

Clinical and morphological consequences of permanent indwelling transmural plastic stents in disconnected pancreatic duct syndrome

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ABSTRACT

Background: Long-term indwelling transmural stents in patients with walled-off necrosis (WON) and disconnected pancreatic duct syndrome (DPDS) is an effective strategy to decrease risk of recurrence of pancreatic fluid collection (PFC). However, long-term studies on the safety and efficacy of this strategy are lacking. **Methods:** Retrospective analysis of database of patients with WON treated with endoscopic transmural drainage over the past 8 years was done to identify patients with DPDS and indwelling transmural stents for >3 years. **Results:** During the past 8 years, 56 patients with indwelling transmural stent for >3 years were identified and 67.85% of these patients had 10 Fr stents and 32.15% of patients had 7 Fr stents. On follow-up, 5 (8.9%) patients had pancreatic pain with one patient (1.78%) developing recurrence of PFC despite stent being *in situ*. Two (3.5%) patients had asymptomatic spontaneous external migration of the transmural stent. Fourteen (25%) patients developed diabetes. Two (3.5%) patients developed local complications due to indwelling stent (stent eroded into descending colon in one patient and stent-induced parenchymal calcification in the other). Forty-eight (85.7%) patients underwent EUS on follow-up and disconnected pancreas revealed ≥ 5 criteria for the diagnosis of chronic pancreatitis in 15 (31.25%) patients. **Conclusions:** Long-term indwelling transmural plastic stents in patients with WON and DPDS are safe and effective with minimal complications. Despite the presence of stents, disconnected pancreas develops morphological changes resembling chronic pancreatitis in one-third patients and clinical consequences of these changes need to be further evaluated.

Key words: Acute pancreatitis, EUS, local complications, stent

INTRODUCTION

Acute pancreatitis (AP) is an inflammatory condition of the pancreas and is associated with high morbidity and mortality. It can range in severity from mild self-limiting illness to severe disease with various

organ failures and high mortality ranging up to 15%–40%.^[1] Acute necrotizing pancreatitis (ANP) can cause necrosis of main pancreatic duct along with

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surrounding pancreatic parenchymal tissue. Complete disruption of main pancreatic duct with the presence of viable pancreas upstream of disruption leads to disconnected pancreatic duct syndrome (DPDS).^[2,3] It is a unique situation as the upstream viable pancreas becomes an isolated functioning tissue which continues to secrete enzyme rich pancreatic juice causing formation of peripancreatic fluid collection (PFC). Although initially under-recognized, studies have shown that DPDS can occur in up to 30%–80% of patients with ANP.^[2,4-7]

Endoscopic step-up approach is considered as the preferred treatment approach in the management of symptomatic PFC.^[8-10] The presence of DPDS poses many unique challenges in endoscopic management of pancreatic collection. Studies have shown that AP patients with DPDS are more likely to require multiple endoscopic interventions as well as surgery with consequent longer hospital stay.^[4,11] Moreover, transpapillary endotherapy in the presence of DPDS is not much effective.^[12] Recurrence of PFC is one of the major concerns in the endoscopic transmural management of collections associated with DPDS. Studies have shown that 17%–38% of patients with DPDS show recurrence of PFC during follow-up if transmural stents were removed after resolution of collection.^[4,13] Hence, keeping transmural stents *in situ* for indefinite period, even after resolution of PFC, has shown to be an effective strategy for the prevention of the recurrence of PFCs.^[4,13,14] However, these studies have limited follow-up duration as well as fewer patients with walled-off necrosis (WON).

