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2018-06-27

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Repository Citation

Fasullo MJ, Al-Azzawai Y, Kheder J, Abergel J, Wassef WY. (2018). Comparing efficacy of lumen-apposing stents to plastic stents in the endoscopic management of mature peripancreatic fluid collections: a single-center experience. Open Access Articles. <https://doi.org/10.2147/CEG.S167736>. Retrieved from <https://escholarship.umassmed.edu/oapubs/3517>

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Comparing efficacy of lumen-apposing stents to plastic stents in the endoscopic management of mature peripancreatic fluid collections: a single-center experience

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Introduction: Mature peripancreatic fluid collection (MPFC) is a known and often challenging consequence of acute pancreatitis and often requires intervention. The most common method accepted is the “step-up approach,” which consists of percutaneous drainage followed, if necessary, by minimally invasive retroperitoneal necrosectomy. Our paper aims to distinguish between plastic stents and lumen-apposing stents in the endoscopic management of MPFC in terms of morbidity, mortality, and haste of fluid collection resolution.

Methods: A retrospective analysis was performed at UMass Memorial Medical Center in patients with a diagnosis of MPFC. Utilizing medical records, clinical data, radiology, as well as endoscopic evidence, patients were differentiated by stent type used (plastic versus lumen-apposing) for the management of the MPFC. The primary outcome of the study was to assess the time to MPFC resolution following the placement of either plastic or lumen-apposing stents (on endoscopic ultrasound or computerized tomography scan) using a multivariate analysis with a logistic regression model.

Results: A total of 54 patients were included in this study from UMass Memorial Medical Center between 2012 and 2015. Twelve (22%) of these patients received lumen-apposing stents and 42 (78%) of these patients received plastic pigtail stents. For the lumen-apposing stent group, the mean interval between stent placement and resolution of MPFC was 57 days as compared to 102 days for plastic pigtail stents ($p=0.02$). The mean interval for placement/removal of lumen-apposing stents was 48 days as compared to 81 days for plastic pigtail stents ($p=0.01$). Stent migration was seen in 5 patients (11%) who received a plastic pigtail stent compared to 0 (0%) patients who received a lumen-apposing stent.

Discussion: Our study demonstrates that lumen-apposing stents result in a significant reduction in the interval between stent placement and MPFC resolution as well as the time from stent placement to removal, when compared to plastic pigtail stents, the prior standard-of-care. Our study reached similar conclusions regarding the number of stents placed. However, we did not find a significant difference between the complication rates, specifically peri- and postprocedural bleeding or perforation, between the 2 study groups, as demonstrated in prior papers.

Keywords: pancreas, lumen-apposing, necrosectomy, fluid collection, plastic pigtail stent

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Introduction

Mature peripancreatic fluid collection (MPFC) is a known and often challenging consequence of acute pancreatitis. Approximately 10% of cases of acute pancreatitis are complicated by peripancreatic fluid collections.¹ Under certain circumstances, they

can also manifest in the setting of chronic pancreatitis or pancreatic trauma. In 2013, the Atlanta classification of acute pancreatitis underwent notable changes to the taxonomy of cysts. Based on this new classification, the cystic lesions are divided into 3 subgroups.² The first being acute peripancreatic cystic lesions which occur in the setting of acute pancreatitis.^{3,4} These are typically extrapancreatic and contain no fluid, solid, or necrotic material. The second group is walled-off pancreatic necrosis which generally form late (>4 weeks) after an episode of acute pancreatitis. They are generally walled-off regions of pancreatic necrosis filled with liquid and/or solid components. The last type, the classic pancreatic pseudocyst, also develops late (>4 weeks) and contains only liquid elements.⁵ No acute peripancreatic cystic lesions were included in our study, as those are not generally considered to be amenable to drainage. Data suggest that ~40% of MPFC resolve without intervention. Traditionally, persistent MPFCs were managed by open surgical internal drainage, with considerable morbidity and mortality.^{6,7} Technological innovation has allowed for less-invasive options including percutaneous and endoscopic drainage.⁸ Endoscopic ultrasound (EUS)-guided transmural drainage is now a mainstay of minimally invasive intervention for managing MPFC. This technique has yielded similar success rates when compared to surgical intervention, with much lower rates of complications.⁹

