Impact of transmural plastic stent on recurrence of pancreatic fluid collection after metal stent removal in disconnected pancreatic duct: a randomized controlled trial

GRAPHICAL ABSTRACT

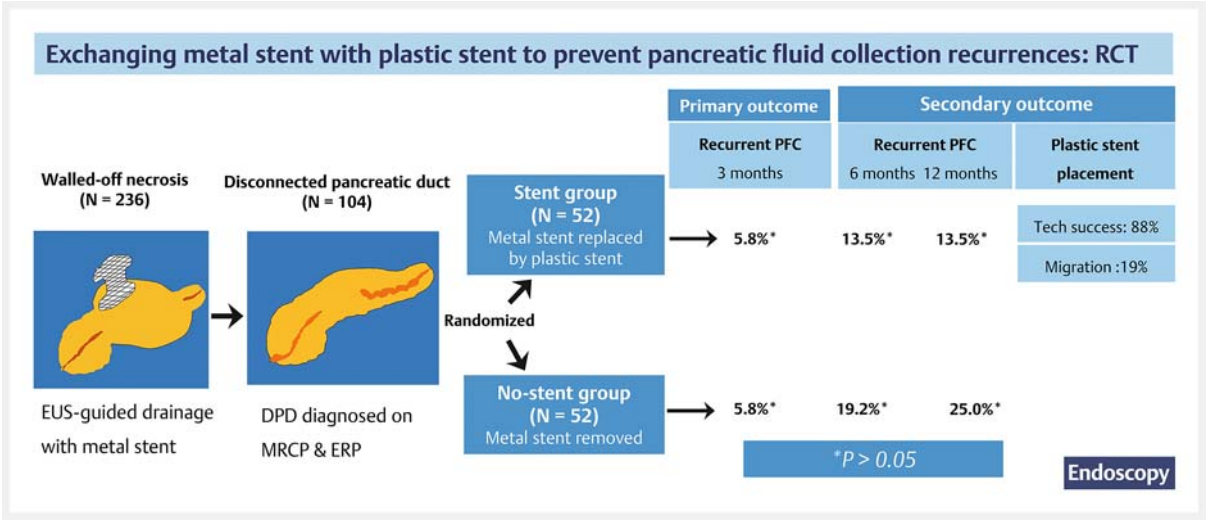

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Fig. 1 s, Tables 1 s–3 s
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ABSTRACT

Background Disconnected pancreatic duct (DPD) after development of walled-off necrosis (WON) predisposes to recurrent (peri)pancreatic fluid collection (PFC). In this randomized controlled trial, we compared plastic stents with no plastic stent after removal of a large-caliber metal stent (LCMS) on incidence of recurrent PFCs in DPD.

Methods Consecutive patients with WON who underwent endoscopic ultrasound (EUS)-guided drainage with LCMS between September 2017 and March 2020 were screened for eligibility. At LCMS removal (4 weeks after drainage), patients with DPD were randomized to plastic stent or no stent groups. The primary outcome was incidence of recurrent PFC at 3 months. Secondary outcomes were technical success of plastic stent deployment, adverse events, stent migration, and recurrence of PFC at 6 and 12 months.

Results 236 patients with WON underwent EUS-guided drainage using LCMS, and 104 (males 94, median age 34 years (interquartile range [IQR] 26–44.7) with DPD were randomized into stenting (n = 52) and no-stenting (n = 52) groups. Plastic stent deployment was successful in 88.5 %. Migration occurred in 19.2 % at median follow-up of 8 months (IQR 2.5–12). Recurrent PFCs occurred in six patients at 3 months (stent n = 3, no stent n = 3). There was no significant difference in PFC recurrence between the two groups at 3, 6, and 12 months. Reintervention was required in seven patients with recurrent PFCs, with no significant difference between the two groups.

Conclusion In patients with WON and DPD, deployment of plastic stents after LCMS removal did not reduce recurrence of PFC.