Despite initial enthusiasm, recent studies have shown that the lumen-apposing metallic stents (LAMs) and plastic stents both have comparable success rate even in patients with WON.^[15] Moreover, recent studies have shown alarming incidence of various life-threatening complications of in dwelling LAMS like increased risk of bleeding, especially pseudoaneurysm-related bleed, increased risk of “buried stent” and biliary compression, especially if stents are kept *in situ* for a longer period.^[15,16] These data have now changed the management protocol toward early removal of LAMS and replacing it with plastic stent.^[17] However, very limited data are available on the safety and efficacy of such permanently left transmural stents despite being commonly practiced.^[18] We had previously reported the safety and efficacy of permanently left transmural stents in 30 patients over a mean follow-up period of

20 months and found them to be safe and effective.^[18] However, data on the safety and efficacy of longer indwelling transmural stents are scanty. Furthermore, the morphological changes in the disconnected segment of pancreas following long-term transmural stents have not been evaluated. Therefore, we retrospectively searched our data base to identify patients of WON and DPDS with indwelling transmural stent/stents for >3 years and evaluated the long-term safety and efficacy of this strategy of leaving transmural stents permanently. Furthermore, the morphological changes in the disconnected segment of the pancreas following long-term transmural stents were evaluated by retrieving the EUS findings from the database.

METHODS

Retrospective analysis of prospectively maintained database of patients with WON (as defined by the revised Atlanta classification [1]) and DPDS who underwent EUS-guided transmural drainage followed by the placement of permanent indwelling transmural plastic stent in our unit from June 2011 to May 2019 was done. Only patients with regular follow-up and transmural stent *in situ* for >3 years were included in the analysis. Informed consent was obtained from all the patients before the endoscopic interventions.

Procedure details

The indications of transmural drainage of WON were continuous abdominal pain not relieved by frequent use of analgesics, fever, symptoms of gastric outlet obstruction, or biliary obstruction. EUS-guided drainage was performed if collection was predominantly central and located adjacent to the stomach or duodenum. EUS-guided drainage was performed by a single experienced endosonologist (SSR) using a linear scanning echoendoscope (EG-3870 UTK linear echoendoscope, Pentax Inc., Tokyo, Japan or UCT180 linear echoendoscope, Olympus Optical Co Ltd, Tokyo, Japan). The technical details of the EUS-guided drainage procedure have been published previously by us.^[8,18] The stents used for drainage varied during the study. In the initial period of the study, all patients were treated by multiple transmural plastic stents. After the availability of biflanged self-expanding metallic stents (BFMS), depending on financial affordability, patients were either treated with multiple plastic stents or BFMS (NAGI stent, Taewoong Medical Co., Ltd., Seoul, Korea or Plumber Stent, MI Tech Gyeonggi-Do, 17706, Korea).

Patients with multiple plastic stents

Patients with symptomatic improvement and resolved WON, endoscopic retrograde cholangiopancreatography (ERCP) or magnetic resonance cholangiopancreatography (MRCP) was done to document pancreatic duct disruption or DPDS. DPDS was defined as a complete disruption of the main pancreatic duct with viable upstream pancreas becoming isolated from the main pancreatic duct downstream.¹⁴ In patients with the normal pancreatic duct, all transmural stents were removed, whereas in patients with partial duct disruption, transpapillary bridging stent was placed that was subsequently removed along with the previously placed transmural stents after documenting healing of disruption. In patients with DPDS, one or more transmural stents were left indefinitely.

Patients with biflanged self-expanding metallic stent

The management protocol was similar to that of plastic stents as described above except that in patients with DPDS, following resolution of WON, an attempt was made to replace the metallic stent with a 7 or 10Fr double pigtail plastic stent that was left *in situ* for an indefinite period.

Follow-up protocol

After the initial clinical success, the patients were on three monthly follow-up or earlier if they develop any recurrence of symptoms. The patients underwent an abdominal X-ray to document the presence of transmural stents and blood sugar measurement, including HbA1c at six monthly intervals. Patients reporting new-onset symptoms such as abdominal pain, jaundice, bleeding, or abdominal lump underwent contrast-enhanced computed tomography (CT) abdomen to know the presence and position of transmural stents and also to detect any recurrence of PFC. Patients with recurrence of PFC also underwent additional investigations such as MRCP, EUS, and ERCP for further management.

