Early removal of biflanged metal stents in the management of pancreatic walled-off necrosis: a prospective study

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ABSTRACT

Background and study aims Dedicated stents placed under endoscopic ultrasound (EUS) guidance have shown promise for the management of pancreatic walled-off necrosis (WON). A long duration of stent placement may increase the risk of adverse events. We prospectively evaluated the effects of (i) early removal of biflanged metal stents (BFMSs) and (ii) additional stenting of the pancreatic duct with plastic stents in patients with ductal leaks, on the risk of WON recurrence.

Patients and methods Symptomatic patients with pancreatic WON underwent EUS-guided BFMS placement, followed by necrosectomy, when required, from Day 3. A 5 Fr plastic stent was placed in patients with ductal leak. BFMS was removed when the WON cavity had collapsed completely. Patients were followed up at 3-month intervals.

Results BFMS placement was successful in all 88 patients. A total of 64 patients (72.7%) underwent necrosectomy (median 3 sessions). All BFMSs were removed at a median of 3.5 weeks (range 3-17 weeks). Ductal disconnection and leak occurred in 53/87 (60.9%) and 61/87 (70.1%) patients, respectively. A 5 Fr stent was placed in 56/61 patients (91.8%) with ductal leak. Overall, 22 patients (25.0%) had adverse events (17 mild, 1 moderate, 3 severe, 1 fatal). Recurrence was noted in 8/88 (9.1%) at a median follow-up of 22 months. The recurrence rate was higher in patients with ductal disconnection than in those without (13.2% vs. 2.9%; P = 0.08), and was similar in patients with vs. without pancreatic duct stenting (7.1% vs. 12.9%; P=0.44). Seven recurrences (87.5%) partially regressed on follow-up and did not require therapy; in one case, drainage with a plastic stent was performed.

Conclusions Short-term BFMS placement is an effective therapy for pancreatic WON. The majority of recurrences developed in patients with ductal disconnection and did not require therapy. Additional pancreatic duct stents probably do not influence the recurrence rate.

Introduction

The management of pancreatic walled-off necrosis (WON) is currently in a state of flux owing to advances in technology. The advent of dedicated stents placed under endoscopic ultrasound (EUS) guidance, including the lumen-apposing metal stent (LAMS) and biflanged metal stent (BFMS), in the past few years has made it possible for the endoscopist to easily access the cyst cavity and perform endoscopic necrosectomy [1]. The wide diameter of LAMS and BFMS allows repeated passage of the endoscope and accessories, until the desired goal of cavity closure is achieved. Initial results with LAMS and BFMS for pan-

creatic WON are promising, with an initial success rate of about 85% and complication rates of 15% - 21% [1 – 3].

However, there are still unanswered questions, including how long the stent should be left in situ after placement, among others. A longer duration of stent placement may be associated with higher risk of adverse events, such as bleeding, stent migration, and buried stent [4,5]. The tendency for a longer duration of stent placement stems from the current evidence, which suggests that recurrence of pancreatic fluid collections (PFCs) may be higher, especially in patients with pancreatic duct leaks and the "disconnected duct" syndrome, if the stent is removed early [6]. There are no studies to show

whether pancreatic duct leaks and disconnections play a role in recurrence following LAMS or BFMS placement.

We conducted this study to evaluate the impact of (i) early removal of BFMS, and (ii) additional stenting of the pancreatic duct with plastic stents, on the risk of WON recurrence. We also studied the rate of ductal leaks and disconnection in patients with pancreatic WON, and the accuracy of magnetic resonance cholangiopancreatography (MRCP) in diagnosing these conditions

