

Review

Lumen-apposing metal stents for pancreatic fluid collection drainage: a review of current outcomes

Biomedicine and Surgery

Pavić Tajana, Kralj Dominik, Hrabar Davor

Division of Gastroenterology and Hepatology, University Hospital Center "Sestre milosrdnice", Zagreb, Croatia

ABSTRACT

Local complications of acute pancreatitis in the form of pancreatic fluid collections are a source of substantial morbidity and mortality demanding a multidisciplinary expert approach. The use of minimally invasive methods in this setting has been associated with shortened hospital stays, decreased costs and improved outcomes. In addition, endoscopically performed necrosectomy has been used to facilitate drainage but was limited due to the lack of dedicated equipment and was performed in rare expert centers. Recently developed lumen-apposing metal stents were designed to overcome the shortcomings of previously used methods. Their diameter and biphanged design prevents migration, facilitates drainage, and permits repeated endoscope entry into the necrotic cavity to perform direct necrosectomy. Recent reports on larger series of patients laud their technical and clinical success rate with relatively low adverse event occurrence considering the invasiveness of the procedure and the population of patients involved. The uptake of endoscopically performed drainage can be attributed to the increasing use of lumen-apposing metal stents as evident by the number reports published in recent years. Growing experience and future studies should lead to evidence based guidelines and refinement of these methods.

KEYWORDS: acute pancreatitis, lumen-apposing metal stent, pseudocyst, walled-off necrosis, direct endoscopic necrosectomy

Correspondence to: Pavić Tajana, MD, PhD, Division of Gastroenterology and Hepatology, University Hospital Center Sestre milosrdnice, HR-10000 Zagreb, Croatia, e-mail: tajana.pavic@gmail.com

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INTRODUCTION

Pancreatic fluid collections represent a heterogeneous group of local complications following acute pancreatitis that have substantial differences in their management. According to the revised Atlanta criteria PFCs arising from interstitial pancreatitis are termed acute peripancreatic fluid collections (APFC) and if they fail to resolve in the first four weeks they are considered pseudocysts (PC). On the other hand, the sequelae of necrotizing pancreatitis are called acute necrotic collections (ANC) and contain both solid and liquid parts. ANCs persisting for four weeks and longer induce the formation of an inflammatory wall and turn into an encapsulated collection of necrotic material called a walled-off necrosis (WON) (1). Sterile ANCs rarely require intervention early in the course of

disease, and in the later phase only in the presence of debilitating symptoms such as abdominal pain and/or significant mechanical gastric or biliary obstruction. Asymptomatic WON does not require intervention, regardless of size, while symptomatic WON generally requires intervention late in the course (>4 weeks) if there is intractable pain, obstruction, or in the presence of infection which can drive mortality rates up to 30% (2). Pseudocysts are PFCs containing fluid without or with very little solid/necrotic material and drainage is indicated in case of symptomatic collection, gastric outlet or biliary obstruction, refractory abdominal pain, ongoing systemic illness, anorexia, weight loss lasting more than 8 weeks (3).

Over the years many different modalities have been utilized in the management of pseudocysts

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and WON due to the variability in size and location of the collections as well as differences in local expertise. Endoscopic methods of intervention have become the mainstay of chronic PFC management, while surgery is used as an adjunctive treatment and in cases where an endoscopic approach is not deemed feasible. The superiority of endoscopic

drainage of fluid and/or necrotic material. Over the years plastic stent placement was commonly used for endoscopic drainage with good results for pseudocysts, but unsatisfactory for WON. Biliary and esophageal metal stents which offer the diameter needed to drain necrotic collections have been increasingly used but are prone to migration.