Patients were also advised to undergo EUS to study the morphological changes in the disconnected pancreas. The patients giving informed consent for the endoscopic procedure underwent EUS under conscious sedation. The database of patients who had undergone EUS was searched for the ductal as well as parenchymal findings in the disconnected segment of the pancreas.¹⁹

RESULTS

One hundred and seventy-nine patients of WON were treated with EUS-guided transmural drainage

during the study period and 138 (77.09%) patients had DPDS. Of 138 patients, 56 patients had an indwelling transmural stent/stents for >3 years, were on regular follow-up, and these patients were included in the final analysis. In the study cohort, 39 patients were male, and the mean age was 37.6 years. The etiology of AP was alcohol in 39 (69.6%) patients, gall stone in 13 (23.2%) patients, drug in 1 (1.8%) patient, hypertriglyceridemia in 1 (1.8%) patient and idiopathic in 2 (3.6%) patients. The median size of WON was 10.2 cm, and in 41 (73.2%) patients, WON were localized to the body of the pancreas. Persistent abdominal pain requiring frequent analgesics use was the most common indication for WON drainage (67.8%) followed by fever not responding to conservative management (25.0%) [Table 1]. The initial drainage of WON was done with BFMS in 10 (17.8%) and multiple plastic stents in 46 (82.2%) patients, respectively. The technical success was 100% without any immediate complications. Five (8.9%) patients required additional percutaneous drainage for peripheral PFC. However, none of these patients required surgery.

Follow-up of patients

Following the resolution of WON, DPDS was confirmed on ERCP in 48 (85.7%) patients and by MRCP in 8 (14.3%) patients. The site of disconnection was neck, proximal body, and distal body in 28 (50%), 16 (28.6%), and 12 (21.4%) patients, respectively. The plastic stents left indefinitely were 7F 5 cm in 18 (32.14%) patients and 10F 5 cm stents in 38 (67.86%) patients. Thirty-one patients had one indwelling transmural stent, 20 patients had 2 indwelling

Table 1. Characteristics of pancreatic collection (n=56)

Characteristics	Number
WON size (cm), median	10.2
Location of WON, n (%)	
Head	6 (10.7)
Body	41 (73.2)
Tail	9 (16.1)
Indication of drainage, n (%)	
Fever	14 (25.0)
Pain	38 (67.8)
Jaundice	2 (3.6)
GOO	2 (3.6)
Solid debris, n (%)	
<10	8 (14.3)
10-40	36 (64.3)
>40	12 (21.4)

WON: Walled-off necrosis, GOO: Gastric outlet obstruction

transmural stents and five patients had three or more indwelling transmural stents [Table 2].

All included patients were on the regular clinic or telephonic follow-up. The mean duration of follow-up was 69.4 ± 18.8 months (range: 37–96 months). During follow-up, 2 (3.6%) patients had asymptomatic external migration of all the placed transmural plastic stents. Both the patient-reported passage of stents (one 7F stent in one patient and both 7Fr stents in the other patient) in stool. However, both patients were asymptomatic and neither of them had a recurrence of the pancreatic collection during follow-up period.

On follow-up, 5 (8.9%) patients had pancreatic pain with one patient (1.78%) developing recurrence of PFC despite stent being *in situ*. One patient (1.78%) developed symptomatic recurrence of fluid collection despite transmural stent (1 7Fr stent) being *in-situ* [Figure 1]. This patient had earlier developed WON following alcohol-induced ANP and was successfully treated with EUS-guided transmural drainage. Since then, he was on regular follow-up and was abstaining from alcohol. However, 58 months later, he presented with abdominal pain and CT revealed 8 cm pseudocyst near the tail of the pancreas. The recurrent fluid collection was successfully treated with repeat endoscopic transmural drainage using a single 10 Fr stent, and he is asymptomatic since then.