Patients and methods

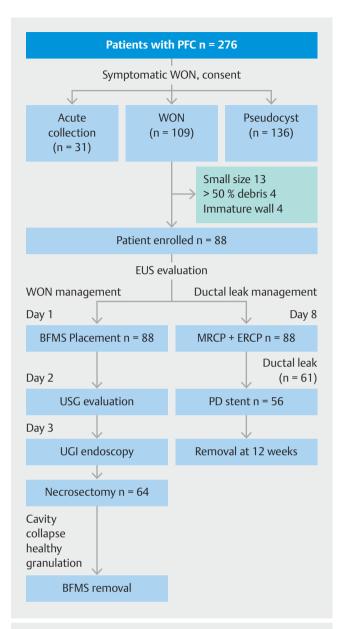
This was a prospective study carried out between March 2011 and December 2016. Institutional Review Board approval was obtained for the study. Trial registration was not done as it was not mandatory for publications when the trial was started in 2011. Symptomatic patients with pancreatic WON and a necrotic content of less than 50% of the cyst volume were offered BFMS placement and necrosectomy. Patients who were unfit for propofol anesthesia, those with asymptomatic collections, a bleeding diathesis, or those in whom the WON was more than 2 cm away from the stomach wall or showed a partially immature wall, were excluded.

Informed consent for the trial was obtained from all patients. The protocol followed for these patients is shown in Fig. 1. Pre-treatment evaluation included a computed tomography (CT) scan and EUS. Special care was taken to look for pseudoaneurysms within the cyst and presence of collateral vessels due to splenic vein thrombosis. The amount of debris was quantified approximately by assessing the percentage of cyst cavity occupied by debris during EUS evaluation.

Patients received prophylactic antibiotics (cefotaxime 1 g intravenously), which was continued for 72 hours post-procedure. Propofol anesthesia was used for all patients.

The method of stent placement has been described previously (▶ Fig. 2) [7]. Briefly, an appropriate puncture site was chosen by careful endosonographic evaluation (GF-UCT-140 and 180; Olympus, Tokyo, Japan). A 19-gauge needle was used (Expect – Boston Scientific, Marlborough, Massachusetts, USA; or Echotip - Cook Medical, Bloomington, Indiana). A 0.035inch quidewire (Dreamwire; Boston Scientific) was passed and coiled within the cyst cavity. A 6 Fr cystotome (G-Flex, Nivelles, Belgium), followed by an 8-mm balloon catheter (CRE balloon; Boston Scientific) were used to dilate the track. The BFMS (Nagi Stent, 2 or 3 cm long, 16 mm wide; Taewoong, Seoul, Korea) was deployed under combined EUS and flouroscopic guidance. The echoendoscope was then removed, and a gastroscope was passed for more efficient suction. The stomach was emptied of WON contents, but no attempt was made to enter the pancreatic WON cavity. The patient resumed a soft diet in the evening, if there were no pain or vomiting for 4 hours post-procedure. All patients were hospitalized for the procedure.

An ultrasonography of the abdomen was performed after 24 hours to check the residual cavity size. The purpose of the ultrasonography was to assess reduction in cavity size, and not to change any treatment plan. An endoscopy was done in all patients on Day 3 to check for stent blockage by necrotic material,



▶ Fig. 1 The patient management protocol. BFMS, biflanged metal stent; ERCP, endoscopic retrograde cholangiopancreatography; MRCP, magnetic resonance cholangiopancreatography; PFC, pancreatic fluid collection; PD, pancreatic duct; UGI, upper gastrointestinal; USG, ultrasonography. WON, walled off necrosis.

which was anticipated as we did not perform necrosectomy on Day 1. Necrosectomy was done if necessary. If the patient was asymptomatic they were then discharged.

Necrosectomy was performed in patients with blocked stents or in those who developed a fever. All necrosectomy sessions, except for the first one on Day 3, were performed on an outpatient basis. Once initiated, further sessions were done at 5–7-day intervals until the entire cavity was clean. Necrosectomy was performed using a basket (RothNet; US Endoscopy, Mentor, Ohio, USA) or a snare. Small pieces of debris were carefully removed under direct vision. Patients who did not need necrosectomy underwent endoscopic assessment of the WON



► Fig. 2 Steps in the placement of a biflanged metal stent (BFMS) and necrosectomy. a Needle puncture. b Track dilation with 6 Fr cystotome. c Balloon dilation to 8 mm. d Deployment of the BFMS distal end (endoscopic ultrasound image). e Final deployment (endoscopic view). f Necrotic debris blocking the stent. g Necrosectomy. h Clean cyst cavity after four sessions of necrosectomy.

cavity every 2 weeks, starting after the endoscopic retrograde cholangiopancreatography (ERCP) session on Day 8. The BFMS was removed when endoscopy showed collapse of the WON cavity and pink granulation tissue on the WON wall (> Fig. 3). Thus, the criterion for BFMS removal was endoscopic healing of the WON cavity.

