HOT AXIOS™ STENT AND DELIVERY SYSTEM (aggiornamento 2020)

RAPID HTA REVIEW		
Numero richiesta	**Data richiesta**	**Richiedente**
42482	08/05/2018	GASTROENTEROLOGIA ED ENDOSCOPIA - AOUS

Dati generali della tecnologia in valutazione			
Nome commerciale			
HOT AXIOS™ STENT AND DELIVERY SYSTEM			
Nome generico			
Stent e sistema di rilascio con elettrocauterizzazione per ecoendoscopia			
Nome produttore			
Xlumena			
Nome fornitore			
Boston Scientific			
CND	**Marchio CE**		
P0502 - Protesi biliari e pancreatiche	Si (2014)		
RDM – REF		**Classe di rischio**	**Approvazione FDA**
1106609		IIb	Si
Campo di applicazione			
Drenaggio endoscopico transgastrico o transduodenale di una pseudocisti pancreatica o del tratto biliare.			
Paziente target			
Paziente affetto da: - complicanze della pancreatite acuta o cronica, - stenosi delle vie biliari con ostruzioni non superabili tramite drenaggio per via retrograda - colecistiti non trattabili chirurgicamente			
Indicazione d'uso			
Lo stent e sistema di rilascio con elettrocauterizzazione HOT AXIOS è indicato per facilitare il drenaggio endoscopico transgastrico o transduodenale di una pseudocisti pancreatica o del tratto biliare.			
Principali competitor			
Altri stent metallici "lumen-apposing metal stent" (LAMS) quali il NITI-S stent e lo stent Axios e gli stent in plastica.			

Dettagli tecnologici
Descrizione
Lo stent a sistema di rilascio con elettrocauterizzazione HOT AXIOS è un dispositivo endoscopico studiato per consentire di inserire per via ecoendoscopica uno stent transenterico tra il tratto gastrointestinale e una pseudocisti pancreatica o il tratto biliare. Lo stent HOT AXIOS è uno stent in nitinol flessibile, autoespandibile e completamente rivestito in silicone, compatibile a risonanza magnetica, precaricato nel sistema di rilascio con

elettrocauterizzazione. Sono disponibili varie misure e non contiene lattice.
Il sistema di rilascio ha la funzionalità di cauterizzazione compatibile con gli ecoendoscopi terapeutici aventi un canale operativo di diametro pari o superiore a 3,7 mm; all'interno del sistema di rilascio possono essere utilizzate guide da 0.035'.

Elementi di innovazione

Rispetto ad altri LAMS, lo stent HOT AXIOS (considerato di seconda generazione) presenta la funzione di elettrocauterizzazione.

Evidenze cliniche ed economiche

Studi clinici

La ricerca di letteratura condotta con la banca dati MEDLINE versione Pubmed (sito internet: www.pumed.org) il 29 Giugno 2020 è riassunta nell'Appendice 1 a fine testo.

Benefici attesi

Risoluzione delle pseudocisti ed evitamento di ricadute.

Stima di spesa annua e costo terapia per paziente (se applicabile)

Prodotto	Pezzi per confezione	Prezzo per confezione (euro)	Prezzo unitario (euro)	Stima consumo annuo (pezzi)	Stima spesa annua (euro)	Costo terapia per paziente (euro)
Hot Axios	1	circa 3.000	circa 3.000	informazione riservata		

NOTA: i prezzi sono IVA esclusa.
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Dati riassuntivi

Numero richiesta	Data richiesta	Richiedente
42482	08/05/2018	GASTROENTEROLOGIA ED ENDOSCOPIA - AOUS

Tecnologia in valutazione

Hot Axios stent and delivery system

Eventuali esperti esterni coinvolti

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Conclusioni

La procedura endoscopica con l'utilizzo di stent rappresenta un approccio sempre più utilizzato per il drenaggio delle pseudocisti pancreatiche. Lo stent Hot Axios è uno dei vari "lumen-apposing metal stent" (LAMS) disponibili in commercio per l'esecuzione di questa tecnica.
La ricerca di letteratura riportata nell'Appendice 1 dimostra esaustivamente che questa tecnica è sostenuta da robuste evidenza ed è riconosciuta dalle linne guida più autorevoli.
Si esprime parare favorevole.

Data di redazione della scheda

17/07/2018

Data di revisione della scheda
30/06/2020

APPENDICE 1

Search based on keyword: "lumen-apposing metal stents"

Sent On: Mon Jun 29 08:30:41 2020

La parti salienti sono evidenziate in grassetto e in colore rosso.

