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Lumen-apposing metal stents versus biliary fully-covered metal stents for EUS-guided drainage of pancreatic fluid collections: a case control study

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Authors

Ana Garcia Garcia de Paredes[1], Juan Angel Gonzalez Martin[1], Jose Ramon Foruny Olcina[1], Diego Juzgado Lucas[2], Fernando Gonzalez Panizo[2], Sergio Lopez Duran[1], Alba Martinez Sanchez[1], Alfonso Sanjuanbenito[3], Alejandra Caminoa[4], Agustin Albillos[1], Enrique Vazquez-Sequeiros[1]

Institutions

1 Gastroenterology and Hepatology Department. Hospital Universitario Ramon y Cajal, IRYCIS, Universidad de Alcala, Madrid, Spain
2 Department of Gastroenterology. Hospital Universitario Quiron Madrid. Madrid, Spain
3 Surgery Department. Hospital Universitario Ramon y Cajal, IRYCIS, Universidad de Alcala, Madrid, Spain
4 Pathology Department. Hospital Universitario Ramon y Cajal, IRYCIS, Universidad de Alcala, Madrid, Spain

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Corresponding author
Enrique Vázquez-Sequeiros MD, PhD, Endoscopy Unit, Gastroenterology and Hepatology Department, Hospital Universitario Ramón y Cajal, IRYCIS, Universidad de Alcalá, Madrid, Spain
Fax: +34918835348
evazquezse@gmail.com

ABSTRACT

Background and study aims Endoscopic ultrasound (EUS)-guided drainage has become first-line treatment for pancreatic fluid collections (PFC). The aim of this study was to compare the effectiveness and safety of biliary fully-covered self-expandable metal stents (BFCSEMS) and lumen-apposing metal stents with electrocautery (EC-LAMS).

Patients and methods From April 2008 to March 2017, consecutive patients with symptomatic PFC drained under EUS-guidance with metal stents were included. Patients drained with EC-LAMS were considered the study group and those drained with BFCSEMS the control group. Two primary endpoints were evaluated: effectiveness (defined as reduction of ≥ 50 % of PFC size in cross-sectional imaging and improvement of symptoms 6 months after the transmural drainage) and safety.

Results Thirty patients were drained with EC-LAMS and 60 patients with BFCSEMS. Patients and PFC baseline characteristics in both groups were similar. Use of a coaxial double pigtail plastic stent and a nasocystic lavage catheter was significantly less frequent in patients drained with EC-LAMS (33 % vs. 100 %, and 13 % vs. 58 %, respectively; $P < 0.0001$). Technical success was 100 % in both groups. Procedure time was < 30 minutes in all patients drained with EC-LAMS and over 30 minutes in all patients drained with BFCSEMS ($P = 0.0001$). Clinical success was higher with a tendency to significance in patients drained with EC-LAMS (96 % vs. 82 %, $P = 0.055$) and the adverse event rate was lower (4 % vs. 18 %, $P = 0.04$). No case of procedure-related mortality was recorded.

Conclusions EC-LAMS and BFCSEMS are both effective for EUS-guided drainage of PFC. However, EC-LAMS requires less time to be performed and appears to be safer.

Introduction

Pancreatic fluid collections (PFC) may result as a complication of acute or chronic pancreatitis, pancreatic surgery or trauma. The revised Atlanta classification [1] categorizes PFC into acute and chronic collections according to time since diagnosis (>4 or <4 weeks), development of a mature wall, and presence or absence of necrosis. The majority of PFC remain asymptomatic and resolve spontaneously [2, 3]. However, when a PFC becomes symptomatic, infected or it enlarges rapidly, drainage is usually required [4–6].

Endoscopic ultrasound (EUS)-guided drainage has been proven to be superior to other PFC drainage techniques [7], associated with less morbidity, better quality of life, and a lower cost as compared with surgery [8–10] and it is better-tolerated than percutaneous drainage avoiding complications such as pancreaticocutaneous fistula [11–13].