MRCP followed by ERCP were performed in all patients on Day 8 of BFMS placement. Day 8 was chosen to allow sufficient time for adequate drainage of cyst contents, which could interfere with MRCP images. An ERCP with 5 Fr stent placement was performed in patients with a ductal leak. The stent was left in situ for 12 weeks, and then removed.

All data were entered into a standardized database. PFCs were classified according to the revised Atlanta classification [8]. Technical success was defined as the ability to place a stent in the appropriate position. Functional success was defined as a reduction in cavity size by >50% on ultrasonography at 24 hours. Adverse events were defined and graded according to

the American Society for Gastrointestinal Endoscopy lexicon criteria [9]. Recurrence was defined as occurrence of a fresh PFC after removal of the BFMS.

Patients underwent follow-up abdominal ultrasonography every 3 months. Patients with recurrent PFCs were checked for symptoms. If patients were asymptomatic, they underwent ultrasonography every month until a reduction in cyst size was noted. The ultrasound frequency was then reduced to every 3–6 months. Patients who showed an increased size were counseled and advised on follow-up if they were asymptomatic; drainage was offered to patients who were unwilling to wait. Symptomatic patients underwent placement of a transgastric plastic stent into the cavity.



▶ Fig. 3 Endoscopic assessment of pancreatic walled-off necrosis (WON) cavity. a Clean cavity after necrosectomy. The cavity has not collapsed and is not covered by granulation tissue. The biflanged metal stent (BFMS) should remain in situ at this point. b Complete collapse of the WON cavity, with granulation tissue seen at the distal end of the BFMS, indicating appropriate time for stent removal.

Results

The study included patients between March 2011 and December 2016. During this period, 276 patients with PFCs were evaluated. These included 136 pseudocysts, 109 pancreatic WON, and 31 acute fluid collections. Of the 109 WON patients, 88 underwent BFMS placement. The reason for nonintervention in the remaining 21 patients included asymptomatic or small sized WON in 13, more than 50% debris in 4, and immature wall in 4 patients. The clinical profile of the BFMS patients is shown in ► Table 1.

Stent placement

The early outcome results are shown in ▶ Table 2. The BFMS placement was technically successful in all patients. Ultrasonography at 24 hours showed > 50% reduction in WON cavity size (functional success) in 71 patients (80.7%). Endoscopy on Day 3 showed necrotic debris blocking the stent in 52 patients (59.1%).

Necrosectomy

A total of 64 patients (72.7%) underwent multiple sessions of necrosectomy at 5-7-day intervals. These included the 52 patients in whom the stent was blocked on Day 3, and 12 additional patients who developed fever within the first week. The median number of sessions required for complete necrosectomy was 3 (range 2-6 sessions).

BFMS removal

The BFMS were removed at a median of 3.5 weeks (range 3 – 17 weeks). Only one patient required a stent in situ for more than 10 weeks. All stents could be removed easily without any adverse events.

Disconnected duct and ductal leaks

Pancreatic duct opacification during ERCP and MRCP was achieved in 87 patients (one patient died before ERCP or MRCP could be done). ERCP showed ductal disconnection in 53/87 patients (60.9%), and MRCP showed the same in 72/87 patients (82.8%). The disconnection was in the neck/body region in all patients. Ductal leak was demonstrated by ERCP in 61/87 patients (70.1%), and was suggested by MRCP in 34 patients (39.1%). The leak was in the body region in 45 patients and in the tail region in 16 patients.

Four patterns of ductal abnormalities and leaks were identified (▶ Fig. 4, ▶ Fig. 5). A total of 35 patients had both disconnection and leak (Type I). The leak in all of these patients was near the head end of disconnection. Disconnection without ductal leak was seen in 18 patients (Type II), while ductal leak without disconnection was seen in 26 patients (Type III). A total of 16 of these were in the tail region and the rest were in the body region. Eight patients had neither disconnection nor leak (Type IV).