Introduction

Endoscopic ultrasound (EUS)-guided drainage is preferred over surgery or interventional radiology-assisted drainage procedures for the management of walled-off necrosis (WON) [1–3]. Dedicated large-caliber metal stents (LCMSs) are increasingly being utilized for the management of WON [4]. Although, recent evidence indicates similar efficacy between metal and plastic stents, LCMSs provide wide cystoenteric communication, and endoscopic necrosectomy is easier with LCMSs [5]. Therefore, LCMSs are preferred over plastic stents for drainage in patients with WON. However, concerns regarding recurrence of pancreatic fluid collections (PFCs) after the removal of metal stents remain unaddressed. Disconnected pancreatic duct (DPD), defined as loss of continuity of the pancreatic duct, with isolation of viable upstream parenchyma, has been implicated as one of the major determinants for the development of recurrent PFCs after the removal of stents [6–8]. DPD is commonly observed in patients with WON suggesting that a substantial proportion may be predisposed to recurrent PFCs after the removal of LCMSs [9]. Indwelling plastic stents have been shown to reduce the recurrence of PFC especially in the presence of DPD [8, 10–13]. Unlike plastic stents, which can be kept in situ for a long duration, early removal of LCMSs is advocated to mitigate the risk of adverse events such as bleeding and buried stent syndrome [14]. In such a scenario, the replacement of an LCMS with one or more transmural plastic stents may potentially prevent the recurrence of a PFC [15].

In this study, we aimed to compare the effect of replacing an LCMS with a plastic transmural stent versus no plastic stent on the incidence of recurrent PFCs in patients with DPD after resolution of WON.

Methods

Consecutive patients with WON, defined as per the revised Atlanta guidelines [16], who underwent EUS-guided drainage between September 2017 and March 2020 at a tertiary care center were screened for eligibility into the trial. The eligibility criteria for inclusion into the study were resolution of WON drained using an LCMS and the presence of DPD. The presence of DPD was confirmed on magnetic resonance cholangiopancreatography (MRCP) and endoscopic retrograde pancreatography (ERP) at 4 weeks prior to LCMS removal. Exclusion criteria were as follows: 1) age < 18 years; 2) normal-appearing pancreatic duct or absence of DPD on imaging; 3) imaging suggestive of chronic pancreatitis; 4) spontaneous migration of the LCMS before scheduled removal; and 5) refusal to provide written informed consent and comply with the study protocol.

After obtaining written informed consent, eligible patients were randomized in a 1:1 ratio into two groups. In the stent group, one or more transmural plastic stents (7 Fr, 5 cm) were placed after removal of the LCMS, and in the no-stent group, the LCMS was removed without replacement with a plastic stent.

The study was approved by the institutional review board committee and the protocol was finalized by multidisciplinary team (see **Fig. 1 s** in the online-only Supplementary material). All authors had access to the study data and approved the final version of the manuscript.

Randomization

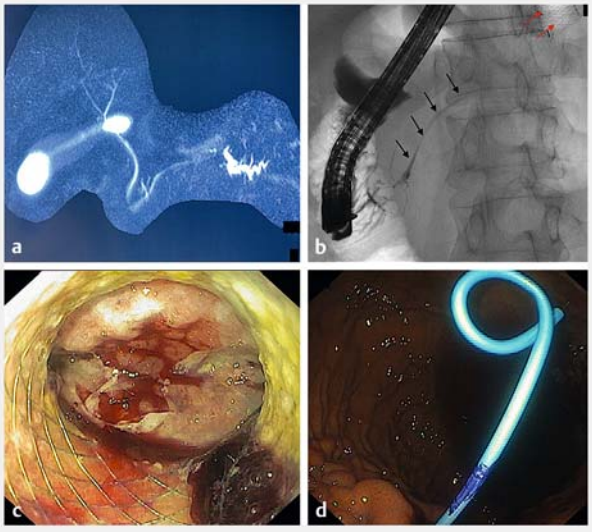
The study participants were randomized in a 1:1 ratio to either the stent group or the no-stent group after confirming the resolution of WON and the presence of DPD. Computer-generated block randomization was performed, and codes were placed in sequentially numbered sealed envelopes. The envelopes were opened and revealed to the endoscopist at the time of removal of the LCMS.

Endoscopic drainage

WON, diagnosed on cross-sectional imaging including computed tomography (CT) or magnetic resonance imaging (MRI), underwent EUS-guided drainage with LCMS placement (Nagi; Taewoong Medical, Gyeonggido, South Korea), as per the standard technique [17]. The collections occupying the head and neck of the pancreas were classified as proximal collections, and those occupying the body and tail were classified as distal collections. A “step-up approach” was followed in patients with persistent symptoms, as previously described [9, 17].

