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Endoscopic ultrasound-guided transmural drainage for pancreatic fistula or pancreatic duct dilatation after pancreatic surgery

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Running title: EUS-TD of pancreatic fistula

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Abstract

Background Endoscopic ultrasound (EUS)-guided drainage is widely used to manage pancreatic pseudocysts. Several studies have reported the use of EUS-guided drainage for pancreatic fistula and stasis of pancreatic juice caused by stricture of the pancreatic duct after pancreatic resection.

Methods In total, 262 patients underwent surgery involving pancreatic resection in our hospital from April 2005 to March 2010. Ninety patients (34%) developed a grade B or C postoperative pancreatic fistula (POPF) that required additional treatment. We performed EUS-guided transmural drainage (EUS-TD) for six patients (2.1%) with a pancreatic fistula or dilatation of the main pancreatic duct visible by EUS. Eighteen patients (6.8%) received percutaneous drainage. The success rates of EUS-TD and percutaneous drainage were compared in a retrospective analysis.

Results EUS-TD was successfully performed without complications in all six cases, with five of the six patients being successfully treated with only one trial of EUS-TD. The final technical success rate was 100% for EUS-TD and for percutaneous drainage. Both the short-term and long-term clinical success rates of EUS-TD were 100%, and those of percutaneous drainage were 61.1% and 83%, respectively. The differences in these rates were not significant (short-term success, $P = 0.091$; long-term success, $P = 0.403$). However, the period to clinical success was significantly shorter with EUS-TD (5.8 days) than with percutaneous drainage (30.4 days; $P = 0.0013$) in our series.

Conclusions EUS-TD appears to be a safe and technically feasible alternative to percutaneous drainage and may be considered a first-line therapy for pancreatic fistulas visible by EUS.

Abbreviations:

CT, computed tomography; EUS, endoscopic ultrasound; EUS-TD, EUS-guided transmural drainage; MPD, main pancreatic duct; POPF, postoperative pancreatic fistula; US, ultrasound; DPDS, Disconnected pancreatic duct syndrome

Introduction

Postoperative pancreatic fistula (POPF), a serious and potentially lethal complication, is the main unsolved problem in pancreatic surgery. The principle underlying this treatment is drainage of the pancreatic fluid that has collected within the abdominal cavity. The surgeon usually places the drainage tube near the pancreatic stump or the anastomotic site of pancreaticoenterostomy to drain the collected fluid in cases of leakage (pancreatic fistula).

However, additional drainage may be needed when the drainage work during the operation is inadequate. Despite the expansive growth pattern of pancreatic pseudocysts followed by acute or chronic pancreatitis, the POPF space extends to the peritoneal cavity between visceral organs. This space is usually located deep in the peritoneal cavity and it has an irregular and complex shape. These caused treatment with both surgical and interventional ultrasound (US) or computed tomography (CT)-guided drainage procedures to be problematic. The incidence of postoperative pancreatic fistula (POPF) has been reported to be 5–20% after pancreaticoduodenectomy and is associated with high mortality [1]. The Japanese Society of Hepato-Biliary-Pancreatic Surgery reported that the rate of POPF after pancreaticoduodenectomy was 30.2% [1]. Even with recent advances in pancreatic surgery, POPF remains the major contributor to morbidity after pancreatic resection.

The treatment of choice for POPF is external or internal drainage of pancreatic juice, which can be accomplished by surgical drainage, image-guided percutaneous drainage, or endoscopic drainage. A surgical cyst-enteric anastomosis has traditionally been performed, with high morbidity rates ranging from 7 to 37% [2, 3]. Percutaneous drainage offers satisfying results, but it requires a long therapy period (several weeks to months) owing to the indwelling catheter and is occasionally associated with the formation of an external fistula [4, 5]. Furthermore,

cutaneopancreatic fistulas that form after percutaneous drainage are usually intractable.

Endoscopic drainage has been performed increasingly during the last 10 years [6–8]. Two approaches have been used for endoscopic access: through the gastrointestinal wall by creating a cystogastrostomy/cystoduodenostomy (transmural drainage) or via the papilla (transpapillary drainage). Both approaches, which usually require the insertion of one or more plastic stents [9], have success rates of 70–87% and complication rates of 11–34% [10, 11].

Recently, endoscopic ultrasound (EUS)-guided transmural drainage (EUS-TD) has been widely used to manage pancreatic pseudocysts, and its applications have been extended gradually with the development of more innovative techniques and devices. Several reports have indicated the feasibility of EUS-guided drainage of pancreatic fistulae and stasis of pancreatic juice caused by a pancreatic duct stricture after pancreatic resection [12, 13]. However, no detailed reports are available comparing EUS-TD and percutaneous drainage of a pancreatic fistula after pancreatic resection. To examine the utility and efficacy of EUS-TD, we report six consecutive successful pancreatic fistula and pancreatic duct dilatation cases treated by EUS-TD through the gastrointestinal tract and compare the outcomes with those of cases treated by conventional percutaneous drainage.