Pancreatic duct stents

Placement of a 5 Fr plastic stent in the pancreatic duct was successful in 56/61 patients (91.8%) with ductal leak. Stent placement could not be done in four patients with disconnection and

► Table 1 Patient characteristics.		
Patients, n	88	
Sex, n (%)		
Male	67 (76.1)	
Female	21 (23.9)	
Age, median (range), years	41 (15 – 71)	
Pancreatitis, n (%)		
Acute	76 (86.4)	
Chronic	12 (13.6)	
Etiology, n (%)		
Alcohol	23 (26.1)	
Biliary	19 (21.6)	
 Idiopathic 	46 (52.3)	
Duration from pancreatitis, median (range), days	90 (25 – 480)	
Cyst size, median (range), cm	12 (7 – 15)	
Amount of necrotic debris, n (%)		
4 <33%	54 (61.4)	
• 33%-50%	34 (38.6)	

► Table 2 Procedure outcomes.		
Patients, n	88	
BFMS placed, n	88	
Technical success, %	100	
Functional success*, n (%)	71 (80.7)	
Necrosectomy, n (%)	64 (72.7)	
• No. of sessions, median (range)	3 (2-6)	
Adverse events, n (%)		
• Mild		
– Fever	12 (13.6)	
- Pancreatitis	3 (3.4)	
- Stent migration	2 (2.3)	
 Moderate 		
- Bleeding	1 (1.1)	
 Severe 		
- Bleeding	2 (2.3)	
- Abscess (surgery required)	1 (1.1)	
• Fatal		
- Death of unknown cause	1 (1.1)	

Reduction in WON cavity size by > 50% at 24 hour ultrasonography.

one patient with leak alone, owing to inability to pass a guidewire into the pancreatic duct. In 31 patients with disconnection, the stent was placed up to the site of the leak, as bridging could not be done. In 25 patients, the stent bridged the leak. The stents were removed after 12 weeks. Three patients developed mild pancreatitis following ERCP. At 12 weeks, 51 stents were removed, and 5 had spontaneously migrated into the duodenum.

Adverse events

Adverse events developed in 22 patients (25.0%). According to the ASGE lexicon criteria, the adverse events were mild in 17 patients (19.3%), moderate in 1 (1.1%), severe in 3 (3.4%), and fatal in 1 (1.1%). A total of 12 patients had fever. Three patients had bleeding, defined as hematemesis or melena with or without a fall in hemoglobin level. All of the bleeding episodes happened more than 1 week after the stent placement. One patient bled on Day 8 and required two units of blood. Gastroscopy showed blood at the stent orifice, but no active bleeding was noted. Angiography showed no active bleed. The bleeding was probably caused by the stent eroding a vessel in the WON cavity wall. A double-pigtail plastic stent was placed through the BFMS and the bleeding did not recur. The other two bleeding episodes were due to pseudoaneurysms within the cyst wall, and required embolization. One patient developed an abscess and septicemia, and had to undergo surgery. One patient died on Day 5 at home following acute chest pain, before any investigations could be done. In addition, two stents migrated into the stomach during necrosectomy; these stents were immediately replaced. Three patients developed mild pancreatitis following ERCP and ductal stenting.

Hospitalization

The median number of hospitalizations was 1 (range 1-3), while the median hospitalization length was 3 days (range 3-12 days).

Recurrence

The long-term outcomes are shown in **Table 3**. During a median follow-up of 22 months (3 – 46 months), eight recurrences were noted. All recurrences had clear contents without any necrotic debris (> Fig. 6). The correlation of ductal abnormality type with recurrence is shown in ▶ Table 4. Five recurrences developed in patients with Type I ductal abnormality, while two developed in Type II, and one in type IV. Thus, 87.5% of recurrences developed in patients with disconnected ducts, and 37.5% had no documented ductal leak. The recurrence rate in patients with disconnection (7/53, 13.2%) was higher than those without (1/35, 2.9%), but the difference did not reach statistical significance (P=0.08). Apart from one recurrence that developed within 2 weeks of BFMS removal, all recurrences were detected after 6 months of BFMS removal. Only one patient with immediate recurrence following BFMS removal became symptomatic and underwent plastic stent placement. The other recurrences have gradually regressed in size over the follow-up period, and have not required therapy (> Fig. 6). Four recurrences developed in patients who had a pancreatic

