Comparative outcome of single versus two double-pigtail stents for endoscopic drainage of pancreatic fluid collections with minimal necrosis: a retrospective analysis

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Abstract

Background: **Endoscopic ultrasound (EUS)-guided cystogastrostomy is the treatment of choice for managing symptomatic pancreatic fluid collections (PFC). However, studies on the number of stents for optimal drainage of PFCs are limited. Hence, the present study was conducted to compare the outcome of single versus two double-pigtail stents for endoscopic drainage of PFCs.**

Methods: **This is a single-center, retrospective analysis of patients undergoing endoscopic drainage of PFCs with minimal necrosis (pseudocyst or walled-off necrosis with <30% solid content) at a tertiary center in South India from October 2020 to October 2022. Post-procedure, patients were followed up for clinical improvement, and stents were removed after documentation of cyst size reduction on imaging.**

Results: **Sixty-three patients (82.5% males, median age: 34 years) fulfilling the selection criteria were included. For single stent placement (n = 47), stents of size 8.5 Fr or 10 Fr were used, while for placement of two stents (n = 16), 7 Fr stents were used. The technical success rate was 100%. Intraprocedural and early post-procedural adverse events (all mild to moderate) were comparable between the groups (17.0% with single stent vs. 25.0% with two stents, p = NS). Clinical success was achieved in 93.6% of patients, with no difference between both groups. Three patients in the single stent group required additional procedures. All patients underwent successful stent removal after a median follow-up of 14 weeks.**

Conclusion: **A single pigtail stent of 8.5 Fr or 10 Fr size for EUS-guided cystogastrostomy provides efficacy and safety similar to that of two stents.** (Acta gastroenterol. belg., **2024,** 87, **1-5**).

Keywords: Endoscopic ultrasound, pseudocyst, cystogastrostomy, chronic pancreatitis, endoscopic stenting.

Introduction

Pancreatic fluid collections (PFC) are divided into two major types based on their contents - walled-off necrosis (WON) and pancreatic pseudocysts (1). WON is seen mostly after an attack of necrotizing pancreatitis, while pseudocyst can be associated with both acute as well as chronic pancreatitis. The indications of drainage include PFCs symptomatic with pain, infection, and pressure due to compression of adjacent structures leading to gastric outlet obstruction or biliary obstruction (1).

Endoscopic drainage is preferred over surgical and percutaneous drainage as it establishes internal drainage without the morbidity associated with surgery (1). The choice of a stent for endoscopic management depends on the type of PFC (2), with metal stents being preferred for WON and plastic stents for pseudocysts (3). In a previous meta-analysis, metal stents were associated with a higher clinical success rate than plastic stents in WON and pseudocyst (4). However, two subsequent randomized trials reported no significant difference in treatment outcomes between lumen-apposing metal stents and plastic stents (5,6). Also, the subgroup analysis in the meta-analysis for pseudocyst was limited by a small number of studies (4). Hence, plastic stents may not inferior to metal stents for drainage of PFCs.

There is a conflict in current practice regarding the number and size of plastic stents for EUS-guided drainage of PFCs. The Indian guidelines state that double-pigtail plastic stents (DPPS) provide adequate drainage with an acceptable safety profile for both pseudocysts and WON (3). However, they do not mention the number of stents. The Asian EUS guidelines recommend one to two DPPS for pseudocyst drainage (7). To date, no study has investigated the number of plastic stents for optimal drainage of a PFC. Hence, the present study aimed to compare the outcome of a single or two DPPS for PFCs with minimal necrosis.

Methods

Study design and patient selection

This was a single-center, retrospective observational study of patients undergoing endoscopic drainage of PFCs at a tertiary health care center in South India from October 2020 to October 2022. Written consent was taken from all the patients prior to the procedures. The present study was conducted as per the Declaration of Helsinki.

All patients in the age group of 18-80 years with pancreatic pseudocysts or WON with less than 30% necrotic contents undergoing endoscopic drainage with plastic stent placement were included in this study. Exclusion criteria included: (i) WON with > 30% solid content, (ii) multiseptated cysts, (iii) use of metal stent,

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(iv) presence of associated pancreatic ascites, and (v) lack of clinical follow-up.