PubMed Results

1. **Endosonography-guided Transmural Drainage of Pancreatic Fluid Collections: Comparative Outcomes by Stent Type**

Surg Endosc. 2020 Jun 15. doi: 10.1007/s00464-020-07699-x. Online ahead of print.

Authors

Ahmed Kayal [1 2], Niloofar Taghizadeh [3], Takuya Ishikawa [1 4], Emmanuel Gonzalez-Moreno [1 2 5], Sydney Bass [1], Martin J Cole [1], Steven J Heitman [1 2 3], Rachid Mohamed [1], Christian Turbide [1], Yen-I Chen [6], Nauzer Forbes [7 8]

Abstract

Background: Pancreatic fluid collections (PFCs), including walled-off necrosis (WON), are commonly described sequelae of pancreatitis. Endosonography-guided PFC drainage can be performed using plastic stents (PS), fully covered self-expanding metal stents (FCSEMS), or lumen-apposing metal stents (LAMS). We performed a retrospective study comparing clinical outcomes and adverse events by stent type.

Methods: In this historical cohort, patients undergoing endosonography-guided PFC drainage from 2010 to 2019 were divided into groups: those treated with (1) PS, (2) FCSEMS, and (3) LAMS. Clinical success, the primary outcome, was defined as complete resolution or size reduction of ≥ 50%, with resolution of symptoms and no reintervention required at 3 months following the index procedure. Adverse events (AEs) and procedure times were also evaluated.

Results: Fifty-eight patients were included. Procedure times were significantly shorter with LAMS (21.4 ± 10.8 min versus 53.0 ± 24.4 min for FCSEMS and 65.9 ± 23.4 min for PS, $p < 0.001$). Clinical

success rates for WON were higher with LAMS compared with FCSEMS (95.7% vs 66.7%, respectively; p = 0.04). For all PFCs, treatment with LAMS trended towards higher clinical success rates compared with PS and FCSEMS (96.3% vs 81.8% vs 77.8%, respectively; p = 0.14). Early AEs (within 1 week) occurred at significantly lower rates in the LAMS group compared to PS and FCSEMS (0% vs 33.3% vs 10.6%, respectively; p = 0.006), as did late AEs (7.4% vs 44.5% vs 40%, respectively; p = 0.01).

Conclusions: LAMS is superior in terms of WON clinical success, favorable in terms of lower adverse event profile, and shorter in terms of procedural time compared to FCSEMS and PS. LAMS can be considered as an initial approach for WON, given that clinical success in WON is lower when using PS or FCSEMS, though more high-quality data are needed.

2. **Endoscopic Ultrasound-Guided Gastro-Enteric Anastomosis: A Systematic Review and Meta-Analysis**

Dig Liver Dis. 2020 Jun 3;S1590-8658(20)30170-5. doi: 10.1016/j.dld.2020.04.021. Online ahead of print.

Authors

Giulio Antonelli [1], Bojan Kovacevic [2], John Gasdal Karsensten [3], Evangelos Kalaitzakis [4], Giuseppe Vanella [5], Cesare Hassan [6], Peter Vilmann [2]

Abstract

Background and aims: Endoscopic ultrasound-guided gastro-enteric anastomosis (EUS-GEA) using lumen-apposing metal stents (LAMS) is emerging as a minimally invasive alternative to surgery across several indications. Literature on this subject is heterogeneous, with variable reporting of techniques and outcomes. Our aim was to perform a meta-analysis of published data on EUS-GEA, providing a pooled estimate of technical and clinical outcomes.

Methods: The protocol was registered in PROSPERO (Reg. no. CRD42018111110). PubMed, Embase, Scopus, and Web of Science databases were searched until February 2019 for studies describing patients undergoing EUS guided enteric anastomosis. PRISMA methodology was used. Pooled technical and clinical success rates as well as pooled adverse events rates were calculated. Study quality, publication bias, and heterogeneity were explored.