The other four patients with pancreatic pain had an indwelling transmural stent, and there was no recurrence of PFC. None of the patients had elevated amylase or lipase with no radiological evidence of AP. One patient presented with episodic abdominal

pain 48 months after transmural stenting (7F 5 cm double pigtail plastic stent). CT abdomen showed distal flange of pigtail was inside the pancreatic parenchyma near distal body, which was surrounded by punctate calcification. Stent was removed, and the patient was treated conservatively. The patient responded to treatment and became pain-free on follow-up. The remaining three patients presented with abdominal pain 52, 68, and 77 months after insertion of transmural stents. In these patients, CT revealed dilated main pancreatic duct in the disconnected segment of the pancreas with no parenchymal calcification or ductal calculi. EUS revealed dilated pancreatic duct with the hyperechoic wall along with dilated side branches in all these three patients. Furthermore, hyperechoic foci and strands along with lobularity were observed in all these three patients. These patients had 3, 1, and 1 episode of pain, respectively, during the follow-up period. None of the patients required hospitalization, and all had self-limiting pain that responded to nonsteroidal anti-inflammatory drugs.

Forty-eight (85.7%) patients underwent EUS after 3-year follow-up and 26 (54%) patients had atrophy of the disconnected pancreas [Figure 2]. The downstream pancreatic head and adjacent body revealed hyperechoic foci and hyperechoic strands in 16 and 9 patients, respectively, and none of these patients had ≥ 5 EUS criteria for the diagnosis of chronic pancreatitis in this uninvolved segment of the pancreas. Furthermore, none of these 26 patients had pancreatic symptoms on follow-up, but 11/26 (42%) patients had diabetes. All these 11 patients required insulin for the control of blood sugars. None of these patients had steatorrhea.

Table 2. Follow-up characteristic of the study population (n=56)

Characteristics	
Median follow-up (months)	69.4 \pm 18.8
Location of disruption, n (%)	
Neck	28 (50.0)
Proximal body	16 (28.6)
Distal body	12 (21.4)
Transmural stent used, n (%)	
7 F	18 (32.14)
10 F	38 (67.86)
Number of stent kept <i>in situ</i> , n (%)	
1	31 (55.4)
2	20 (35.7)
3 or more	5 (8.9)



Figure 1. Computed tomography abdomen: Recurrent pancreatic fluid collection despite the presence of transmural stent *in situ*

Of the remaining 22 patients, ≥ 5 EUS criteria for the diagnosis of chronic pancreatitis in the disconnected pancreas were observed in 15 (31.25%) patients [Figures 3 and 4, and Table 3]. Five of these patients had presented with abdominal pain, as described above. The EUS parenchymal criteria observed were: hyperechoic foci ($n = 22$), hyperechoic strands ($n = 22$), lobularity ($n = 15$), and cysts ($n = 1$). The ductal criteria observed were as follows: main duct dilatation (21), visible side branches (10), hyperechoic margins (19), duct irregularity (12), and stones (0). Three of these 22 patients (13%) patients developed diabetes, and all these patients required insulin for control of blood sugars. Similar to the patients with pancreatic atrophy, none of these 22 patients had ≥ 5 EUS criteria for the diagnosis of chronic pancreatitis in the downstream pancreas (Hyperechoic foci and hyperechoic strands in 12 and 7 patients, respectively).

Two (3.5%) patients developed complications because of indwelling transmural stent. One patient developed stent induced parenchymal calcification, as described in detail earlier. In another patient, the transmural stent eroded into descending colon 52 months after the successful resolution of WON. This patient presented with hematemesis due to splenic artery pseudoaneurysm that developed 3 weeks after an attack of acute necrotizing pancreatitis following an alcohol binge. Surgical ligation of bleeder and placement of drain in the lesser sac was done. Two weeks later, the patient developed feculent discharge in drain, and CT revealed transmural stent eroding into the descending colon. The transmural stent was removed by pulling it out from the stomach, and the gastric defect was closed with hemoclip. The patient had an uneventful recovery and is asymptomatic since then.

