

Peripancreatic fluid collections, plastic stents, and different sub-types of metal stents: Where does the evidence land?

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Abstract

Background: Peripancreatic fluid collections (PFCs) are a frequent complication of acute pancreatitis. Symptomatic PFCs may need to be drained, and there are multiple endoscopic accessories that can facilitate the procedure. This paper aims to compare the success rate, number of procedures required for resolution and adverse events rate for PFCs EUS-guided drainage with plastic stents and lumen-apposing metal stents (LAMS).

Methods: This is a retrospective analysis of a consecutive sample of patients that was collected from 2013 – 2019. The medical records of these patients were reviewed, and the outcomes for each type of stent (plastic vs LAMS, and different subtypes of LAMS) were compared in terms of clinical success, number of re-interventions needed, and adverse events.

Results: A total of 33 patients (23 males) were treated for PFCs with EUS-guided drainage and stenting. The patients' ages ranged between 14 and 85 years (mean \pm SD: 43.5 \pm 19 years). Overall, there was no difference between plastic stents and LAMS in terms of symptomatic recovery ($P = 0.24$), but metal stents had better results with regards to radiological resolution ($P = 0.03$), and were associated with a higher number of necrosectomies ($P = 0.029$). Adverse events occurred more frequently in patients who had plastic stents, but direct comparison between the two groups showed that the difference was not statistically significant ($P = 0.2$). Stratification for different LAMS subtypes showed no difference in terms of symptomatic or radiological resolution ($P = 0.49$), number of rescue procedures ($P = 0.41$), and adverse events ($P = 0.81$).

Conclusion: Our study, along with the current available evidence, suggests a slight advantage of metal stents over plastic stents in terms of clinical success, need for rescue procedures, and incidence of adverse events. Furthermore, it provides empirical evidence that the different sub-types of LAMS perform similarly when compared against each other.

Keywords: EUS-guided drainage, lumen-apposing metal stents, peripancreatic fluid collections, plastic stents

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INTRODUCTION

Peripancreatic fluid collections (PFCs) are a frequent complication of acute pancreatitis, and less commonly, of chronic pancreatitis, abdominal trauma, surgery, and pancreatic ductal obstruction.^[1] Based on the duration after initial injury (less or more than four weeks) and the presence or absence of necrosis, the revised Atlanta classification system categorizes PFCs into four subtypes: acute peripancreatic fluid collections, acute necrotic collections, pancreatic pseudocysts (PPC), and walled-off necrosis (WON).^[2] This classification is essential as the management varies depending on the type of collection. Most acute peripancreatic fluid collections or acute necrotic collections do not require specific management. Asymptomatic PPCs and WON do not require intervention either. However, symptomatic PFCs that present with persistent abdominal pain, fever, early satiety, nausea and vomiting, and concern for infection, may need to be drained. Draining the collection can be accomplished surgically, percutaneously, or endoscopically. With the advent of advanced endoscopic tools and expertise, along with a better understanding of the pathophysiology, minimally invasive endoscopic drainage has become the favoured approach.^[3-5]

There are two main types of stents used in the endoscopic management of PFCs: double-pigtail plastic stents (PS), and metal stents, which include the traditional fully-covered, self-expanding metal stents (FCSEMS), and the novel lumen-apposing, fully-covered, self-expanding metal stents (LAMS). Although the LAMS is a dedicated device for PFC drainage and has technical advantages, few data compared the efficacy and adverse events across its three commercially available sub-types. To date, there are no final recommendations on the best stent type in the management of PFCs. Therefore, using retrospectively collected data of EUS-guided PFC drainage at a tertiary care centre in Saudi Arabia, we aim to compare the success rate, number of procedures required for resolution, and adverse events rates for PFCs (PPC and WON) drainage with PS and LAMS.

METHODS

This is a retrospective analysis to present our experience with the two types of stents from 2013-2019. Electronic hospital records were searched using “pancreatitis, pancreatic collection, pancreatic pseudocyst, and pancreatic necrosis/necrotic collection/walled off necrosis.” After the search results were closely examined, a consecutive sample of all patients who were endoscopically treated for PFCs throughout this period was taken. The data collected

included their demographics (age and gender), clinical presentations, and type of stent used for the procedure.

The primary outcome measure of interest was the clinical success associated with each type of stent, which was defined by the resolution of symptoms, or the resolution of the PFC on imaging during the 4 weeks that followed the procedure. The number of re-interventions that were needed to achieve complete resolution was also of interest, and included drainage procedures and necrosectomies. Lastly, all the immediate and delayed complications that occurred over the four weeks that followed the procedure were collected and directly compared across the different types of stents used in this study.