Nevertheless, there are still many questions regarding EUS-guided drainage of PFC that need to be answered. One of them is the type of stent that is more efficient. Plastic stents have been traditionally employed for transmural drainage of PFC with good results for pseudocysts but with less satisfying outcomes for more complex PFC like walled-off pancreatic necrosis (WON) [14]. This is probably due to their small lumen, which may result in stent occlusion by necrotic debris, requiring further interventions and placement of multiple stents to achieve adequate drainage, which might be technically challenging [15, 16]. These limitations may potentially be avoided by using large-bore metal stents. Biliary fully-covered self-expandable metal stents (BFCSEMS) [17] and lumen-apposing metal stents with electrocautery (EC-LAMS) have shown to be effective and relatively safe for PFC drainage [18]. Little is known regarding which type of metal stent is better suited for this indication if a metal stent is our election for drainage. Therefore, we designed a study with the following aim: to compare the effectiveness and safety of BFCSEMS versus EC-LAMS for EUS-guided drainage of encapsulated PFC.

Patients and methods

Study design and population

The study was conducted at two institutions and approved by the Ethics Committee. EUS-guided PFC drainage was only performed in chronic (>4 weeks from presentation), encapsulated (presence of a well-defined wall on computed tomography [CT]-scan), and symptomatic (abdominal pain, gastric outlet or biliary obstruction, rapidly enlarging, or infected) [6] PFC (pseudocysts or WON). All PFC were characterized by CT scan and/or magnetic resonance imagining (MRI) before endoscopic drainage and defined as per the revised Atlanta classification [1].

It is our routine clinical practice that all PFC drainages are prospectively collected into an Institutional Review Board approved database. The study design was a comparative case control study, in a proportion 1:2. The first 30 consecutive patients drained with EC-LAMS (Hot Axios 10×15 mm, Boston Scientific; Marlborough, Massachusetts, United States) performed between February 2015 and March 2017 were classified as "cases" (Group A). Patients in Group A were compared with a cohort of 60 consecutive patients drained with BFCSEMS (Wallflex 10×60 mm, Boston Scientific; Marlborough, Massachusetts, United States) performed between April 2008 and February 2015 prospectively registered and characterized in our data base; these patients served as "controls" for comparisons (Group B). Exclusion criteria were: 1) PFC located >1 cm from the gastrointestinal lumen; and 2) follow-up of less than 6 months. Patient baseline demographic data (sex and age), etiology of pancreatitis, history of chronic pancreatitis, size and type of PFC, time of evolution from diagnosis to transmural drainage, and previous failed drainage attempts were recorded.

Procedure

All procedures were performed by two experienced endoscopists. Patients were administered broad-spectrum antibiotics before and after the procedure (ciprofloxacin 400 mg intravenously before the procedure followed by 500 mg twice a day orally for 5 days). Drainage was performed under deep sedation or general anesthesia with orotracheal intubation according to the anesthesiologist criteria. Procedures were performed with a therapeutic linear echoendoscope (Olympus GF-UCT180) and a 19-gauge needle (Boston Scientific; Marlborough, Massachusetts, United States) in all cases. Ten cc of PFC content were routinely aspirated and sent for microbiologic study. A 0.035-inch guidewire was inserted through the needle and coiled inside the collection under fluoroscopic guidance. Then, in the EC-LAMS cohort (Group A) puncture of the collection using the electrocautery catheter tip was performed and the stent was inserted. The distal flange was deployed under EUS guidance and the proximal flange under endoscopic view. In patients drained with BFCSEMS (Group B), once the wire was inserted, a cystotome (Cysto-Gastro 6 Fr, Albyn Medical) with electrocautery was passed over the wire through the wall. A biliary balloon dilatation catheter was then used to dilate the cyst-enterostomy tract (4–6 mm) to facilitate stent insertion. Afterward a BFCSEMS stent was inserted over the wire. Finally, in both groups a coaxial 7 Fr double pigtail plastic stent (Compass BDS, Cook Medical) to anchor and prevent stent migration was placed in some patients when considered necessary by the endoscopist. Also, a 7 Fr nasocystic catheter (Liguory, Cook Medical) for lavage with continuous perfusion of saline solution (500 cc–2000 cc per day depending on patient tolerance) for 5 to 7 days was placed in some cases in the presence of solid debris at the discretion of the endoscopist. Direct mechanical endoscopic necrosectomy was also allowed if the endoscopist considered so.