MRI with MRCP was performed to confirm the resolution of WON and document the presence or absence of DPD prior to

the scheduled removal of the LCMS at 4 weeks. Subsequently, ERP was first performed to reconfirm DPD suspected on MRCP. Standard measures to prevent post-ERP pancreatitis, including rectal nonsteroidal anti-inflammatory drugs and intravenous fluids, were implemented in all patients in the absence of an obvious contraindication. The technique of ERP to confirm DPD was as follows. The pancreatic duct was opacified with contrast injection using a standard triple-lumen sphincterotome (CleverCut 3V [Olympus, Tokyo, Japan] or Tritome [Boston Scientific, Marlborough, Massachusetts, USA]) and contrast was injected very gently to outline the duct without any excessive pressure. Occasionally, wire-guided cannulation of the pancreatic duct was performed when standard cannulation failed. The sphincterotome was gently pushed over the guidewire and contrast injected to opacify the pancreatic duct. Sphincterotomy and deep catheterization were avoided in patients with DPD. Patients with DPD confirmed on both MRCP and ERP were randomized into the stent and no-stent groups. During the same session of ERP, the LCMS was removed. In the stent group, the LCMS was replaced with one or two plastic stents (7 Fr, 5 cm; Wilson-Cook Endoscopy, Winston-Salem, North Carolina, USA), whereas in the no-stent group the LCMS was removed without replacement with plastic stents (▶ **Fig. 1a–d**).



▶ **Fig. 1** Documentation of disconnected duct on both magnetic resonance cholangiopancreatography (MRCP) and endoscopic retrograde pancreatography (ERP) followed by large-caliber metal stent (LCMS) removal and plastic stent placement. **a** MRCP showing non-projection of the main pancreatic duct in the body region, with dilated isolated upstream pancreatic duct. **b** ERP showing normal-diameter pancreatic duct in the head and proximal body, with non-visualization of the upstream duct (black arrows) and biflanged metal stent in situ (red arrows). **c** Endoscopic view through the LCMS showing collapsed cavity. **d** After LCMS removal, transmural plastic stenting into the cavity.

Follow-up

All patients were evaluated at 3 months, 6 months, and every 6 months thereafter. Evaluation at each visit included symptoms, blood sugar, and imaging to look for recurrent PFCs. Transabdominal ultrasonography was the primary imaging modality used to document the recurrence of PFCs. In symptomatic patients or when transabdominal ultrasonography was deemed to be suboptimal, cross-sectional imaging including CT or MRI were performed. X-ray of the abdomen was performed at each visit to confirm the presence of transmural plastic stents in situ. Instances of spontaneous stent migration were systematically recorded. Subsequent X-rays were avoided in patients with spontaneous stent migration detected on imaging.

Management of recurrent fluid collections

The management of recurrent PFCs was primarily based on the presence of symptoms and feasibility of EUS-guided drainage. Surgery or percutaneous drainage were considered in endoscopically non-accessible collections. Asymptomatic cases and those with small PFCs (< 4 cm) were managed conservatively and followed as per standard protocol (i. e. symptom evaluation and imaging at 3 months, 6 months, and 6 monthly thereafter).

Definitions

DPD was defined as a nonprojected segment of pancreatic duct with isolated portions of upstream duct on MRCP (▶ **Fig. 1a**). On ERP, complete "cut-off" of the main pancreatic duct with no contrast opacification of upstream pancreatic duct was considered to be diagnostic of DPD (▶ **Fig. 1b**) [6].

Resolution of WON was defined as complete disappearance of the PFC or reduction down to a size of < 2 cm on MRI.