► Table 3 Data on recurrence in 88 patients treated with biflanged metal stent.	
Total recurrence, n (%)	8 (9.1)
Coexisting pathology of the pancreatic duct	
Disconnected duct	7
Ductal leak	5
Recurrent cyst size, median (range), cm	6 (3 – 7)
Amount of necrotic debris	None
Clinical symptoms, n	1
Management, n (%)	
 Plastic stent 	1
 None (spontaneous regression) 	7 (87.5)
Recurrent cyst size at last follow-up, median (range), cm	2.5 (2-4)

▶ **Table 4** Impact of disconnections and leaks on recurrence*.

Patients	Recurrence	
88	8	
Pattern type, n (%)		
35 (39.8)	5 (62.5)	
18 (20.4)	2 (25.0)	
26 (29.5)	0	
8 (9.1)	1 (12.5)	
)	35 (39.8) 18 (20.4) 26 (29.5)	

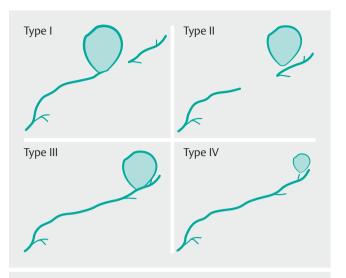
duct stent, and four developed in those who did not have a stent. Thus, the recurrence rate in those with a ductal stent was not significantly different from those without (7.1% vs. 12.9%; P=0.44).

Discussion

* See Fig. 4 for detailed explanation.

We conducted this study to assess whether short-term BFMS placement is an effective therapy for pancreatic WON in terms of short-term adverse events and recurrence rates. We also assessed whether a pancreatic duct stent in patients with established ductal leaks would prevent or reduce recurrent collections. These twin aims necessitated additional investigations in the form of MRCP, ERCP, and endoscopy, in order to accurately assess WON cavity collapse and ductal abnormalities. Our results suggest that, whereas short-term BFMS placement is an effective therapy for pancreatic WON, pancreatic duct stents may not be entirely effective in controlling the recurrence.

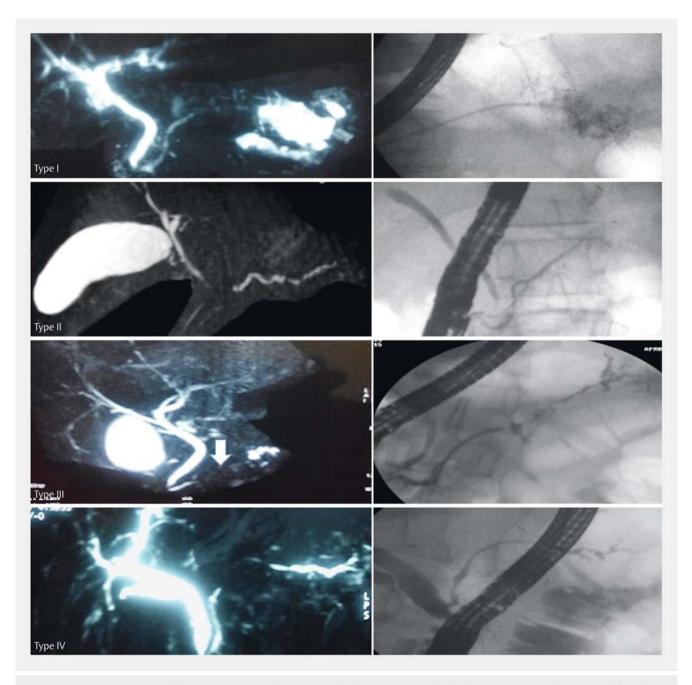
We chose an endoscopic criterion to determine WON cavity collapse and the resultant need to remove the BFMS. This was possible because the wide diameter of BFMS allows appropriate inspection of the WON cavity and assessment of whether the BFMS can be removed or should remain in situ (**Fiq.3**). A so-



▶ Fig. 4 Four types of pancreatic duct disconnection and leaks found at endoscopic retrograde cholangiopancreatography. Type I shows a disconnection in the neck/body region, with a ductal leak at the proximal end. Type II shows a disconnected duct with a walled-off necrosis (WON) distal to the disconnection. It is not possible to ascertain the ductal communication of WON. Type III shows a ductal leak without disconnection. Type IV shows a noncommunicating WON, with no disconnection.

nography or CT scan does not give adequate information about development of healthy granulation tissue.