DISCUSSION

Recurrence of PFC is one of the major concerns following successful endoscopic transmural drainage of WON associated with DPDS because of uncorrected pancreatic duct anatomy. Moreover, DPDS is commonly found in patients with WON. In our study, we found that 77% of patients with WON had DPDS, and this finding is similar to the results observed by Bang *et al.* where the reported frequency of DPDS in patients with WON was 84%.¹⁴ The endoscopic transmural drainage of WON in the presence of DPDS leads to drainage of the disconnected pancreas into the gastrointestinal tract (duodenum or stomach) through

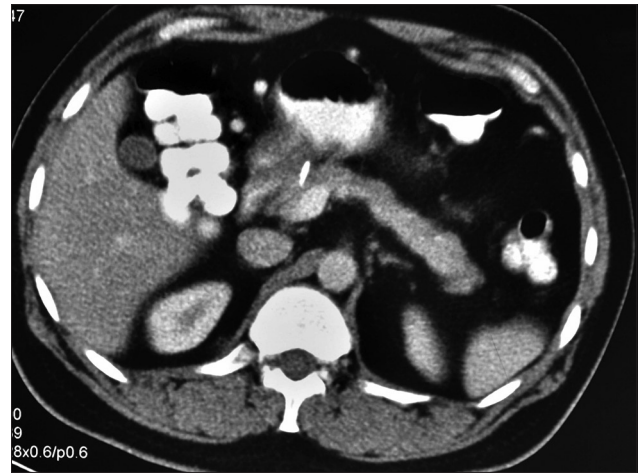


Figure 2. Computed tomography abdomen: Atrophy of the disconnected segment of pancreas. Transmural stent being seen *in situ*

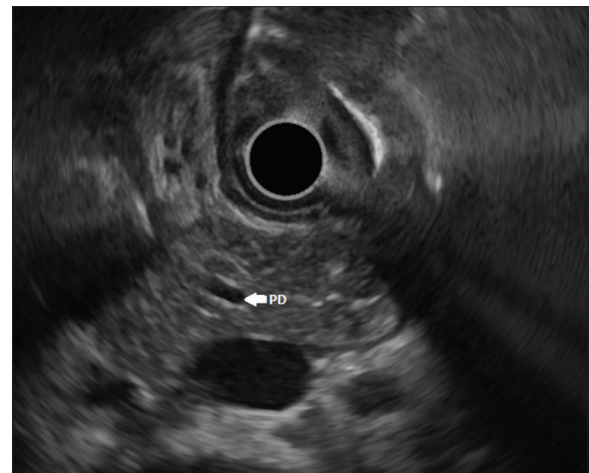


Figure 3. EUS: Disconnected segment of the pancreas shows dilated pancreatic duct with hyperechoic wall, hyperechoic foci and strands, and lobularity



Figure 4. EUS: Disconnected segment of the pancreas shows the hyperechoic wall of the pancreatic duct (arrow) with hyperechoic foci and strands and lobularity

Table 3. Follow-up EUS imaging in the study patients (n=48)

Changes in disconnected pancreas	Number of patients
Parenchymal criteria	
Hyperechoic foci	22
Hyperechoic strands	22
Lobularity	15
Cysts	1
Pancreatic atrophy	26
Ductal criteria	
Main duct dilatation	21
Visible side branches	10
Hyperechoic margins	19
Duct irregularity	12
Stones	0

the collection. Removal of transmural stents leads to closure of this internal drainage route of the disconnected pancreas leading to increased risk of recurrence of PFC. Therefore, to reduce this risk of recurrence, transmural stents are left *in situ* permanently so that the disconnected pancreas has an alternative internal drainage route.

The studies have shown that leaving transmural stents permanently reduces the risk of recurrence of PFC in patients with WON and DPDS.^[8,14,20] Recently, Bang *et al.* conducted retrospective analysis of the impact of DPDS on endoscopic management of PFCs. They studied 114 patients with WON and 84% of patients had DPDS. They reported that patients with DPDS who kept transmural stent *in situ* had lower rate of PFC recurrence compared to patients in whom transmural stents were removed (17.4% *vs.* 1.7%; $P < 0.001$).^[4] In the current study also only one patient with DPDS and indwelling transmural stents developed recurrence of fluid collections over a mean follow-up 69 months.