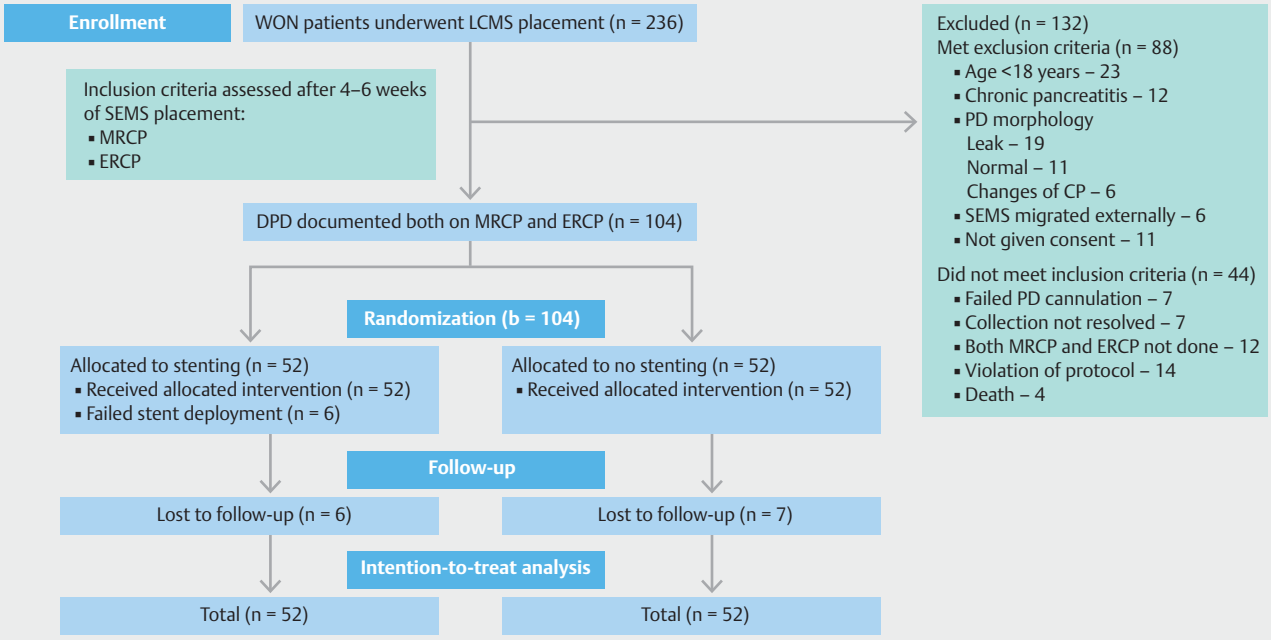
Recurrent PFC was defined as the occurrence of a new fluid collection at the same location after prior documented resolution of WON during follow-up [18].

Outcomes

The primary outcome of the study was the incidence of recurrent PFC between the two groups at 3 months after the removal of the LCMS. Secondary outcomes included technical success of plastic stent placement, adverse events associated with plastic stent deployment, migration of plastic stent, and recurrence of PFC at 6 and 12 months.

Sample size calculation

The primary analysis of the study was to evaluate the difference in the incidence of recurrent PFCs between the two groups. Previous studies have shown zero recurrence in the group receiving long-term indwelling plastic stents and 15 %–17 % in the no-stenting group in patients with DPD [8–10]. We postulated that the exchange of LCMSs with plastic stents would be superior in preventing recurrent PFCs compared with the no-stent group. Considering the difference of 15 % reduction in recurrence with stent exchange, the sample size calculated was 90 (45 cases per group) to demonstrate the superiority, with a power of 80 % and type I error of 0.05. The total number of cases to be enrolled was calculated to be 100 to account for an approximate dropout rate of 10 %.



▶ **Fig. 2** Consort flow diagram of study patients and follow-up. LCMS, large-caliber metal stent; MRCP, magnetic resonance cholangiopancreatography; ERP, endoscopic retrograde pancreatography; PD, pancreatic duct; SEMS, self-expandable meta stent; DPD, disconnected pancreatic duct.

Statistical analysis

Continuous variables were expressed as median with interquartile range (IQR) and compared using Mann–Whitney *U* test. Categorical variables were expressed as proportions and evaluated by the chi-squared test or Fisher's exact test as indicated. Outcomes were presented as point estimates of proportions with 95 % confidence interval (CI). Univariate analysis was performed to identify predictors for recurrent PFCs in patients with DPD. Statistical analysis was performed using SPSS version 26 (IBM Corp., Armonk, New York, USA). All analyses were performed as per intention-to-treat (ITT) as well as per protocol. A two-tailed $P<0.05$ was considered statistically significant.

Results

A total of 236 patients with WON underwent EUS-guided drainage using an LCMS during the study period. Of these, 104 patients with DPD (males 94, median age 34 years (IQR 26–44.7) were randomized into two groups (▶ **Fig. 2**). Of the 52 patients in the stent group, a single plastic stent was placed in 38 patients (73.1 %) and two plastic stents were placed in 8 patients (15.4 %). Technical failure of plastic stent deployment occurred in six patients (11.5 %).