Management and follow-up

All patients underwent regular outpatient follow-up and cross-sectional imaging after the procedure with intervals set according to the responsible physician criteria. All patients included were followed for at least 6 months and underwent a contrast-enhanced CT of the abdomen 4 to 8 weeks after drainage and 3 to 6 months after the procedure to assess for PFC resolution.

The stent was removed endoscopically according to clinical evolution after confirmation of the resolution of the collection.

Outcomes

The following two issues were analyzed as primary endpoints of the study: 1) effectiveness; and 2) safety of EC-LAMS versus BFCSEMS for EUS-guided drainage of PFC.

Definitions

Technical success: ability to access and drain the PFC by placement of a transmural stent. Clinical success: reduction of ≥ 50 % of PFC size in cross-sectional imaging (CT) and improvement of symptoms 6 months after the transmural drainage. Adverse events (AEs): defined according to the American Society for Gastrointestinal Endoscopy (ASGE) lexicon criteria [19]. Time required to perform the procedure: evaluated and classified as < 30 or > 30 minutes from the beginning of the procedure until drainage had been completed. Duration of time required for PFC drainage was recorded in each patient and included into a predefined database as follows: < 30 minutes, 30 to 60 minutes, 61 to 90 minutes, 91 to 120 minutes or > 120 minutes. Data were considered categorical and analyzed accordingly.

Statistical analysis

Continuous variables showing a normal distribution were expressed as mean ± standard deviation (SD); otherwise as median and interquartile range (IQR). Mean comparisons were performed using parametric methods for normally distributed continuous data (Student's *t* test) and nonparametric methods (Mann-Whitney U test) for non-normally distributed continuous data. Categorical variables were expressed as absolute values and their relative frequencies, and intergroup comparisons were made by using the Chi-squared test or Fisher's exact test when necessary. Relevant patient baseline characteristics (age, sex, etiology of pancreatitis, history of chronic pancreatitis, type of PFC, size of collection, time since diagnosis, prior drainages) were analyzed in both groups to determine if they were comparable. The design of the study determined that in case of imbalance for any of these characteristics between cohorts, multiple stepwise logistic regression analysis had to be performed for adjustment. All analyses were two-tailed and statistical significance was set at $P < 0.05$. We decided not to adjust for multiple comparisons taking into account that we had two preplanned primary endpoints and that we acknowledged the limitations of the study due to its retrospective nature. If we adjusted for multiple comparisons, statistical significance would have been set at $P < 0.025$. All statistical tests were performed using the software package JMP 7.0.2, SAS Institute Inc. Cary, North Carolina, United States.

Results

Characteristics of the study population

As per the study design, a total of 90 patients with symptomatic encapsulated PFC drained by EUS-guided transmural placement of a metal stent were included. Thirty patients were drained with EC-LAMS (cases: Group A) and 60 patients with BFCSEMS (controls: Group B). As shown in ▶ **Table 1**, patient and PFC characteristics were similar in both groups. PFC were categorized as WON in 53 % of patients in EC-LAMS and in 47 % of patients in BFCSEMS group. Four patients (13 %) in the EC-LAMS group and six patients (10 %) in the BFCSEMS group had a previous attempt at PFC drainage by a percutaneous approach.

Technical aspects of the procedure

All procedures were performed using a transgastric approach. Ten patients (33 %) in the EC-LAMS group and 60 (100 %) in the BFCSEMS had a coaxial 7 Fr double pigtail plastic stent placed to prevent migration (33 % vs 100 %, $P < 0.0001$). Four patients in the EC-LAMS group (13 %) and 35 (58 %) in the BFCSEMS group had a nasocystic lavage catheter placed for perfusion of saline solution through the stent due to the presence of large amount of solid debris ($P < 0.0001$). Endoscopic necrosectomy was performed in only one patient per group (3.3 % in EC-LAMS group and 1.6 % in BFCSEMS group, $P = 0.58$). Although there were more unplanned subsequent endoscopic procedures (excluding those planned procedures aimed to stent removal) in the BFCSEMS group (10 patients, 16 %) compared to the EC-LAMS group (1 patient, 3 %), differences did not reach statistical significance ($P = 0.06$).