Results: Twelve studies including 290 patients were included, published between 2016 and 2019. All studies but one were retrospective. Main procedure indication was gastric outlet obstruction (62.4%), followed by ERCP access (27.9%) in patients with gastric bypass surgery. Direct puncture technique was the most frequently adopted (68.2%). Pooled technical success rate (12 studies, 290

patients) was 93.5% [95% confidence interval (CI) 89.7-6.0%; I^2:0%], while clinical success rate (11 studies, 260 patients) was 90.1% [95%CI 85.5-93.4%; I^2:0%]. Pooled total adverse events rate (11 cohorts, 261 patients) was 11.7% [95%CI 8.2-16.6%; I^2:0%], mainly mild/moderate: 10.6% [95%CI 7 - 15.6%]. No publication bias or significant heterogeneity was found.

Conclusions: EUS-GEA has a high rate of technical and clinical success when performed in expert centers. **The procedure appears to be relatively safe, and might represent a non-inferior minimally invasive alternative to surgery**. The paucity of long-term clinical outcomes suggests prudency and need for further research, especially regarding non-malignant indications.

3. **Are Lumen-Apposing Metal Stents More Effective Than Plastic Stents for the Management of Pancreatic Fluid Collections: An Updated Systematic Review and Meta-analysis**

Gastroenterol Res Pract. 2020 Apr 20;2020:4952721. doi: 10.1155/2020/4952721. eCollection 2020.

Authors

Shali Tan [1], Chunyu Zhong [1], Yutang Ren [2], Xujuan Luo [1], Jin Xu [1], Yan Peng [1], Xiangsheng Fu [3], Xiaowei Tang [1]

Abstract

Background and aims: Recently, a new type of metal stent, named lumen-apposing metal stents (LAMS), has been designed to manage pancreatic fluid collections (PFC), and a few studies have reported its efficacy and safety. Therefore, we conducted this meta-analysis to investigate the role of LAMS for PFC.

Methods: We searched the studies from PubMed, MEDLINE, Embase, and Cochrane databases from inception to May 2019. We extracted the data and analyzed the technical success, clinical success, and adverse events of LAMS to evaluate its efficacy and safety.

Results: Twenty studies with 1534 patients were included. The pooled technical success, clinical success, and adverse event rates of LAMS for PFC were 96.2% (95% confidence interval (CI): 94.6%-97.4%), 86.8% (95% CI: 83.1%-89.8%), and 20.7% (95% CI: 16.1%-26.1%), respectively. Eight studies including 875 patients compared the clinical outcomes of LAMS with plastic stents. The pooled risk ratio (RR) of technical success and clinical success for LAMS and plastic stent was 1.01 (95% CI: 0.98-1.04, P = 0.62) and 1.06 (95% CI: 1.01-1.12, P = 0.03), respectively. As for the overall adverse events, the pooled RR was 1.51 (95% CI: 0.67-3.44, P = 0.32).

Conclusions: **Our current study revealed that LAMS has advantages over plastic stents for PFC, with higher clinical success rate and lower complication rate of infection and occlusion.**

4. **Effectiveness and Safety of EUS-guided Choledochoduodenostomy Using Lumen-Apposing Metal Stents (LAMS): A Systematic Review and Meta-Analysis**

Surg Endosc. 2020 Jul;34(7):2866-2877. doi: 10.1007/s00464-020-07484-w. Epub 2020 Mar 5.

Authors

Rajesh Krishnamoorthi [1], Chandra S Dasari [2], Viveksandeep Thoguluva Chandrasekar [2 3], Harshith Priyan [4], Mahendran Jayaraj [5], Joanna Law [6], Michael Larsen [6], Richard Kozarek [6], Andrew Ross [6], Shayan Irani [6]

Abstract

Background: Endoscopic ultrasound-guided choledochoduodenostomy (CDD) is emerging as an alternative technique for biliary drainage in patients who fail conventional endoscopic retrograde cholangiopancreatography (ERCP). The lumen-apposing metal stents (LAMS) are being increasingly used for CDD. We performed a systematic review and meta-analysis to evaluate the effectiveness and safety of CDD using LAMS.

Methods: We performed a systematic search of multiple databases through May 2019 to identify studies on CDD using covered self-expanding metal stents. Pooled rates of technical success, clinical success, adverse events, and recurrent jaundice associated with CDD using LAMS were estimated. A subgroup analysis was performed based on use of LAMS with electrocautery-enhanced delivery system (EC-LAMS).