The distribution of site of DPD was similar in both groups. Other baseline characteristics are shown in ▶ **Table 1**.

Primary outcome

At 3 months after LCMS removal, 91/104 patients (87.5 %) were available for follow-up, including 46 (88.5 %) in the stent group and 45 (86.5 %) in the no-stent group. On ITT analysis, recurrence of PFCs was documented in six patients (5.8 %) (i. e. three patients in each group at 3 months: stent 0.058 [95 %CI 0.62–8.77]; no-stent 0.058 [95 %CI 0.62–8.77]) (▶ **Table 2**). On per protocol analysis (excluding cases with failed stent deployment, loss to follow-up, and early stent migration), there was no significant difference seen in PFC recurrence between the two groups (stent group 0.073 [95 %CI 0.62–8.77]; no-stent group 0.067 [95 %CI 0.62–0.877]) (**Table 1 s**).

Secondary outcomes

Plastic stents were successfully placed in 46 patients (0.885 [95 %CI 33.67–61.35]) in the stent group. In six patients (0.115 [95 %CI 2.20–13.05]), plastic stent deployment failed due to collapsed cyst cavity. There were no major adverse events associated with the deployment of plastic stents. Self-limiting abdominal pain without evidence of pancreatitis was noticed in two patients (0.038 [95 %CI 4.79–18.39]) after placement of transmural plastic stents. Spontaneous external migration of plastic stents was recorded in 10 patients (0.192 [95 %CI 4.79–18.39]) at a median follow-up of 8 months (IQR 2.5–12) (▶ **Table 2**).

Data for 91 (87.5 %; stent 46, no stent 45) and 83 (79.8 %; stent 42, no stent 41) patients were available at 6 months and 12 months, respectively. The median duration of follow-up in

▶ **Table 1** Baseline characteristics of patients randomized into stenting and no-stenting groups.

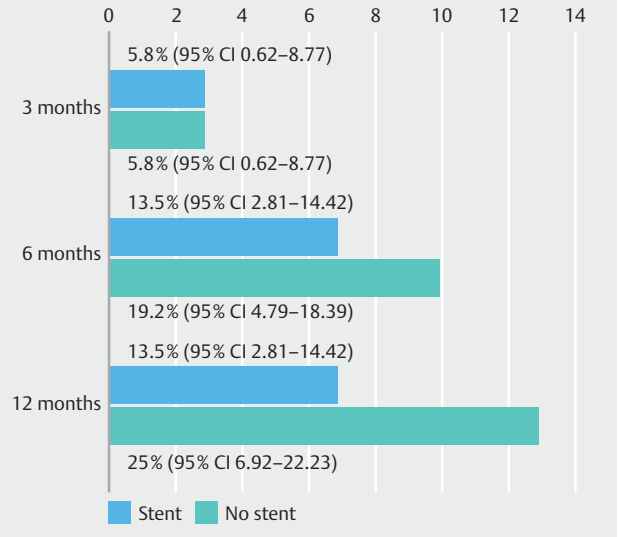
	Stent group (n = 52)	No-stent group (n = 52)	*P* value
Age, median (IQR), years	32 (24.5–45)	35 (26–43.8)	0.58
Sex, male, n (%)	48 (92.3)	46 (88.5)	0.74
Known diabetes mellitus, n (%)	9 (17.3)	7 (13.4)	0.79
Etiology of pancreatitis, n (%)			0.08
▪ Idiopathic	29 (55.8)	19 (36.5)	
▪ Ethanol	16 (30.8)	18 (34.6)	
▪ Biliary	5 (9.6)	14 (26.9)	
▪ Others	2 (3.8) (1 hyperparathyroidism, 1 traumatic)	1 (1.9) (1 post-ERP pancreatitis)	
Location of WON, n (%)			> 0.99
▪ Proximal (head-neck)	15 (28.8)	15 (28.8)	
▪ Distal (body-tail)	37 (71.2)	37 (71.2)	
Multiple collections, n (%)	9 (17.3)	11 (21.2)	0.80
Size of WON, median (IQR)			
▪ Transverse axis, mm	124 (107.2–146.5)	114 (61–190)	0.14
▪ Vertical axis, mm	90 (72.5–110)	85 (71–100)	0.20
▪ WON debris, %	22.5 (11.2–30)	20 (15–30)	0.86
Route of drainage, n (%)			
▪ Transgastric	52 (100)	52 (100)	> 0.99
▪ Transduodenal	0 (0)	1 (1.9)*	> 0.99
Additional interventions, n (%)			
▪ NCT placement	21 (40.4)	17 (32.7)	0.42
▪ Necrosectomy	19 (36.5)	16 (30.8)	0.53
– Necrosectomy sessions, median (IQR)	2 (1–3)	1 (1–2)	0.35
▪ Others	7 (13.5) (5 PCD, 1 ICD, 1 STA)	6 (11.5) (3 PCD, 3 STA)	> 0.99
Complications during index intervention, n (%)			0.53
▪ Bleeding	3 (5.8)	2 (3.8)	
▪ Metal stent migrated and repositioned during necrosectomy	4 (7.7)	2 (3.8)	
Duration of LCMS placement before removal, median (IQR), days	33 (26–41.7)	36.5 (24.7–46)	0.19
Site of DPD, n (%)			0.96
▪ Head	5 (9.6)	4 (7.7)	
▪ Genu	16 (30.8)	17 (32.7)	
▪ Body	27 (51.9)	28 (53.8)	
▪ Tail	4 (7.7)	3 (5.8)	
Pancreas divisum, n (%)	2 (3.8) (genu)	2 (3.8) (mid-body, tail)	
Status of stenting, n (%)		N?A	
▪ Migrated spontaneously	10 (19.2)		
Recurrent acute pancreatitis	10 (19.2)	5 (9.6)	0.26
Follow-up duration, median (IQR), months	19 (14.75–23.25)	18 (14.5–20.5)	0.30