Due to the differences in diameter and design between the three commercially available LAMS,^[6] patients who underwent LAMS placement were stratified and compared based on the main outcome measures mentioned above. Furthermore, subgroup analysis was carried out based on the type of the collection (PPC vs WON).

Statistical analysis

The data was analyzed using IBM SPSS® Statistics software. The patients were grouped based on the type of stent that was used for treatment (Plastic vs metallic) and the outcomes for each group were compared using the Chi-square test in terms of success and adverse events rates, and by using *t*-test for independent samples in terms of the number of procedures that were required to achieve complete resolution. One way analysis of variance (ANOVA) was used to compare the number of rescue procedures that were required for each type of metal stents used in this series.

RESULTS

During the period of interest, 33 patients (23 males) were treated for peripancreatic fluid collections with endoscopic ultrasound (EUS)-guided drainage and stenting. The patients' ages ranged between 14 and 85 years (mean \pm SD: 43.5 \pm 19 years), and they mostly presented with persistent abdominal pain that was caused by an underlying acute pancreatitis (85%), abdominal trauma (6%), suspected pancreatic neoplasm (6%), or abdominal surgery (3%). Other symptoms included nausea and vomiting (9%), gastric outlet obstruction (3%), fever (3%), and obstructive jaundice (3%).

In terms of findings on imaging [Figure 1], 16 patients (48.5%) had a pancreatic pseudocyst on computed tomography (CT), one of these patients had an infected pseudocyst (3%), and 17 (51.6%) had a walled-off necrosis.

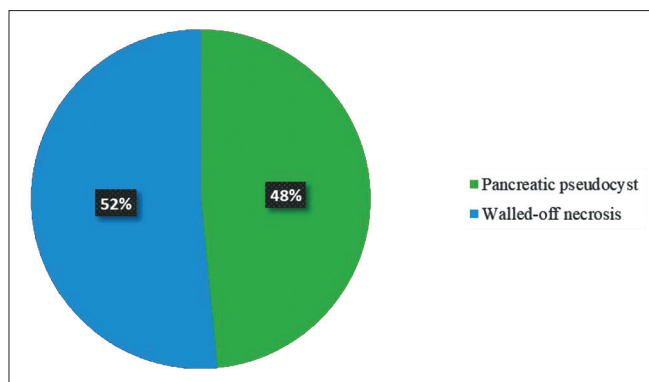


Figure 1: Types of PFCs that were found on imaging in this series

Drainage and stenting procedures were performed by several endoscopists and were all done through the stomach (cystgastrostomy). Four types/sub-types of stents were found to have been used in this series. The double pigtail stents (plastic, 10 Fr × 7-10 cm in size) were used in 12 patients (36.4%), whereas the lumen-apposing metal stents, AXIOS™ (10 mm × 15 mm in diameter), TaeWoong Medical’s SPAXUS™ (20 mm × 16 mm in diameter) and NAGIT™ (20 mm × 16 mm in diameter) were used in 19 (57.6%) patients. A combination of two or more of the above-mentioned stent types were used in 2 patients (6%). Overall, metal stents were favored in patients with WON and technically difficult drainage procedures, whereas plastic stents were mostly used to drain uncomplicated collections. A combination of both stents was used when multiple collections were present.

As explained above, the clinical success of the procedure was evaluated by the improvement of symptoms, as well as the resolution of the collection on imaging over four weeks of follow-up. Overall, 31 patients (94%) experienced complete symptomatic recovery and 28 patients (85%) were found to have full resolution of the PFC on post-procedural imaging. Of the 15% of patients who were not found to achieve the outcome of interest on imaging, 9% reported symptomatic improvement, and 6% were lost to follow-up.

Two patients in the plastic stent group failed to achieve the desired outcome. When the clinical success rate was compared

Table 1: Chi-square test assuming both patients lost to follow up achieved the desired radiological outcome

	Resolved on imaging	Unresolved on imaging	Total
Plastic	10	2	12
Metallic	19	0	19
Both	1	1	2
Total	30	3	33

Pearson Chi-square=6.78. P=0.03

Table 2: Chi-square assuming one patient lost to follow up did not achieve the desired radiological outcome

	Resolved on imaging	Unresolved on imaging	Total
Plastic	10	2	12
Metallic	18	1	19
Both	1	1	2
Total	29	4	33

Pearson Chi-square=3.77. P=0.14

between the plastic and metallic stents in terms of symptomatic recovery, the difference was not statistically significant (P = 0.24). However, when it came to the resolution on imaging, two scenarios were plausible (where the loss of follow-up of two patients was assumed). When Chi-square test was applied to the best case scenario, and both patients were assumed to have achieved a favorable radiological outcome, the difference between plastic and metallic stents was significant (P = 0.03). When, nonetheless, the analysis was repeated assuming that either one or none of the patients achieved the desired radiological outcome, that significance was lost [Tables 1-3].