Endoscopic treatment, in the form of drainage or necrosectomy, is indicated if complications are present such as necrosis, pain, and infection.¹⁰ Endoscopic management of MPFC typically involves placement of transmural stents to facilitate drainage and provide access. The most common method accepted is the “step-up approach,” which consists of percutaneous drainage followed, if necessary, by minimally invasive retroperitoneal necrosectomy.¹¹ The endoscopic techniques include cystoduodenostomy, cystgastrostomy, and cystjejunostomy. Cystoduodenostomy is performed when MPFCs are located in the head of the pancreas and abut the duodenum. Cystgastrostomy is typically done when the MPFCs are located in the body or tail of the pancreas and abut the stomach wall. Finally, cystojejunostomy is chosen when the MPFCs are very large and extend beyond the epigastric region, which creates a difficult point of access from the aforementioned techniques.¹² Both plastic pigtail stents and lumen-apposing stents are currently used for drainage.

Relatively few studies have compared different types of endoscopic management of MPFC (which includes walled-off pancreatic necrosis and pancreatic pseudocysts). Our paper aims to distinguish between plastic stents and lumen-apposing stents in the endoscopic management of MPFC in

terms of morbidity, mortality, and haste of fluid collection resolution.

Methods

Patient selection

A retrospective analysis was performed at UMass Memorial Medical Center in patients with a diagnosis of MPFC. All symptomatic patients were screened with computed tomography (CT) and/or magnetic resonance imaging (MRI) to confirm the presence of a MPFC that is amenable to drainage. Selected patients underwent EUS for characterization of the MPFC followed by cystgastrostomy between 2012 and 2016. All procedures were performed by a senior gastroenterologist at UMass trained in advanced endoscopy. Patients were characterized by age, sex, race, and cause of acute pancreatitis. Measurement of the individual MPFC was taken into consideration during statistical analysis as subgroups based on diameter were analyzed separately. Utilizing medical records, clinical data, radiology, as well as endoscopic evidence, patients were differentiated by stent type used (plastic versus lumen-apposing) for the management of the MPFC. As this was a retrospective study, patient consent was not obtained for this study, but protective measures were taken to provide confidentiality including working only at password protected hospital computers and deidentifying patients immediately upon data collection. The institutional review board at UMass Memorial Medical Center approved this study, with a waiver of patient informed consent according to HIPAA regulations HHS 45 CFR 46.101.

Procedure

Initial endoscopy was performed utilizing an EUS scope (Olympus America, Center Valley, PA, USA). Upon visualization of the fluid collection, the wall of the collection was interrogated using color Doppler imaging to exclude interposed vessels. The collection was then punctured under endosonographic guidance utilizing a 19-gauge needle (Cook Endoscopy, Winston-Salem, NC, USA). The initial puncture was used to drain the fluid, which sent for Gram stain and culture. The collection was then injected with full-strength ionic contrast and an image of the collection was obtained under fluoroscopy. Utilizing fluoroscopic guidance, a standard 0.035 inch Soft Jagwire (Boston Scientific Corp, Natick, MA, USA) was inserted into the collection and allowed to coil. In plastic stents group, the cystgastrostomy was then dilated with a 5-7-10 French catheter dilator (Cook Endoscopy) followed by 12–15 mm and 15–18 mm balloon dilators (Cook Endoscopy). Stents were placed to maintain access

and accomplish drainage according to the step-up approach. In the lumen-apposing stent group, a self-expanding 10 mm by 1 cm metal stent was deployed (AXIOS stent, Boston Scientific Corp) utilizing fluoroscopic, endoscopic view and EUS guidance.