IQR, interquartile range; ERP, endoscopic retrograde cholangiopancreatography; WON, walled-off necrosis; NCT, nasocystic tube; PCD, percutaneous catheter drainage; ICD, intercostal drainage; STA, single time aspiration; LCMS, large-caliber metal stent; DPD, disconnected pancreatic duct; N/A, not applicable.
* One patient received drainage via both routes.

▶ **Table 2** Primary and secondary outcomes of the study.

	Stent group (n = 52)	No-stent group (n = 52)	*P* value
Primary outcome			
Recurrent PFC at 3 months, proportion (95 %CI)	0.058 (0.62–8.77)	0.058 (0.62–8.77)	>0.99
Secondary outcomes			
Technical success associated with plastic stent deployment, proportion (95 %CI)	0.885 (33.67–61.35)	–	
Complications associated with plastic stent deployment, proportion (95 %CI)	0.038 (0.24–7.22)	–	
Plastic stent migration, proportion (95 %CI)	0.192 (4.79–18.39)		
Recurrent PFC at 6 months, proportion (95 %CI)	0.135 (2.81–14.42)	0.192 (4.79–18.39)	0.43
Recurrent PFC at 12 months, proportion (95 %CI)	0.135 (2.81–14.42)	0.25 (6.92–22.23)	0.14

PFC, pancreatic fluid collection; CI, confidence interval.



▶ **Fig. 3** Bar chart showing recurrent pancreatic fluid collections in stenting and no-stenting group at 3 months, 6 months, and 12 months.

the stent and no-stent groups was 19 months (IQR 14.75–23.25) and 18 months (IQR 14.5–20.5), respectively.

The majority (85 %) of the recurrences developed within the first 6 months: 7 patients (0.135 [95 %CI 2.81–14.42]) in the stent group and 10 patients (0.192 [95 %CI 4.79–18.39]) in the no-stent group. At 12 months' follow-up, total recurrent PFCs occurred in 20 patients, with 7 patients (0.135 [95 %CI 2.81–14.2]) in the stent group and 13 patients (0.25 [95 %CI 6.92–22.23]) in the no-stent group (▶ **Table 2**, ▶ **Fig. 3**). Overall, recurrent PFCs had developed in 17 (16.3 %) and 20 (19.2 %) patients at 6 months and 12 months, respectively. There was no significant difference in the recurrence rates in the ITT or per protocol analyses (▶ **Table 2**, **Table 1 s**).