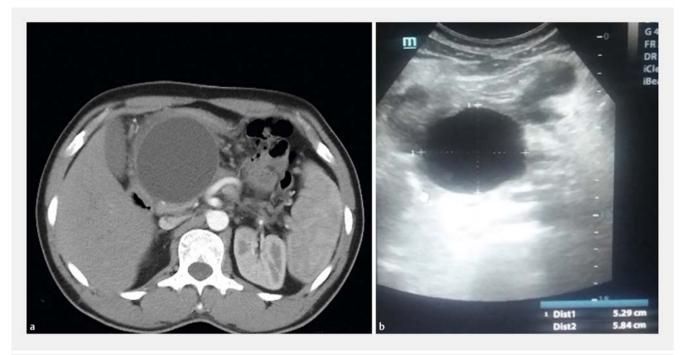
Recent studies with LAMS have shown a success rate of about 85% and complication rates of up to 21% [10,11]. The high technical and functional success rates in our study are due to careful patient selection. We did not include patients with a large amount of necrosis, cysts away from the stomach wall, and those with partially immature walls with fluid tracking. BFMSs are efficient for immediate drainage, as demonstrated in this study by the reduction in cyst size by >50% in 24 hours on ultrasonography. We followed a protocol for necrosectomy starting from an endoscopy at 72 hours, which showed debris blocking the stent in 59.1% patients. The aim of the aggressive necrosectomy was to return the WON cavity to a healthy state, so that the BFMS could be removed as soon as possible. The latter was mandated by dual concerns that a slowly resolving WON could lead to tissue hyperplasia and stent entrapment at the anastomosis, and that a persistent cavity with a long-term indwelling stent could develop inflammation and infection, as is seen in bile ducts. This strategy worked well for our patients, as the WON cavity collapsed and showed healthy granulation tissue, so that the BFMS could be removed at a median duration of 3.5 weeks, without a higher adverse event rate. Severe adverse events were encountered in 3.4% of patients, and the single death was probably due to an unrelated cause. We did not encounter a high post-procedure bleeding rate with BFMS placement, as has been reported recently with LAMS [5]. Although the Nagi stent has been classified as a BFMS (as opposed to an LAMS, which are characterized by higher tensile strength and apposition capability), the lumen-apposing properties may not be not as important for WON drain-



▶ Fig. 5 Magnetic resonance cholangiopancreatography (MRCP) and endoscopic retrograde cholangiopancreatography (ERCP) of ductal abnormalites. Type I abnormality. Both MRCP and ERCP in this patient show a disconnected duct with free leak in the cyst cavity, just before the disconnection. Type II abnormality. Both MRCP and ERCP show a ductal disconnection in the neck region. MRCP shows the duct beyond disconnection. Type III abnormality. There is a communicating leak in the tail region, without a disconnection. MRCP, however, suggests a disconnection (arrow). Type IV abnormality. Normal pancreatic duct with no leak or disconnection. MRCP, however, suggests a disconnection.

age as they are for gallbladder drainage and gastrojejunostomy [12]. Both types of stents have a wide diameter, short length, and wide flanges, thus allowing repeated necrosectomy sessions. Based upon these data, following satisfactory necrosectomy, an endoscopy at 3 – 6 weeks from the date of stent placement should be enough to assess the WON cavity and perform BFMS removal at the same time.