However, there are concerns and risks of leaving a plastic prosthesis for an indefinite period. The significant concerns of permanent transmural stents are complications such as infection, bleeding, stent migration, stent fracture, gastrointestinal perforation, or intestinal obstruction due to stent migration. However, fortunately, these theoretical adverse effects of permanent transmural stents have not been frequently reported in literature. The published studies have shown that the strategy of leaving transmural stents permanently following the successful resolution of WON with DPDS is not associated with major complications and decreases the risk of recurrence of PFC.^[14,18,20] However, these studies have limitations

of a relatively shorter follow-up period varying from the mean of 20–28 months, and there are few reports of significant complications occurring because of the presence of transmural stents for a longer duration.^[21,22] Recently, Yamauchi *et al.* retrospectively evaluated 53 patients with PFC and prolonged indwelling transmural stents and found that over a median stenting period of 20.9 (range 0.8–142.3) months, three patients developed colonic perforation because of pigtail stents. They concluded that long-term indwelling transmural stents pose a risk of intestinal perforation, and if possible, it may be better to avoid long-term placement.^[21] In this study, only one patient had colonic perforation and that too developed after a complicated clinical course of recurrent ANP following an alcohol binge. The other significant complication observed was pancreatic parenchymal calcification at the site of the pigtail of the plastic stent. Thus, the long-term follow-up data from our study suggests that permanent indwelling transmural stents are not associated with significant stent-related complications. Furthermore, two of our patients had asymptomatic external migration of the transmural stents. This is in accordance with previous studies where a subset of patients with DPDS do not have a recurrence of PFC despite the external migration of all the transmural stents. In our previous retrospective study on patients with WON and DPDS, we compared the profile of patients with recurrent PFC following the migration of transmural stents with that of patients who had asymptomatic migration of stents.^[23] We found that early migration of stents, ductal disruption in the pancreatic head as well as the absence of diabetes, steatorrhea, and pancreatic atrophy seem to increase risk of recurrent PFC following the migration of transmural stents in patients with DPDS. Thus, patients who have diabetes, pancreatic atrophy, and steatorrhea with distal (toward the pancreatic tail) duct disconnection can be considered for elective removal of transmural stents after 6 months. However, this approach of elective removal of stents needs to be confirmed by prospective long-term study comparing it with the conventional approach of leaving stents *in situ*. An important observation in the current study was that 5 (8.9%) patients had one or more episodes of pancreatic pain despite the presence of transmural stent/stents *in situ*, and all these patients had EUS features of chronic pancreatitis in the disconnected segment. In the current study, we had the first time evaluated the natural course of the disconnected pancreas and its consequences. In this study, 15/48 (31.25%) patients had ≥ 5 EUS

criteria for the diagnosis of chronic pancreatitis in the disconnected pancreas, whereas none of these patients had similar EUS changes in the downstream head of the pancreas. Although majority of patients with these EUS morphological changes were asymptomatic, these findings suggest that over a period the disconnected segment of the pancreas undergoes morphological changes. These observations raise important questions:

1. What is the cause of the evolution of these morphological changes in the disconnected segment? Is it an obstructive chronic pancreatitis of the disconnected segment?
2. Would placing multiple instead of single transmural plastic stents permanently for effective transluminal drainage be able to prevent these morphological changes?
3. Would surgery, by providing permanent and effective drainage of disconnected pancreas, be able to prevent these morphological changes?
4. What are the long-term clinical consequences of these morphological changes in the disconnected pancreas?

A longer follow-up comparative study is needed to answer many of these questions as well as determine the long-term clinical consequences of these morphological changes resembling chronic pancreatitis in the disconnected pancreas. Small sample size and retrospective nature are important limitations of our study. However, we had maintained the database prospectively and included only patients who were on regular follow-up and had completed follow-up for >3 years after transmural drainage, and hence, chances of bias can be reduced.

CONCLUSIONS

DPDS is a very common entity in patients with WON. Long-term transmural stenting is a safe and effective modality to prevent recurrence of PFC after initial endoscopic transmural drainage. Although it is not associated with severe complications, timely follow-up and watchfulness are necessary to detect and manage any complications due to indwelling transmural stents. Morphological changes resembling chronic pancreatitis in the disconnected segment is a concerning observation that needs further studies to determine the etiopathogenesis as well as clinical consequences.

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Conflicts of interest

There are no conflicts of interest.

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