Clinical success was also evaluated depending on the type of the collection. Thus, patients with pancreatic pseudocysts and walled-off necrosis were analyzed separately. In patients who had PPCs, there was no difference in clinical outcomes between plastic and metal stents (90 vs 100%, respectively, P = 0.4). In patients who had WON, however, the difference was in favor of metal stents (50 vs 100%, P = 0.01). These results are tabulated in Table 4.

With regards to the number of re-interventions that were needed to achieve complete resolution, patients who had a plastic stent needed, on average, one drainage procedure, whereas those who had a metal stent needed two (mean ± SD: 2 ± 1.6). A t-test comparison between the two stents showed that this difference was significant (P = 0.029). Two types of re-interventions were of interest in this series; EUS-guided drainage procedures as well as endoscopic necrosectomies. When the two types of re-interventions were compared separately, the difference between the two groups was found to be largely driven by the higher number of necrosectomies that were performed in WON patients, whose collections were mostly drained using metal stents.

Table 3: Chi-square assuming both patients lost to follow up did not achieve the desired radiological outcome

	Resolved on imaging	Unresolved on imaging	Total
Plastic	10	2	12
Metallic	17	2	19
Both	1	1	2
Total	28	5	33

Pearson Chi-square=2.23. P=0.38

Table 4: Subgroup analysis of clinical outcomes by PFC type

	Number	Number (%) improved	Difference
Plastic (PPC)	10	9 (90)	Chi-square=0.6, P=0.4
Metallic (PPC)	6	6 (100)	
Plastic (WON)	2	1 (50)	Chi-square=6.5, P=0.01
Metallic (WON)	13	13 (100)	
Combined (WON)	2	2 (100)	
Total	33	31 (94)	33

Four patients (12%) in our series were reported to have experienced adverse events. Two had gastrointestinal bleeding (6%), one had a recurrence of the collection (3%), and one was found to have stent migration (3%). Nevertheless, the occurrence of these adverse events in the two groups was not found to be significantly different ($P = 0.2$). When adverse events were stratified based on the type of the collection, 20% of PPC patients were found to have had a bleeding event with plastic stents, but none with metal stents. On the other hand, 7.7% of WON patients had stent migration, and 7.7% had a recurrence. The migration event occurred with a patient who had both a plastic stent and a LAMS, whereas the recurrence occurred in a patient who had a LAMS. Chi-square comparison between groups, nonetheless, showed that none of these differences were significant [Table 5].

Lastly, subgroup analysis was carried out to compare the different types of LAMS against each other. No difference was found in terms of symptomatic or radiological resolution ($P = 0.49$), number of rescue procedures ($P = 0.41$), and adverse events ($P = 0.81$).

DISCUSSION

This was a retrospective study comparing plastic versus metal stents for peripancreatic fluid collections in terms of clinical success, number of needed re-interventions, and adverse events, at one tertiary care center in Riyadh. The results of our analysis suggest a slightly better clinical result with metal stents, but at the expense of a higher number of needed interventions to achieve complete radiological resolution. Our findings also suggest that patients who undergo LAMS placement achieve similar outcomes in terms of clinical and radiological improvement, number of rescue procedures, and complications, regardless of LAMS subtype.

Table 5: Subgroup analysis of adverse events by PFC type

	Number	Number of adverse events (%)	Difference
Plastic (PPC)	10	2 (20)	Chi-square=1.3, P=0.25
Metallic (PPC)	6	0 (0)	
Plastic (WON)	2	0 (0)	Chi-square=0.32, P=0.57
Metallic (WON)	13	1 (7.7)	
Combined (WON)	2	1 (7.7)	
Total	33	4 (12)	33