Clinical outcomes and AEs

Technical success was achieved in 100 % of cases in both groups. Procedure time was less than 30 minutes in all 30 patients drained with EC-LAMS and in none of the 60 patients drained with BFCSEMS ($P = 0.0001$). Clinical success was achieved in 29 patients (96 %) drained with EC-LAMS and in 49 (82 %) drained with BFCSEMS ($P = 0.055$). None of the patients drained with EC-LAMS (0 %) and three of the patients drained with BFCSEMS (5 %) required surgery as a rescue therapy after transmural drainage ($P = 0.29$). The median time that stents remained implanted before removal was similar in both groups: 98 days (IQR: 92–102; range: 56–122) in the EC-LAMS group and 115 days (IQR: 74–133; range: 45–122) in the BFCSEMS group, $P = 0.37$. There were no episodes of PFC recurrence after stent removal during the predefined 6-months surveillance period.

In the EC-LAMS group there was only one AE recorded, which occurred in a WON patient within the first 2 weeks after the procedure: a stent dysfunction that led to secondary infection of the collection which was resolved by endoscopic stent replacement. There were 11 patients (9 WON and 2 pseudocysts) that presented with AEs in the BFCSEMS: one patient with a WON complicated with bleeding within the first 48 hours after drainage that required surgery, and 10 cases (8 WON and 2 pseudocysts) of stent dysfunction with secondary infection (8 occurred within the first 14 days after drainage, one 4 weeks after drainage and one 6 weeks after the procedure), eight of them were solved with endoscopic replacement of the stent and two of them required surgery. There were no cases of stent migration in either group. The AE rate was significantly lower (4 % vs. 18 %, $P = 0.04$) in patients drained with EC-LAMS. Most of the AEs (83 %) occurred within the first 2 weeks after drain-

▶ **Table 1** Baseline characteristics of patients and pancreatic fluid collections.

	(Group A) EC-LAMS n = 30	(Group B) BFCSEMS n = 60	*P*
Sex masculine, n (%)	19 (63 %)	40 (67 %)	0.46
Age, mean ± SD, years	61.3 ± 10.2	63.1 ± 9.8	0.94
Etiology of pancreatitis, n (%)			
▪ Gallstone	21 (70 %)	45 (75 %)	0.6
▪ Alcohol	9 (30 %)	15 (25 %)	2
Chronic pancreatitis, n (%)	7 (23 %)	10 (17 %)	0.56
Type of PFC			
▪ Pseudocyst	14 (47 %)	32 (53 %)	0.8
▪ WON	16 (53 %)	28 (47 %)	7
Size of PFC, mean ± SD, mm	74.6 ± 14.5	73.9 ± 11.9	0.87
Time since diagnosis, mean ± SD, days	45.7 ± 8.2	43.8 ± 7.3	0.27
Previous drainage of PFC, n (%)	4 (13 %)	6 (10 %)	0.98

SD, standard deviation; PFC, pancreatic fluid collection; WON, walled-off pancreatic necrosis.

▶ **Table 2** Clinical outcomes and adverse events.

	(Group A) EC-LAMS n = 30	(Group B) BFCSEMS n = 60	*P*
Technical success, n (%)	30 (100 %)	60 (100 %)	1
Procedure time < 30 minutes, n (%)	30 (100 %)	0 (0 %)	< 0.0001
Clinical success, n (%)	29 (96 %)	49 (82 %)	0.055
Need of surgery as rescue therapy, n (%)	0 (0 %)	3 (5 %)	0.29
Adverse events, n (%)	1 (4 %)	11 (18 %)	0.04
▪ Early (< 14 days)	1	9	
▪ Late (> 14 days)	0	2	
Procedure-related mortality, n (%)	0 (0 %)	0 (0 %)	1

Intergroup comparisons were made by using the Fisher's exact test.

age. No case of delayed bleeding was registered. No case of mortality associated with the procedure was recorded. Clinical outcomes and AEs are summarized in ▶ **Table 2**.

Discussion

EUS-guided transmural drainage has become the first-line treatment option for symptomatic PFC. However, there is still an ongoing debate about which is the optimal stent for this procedure, and it is controversial whether plastic or metal stents should be used. In case of opting for a metal stent, it is unknown which one is the best option. Our study specifically compared two types of metal stents for this purpose, and we observed that EUS-guided drainage of PFC with EC-LAMS requires less time to be performed and appears to be safer.