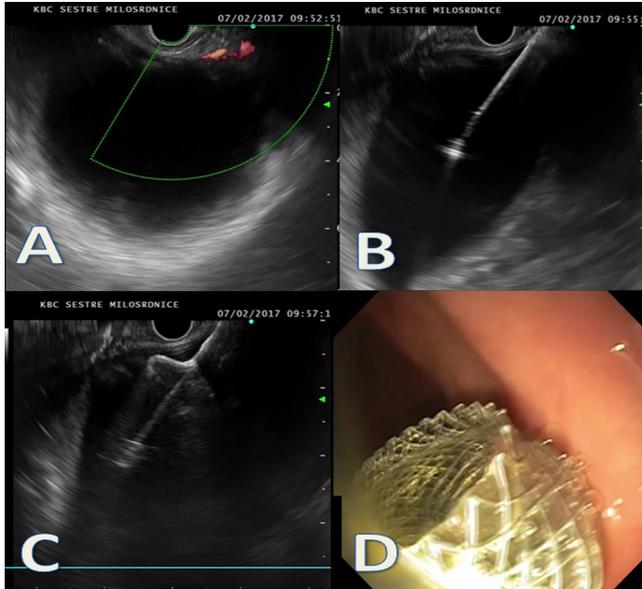


Figure 1. Technique of EUS guided drainage of pancreatic fluid collection and lumen-apposing metal stents (LAMS) placement. A) EUS evaluation of pancreatic fluid collection. B) Puncture of the collection with 22 G fine aspiration needle for fluid evaluation. C) Placement of the LAMS (Hot Axios) under EUS-guidance; inner flange opened in the collection cavity. D) Endoscopic picture of the outer flange of the LAMS opened in the stomach.

and/or minimally invasive methods over surgery for PFC drainage became more apparent after studies by Kumar et al. and Bakker et al. who showed that endoscopic drainage and necrosectomy in WON are associated with higher efficacy, shorter length of stay, and lower health care costs (4,5). Endoscopic methods are based on forming a fistulous channel between a collection and the gut lumen enabling

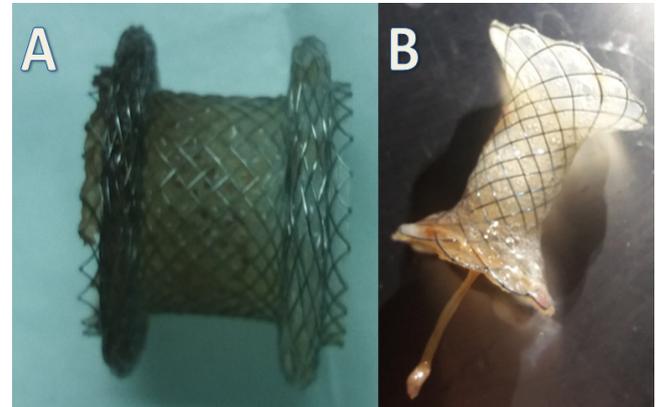


Figure 2. Lumen-apposing metal stents. A) Axios stent, B) Nagi stent

This has led to the development of several dedicated medical devices such as LAMS designed to offset migration and enable interventions.

LUMEN-APPOSING METAL STENTS

Lumen-apposing-stents have been designed to address the main issues arising from the use of non-dedicated devices in attempts of endoscopic drainage. The diameter of biliary fully-covered self-expanding metal stents (FCSEMS) does not allow endoscope passage and the stent may migrate requiring surgical intervention (6). Novel LAMS solve this issue through a specific design described as „biphanged“, „saddle-shaped“ and „dumbbell“ allowing mural anchoring on both the gut and collection wall. The diameter of up to 15 mm of the available LAMS permits direct endoscope passage enabling entry into a collection

Table 1. Summary of recent studies using lumen-apposing metal stents (LAMS) in pancreatic fluid collections.