Despite the technical advantages that metal stents hold over traditional plastic stents, studies have not consistently shown them to be superior in clinical success rate. For example, a meta-analysis of 698 patients in 2014 found no difference in treatment success in pseudocysts drained with plastic or metal stents.^[7] Similarly, a systematic review that included 17 studies (881 patients) showed no difference in overall treatment success between patients treated with plastic stents and fully-covered, self-expanding metal stents (FCSEMS) (81% vs 82%) for both PPC (85% vs 83%) and WON (70% vs 78%).^[8] However, one important limitation in these reviews was pooling the results of studies that did not include a direct comparison between the two types. This is perhaps the main reason that more recent meta-analyses contradict these results and instead support the use of metal stents over plastic stents.^[9-11] For instance, a 2018 meta-analysis found a higher clinical success rate in the metal stent group than in the plastic stent group (94.1 vs 82.6%, with pooled OR of 3.39) for both PPC (98.3 vs 90.8%) and WON (93.7 vs 81.8%).^[10] The difference in treatment effect suggested by this study was the largest one found in the literature (95% CI; 2.05-5.6). In contrast, the results of other recent reviews suggest smaller differences (RR of 1.08, 95% CI; 1.02-1.14), which is consistent with our findings.^[11] Since these reviews included studies of comparable quality and risk of bias, this discrepancy in the pooled estimates can be explained by the fact that treatment effects can sometimes be inflated when expressed in odds ratios (as opposed to relative risks and weighted pooled rates). Moreover, these estimates were largely driven by retrospective comparisons that had a moderate risk of bias.

Similar heterogeneity was found with regards to reinterventions, marginally, favoring metal stents. For example, in a study conducted by Mukai *et al.* comparing plastic and metal stents for WON management, salvage sessions, including direct endoscopic necrosectomy and additional endoscopic drainage procedures, were required in 8 patients in the plastic stent group and in 20 patients in the metal stent group (29.6 vs 46.5%; $P = 0.16$). Although rescue sessions were needed more often in the metal stent group, the mean number of additional procedures was less in the metal stent group than in the plastic stent group (2.7 ± 1.8 vs 4.1 ± 3.4 ; $P = 0.14$). Along the same line, a 2018 paper compared LAMS and PS in 94 cases of WON, and showed that WON was more likely to resolve without subsequent endoscopic transmural necrosectomy in the LAMS group than in the PS group (60.4 vs 30.8%; $P = 0.01$).^[12] While these differences were remarkable when the comparison was made specifically for WON, recent reviews that compared reinterventions regarding all types of PFCs tended to report insignificant differences.^[11,13] Perhaps one reason our findings

did not go in the same direction was the endoscopists' inclination to use LAMS in complicated collections, and keep for shorter times to avoid delayed bleeding.^[14] This might have eventually mandated more interventions to fully drain the collections. Additionally, knowing that metal stents provide an easier shift to direct necrosectomy than plastic stents,^[15] the attending endoscopists might have been drawn to using them more in WON patients.

In terms of adverse events, our study was consistent with the available evidence that patients who undergo plastic stent placement are more likely to experience adverse events in general,^[9] and bleeding in particular.^[11] A 2017 meta-analysis reported that the number needed to treat with metallic stents to prevent the occurrence of one adverse event over plastic stents was 7.45,^[9] which can have a remarkable impact in practice. Another, more recent review found that patients who have their collections drained by metal stents were 58% less likely to experience general adverse events, and 63% less likely to have post-procedural bleeding.^[11] One important strength of that review was the low level of heterogeneity regarding this particular outcome, which increases confidence in the results. However, owing to the small sample size, our study was not powered enough to detect significance.

Perhaps one advantage that stands in favor of plastic stents is the cost. With the marginal differences found in the literature regarding clinical outcomes and reinterventions, one might argue that cost containment should be considered before drawing conclusions on superiority. However, while affordability might facilitate patient access to treatment on an individual level, cost-effectiveness remains the parameter that determines the intervention's value on a mass scale. That said, a recent cost-effectiveness analysis that compared plastic stents against LAMS in WON showed an advantage for LAMS.^[16] The same was not true for PPC drainage, nonetheless,^[17] making the evaluation of cost/benefit ratio on a case-by-case basis the better approach in these patients.

In conclusion, our study, along with the current available evidence, suggests a slightly higher advantage of metal stents over plastic stents in terms of clinical success, need for rescue procedures, and a remarkable difference in terms of incidence of adverse events. Furthermore, our study provides empirical evidence that the different sub-types of LAMS perform similarly when compared in terms of the three aforementioned parameters. However, it is important to keep in mind that the current evidence is largely of moderate quality. To date, there has been only one randomized trial that compared metallic (FCSEMS) against

plastic stents,^[18] but it is worth noting that clinical success was considered a secondary outcome, meaning that the trial's sample size was not calculated to provide power in that context. Furthermore, the trial did not evaluate how the two stents compare in terms of reinterventions, and there is still a lack of conclusive evidence with regards to how LAMS perform against traditional FCSEMS, and how different commercially available LAMS perform against each other.

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Conflicts of interest

There are no conflicts of interest.

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