Outcomes in patients with recurrent fluid collections

The location and median size of recurrent PFCs were similar in the stent and no-stent groups (53 mm [IQR 44–98] vs. 51 mm [IQR 44–80]; *P* = 0.96). Out of 20 patients with recurrent PFCs, reintervention was required in 7 patients (35.0 %) with symptomatic recurrences (**Table 2 s**).

In the stent group with recurrent PFCs (n = 7), single and double plastic stents were retained in 3 and 2 patients, respectively. Stent migration was recorded in the remaining two patients at 1 and 3 months, respectively. There was no significant difference in recurrence rates between single and double stenting groups (*P* = 0.20).

Of the seven patients with recurrent PFCs, reintervention was required in three (EUS-guided drainage using LCMS for large PFC in one, surgical cystogastrostomy in one, and distal pancreatosplenectomy in one). No intervention was required in the remaining four patients (two asymptomatic, two spontaneous regression) (**Table 2 s**).

Of the 13 recurrences in the no-stent group, reintervention was required in four patients with symptomatic PFCs, who were managed successfully by EUS-guided drainage using plastic stents. No reintervention was required in eight cases (asymptomatic in three, spontaneous regression in four, small size of collection in one). One case with asymptomatic recurrent PFC was not available for follow-up at 1 year (**Table 2 s**).

There was no significant difference in the rate of reinterventions for recurrent PFCs between the two groups (*P* = 0.62).

Comparison of patients with and without recurrent PFC

The location of the DPD and other characteristics at baseline were similar in patients with (n = 20) and without (n = 71) recurrent PFCs. However, a trend of recurrence of PFCs was observed toward distal collections (*P* = 0.05) (**Table 3 s**).

Discussion

The current study shows that after resolution of WON, the exchange of metal stents with plastic stents is not superior to no stenting in the prevention of recurrent PFCs at 3 months, 6 months, and 12 months.

The safety and efficacy of endoscopic drainage using LCMSs is well established. However, recurrent PFCs develop in a proportion of cases after the removal of transmural stents, presumably due to closure of the cystogastric communication over time. Indwelling transmural plastic stents reportedly reduce the rate of recurrence in high-risk patients especially those with DPD [8, 10, 18, 19]. However, unlike plastic stents, LCMSs should be removed, preferably within 4 weeks, to avoid potential adverse events. The exchange of LCMSs with plastic stents appears to be a potential option to prevent the recurrence of PFCs by maintaining the continuity of the cystogastric fistula established during the index drainage [15].

In this randomized controlled study, we investigated the impact of replacing an LCMS with one or more plastic stents compared with no stent on the incidence of recurrent PFCs. The study included selected patients with WON at high risk for recurrence of PFC (i. e. those with DPD).

In the overall study cohort, recurrent PFCs were noticed in 5.8 %, 16.3 %, and 19.2 % at 3 months, 6 months, and 12 months, respectively. Our results match those of earlier studies and suggest that recurrence of PFCs occurs in a considerable proportion of patients with DPD even after initial successful resolution [8–10, 15, 19–21]. There was no difference between the plastic stent vs. no-stent group in the incidences of recurrent PFCs at 3 months, 6 months, and 12 months. However, there was a threefold increase in the incidence of PFCs at 1 year compared with 3 months, and the relative increase was higher in the no-stent group (13.5 % vs. 25.0 %).