We found a high rate of disconnected duct and ductal leaks in our patients. MRCP over-diagnosed disconnected ducts, and under-diagnosed ductal leaks. We performed MRCP and ERCP on Day 8 to allow sufficient time for collapse of the cyst cavity, and thus improve the diagnostic potential of MRCP. However, it is possible that the residual necrosis and inflammation interfered with the detection of leaks, contrary to our earlier data on pseudocysts, where MRCP was found to be accurate, although in a smaller number of patients [7]. Data about the utility of MRCP in PFC are conflicting, with some reports showing good accuracy [13]. ERCP remains the gold standard for diag-



► Fig. 6 Recurrent pancreatic fluid collection 1 year after biflanged metal stent removal. a The collection contains homogeneous contents and measures 9.7×7.4 cm. b An ultrasonography performed 4 weeks later shows spontaneous regression in the collection size (5.8×5.2 cm). The patient had no symptoms except for mild pain.

nosis of disconnected duct, but it is not capable of detecting leaks beyond the disconnected duct, as neither contrast nor guidewire can progress beyond the disconnection. Unless we do percutaneous or EUS-guided antegrade injection in the tail, it is not possible to determine the exact relationship of the cyst to the duct in the disconnected pancreatic segment. Thus, the published data may not be very accurate. We found four distinct patterns of disconnections and leaks. Other studies on ERCP have shown different patterns, but these studies are primarily oriented towards surgical management [14].

The commonest abnormality was disconnection with ductal leak near the head end of disconnection. Thus, the cyst communicates with the pancreatic duct as evidenced by contrast filling of the cyst during ERCP. A plastic stent placed through the papilla, or a long-term plastic stent placed through the stomach wall, is unlikely to improve upon the drainage provided by BFMS in such abnormalities. A Type II abnormality, with the cyst in relation to the disconnected pancreatic tail could, theoretically, be helped by permanent indwelling transluminal stents, if the disconnection is severe and permanent, but our data do not suggest the necessity of such a strategy.

We encountered technical difficulties in placing a pancreatic duct stent across the leak, as has been reported in other studies. This is probably explained by the complex anatomical variations in the disconnected ducts. It is not possible to bridge the ductal defect in the majority of patients. There was no difference in the outcome of patients who underwent placement of a pancreatic duct stent. The recurrence rates were similar in those who received and those who did not receive a pancreatic ductal stent. However, a comparison of stented patients with

those not stented may not accurately tell us about the utility of pancreatic duct stents, as most of the nonstented patients in our study did not have ductal leaks. Current evidence regarding ductal stenting is equivocal about its role in reducing recurrences [15, 16].

We utilized transabdominal ultrasonography for follow-up and detection of recurrences. Although ultrasonography is inferior to CT scan for this purpose, we used this imaging technique as the patients were likely to be asymptomatic and a CT scan every 3 months would not be appropriate or cost-effective. The recurrence rate in our study is in line with other published studies [17,18]. The nature of recurrence is similar to that of a pseudocyst; thus, the term "recurrence" does not appear to be appropriate. All patients had clear cyst contents with no necrotic material, and all except one were detected on routine follow-up, and were asymptomatic. It is not possible to categorically state whether these cysts originated from the original disruption, or were the result of a permanently disconnected duct. However, it is possible that they are the latter, as some recurrences developed in patients without a demonstrated ductal leak, and all of them were homogeneous without necrotic debris within. In the absence of a control arm it is difficult to judge whether the rate of recurrence with short-term BFMS is less or more than that with long-term BFMS, but the rate is comparable to other studies. There is paucity of data on the natural history of disconnected ducts, with initial reports probably reporting the clinically worst cases [19-21]. The Mayo Clinic study does mention spontaneous resolution of disconnected ducts, as well as development of chronic pancreatitis and atrophy [19]. It is conceivable that the majority of disconnected ducts resolve once the inflammatory process subsides, while the most severe ones develop permanent issues such as stricture, collection, or fistula.

All except one of our recurrences had spontaneous regression, indicating a more benign course than has been suggested to date. It is possible that most of the recurrences do not need therapy and resolve with time. This is the first study to suggest that most recurrences do not need therapy, and further studies should clarify this.

In conclusion, we have shown that short-term BFMS placement is a safe and effective treatment of carefully selected symptomatic pancreatic WON. MRCP does not appear to be efficient in detecting disconnections and leaks. There is a high incidence of disconnections and leaks with pancreatic WON, but placement of pancreatic duct stents may not improve the outcome because of accompanying anatomical complexities. Recurrences are mostly asymptomatic and do not need aggressive therapy.

Competing interests

None.

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