In the current study, drainage of PFC (pseudocysts and WON) with EC-LAMS was superior with a tendency to significance compared to BFCSEMS in terms of clinical success (96 % vs. 82 %, $P < 0.05$). Some previous retrospective studies have not shown clear differences between BFCSEMS and LAMS regarding resolution of WON, but BFCSEMS required more procedures and LAMS were superior in terms of long-term patency [15]. The increased likelihood of resolution of PFC with EC-LAMS in this study may have been influenced by differences in stent inner diameter (15 mm in EC-LAMS and 10 mm in BFCSEMS) and the higher use of preventive measures for stent

migration such as plastic pigtail coaxial stents and nasocystic catheters for lavage in the BFCSEMS, narrowing the stent lumen and favoring stent occlusion and dysfunction.

Previous large reports with EC-LAMS [20, 21] have shown similar good results. Rinella et al. performed a multicentric retrospective study in 93 patients with PFC drained with EC-LAMS, reporting a clinical success rate of 92.5 % and an AE rate of 5 % similar to findings in the current study. A difference between Rinella's study and the current one is that necrosectomy was performed in 59 % of patients compared to only 3.3 % in our study. Some authors routinely perform direct endoscopic necrosectomy in a scheduled manner, while others will do it in an elective manner in all collections that do not resolve with placement of a transmural stent alone [22]. The safety of the necrosectomy technique is increasingly debated due to the elevated AE rate observed: 35 % complication rate (including perforation, air embolism and severe bleeding) and 6 % mortality rate in a recent meta-analysis [23]. Furthermore, the need for direct endoscopic necrosectomy is becoming more controversial, especially with the increasing use of metal stents and their presumed high clinical success even without necrosectomy, probably attributable to their larger diameter [15]. The high clinical success reported in the current study, which included a high number of WON and in whom necrosectomy was barely used, may support the idea that necrosectomy may not always be necessary to achieve resolution of WON, and that use of this procedure should probably be limited to very dense collections that fail to improve after appropriate drainage. Other approaches such as irrigation to help loosen solid material have been reported [24]. Placement of a nasocystic drain to provide irrigation within the cavity with saline solution has been associated with a higher complete resolution of PFC and lower occurrence of stent occlusion (13 % vs. 33 %, $P = 0.03$) [25], especially in collections with a high amount of necrotic debris. However, it is unclear whether it may offer any advantage when a LAMS is used [15], and the high clinical success rate in the EC-LAMS group despite the low number of patients with nasocystic lavage in our study would support this hypothesis.

Occurrence of AEs was lower in the EC-LAMS group (4 % vs. 18 %, $P = 0.04$). The most frequent AE was stent dysfunction with superposed secondary infection, similar to that reported in previous studies [17], and interestingly there were no bleeding complications in the EC-LAMS group. In the recent interim analysis of a randomized trial, a 50 % rate of complications in the EC-LAMS group was found compared to 0 % in the plastic stent group, raising concerns about LAMS safety [26]. However, it is unclear whether these results may reflect the true risk of complications of LAMS because the rate of AEs in that study was much higher than previously described [15, 21, 27]. On the other hand, this higher rate of AEs could also be due to the fact that it was a controlled study with a stricter follow-up and could therefore reflect more realistic results. We would like to emphasize that in our study, patients with WON presented a higher likelihood of having an AE, and at least in our experience, stent dysfunction (mainly in small caliber stents like BFCSEMS) was the most frequent problem. Results from the current study suggest that EC-LAMS, due to its larger size diameter, are probably better suited to treat WON cases than BFCSEMS. Whether EC-LAMS is better than plastic for PFC and especially for WON drainage is out of the scope of the current study. One may argue why some of these patients with a pancreatic pseudocyst underwent drainage with a metal stent when plastic stents also do an excellent job and with probably fewer AEs. However, we have to argue that at the time of the study, there was little evidence that metal stents (particularly EC-LAMS) could be associated with a higher risk of AEs, as suggested by recent studies and guidelines.