For the plastic stent group, during the second visit, a diagnostic esophagogastroduodenoscopy scope was placed and the cystogastrostomy track was redilated with a 15–18 mm balloon. Upon dilation, an endoscope was inserted through the cystogastrostomy track into the necrotic cavity for the necrosectomy. The necrotic material was removed in a variety of techniques and accessories depending on its consistency. Snares, Roth nets (US Endoscopy, Mentor, OH, USA), and irrigation were used until all necrotic material was removed. At the completion of the debridement, plastic stents were added at the discretion of the endoscopist to maintain drainage. In the lumen-apposing stent group, the cavity was accessed, and debridement were performed in same fashion. Imaging studies were taken, and the procedure was repeated at variable time intervals at the discretion of the endoscopist until resolution of the collection. Once the fluid collection resolved, the patient was brought back for endoscopic stent(s) removal.

Definition of events and study outcomes

The primary outcome of the study was to assess the time to MPFC resolution following the placement of either plastic or lumen-apposing stents assessed by EUS or CT. Secondary outcomes included length of hospital stay following stent placement, time interval until stent removal, and quantity of endoscopic necrosectomies following stent placement.

Statistical analysis

Data were analyzed using the IBM SPSS version 24 statistical software for Mac (IBM Corporation, Armonk, NY, USA). Mean, percentages, and SDs of the mean were used to examine the demographics of the target population. Multivariate analysis using a logistic regression model was applied to primary and secondary end points to determine statistically significant differences between plastic and lumen-apposing stents. The threshold for statistical significance was set at p -values <0.05 , with odds ratios reported together with 95% confidence intervals.

Results

Demographics

A total of 54 patients were included in this study from UMass Memorial Medical Center between 2012 and 2015. Twelve

(22%) of these patients received lumen-apposing stents and 42 (78%) of these patients received plastic pigtail stents. Of our 2 target populations, the mean age of those who received lumen-apposing stents was 51.2, while those who received plastic pigtail stents was 50.4 with a p -value of 0.70. 8 (59%) of those who received lumen-apposing stents were male compared to 28 (67%), $p=0.748$. To ensure similar health status between the two study populations, several comorbidities were analyzed to determine the patients' Charlson Index score. The two groups demonstrated similar comorbidities as the plastic stent group had a Charlson Index score of 5.1 compared to 4.9 for the lumen-apposing group, $p=0.363$ (Table 1).

As far as the cause of initial acute pancreatitis, 22 (40%) were due to cholelithiasis, 15 (28%) alcohol-induced, 8 (15%) idiopathic, 2 (4%) triglyceride-induced, and 7 (13%) was in a category deemed "other" which included such etiologies as medication induced and trauma (Table 2).

Results

All endoscopic procedures were performed at UMass by senior gastroenterologists trained in advanced endoscopy. All 54 (100%) patients had successful placement of stents confirmed by EUS. Two (4%) of patients experienced complications from stent placement (postprocedural bleeding). One case of bleeding was from the lumen-apposing group while 1 was from the plastic stent, $p=0.671$. One case of bleeding was treated with endoscopic cauterization, while the other resolved spontaneously. Fifty-two (100%) patients received prophylactic antibiotics prior to the procedure. Stent migration was seen in 5 patients (11%) who received a plastic pigtail stent compared to 0 (0%) patients who received a lumen-apposing stent. The mean cyst size measured by CT,

Table 1 Demographics

Demographic	Lumen-apposing	Plastic	p -value
Total number	12	42	
Age (mean)	50.4	51.2	0.700
Sex (male)	8 (59%)	28 (67%)	0.748
Charlson index score	4.9	5.1	0.363

Table 2 Etiology of pancreatitis

Etiology of pancreatitis	Total number (%)
Alcohol	15 (28)
Cholelithiasis	22 (40)
Triglyceride	2 (4)
Idiopathic	8 (15)
Other	7 (13)

Table 3 Procedural results

Result	Lumen- apposing	Plastic	p-value
Successful stent placement	12 (100%)	42 (100%)	
Preprocedural antibiotics	12 (100%)	42 (100%)	
Periprocedural bleeding	1 (8%)	1 (2%)	0.671
Stent migration	0 (0%)	5 (11%)	0.811
Cyst size (mean, cm)	7.56	8.45	0.200
Number of stents placed	1.0	4.6	

MRI, or EUS was documented for both groups: 7.56 cm for those who received lumen-apposing stents and 8.45 cm for those who received plastic pigtail stents, with $p=0.2$ demonstrating no difference between the 2 groups. The size of the fluid collection used for our study was the largest diameter documented. The mean number of stents placed, per procedure, was 1.0 for those who received lumen-apposing stents and 4.6 for those who received plastic pigtail stents (Table 3).