Results: Seven studies on CDD using LAMS (with 284 patients) were included in the meta-analysis. Pooled rates of technical and clinical success (per-protocol analysis) were 95.7% (95% CI 93.2-98.1) and 95.9% (95% CI 92.8-98.9), respectively. Pooled rate of post-procedure adverse events was 5.2% (95% CI 2.6-7.9). Pooled rate of recurrent jaundice was 8.7% (95% CI 4.5-12.8). On subgroup analysis of CDD using EC-LAMS (5 studies with 201 patients), the pooled rates of technical and clinical success (per-protocol analysis) were 93.8% (95% CI 90.4-97.1) and 95.9% (95% CI 91.9-99.9), respectively. Pooled rate of post-procedure adverse events was 5.6% (95% CI 1.7-9.5). Pooled rate of recurrent jaundice was 11.3% (95% CI 6.9-15.7). Heterogeneity (I^2) was low to moderate in the analyses.

Conclusion: **CDD using LAMS/EC-LAMS is an effective and safe technique for biliary decompression in patients who failed ERCP**. Further studies are needed to assess CDD using LAMS as primary

treatment modality for biliary obstruction.

5. **Endoscopic Ultrasound-Directed Transgastric ERCP in Patients With Roux-en-Y Gastric Bypass Using Lumen-Apposing Metal Stents or Duodenal Self-Expandable Metal Stents. A European Single-Center Experience**

Rev Esp Enferm Dig. 2020 Mar;112(3):211-215. doi: 10.17235/reed.2020.6897/2020.

Authors

Marina de Benito Sanz [1], Ana Yaiza Carbajo [1], Ramón Sánchez-Ocaña Hernández [1], Carlos Chavarria [1], Sergio Bagaza Pérez de Rozas [1], Francisco Javier García-Alonso [1], Carlos de la Serna Higuera [1], Manuel Perez-Miranda [1]

Abstract

Introduction: endoscopic ultrasound-directed transgastric ERCP is emerging in Roux-en-Y gastric bypass.

Methods: a review of 14 consecutive patients.

Results: fourteen EUS-directed gastro-gastrostomy/gastro-jejunostomy were performed using lumen-apposing metal stents or duodenal self-expandable metal stents. Single-session ERCP was successful in 9/12 cases and deferred procedures or follow-up in 6/7 cases. Papillary access was obtained in all cases. Dislodgment occurred in 4/19 patients and was handled successfully endoscopically. Transgastric stents were removed after a median of 30 days. No recurrence/fistula were noted after a median of 256 days post-removal.

Conclusions: duodenal self-expandable and lumen-apposing metal stents can be used for single-deferred endoscopic ultrasound-directed transgastric ERCP in Roux-en-Y gastric bypass.

6. **Endoscopic Ultrasound-Guided Drainage of Pancreatic Walled-Off Necrosis Using 20-mm Versus 15-mm Lumen-Apposing Metal Stents: An International, Multicenter, Case-Matched Study**

Endoscopy. 2020 Mar;52(3):211-219. doi: 10.1055/a-1096-3299. Epub 2020 Jan 30.

Authors

Nasim Parsa [1], Jose M Nieto [2], Patrick Powers [3], Shuji Mitsuhashi [4], Abdelhai Abdelqader [5], George Hadzinakos [6], Andrea A Anderloni [7], Alessandro Fugazza [7], Theodore W James [8], Alexander Arlt [9], Mark Ellrichmann [9], Jose Ramon Aparicio [10], Arvind J Trindade [11], Tyler K Stevens [12], Prabhleen Chahal [12], Shawn L Shah [13], Ahmed A Messallam [14], Gabriel Lang [15], M Phillip Fejleh [16], Petros C Benias [11], Divyesh V Sejpal [11], Jason Jones [17], Fahad Faisal Mir [18], Mohamad Aghaie Meybodi [19], Yervant Ichkhanian [19], Kia Vosoughi [19], Aleksey A Novikov [4], Shayan S Irani [20], Rishi Pawa [17], Ali M Ahmed [21], Alireza Sedarat [16], William Hsueh [5], Jochen Hampe [22], Reem Z Sharaiha [13], Tyler M Berzin [18], Field F Willingham [14], Vladimir M Kushnir [15], Olaya I Brewer Gutierrez [19], Saowanee Ngamruengphong [19], Matthew T Huggett [6], Todd H Baron [8], Alessandro Repici [7], Douglas G Adler [3], John T Nasr [5], Thomas E Kowalski [4], Vivek Kumbhari [19], Vikesh K Singh [19], Mouen A Khashab [19]

Abstract

Backgrounds: Endoscopic ultrasound (EUS)-guided placement of lumen-apposing metal stents (LAMSs) has gained popularity for the treatment of pancreatic walled-off necrosis (WON). We compared the 20-mm and 15-mm LAMSs for the treatment of symptomatic WON in terms of clinical success and adverse events.