Management protocol

Endoscopic drainage of PFC was performed by three experienced endoscopists with the patient under moderate sedation using midazolam and pentazocine in left lateral position. Periprocedural antibiotics (third-generation cephalosporins) were used in all patients for 3 to 5 days. An oblique-viewing linear echoendoscope (GF-UCT 180 with Olympus EU-ME2 processor) was used for all the procedures. After identification of the collection and surrounding vasculature using the color Doppler, the lesion was punctured under real-time view using a 19-G needle and confirmed by aspiration of fluid. A 0.035-inch guidewire was passed into the cavity of the collection under both EUS and fluoroscopic view, and 2-3 coils were formed to prevent accidental dislodgement. Initial dilatation of the tract was attempted by mechanical dilators (Soehendra® Biliary Dilation Catheter) of size varying from 5 to 6 Fr. In case of failure of passage of mechanical dilator, electrocautery dilatation was attempted using a 6 Fr cystotome, or needle knife in case of unavailability or failure of cystotome. Further dilatation was attempted using either a dilatation catheter of 10 Fr size or a balloon dilator of size 10-11-12 mm (Cook® Hercules Dilation Balloon). The second guidewire was placed using the outer pushing catheter of the one-action stent introduction system before the deployment of the first stent or using a sphincterotome under endoscopic vision after placement of the first stent. DPPS (Shaili endoscopy, India) of size varying from 7 Fr to 10 Fr were deployed under EUS and fluoroscopic guidance. The size and number of stents were at the discretion of the endoscopists. Patients were given periprocedural 3rd generation cephalosporins for 5 days. After 2-3 months, patients underwent a screening CT to assess the resolution of the PFC. In case of resolution, stents were removed.

Outcome measures

The study's primary outcome was clinical success, defined as improvement in the initial presenting symptoms, along with a reduction of the size of the PFC to less than 2 cm on follow-up imaging done at 8-12 weeks. The secondary outcomes included technical success and procedure-related adverse events (AE). Technical success was defined as the successful placement of the stent into the PFC with visible drainage on endoscopic view. We also recorded the intraprocedural and post-procedural AE, which were graded as per the ASGE lexicon (8).

Statistical analysis

Continuous variables were expressed as median with range. Frequencies and percentages were used to express categorical variables. The Mann-Whitney U test was used to compare continuous variables between the groups. The Chi-square test or Fischer's exact test was used to compare categorical data between the groups as appropriate. Statistical significance was defined as a p-value < 0.05. All statistical analyses were performed using SPSS (version 20.0; SPSS Inc., Chicago, IL, USA).

Table 1. — **Baseline characteristics of the patients included in the present study, along with details of the pancreatic fluid collection**

Parameters	Total (n = 63)	Single stent (n = 47)	Two stents (n = 16)	p-value
Age, in years	34 (18-56)	35 (18-55)	31 (21-56)	0.420
Male	52 (82.5%)	39 (83.0%)	13 (81.3%)	1.000
Pancreatitis				0.747
Acute	17 (27.0%)	12 (25.5%)	5 (31.3%)	
Chronic	46 (73.0%)	35 (74.5%)	11 (68.8%)	
Etiology				0.610
Alcohol	37 (58.7%)	29 (61.7%)	8 (50.0%)	
Biliary	11 (17.5%)	7 (14.9%)	4 (25.0%)	
Idiopathic	15 (23.8%)	11 (23.4%)	4 (25.0%)	
Indication				0.702
Pain	57 (90.5%)	42 (89.4%)	15 (93.8%)	
GOO	4 (6.3%)	3 (6.4%)	1 (6.3%)	
Jaundice	2 (3.2%)	2 (4.3%)	0 (0.0%)	
Location				0.320
Body	53 (84.1%)	38 (80.9%)	15 (93.8%)	
Head	6 (9.5%)	6 (12.8%)	0 (0.0%)	
Tail	4 (6.3%)	3 (6.4%)	1 (6.3%)	
Size, in mm	90 (65 -150)	85 (65-150)	105 (86-125)	0.000
Wall thickness, in mm	4 (3-6)	4 (3-6)	4 (3-6)	0.822

GOO: Gastric outlet obstruction

Results

Baseline characteristics of the patients

A total of 86 patients underwent endoscopic drainage, of which 63 fulfilled the selection criteria. Table 1 shows the baseline characteristics of the included patients. The median age of the patients was 34 (range: 18-56) years, with 82.5% being males. Most patients had underlying chronic pancreatitis (73%). None of the patients had disconnected pancreatic duct syndrome as assessed by magnetic resonance cholangiopancreatography. Alcohol was the commonest etiology of pancreatitis (58.7%), followed by idiopathic (23.8%) and biliary (17.5%). The commonest indication for endoscopic drainage of the PFC was pain (90.5%). Five (9.5%) patients required drainage in view of obstructive symptoms [3 for gastric outlet obstruction (GOO) and 2 for biliary obstruction]. Most of the symptomatic PFCs were located in the pancreatic body region (84.1%), with a median size of 90 (65-150) mm and median wall thickness of 4 (3-6) mm. There was no difference between the groups (single vs. two stents) except for the size of the collection, which was significantly higher in cases undergoing placement of two stents.