Study	Type of LAMS	n	Technical success (%)	Clinical success (%)	Adverse events (%)
Walter et al., 2015	AXIOS	61	98.0	93.0	9.0
Shah et al., 2015	AXIOS	33	91.0	93.0	15.2
Chandran et al., 2015	NAGI	47	98.0	76.6	20.4
Siddiqui et al., 2016	AXIOS	82	97.5	94.0	9.8
Sharaiha et al., 2016	AXIOS	124	100.0	86.3	11.3
Rinninella et al., 2015	Hot AXIOS	93	98.9	95.2	5.0
Lakhtakia et al., 2016	NAGI	205	99.0	96.5	3.9
Vazquez-Sequeiros et al., 2016	AXIOS	211	97.0	94.0	21.0

to perform debridement or necrosectomy. The silicone membrane covering the stents minimizes ingrowth and allows for easier removal. The delivery method is also one of the key features of these novel stents allowing for, depending on the model, a streamlined placement thereby significantly decreasing the intervention duration (Figure 1) (7). The first novel metal stent appearing on the market was Axios (Xlumena, Mountain View, CA, United States) (Figure 2A) with an increasing number of other manufacturers contributing to the selection including the Nagi stent (Taewoong Medical Co, Ilsan, South Korea) (Figure 2B), Niti-S SPAXUS stent (TaeWoong Medical Co., Ltd., Ilsan, South Korea), Aixstent (LeufenMedical, Aachen, Germany) and the Hanarostent BCF (M.I. Tech. Co., Inc., Seoul, South Korea).

TECHNICAL AND TREATMENT SUCCESS

Multiple recent studies with LAMS have demonstrated excellent technical rates regarding success of stent deployment as well as a more than satisfying clinical efficacy. Results are summarized in Table 1 (8–15).

PCs can be managed with both surgical and endoscopic methods of cystogastrostomy and with equal efficacy as shown by Varadarajulu et al, but with lower costs and shorter hospital stay in the endoscopic group (16). LAMS were first used for PC drainage in a pilot study by Itoi et al. (17) with excellent clinical and technical success. Bang et al have shown in an earlier study an overall treatment success of up to 94.3% in draining PCs with plastic pigtail stents, and have found no differences between LAMS and plastic stents in PC drainage regarding technical and treatment success other than placement procedure length. They raised the question of the justification of three-fold higher costs associated with the use of novel metal stents compared to plastic stents in PC drainage (7,18).

In the management of WON, endoscopic drainage is the preferred method compared to surgery (4,5). The optimal modality of achieving endoscopic drainage and subsequent management is still a matter of great debate. The advent of dedicated large diameter LAMS designed to prevent migration and enable endoscopic necrosectomy has led to an increased number of WON drainage procedures performed, as evident by the growing number of recent publications. In a recent retrospective multicentre case series of 124 patients with WON, technical and clinical success of 100% and 86.3% respectively was reported. Concomitant

therapy included nasocystic irrigation and hydrogen peroxide-assisted necrosectomy. The median number of interventions performed was 2, while complete resolution of WON was achieved in 34 patients in a single session. Clinical success was associated with a larger stent diameter (15 mm) and removal after resolution was 100% successful in all patients (12). A recent retrospective cohort study involved 313 patients with symptomatic WON in whom drainage procedures were performed using plastic stents (n=106), FCSEMS (n=121) and LAMS (n=86). Fifty-nine patients had placement of a nasocystic catheter for performing lavage with saline and direct endoscopic necrosectomy (DEN) was performed significantly more often in the LAMS group. On 6-month follow-up complete resolution of WON was lowest in the plastic stent group (81%), with 95% and 90% resolution rate in FCSEMS and LAMS group respectively. A significantly lower number of procedures were required to achieve WON resolution in the LAMS group. The authors conclude that, in the case of WON, the higher price of LAMS is compensated by its increase in efficacy compared to plastic and FCSEMS (11).