Primary outcome

The primary outcome of this paper was the time in days for MPFC resolution. Resolution was defined as an MPFC diameter reduction $>80\%$ seen on CT, MRI, or EUS. For the lumen-apposing stent group, the mean interval between stent placement and resolution of MPFC was 57 days as compared to 102 days for plastic pigtail stents ($p=0.02$). Another relevant finding of this study was the time (days) between stent placement and removal. The mean interval for placement/removal of lumen-apposing stents was 48 days as compared to 81 days for plastic pigtail stents ($p=0.01$). This demonstrated a statistically significant mean reduction of 23 days between the 2 groups.

Secondary outcomes

There were several secondary outcomes of this study. The number of endoscopic necrosectomies required for each group was analyzed. Five (42%) of the 12 patients who received lumen-apposing stents required a subsequent necrosectomy compared to 23 (54%) of the 42 patients who received plastic pigtail stents ($p=0.24$). The interval between stent placement and patient discharge from the hospital was analyzed as well. Stent-discharge interval for the lumen-apposing stent group was 2.7 days compared to 2.8 days for the plastic pigtail stent, $p=0.9$ (Table 4).

A subgroup analysis was performed on all patients who required a necrosectomy following stent placement. For those who received a necrosectomy, the mean age was 51.8 years compared to 52.2 for those who did not receive

Table 4 Primary and secondary outcomes

Outcome	Lumen- apposing	Plastic	p-value
Stent placement – resolution (days)	57	102	0.02
Stent placement – removal (days)	48	81	0.01
Stent placement – discharge (days)	2.7	2.8	0.90
Number of necrosectomy	5 (42%)	23 (54%)	0.24

Note: Bold figures indicate statistical significance result, $p<0.05$.

Table 5 Necrosectomy demographics

Demographic	Necrosectomy	No necrosectomy	p-value
Age	51.8	52.2	0.90
Sex (male)	22 (61%)	12 (39%)	0.40
Sex (female)	9 (50%)	9 (50%)	0.40
Size (mean, cm)	8.4	7.7	0.20
Biliary pancreatitis	15 (53%)	13 (47%)	0.17
Nonbiliary pancreatitis	16 (50%)	16 (50%)	0.18

a necrosectomy, $p=0.9$. Regarding gender, 22 (61%) of 36 males received a necrosectomy, $p=0.4$ along with 9 (50%) of 18 females, $p=0.4$. The size of the MPFC also did not affect the need for necrosectomy. The maximum MPFC diameter for those who received a necrosectomy was 8.4 compared to 7.7 cm, $p=0.2$. Finally, there was no clear relationship between the underlying cause of pancreatitis and the need for necrosectomy portrayed by 15 (53%) of 28 of patients with biliary causes of pancreatitis requiring a necrosectomy, $p=0.17$, compared to 16 (50%) of 32 nonbiliary causes, $p=0.18$ (Table 5).

Discussion

Lumen-apposing stents, including AXIOS (Boston Scientific), are novel lumen-to-lumen self-expandable metallic stents with guided electrocautery insertion designed for enteric drainage of MPFCs.¹³ The large diameter of the stent also provides access for repeated endoscopic necrosectomy without the need for stent replacement. Our study demonstrates that lumen-apposing stents result in a significant reduction in the interval between stent placement and MPFC resolution as well as the time from stent placement to removal, when compared to plastic pigtail stents, the prior standard-of-care. One of the first studies that compared these 2 types of stents was Gornals et al,¹⁵ which demonstrated a higher complication rate and a greater number of stents placed when using pigtail stents compared to lumen-apposing stents. The likely explanation for these findings is due to the presence of a lumen-to-lumen anchorage in lumen-apposing

stents along with a larger diameter and more durable material, which significantly reduce leakage, migration, and tissue trauma.¹⁴ Our study reached similar conclusions regarding the number of stents placed. However, we did not find a significant difference between the complication rates, specifically peri- and postprocedural bleeding or perforation, between the 2 study groups. One final difference between our studies was while our study did not have a defined interval to imaging follow-up, this prospective study used a standardized 6-month interval to follow-up.^{15,16}