Details of endoscopic drainage

Table 2 summarizes the details of the endoscopic procedure and the outcome of patients. Most patients underwent endoscopic drainage through the transgastric route (96.8%), with transduodenal being performed in two cases with collection in the head region, one having GOO and the other having biliary obstruction. Electrocautery was not used in the majority of cases. The primary tract dilatation was performed by a mechanical dilatation catheter in 61.9% of cases, followed by cystotome in 25.4% of cases, and needle knife in 12.7% of cases. Further tract dilatation was performed by dilatation catheters of increasing size in 65.1% of cases and by balloon in 34.9% of cases. Stents of size 7 Fr x 7 cm were used in cases with two stent placements, while stents of size 8.5 Fr x 8 cm or 10 Fr x 10 cm were used for cases with single stent placement.

Outcomes

Technical success was achieved in all cases despite a few difficulties in three cases, including difficulty in primary tract dilatation in one case requiring multiple punctures, shearing of the wire with the need to re-puncture in one, and a mal-deployed stent into the pseudocyst cavity in one. In the mal-deployment case, an additional stent was placed immediately, with tract dilatation and endoscopic retrieval performed after 48 hours. Periprocedural adverse events were seen in 12 (19%) cases, all of which were mild. The commonest AE was increased pain intensity, requiring additional analgesics, which settled over the next 24 to 48 hours. Two patients developed self-limited bleeding after tract dilatation, which was controlled with balloon tamponade. Another two patients developed post-procedural fever, which subsided over the next 48 to 72 hours.

Clinical success was achieved in 93.6% (59/63) of cases, with a comparable rate between single and two stents (p = 0.985). The four cases with clinical failure had a relapse of the cyst after a good initial response requiring percutaneous drainage in two patients and additional stent placement in another two. All the other patients underwent successful stent removal after a median duration of 14 (8-24) weeks.

Table 2. — **Details of the endoscopic procedure and the outcome of patients included in the present study**

Parameters	Total (n = 63)	Single stent (n = 47)	Two stents (n = 16)	p-value
Transgastric drainage	61 (96.8%)	45 (95.7%)	16 (100%)	1.000
Primary tract dilatation				0.649
Dilatation catheter	39 (61.9%)	28 (59.6%)	11 (68.8%)	
Cystotome	16 (25.4%)	12 (25.5%)	4 (25.0%)	
Needle knife	8 (12.7%)	7 (14.9%)	1 (6.3%)	
Further tract dilatation				0.000
Dilatation catheter	41 (65.1%)	41 (87.2%)	0 (0.0%)	
Balloon	22 (34.9%)	6 (12.8%)	16 (100%)	
Stent size				0.000
10 Fr x 5 cm	22 (34.9%)	22 (46.8%)	0 (0.0%)	
8.5 Fr x 8 cm	25 (39.7%)	25 (53.2%)	0 (0.0%)	
7 Fr x 7 cm	16 (25.4%)	0 (0.0%)	16	
Adverse events				0.116
Self-limited bleed	2 (3.2%)	2 (4.3%)	0 (0.0%)	
Maldeployment	1 (1.6%)	0 (0.0%)	1 (6.2%)	
Fever	2 (3.2%)	2 (4.3%)	0 (0.0%)	
Pain abdomen	4 (6.3%)	2 (4.3%)	2 (12.5%)	
Persistent vomiting	3 (4.8%)	3 (6.4%)	0 (0.0%)	
Clinical success	59 (93.6%)	44 (93.6%)	15 (93.7%)	0.985
Stent removal, in weeks	14 (8-24)	14 (8-24)	13 (9-20)	0.227

Discussion

EUS-guided drainage is the standard of care in managing PFCs, including pancreatic pseudocysts. The number of plastic stents for the optimal drainage of PFC remains a topic of debate. The present study compared patients with PFC undergoing endoscopic drainage and reported an overall clinical success rate of 93.6%, with no difference between those who underwent drainage with a single stent or two stents. The adverse event rate and time to stent removal were also comparable (P=NS). This points to the fact that collections with clear contents can be conveniently drained by a single stent without the risk of slippage of the guide wire during the exchange, and also increases efficiency by reducing the procedural duration and the need to use multiple accessories.

Ghoneem et al. conducted a single-arm study on the outcome of using one 10 Fr double-pigtail stent for the management of pancreatic pseudocysts in 37 patients (9). Technical and clinical success was achieved in 100% and 91.4% cases, respectively. In the largest retrospective study of 122 patients with uncomplicated pancreatic pseudocysts by Bang et al., 29.5% of patients had single stent insertion (either 7 Fr or 10 Fr) (10). On multivariate logistic regression analysis, neither the stent size (OR 1.54, 95% CI: 0.23-10.4) nor the placement of a single stent (OR 1.15, 95% CI: 0.25-5.25) predicted the need for more than one intervention. In another study by Lin et al., including both WON and pseudocysts, clinical success was achieved in 93.9% (46/49) of those with single-stent drainage versus 97.4% (37/38) for multiple-stent drainage (P = 0.799) (11). Also, the clinical success was comparable between stent sizes of ≤ 8.5 Fr and 10 Fr. Hence, in patients with PFC, especially pseudocyst, the size and number of stents may not be a major predictor of clinical success.