DIRECT ENDOSCOPIC NECROSECTOMY

The natural history of WON which evolves from acutely formed necrotic tissue being encapsulated and „walled-off“ over a substantial period of time dictates its challenging management. The debris and necrotic material inside a WON can easily become infected leading to increased morbidity and mortality (19). Endoscopic drainage of symptomatic and/or infected WON is the method of choice in such cases and is often combined with DEN. The safety and efficacy of DEN has been established in multiple studies (20–22). DEN involves lavage of the cavity with either saline or hydrogen-peroxide and extraction of necrotic debris under direct vision using available non-dedicated accessories like snares and baskets (Figure 3). The sessions are usually repeated multiple times according to the discretion of the endoscopists. The introduction of LAMS with a larger diameter and anti-migratory design has allowed endoscopist to perform more aggressive necrosectomy and easier access for repeated sessions. Currently, however, there are more unanswered questions in DEN than there are answers. The concept of DEN raises a concern of super infection due to the aggressive nature of the intervention per se. The indication and timing for performing necrosectomy are still not firmly established with some advocating a more conservative approach. Stecher et al. described in

a recent letter cases of diffuse late bleeding from necrotic cavities (WON) that were previously mechanically almost completely emptied of necrotic debris raising the issue of how thorough DEN should be (23). Gornals et al. published results from a series of 12 patients with WON who had multiple endoscopic necrosectomies performed after LAMS placement. They reported a 100% clinical success rate with a serious AE rate of 16.6% including bleeding and infection (24). Lakhtakia et al. have shown in a recent study that using an endoscopic „step-up“ approach to WON drainage involving naso-cystic catheter drainage and stent de-clogging could help avoid DEN in a majority of cases (14).

ADVERSE EVENTS

With an increasing number of endoscopists adopting the use of LAMS for endoscopic drainage and necrosectomy there is a growing body of experience with AE associated with these procedures. So far infections, stent migration/occlusion, buried stent, perforation and bleeding have been reported. Since the rates of AE associated with surgery of necrotic collections rise up to 72%, a less invasive approach should always take priority (25,26). Reports of bleeding associated with LAMS pertain to acute bleeding during the stent placement and delayed bleeding which may occur weeks after the initial placement due to different causes. In a recent letter by Stecher et al. who treated 46 patients with LAMS for infected WON, bleeding complications occurred in 8 patients (17.4%) of which two died. Three cases of bleeding occurred within 24 hours and were presumably caused by injury of gastric veins due to balloon dilation of the access route and were managed conservatively. On the other hand, delayed bleeding into the necrotic cavity occurred up to 5 weeks after LAMS placement in 11% of all LAMS treated patients and was treated by angiographic intervention of the left gastric artery (23). Several reports of bleeding due to LAMS associated pseudoaneurysm formation as well as stents eroding into the collapsing wall of a necrotic cavity have been published and should be stressed (27). Migration may occur during DEN procedures, spontaneously or due to improper deployment, with rates in larger series ranging from 0% to 19% (11,28). Buried stents referring to the overgrowth of gastric or intestinal mucosa over the terminal end of LAMS have been reported in up to 17% in one series (29). Perforation with subsequent peritonitis due to LAMS maldeployment has also been reported (11). Stent occlusion by necrotic debris or food and resulting impaired drainage is expected

to occur but rarely reported (30).

CONCLUSION

The development of LAMS accompanies the evolution in management of PFCs, transitioning from complication-ridden surgeries with poor outcomes to successful minimally invasive percutaneous and endoscopic methods with low AE rates. The benefits of this approach for this challenging group of patients are increasingly recognized by teams of clinicians, endoscopists, surgeons, radiologists and other specialties involved their care. Even though enviable technical and treatment success has been observed in recent large series of patients, many questions are left lingering. Professional exchange of experience in this demanding field should be readily encouraged as minute details noted during the care for these patients, but not mentioned in published papers, may mean all the difference. The management of these patients requires a multidisciplinary team versed not only in endoscopy, but also experienced in demanding clinical scenarios for which available literature is still scarce. As noted by Adler and Siddiqui, results of future studies should attempt to give guidance on the type of LAMS to be used, timing and need for necrosectomy as well as timing of its removal (31).

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