Methods: We conducted a retrospective, case-matched study of 306 adults at 22 tertiary centers from 04/2014 to 10/2018. A total of 102 patients with symptomatic WON who underwent drainage with 20-mm LAMS (cases) and 204 patients who underwent drainage with 15-mm LAMS (controls) were matched by age, sex, and drainage approach. Conditional logistic regression analysis was performed to compare clinical success (resolution of WON on follow-up imaging without reintervention) and adverse events (according to American Society for Gastrointestinal Endoscopy criteria).

Results: Clinical success was achieved in 92.2 % of patients with 20-mm LAMS and 91.7 % of patients with 15-mm LAMS (odds ratio 0.92; *P* = 0.91). Patients with 20-mm LAMS underwent fewer direct endoscopic necrosectomy (DEN) sessions (mean 1.3 vs. 2.1; *P* < 0.001), despite having larger WON collections (transverse axis 118.2 vs. 101.9 mm, *P* = 0.003; anteroposterior axis 95.9 vs. 80.1 mm, *P* = 0.01). There was no difference in overall adverse events (21.6 % vs. 15.2 %; *P* = 0.72) and bleeding events (4.9 % vs. 3.4 %; *P* = 0.54) between the 20-mm and 15-mm LAMS groups, respectively.

Conclusions: **The 20-mm LAMS showed comparable clinical success and safety profile to the 15-mm LAMS, with the need for fewer DEN sessions for WON resolution.**

7. **American Gastroenterological Association Clinical Practice Update: Management of Pancreatic Necrosis**

Gastroenterology. 2020 Jan;158(1):67-75.e1. doi: 10.1053/j.gastro.2019.07.064. Epub 2019 Aug 31.

Authors

Todd H Baron [1], Christopher J DiMaio [2], Andrew Y Wang [3], Katherine A Morgan [4]

Abstract

Description: The purpose of this American Gastroenterological Association (AGA) Institute Clinical Practice Update is to review the available evidence **and expert recommendations regarding the clinical care of patients with pancreatic necrosis and to offer concise best practice advice for the optimal management of patients with this highly morbid condition.**

Methods: This expert review was commissioned and approved by the AGA Institute Clinical Practice Updates Committee and the AGA Governing Board to provide timely guidance on a topic of high clinical importance to the AGA membership, and underwent internal peer review by the Clinical Practice Updates Committee and external peer review through standard procedures of Gastroenterology. This review is framed around the 15 best practice advice points agreed upon by the authors, which reflect landmark and recent published articles in this field. This expert review also reflects the experiences of the authors, who are advanced endoscopists or hepatopancreatobiliary surgeons with extensive experience in managing and teaching others to care for patients with pancreatic necrosis.

BEST PRACTICE ADVICE 1: Pancreatic necrosis is associated with substantial morbidity and mortality and optimal management requires a multidisciplinary approach, including gastroenterologists, surgeons, interventional radiologists, and specialists in critical care medicine, infectious disease, and nutrition. In situations where clinical expertise may be limited, consideration should be given to transferring patients with significant pancreatic necrosis to an appropriate tertiary-care center.

BEST PRACTICE ADVICE 2: Antimicrobial therapy is best indicated for culture-proven infection in pancreatic necrosis or when infection is strongly suspected (ie, gas in the collection, bacteremia, sepsis, or clinical deterioration). Routine use of prophylactic antibiotics to prevent infection of sterile necrosis is not recommended.

BEST PRACTICE ADVICE 3: When infected necrosis is suspected, broad-spectrum intravenous antibiotics with ability to penetrate pancreatic necrosis should be favored (eg, carbapenems, quinolones, and metronidazole). Routine use of antifungal agents is not recommended. Computed tomography-guided fine-needle aspiration for Gram stain and cultures is unnecessary in the majority of cases.

BEST PRACTICE ADVICE 4: In patients with pancreatic necrosis, enteral feeding should be initiated early to decrease the risk of infected necrosis. A trial of oral nutrition is recommended immediately

in patients in whom there is absence of nausea and vomiting and no signs of severe ileus or gastrointestinal luminal obstruction. When oral nutrition is not feasible, enteral nutrition by either nasogastric/duodenal or nasojejunal tube should be initiated as soon as possible. Total parenteral nutrition should be considered only in cases where oral or enteral feeds are not feasible or tolerated.