Indwelling plastic stents are considered as one of the strategies to prevent recurrence of PFCs, and some studies suggest that recurrences are virtually nonexistent in those with indwelling plastic stents [10, 13, 15]. In contrast, our study observed recurrent PFCs in a considerable proportion of patients, even after placement of plastic transmural stents (13.5 % at 1 year). There are few possible reasons for this discrepancy. First, the replacement of LCMSs (placed at index drainage) by plastic stents differs from situations where plastic stents are primarily used for the index drainage. As opposed to drainage of naïve WON, it can be technically challenging to deploy plastic stents in a nearly collapsed cyst cavity previously drained efficiently with an LCMS (▶ **Fig. 1c**). In the current study, the deployment of plastic stents was unsuccessful in six patients (11.5 %). Similarly to our results, Bang et al. also reported technical failure in replacing lumen-apposing metal stents with plastic stents in about a quarter of cases [15]. Second, even if a plastic stent successfully replaces an LCMS, the risk of migration remains high due to space constraints in the remnant cavity. In the current study, the replaced plastic stents migrated externally in 10 patients (19.2 %) at a median of 8 months. We observed that even if the plastic stent remained in situ, a major segment of it hangs within the gastric lumen, anchored to the cyst cavity only by the pigtail. Such plastic stents may not serve the actual purpose of draining and preventing recurrent PFCs when placed in nearly resolved collections. Whether early replacement of LCMSs (at around 2 weeks), prior to complete resolution of WON, reduces the technical failure in plastic stent deployment and improves their retention rates remains to be evaluated in future studies. A recent study from Belgium reported the outcomes of long-term indwelling plastic stents used for index drainage of PFCs. In this study, stent migration occurred in nearly three-quarters at a median follow-up of 19 months [20]. Therefore, it is likely that plastic stents eventually get expelled after resolution of the PFC. A higher rate of early stent migrations in the current study underscores the difference in the plastic stent retention rates of naïve vs. previously drained collections. Third, recurrent PFCs occurred in the stent group even without migration of replaced plastic stents in 5/7 patients, suggesting other mechanisms of recurrences as well. The majority of patients (73.1 %) received one plastic stent. It may be argued that replacement of an LCMS with two plastic stents may be superior to replacement with one stent for prevention of recurrent PFCs. However, the incidence of recurrent PFCs was similar in patients with single or double plastic stents (3 vs. 2; $P = 0.20$). In a previous study by Rana et al., one transmural plastic stent was found to be as effective as two plastic stents in preventing recurrent PFCs [22].

The requirement of reintervention in recurrent PFCs was low and similar in both groups, suggesting that replacing LCMSs with one or more plastic stents does not significantly affect the outcome. Only one-third of patients with recurrent PFCs required an intervention. Similarly to our results, Dhir et al. concluded that the majority (87.5 %) of the recurrences regress on follow-up and do not require a further intervention [19]. Basha et al. reported recurrent collections in about 13 % of patients with DPD; a reintervention was required in only half of the recurrent PFCs [9]. Our results, in concordance with previous observations, suggest that the majority of recurrent PFCs do not require reintervention.

Another notable factor apart from stenting in this study was the etiology of pancreatitis. Many patients had idiopathic pancreatitis; however, there was no significant difference in etiology between the stenting and no-stenting groups, or between those who developed recurrent PFCs and those who did not (▶ **Table 1**, **Table 3 s**). There are sparce data with conflicting results on the effect of etiology of pancreatitis on the incidence of DPD [8, 21]. There are also no data on the effect of etiology on the outcomes in patients with DPD. This study was not powered to analyze outcomes according to etiology, and it may require worldwide evaluation in larger sample sizes to ascertain the effect of etiology in patients with DPD.

There are some important implications of this study. First, the replacement of LCMSs with plastic stents may not be a foolproof strategy for preventing recurrent PFCs in patients with DPD. Second, the technical difficulty in placing plastic stents and early stent migrations underscore the crucial caveats of such an approach to prevent recurrent PFCs. Finally, the majority of recurrent PFCs do not require further intervention, implying that targeting selected cases with symptomatic recurrences may be a more pragmatic and cost-effective strategy when compared with universal, prophylactic exchange of LCMSs with plastic stents.

There are several strengths of this study. This is the first randomized study evaluating the impact of plastic stent replacements in cases primarily drained using LCMSs. The study in-

volved rigorous inclusion criteria (i. e. WON drained using LCMS and documented to have DPD). The presence of DPD was reconfirmed using ERP to avoid inclusion of cases misclassified on MRCP. There are a few limitations of the study. These include a relatively high dropout rate at 1 year (20 %) and a modest follow-up period. Idiopathic pancreatitis was the most common etiology of pancreatitis in our cohort, which may differ from Western populations where alcohol is the most common cause. Nevertheless, the etiology of pancreatitis is unlikely to have a substantial impact on the structural damage of the pancreas (i. e. WON and DPD).

In conclusion, replacement of LCMSs with plastic stents did not significantly reduce the development of recurrent PFCs in patients with DPD. The majority of the recurrences were asymptomatic and did not require reintervention.

Competing interests

The authors declare that they have no conflict of interest.

Clinical trial

Trial Registration: ClinicalTrials.gov | Registration number (trial ID): NCT03436043 | Type of study: Randomized controlled trial

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