The main purpose of single stent insertion is to reduce the procedure duration while reducing the use of multiple accessories and the loss of access during the exchange procedures. One alternative method that could help reduce the use of multiple accessories is the use of 10 Fr cystotome. Using a 10-Fr cystotome allows puncture as well as tract dilatation in the same setting. This obviates the need for a dilatation catheter of 10 Fr, reducing procedural duration and the use of multiple accessories. However, we did not use a 10 Fr cystotome due to the unavailability of the same at our center.

In the present study, periprocedural mild adverse events were seen in 12 (19%) cases, of which self-limited pain abdomen was the most common in 4 (6.3%), followed by persistent vomiting in 3 (4.8%) and fever and self-limited bleed in 2 (3.2%) patients each. In the study by Ghoneem et al., minor AEs were reported in 8.6% of cases (post-procedure abdominal pain and fever) (9). AEs were seen in 14.4% of patients in the study by Lin et al., with secondary infection being the most common (11/13). However, there was no significant difference in the infection rates between single stent and multiple stent groups (p=0.134) and also with respect to the size of DPPS (p=0.138) (11). In a meta-analysis by Yoon et al., the incidence of AE with plastic stents in PFC varied from 8.0% to 36.8% in the included studies, with a pooled incidence of 29.7% (13). Thus, the incidence of AE with a single stent for PFC remains comparable to the previously reported rates.

Concerning the need for intervention, 4.7% of the patients with single stent placement had a relapse of the pseudocyst after a good initial response. In a previous meta-analysis, recurrence of PFC was reported in 0-3.4% of patients with plastic stent placement, which included patients with both single and two stents (13). Ghoneem et al. reported a recurrence rate of 5.7% with single stent placement (9). Thus, the recurrence of the pseudocyst, requiring reintervention, remains low with single stent placement and is comparable to previously reported rates.

The recommended stent dwell time for LAMS or metal stents is 4-6 weeks (3,7,14). However, only the Korean guideline recommends a stent dwell time of 8 weeks for plastic stents (14). Prior to stent removal, ERCP is done to assess for pancreatic duct integrity. With an intact main pancreatic duct on ERCP, all transmural stents should be removed, while in DPDS, the plastic stents are left in situ indefinitely (5). In the present study, patients underwent stent removal after a median duration of 14 (8-24) weeks. However, ERCP was not done in these cases due to financial constraints.

The primary tract dilatation after the initial needle puncture can be done by either electrocautery or non-electrocautery method. In the present study, primary tract dilatation was done using a dilatation catheter of size 5-6 Fr in 61.9% of the cases. However, Ghoneem et al. used electrocautery dilatation for all the cases in their study (9). In a previous study, Kitamura et al. compared electrocautery vs. non-electrocautery dilation catheters for EUS-guided PFC drainage (15). There was no difference in the technical success, clinical success, and incidence of AE between both groups. However, the procedure time in the electrocautery group was significantly shorter than the non-electrocautery group (30 ± 12 min vs. 52 ± 20 min, P < 0.001). The authors concluded that using an electrocautery dilation catheter may reduce the procedure time without increasing the risk of AE. However, the study was underpowered to show a difference in the risk of AE. We could not compare the difference in the procedural duration between electro-cautery vs. non-electrocautery dilation catheters, as the procedural time was not recorded previously.

The present study is one of the few studies comparing the outcome of single vs. two stents for EUS-guided drainage of the PFCs with minimal necrosis. However, there are multiple limitations to the present study, the first being the retrospective design with a small sample size. Secondly, there was a significant difference in the size of the PFC between the groups. Thus, the endoscopists may have been biased to put two stents in larger collections and a single stent in smaller collections. Third, although,

theoretically, the placement of a single stent will reduce the procedural duration, we could not compare the procedural time between the placement of single or two stents. Lastly, long-term data regarding recurrence after stent removal was not available.

To conclude, endoscopic drainage of PFCs with minimal solid contents using a single pigtail stent of 8.5 Fr or 10 Fr size for EUS-guided cystogastrostomy provides similar efficacy and safety as using two stents. Using a single stent may reduce the procedural duration, use of multiple accessories, and loss of access during the exchange procedures. Further randomized studies are required to validate the findings of the present study.

Conflicts of interest

Authors declare no conflict of interest for this article.

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