A recent meta-analysis by Navaneethan et al¹⁷ that included 698 patients and found no difference in treatment success, adverse events, or recurrence rates between MPFC drained with plastic stents vs metal stents. A similar retrospective study comparing plastic stents to lumen-apposing stents by Mukai et al¹⁸ compared plastic pigtail stents to both lumen-apposing stents and a similar novel metal stent, Hanaro (MI Tech, Seoul, Korea), in the drainage of MPFC. Like Navaneethan et al¹⁷ no differences were found in rates of technical success, clinical success, and adverse events between plastic stents and lumen-apposing stents.¹⁸ Both demonstrate results which contrast with our study. One hypothesis for these observed differences could relate to the timeframe between symptom onset and endoscopic intervention. Another theory for these differences could relate to the number of stents used in each of these studies, which are not mentioned.

A meta-analysis in 2017 by DeSimone et al,¹⁹ comparing lumen-apposing metal stents, reported stent migration occurring in ~19% of stents placed. This varies significantly with our study which had 0 (0%) cases of stent migration in the lumen-apposing metal stent group. Possible explanations for this discrepancy could be a smaller patient population in our study, additional stent types being examined in the meta-analysis, and procedural complications that can vary based on the endoscopist's experience. With regard to the number of stents placed, our center used a similar number of stents compared to a recent retrospective analysis by Siddiqui et al,²⁰ with an average of 1 lumen-apposing stent and 2 plastics. While we share the same number of lumen-apposing stents, our center used an average of 4.1 plastic stents, likely representing endoscopist preference as no standardized models have demonstrated an ideal number of stents needed to facilitate drainage.²⁰

One interesting finding in our study was that although lumen-apposing stents demonstrated a significant reduction in time until MPFC regression, there was no difference in the number of endoscopic necrosectomies performed compared

to plastic pigtail stents. A necrosectomy involves direct endoscopic debridement of solid debris found in necrotic MPFC that fails to completely resolve following stent placement. It is generally performed when the infected pancreatic necrosis is walled-off and delineated with at least partial liquefaction and encapsulation and, also, if there is intractable pain, visceral obstruction, or infection.²¹ We did not identify any demographics, including age, sex, size of MPFC or pancreatitis etiology, that was predictive of an increased likelihood of requiring necrosectomy. We postulate that this is likely due to the fact that necrotic tissue must be debrided regardless of the successful reduction in the fluid content of a MPFC.^{22,23}

Our study has several limitations. First, because it is a retrospective review, information collection is incomplete, particularly regarding follow-up evaluation. Next, our cohort was quite homogenous as far as the etiology of pancreatitis is concerned. Also, most patients undergoing endoscopic intervention were not evaluated by a surgeon before their drainage, so we cannot be certain that all management options were adequately considered. Next, it is difficult to account for differences in the endoscopists skill and experience. Finally, one major bias this paper has is that there was no defined interval between stent placement and time to image follow-up. This creates bias in the ability of the gastroenterologist to schedule follow-up sooner, which would appear to lead to faster time to resolution. This would explain why they required the same number of procedures but were still removed earlier. This issue also leads to bias on one of our secondary outcomes of stent migration, where if stents were left in longer they may have a higher rate of migration.

Conclusion

We demonstrated a significant difference in the outcomes of MPFC drainage between lumen-apposing stents and plastic pigtail stents. We have portrayed a clear reduction in the interval to MPFC resolution as well as a reduction in the time until stent removal when lumen-apposing stents were used. Another interesting finding was the significantly lower rate of stent migration with lumen-apposing stents. Lumen-apposing stents not only lead to a decrease in the number of interventions but also, and more importantly, lead to decreased time that a patient will suffer from a MPFC. We hope that our study will be followed by more prospective randomized controlled studies to elucidate the advantages of lumen-apposing stents over plastic stents for MPFC drainage.

Disclosure

The authors report no conflicts of interest in this work.

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