Another concern regarding use of BFCSEMS is risk of migration due to their tubular shape. Placement of a double pigtail plastic stent within the lumen of the metal stent to anchor it and minimize this risk has been frequently reported [28, 29]. This measure to prevent migration was employed in all the patients in the BFCSEMS group in the current study, probably explaining the absence of migration registered.

A secondary endpoint evaluated in the current study was the time required to perform the drainage. Procedural time was significantly lower in the EC-LAMS group compared to BFCSEMS ($P = 0.0001$). Previous studies have highlighted the shorter procedure time with LAMS compared to plastic stents [20, 30]. The shorter procedure time, related to reduction in number of steps required for drainage, may theoretically contribute to a reduction in AEs, and improve therefore the safety of the endoscopic treatment.

One unresolved matter regarding endoscopic drainage of PFC is when to retrieve the stent. There is evidence supporting that plastic stents left in place for a longer time may protect against PFC recurrence especially in case of pancreatic duct disruption, with no safety issues [31]. Regarding metal stents, some studies have raised concerns as they have found a higher rate of AEs, mainly bleeding, when leaving stents for a long time, suggesting that it would be reasonable to remove them no later than 3 months after placement [17]. It should be taken into consideration if a plastic or a metal stent is going to be left for drainage, as it may influence risks of delayed AEs and PFC relapse. If there is a need for long stay of stent (e. g. clinical suspicion for duct disruption), plastic ones could be an excellent choice in the long term and should be kept in mind.

Although there are no strong data favoring use of plastic or metal stents for PFC drainage, many authors prefer to use metal stents (preferably the EC-LAMS) due to their excellent clinical success rate (93–100 %) and reduced AE rate [17, 20, 26, 32]. Furthermore, the simplified introduction and deployment mechanism and reduced procedural time have made the EC-LAMS the preferred stent by many endoscopists. However, when choosing the type of stent for transmural drainage of a PFC, it is important to take into account not only effectiveness and safety but also cost. EC-LAMS like the one used in this study are currently more expensive than BFCSEMS or plastic stents in terms of direct costs. The initial higher cost of EC-LAMS was offset by the cost of additional procedures and necrosectomy sessions with plastic stents in a recent retrospective study [32]. Whether treatment of AEs, length of hospital stay, and readmissions may be influenced by placing one type of stent or another is an interesting and important question that unfortunately this

study is not able to answer. Prospective cost-effectiveness studies should be performed to evaluate whether the benefit of the superior outcomes overcome the economic difference [33].

As there are still a number of questions yet to be answered regarding PFC drainage, we would like to stress the importance of choosing the best type of stent in each individual case. Before we obtain stronger evidence from the literature, it seems reasonable that perhaps, in non-complicated pancreatic pseudocyst, plastic stents could be the first therapeutic option, as well as in patients with poor adherence to follow-up or in whom a disconnected pancreatic duct syndrome, a pseudoaneurysm or a rich vascular network is suspected. Author preferences should not be biased by overenthusiasm and external pressure from the industry, therefore, careful selection of cases should be taken into account before choosing one type of stent.

We have to acknowledge several limitations of our study. The main one is its retrospective design. Retrospective studies are more likely to include patient selection bias, do not account for potential variations in technique during the study period, and patient follow-up is not as uniform as in prospective and controlled studies. In this sense, the majority of patients in our study were not followed after the predefined 6-month surveillance period after stent placement, therefore, we have no further data on late PFC recurrence. EC-LAMS were removed at a median time of 98 days (92–102), therefore, we had roughly a median of 82 days of follow-up in this group after stent removal; in the BFCSEMS group median time for stent removal was 115 days (74–133), thus we had approximately a median follow-up of 65 days after stent removal.

Furthermore, the definition of clinical success may differ from one study to another (some authors considered success only in complete resolution of PFC was obtained, while others like us consider it so if at least a 50 % reduction in PFC size was achieved), therefore making the comparison of results among studies extremely difficult.

Conclusion

In summary, despite some methodological limitations inherent to any case-control design, results of the current study suggest that EC-LAMS may be safer than BFCSEMS. In addition, procedural time potentially may be reduced if a EC-LAMS is used. Further prospective, randomized, comparative studies including cost-analysis are definitively needed to confirm whether these promising results of EC-LAMS in PFC drainage are correct.

Competing interests

None

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