy protocols based on the Declaration of Helsinki. Written informed consent was obtained from all participants. All methods of the present study are in accordance with the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) checklist.

Acknowledgment

Not applicable.

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Conflict of Interests

The authors declare that they have no competing interests.

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