BEST PRACTICE ADVICE 5: Drainage and/or debridement of pancreatic necrosis is indicated in patients with infected necrosis. Drainage and/or debridement may be required in patients with sterile pancreatic necrosis and persistent unwellness marked by abdominal pain, nausea, vomiting, and nutritional failure or with associated complications, including gastrointestinal luminal obstruction; biliary obstruction; recurrent acute pancreatitis; fistulas; or persistent systemic inflammatory response syndrome.

BEST PRACTICE ADVICE 6: Pancreatic debridement should be avoided in the early, acute period (first 2 weeks), as it has been associated with increased morbidity and mortality. Debridement should be optimally delayed for 4 weeks and performed earlier only when there is an organized collection and a strong indication.

BEST PRACTICE ADVICE 7: Percutaneous drainage and transmural endoscopic drainage are both appropriate first-line, nonsurgical approaches in managing patients with walled-off pancreatic necrosis (WON). Endoscopic therapy through transmural drainage of WON may be preferred, as it avoids the risk of forming a pancreatocutaneous fistula.

BEST PRACTICE ADVICE 8: Percutaneous drainage of pancreatic necrosis should be considered in patients with infected or symptomatic necrotic collections in the early, acute period (<2 weeks), and in those with WON who are too ill to undergo endoscopic or surgical intervention. Percutaneous drainage should be strongly considered as an adjunct to endoscopic drainage for WON with deep extension into the paracolic gutters and pelvis or for salvage therapy after endoscopic or surgical debridement with residual necrosis burden.

BEST PRACTICE ADVICE 9: **Self-expanding metal stents in the form of lumen-apposing metal stents appear to be superior to plastic stents for endoscopic transmural drainage of necrosis**. BEST PRACTICE ADVICE 10: The use of direct endoscopic necrosectomy should be reserved for those patients with limited necrosis who do not adequately respond to endoscopic transmural drainage using large-bore, self-expanding metal stents/lumen-apposing metal stents alone or plastic stents combined with irrigation. Direct endoscopic necrosectomy is a therapeutic option in patients with large amounts of infected necrosis, but should be performed at referral centers with the necessary endoscopic expertise and interventional radiology and surgical backup.

BEST PRACTICE ADVICE 11: Minimally invasive operative approaches to the debridement of acute necrotizing pancreatitis are preferred to open surgical necrosectomy when possible, given lower

morbidity.

BEST PRACTICE ADVICE 12: Multiple minimally invasive surgical techniques are feasible and effective, including videoscopic-assisted retroperitoneal debridement, laparoscopic transgastric debridement, and open transgastric debridement. Selection of approach is best determined by pattern of disease, physiology of the patient, experience and expertise of the multidisciplinary team, and available resources.

BEST PRACTICE ADVICE 13: Open operative debridement maintains a role in the modern management of acute necrotizing pancreatitis in cases not amenable to less invasive endoscopic and/or surgical procedures.

BEST PRACTICE ADVICE 14: For patients with disconnected left pancreatic remnant after acute necrotizing mid-body necrosis, definitive surgical management with distal pancreatectomy should be undertaken in patients with reasonable operative candidacy. Insufficient evidence exists to support the management of the disconnected left pancreatic remnant with long-term transenteric endoscopic stenting.

BEST PRACTICE ADVICE 15: A step-up approach consisting of percutaneous drainage or endoscopic transmural drainage using either plastic stents and irrigation or self-expanding metal stents/lumen-apposing metal stents alone, followed by direct endoscopic necrosectomy, and then surgical debridement is reasonable, although approaches may vary based on the available clinical expertise.

8. **EUS-guided Drainage of Pancreatic Fluid Collections Using Lumen Apposing Metal Stents: An International, Multicenter Experience**

Dig Liver Dis. 2019 Nov;51(11):1557-1561. doi: 10.1016/j.dld.2019.05.033. Epub 2019 Jul 2.

Authors

Nikhil A Kumta [1], Amy Tyberg [2], Vicky H Bhagat [2], Ali A Siddiqui [3], Thomas E Kowalski [3], David E Loren [3], Amit P Desai [4], Alex M Sarkisian [4], Elizabeth G Brown [4], Kunal Karia [4], Monica Gaidhane [2], Prashant Kedia [5], Paul R Tarnasky [5], Umangi Patel [5], Douglas Adler [6], Linda J Taylor [6], Maria Petrone [7], Paolo Arcidiacono [7], Patrick S Yachimski [8], Douglas Weine [9], Subha Sundararajan [9], Pierre H Deprez [10], Christina Mouradides [10], Sammy Ho [11], Safeera Javed [11], Jeffrey J Easler [12], Isaac Raijman [13], Enrique Vazquez-Sequeiros [14], Mandeep Sawhney [15], Tyler M Berzin [15], Michel Kahaleh [16]

Abstract

Introduction: Lumen apposing metal stents (LAMS) have been used increasingly for drainage of pancreatic fluid collections (PFC). We present an international, multicenter study evaluating the safety and efficacy of LAMS in PFCs.

Methods: Consecutive patients undergoing LAMS placement for PFC at 12 international centers were included (ClinicalTrials.gov NCT01522573). Demographics, clinical history, and procedural details were recorded. Technical success was defined as successful LAMS deployment. Clinical success was defined as PFC resolution at three-month follow-up.

Results: 192 patients were included (140 males (72.9%), mean-age 53.8 years), with mean follow-up of 4.2 months ± 3.8. Mean PFC size was 11.9 cm (range 2-25). The median number of endoscopic interventions was 2 (range 1-14). Etiologies for PFC were gallstone (n = 82, 42.7%), alcohol (n = 50, 26%), idiopathic (n = 26, 13.5%), and other (n = 34, 17.7%). Technical success was achieved in 189 patients (98.4%). Clinical success was observed in 125 of 135 patients (92.6%). Adverse events included bleeding (n = 11, 5.7), infection (n = 2, 1%), and perforation (n = 2, 1%). Three or more endoscopy sessions were a positive predictor for PFC resolution and the only significant predictor for AEs.

Conclusion: **LAMS has a high technical and clinical success rate with a low rate of AEs**. PFC drainage via LAMS provides a minimally invasive, safe, and efficacious procedure for PFC resolution.

9. **EUS-Guided Choledochoduodenostomy for Distal Malignant Biliary Obstruction Using Electrocautery-Enhanced Lumen-Apposing Metal Stents: First US, Multicenter Experience**

Dig Dis Sci. 2019 Nov;64(11):3321-3327. doi: 10.1007/s10620-019-05688-2. Epub 2019 Jun 7.

Authors

Abdul H El Chafic [1], Janak N Shah [2], Chris Hamerski [3], Kenneth F Binmoeller [3], Shayan Irani [4], Theodore W James [5], Todd H Baron [5], Jose Nieto [6], Ricardo V Romero [2], John A Evans [2], Michel Kahaleh [7]

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Abstract

Background and aims: EUS-guided biliary drainage has emerged as a technique to enable endobiliary drainage in failed ERCP. A newer model, lumen-apposing metal stents (LAMS), with a cautery-enhanced delivery system became available in the USA in late 2015. This cautery-tipped version may facilitate EUS-guided choledochoduodenostomy (EUS-CD), but data using this model are lacking.

Methods: We reviewed outcomes of attempted EUS-CD using cautery-enhanced LAMS from 6, US centers. The following data were collected: patient and procedure details, technical success, adverse events, clinical success (resolution of jaundice or improvement in bilirubin > 50%), and biliary re-interventions.

Results: EUS-CD was attempted in 67 patients (mean age 68.8) with malignant obstruction after failed ERCP between September 2015 and April 2018. EUS-CD was technically successful in 64 (95.5%). A plastic or metal stent was inserted through the lumen of the deployed LAMS in 50 of 64 (78.1%) patients to maintain a non-perpendicular LAMS axis into the bile duct. Adverse events occurred in 4 (6.3%) and included: abdominal pain (n = 2), peritonitis that responded to antibiotics (n = 1), and bleeding requiring transfusion (n = 1). Among 40 patients with follow-up of > 4 weeks, clinical success was achieved in 100%. Biliary re-interventions for obstruction were needed in 7(17.5%), in 3 of 6 (50.0%) that underwent EUS-CD with LAMS alone versus 4 of 34 (5%) with LAMS plus an axis-orienting stent (p = 0.02).

Conclusion: EUS-CD using LAMS with cautery-enhanced delivery systems has high technical and clinical success rates, with a low rate of adverse events. Inserting an axis-orienting stent through the lumen of the LAMS may reduce the need for biliary re-interventions.

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