Patients and methods

In total, 262 patients underwent surgery involving pancreatic resection at our hospital from April, 2005 to March, 2010. A total of 172 patients (65%) did not have POPF and did not undergo additional treatment. Ninety patients (34%) developed POPF and required additional interventional treatment because they had symptoms such as fever and abdominal pain. Sixty-six patients have been cured by conservative therapies, while 24 have not since a convex

array echo endoscope was introduced to our institute in April 2006. When POPFs were visible by EUS, EUS-TD was the first choice for their treatment. Percutaneous drainage was the second choice for treatment of refractory POPFs with symptoms or if they were not visible by EUS. As a result, POPFs in five patients (2.1%) and dilatation of the main pancreatic duct (MPD) caused by a stricture of the anastomosis in one, were detected by EUS and treated by EUS-TD, and patients with a POPF not visible by EUS were treated with percutaneous drainage (18 cases, 6.8%) or with a surgical drain followed by primary surgery (66 cases, 25%) for the duration above.

In the six patients treated with EUS-TD (Table 1), initial surgical indications were pancreatic carcinoma in three, bile duct carcinoma in two, and ampullary carcinoma in one. Pancreatoduodenectomy had been performed in three cases; hepatopancreatoduodenectomy, in two; and distal pancreatectomy, in one. After surgery, five patients (cases 1–5) developed a POPF, and one (case 6) developed dilatation of the MPD. Three patients (cases 1, 2, and 6) experienced fever, abdominal pain, or general fatigue as signs of a pancreatic fistula infection or stasis of pancreatic juice.

Of the 18 POPF patients treated with percutaneous drainage (Table 1), seven with a clinical diagnosis of bile duct carcinoma, three with pancreatic carcinoma, two with intraductal papillary mucinous neoplasm, and one each with ampullary carcinoma, gallbladder cancer, and mucinous cystic neoplasm had initially undergone pancreaticoduodenectomy or distal pancreatectomy. Hepatopancreatoduodenectomy had been performed in three patients diagnosed with bile duct carcinoma (Fig. 1). Data were collected from our endoscopic database and hospital records. Figure 1 shows a flow diagram of the study participants.

Endoscopic therapy

All EUS-guided procedures were performed with the patient in the lateral or prone position and under conscious sedation with midazolam and fentanyl. A convex array echo endoscope (GF-UCT240; Olympus Medical Systems, Tokyo, Japan), an ultrasound system (ProSound SSD-5000; ALOKA, Tokyo, Japan), and a fluoroscope (CUREVISTA; Hitachi Medical Corp., Tokyo, Japan) were used for all procedures. All POPF or dilatation of MPD were visible by EUS, and all punctures were performed through the stomach wall. With regard to EUS-TD of POPF, first, an internal fistula was created between the POPF and the stomach by introducing a 19-gauge needle (Echo Tip Ultra; Cook Endoscopy, Osaka, Japan). Successful POPF access was demonstrated by injection of contrast medium defining a POPF. Next, a 0.035-inch guidewire (Jagwire; Boston Scientific, Tokyo, Japan) was passed through the needle, introduced into the cavity of the POPF, and coiled within the POPF under fluoroscopic guidance. The tract was sequentially dilated with an over-the-wire biliary balloon dilator (6 mm, Hurricane RX; Boston Scientific), a Soehendra biliary dilatation catheter (SBDC-6, -7, -8.5; Cook Endoscopy), or a Soehendra stent retriever (7 Fr; Cook Endoscopy). After dilatation, a double-pigtail stent (7 Fr, 40 mm; Olympus Medical Systems) was deployed into the fluid-filled space. Regarding EUS-TD of the dilated MPD, after the pancreatic duct was identified and regional recurrence was confirmed by color Doppler imaging, the MPD was punctured with a 19-gauge needle (Echo Tip Ultra; Cook Endoscopy), and an internal fistula was created between the MPD and the stomach as the initial step. Successful pancreatic duct access was demonstrated by injection of contrast medium defining a pancreatogram. Next, a 0.035-inch guidewire (Jagwire; Boston Scientific) was passed through the needle and introduced into the cavity of the MPD under fluoroscopic guidance. The tract was sequentially

dilated with a Soehendra dilatation catheter (SBDC-6; Cook Endoscopy). After dilatation, a pancreatic stent (5 Fr, 50 mm; Cook Endoscopy) was deployed into the MPD. Representative images of EUS-TD for POPF associated with the treatment of case 1 are shown in Fig. 2.

Percutaneous drainage of pancreatic fistulas

Percutaneous drainage was performed by an interventional radiologist and a surgeon, who punctured the pancreatic fistula by inserting a 0.035-inch guidewire into the fistula space and then placed an indwelling drainage catheter (7.2 Fr strait catheter; O-HIRATATM, Medico's Hirata, Osaka, Japan, or 8.5 Fr pigtail catheter; UltrathaneTM, Cook Endoscopy) under fluoroscopy, US, or CT guidance.

Technical and clinical success of EUS-TD and percutaneous drainage

Technical success of EUS-TD was defined as the successful placement of a transmural stent or percutaneous catheter into the POPF. Short-term clinical success was defined as a 50% decrease in the POPF or an improvement in the dilated MPD on CT images, and a decrease in serum amylase level in the drainage fluid 1 week after treatment. Long-term clinical success was defined as the resolution of the POPF or improvement of the dilated MPD on CT images 1 month after treatment.

Statistical analysis

Non-normally distributed variables are expressed as medians (range), and nonparametric tests (Mann-Whitney *U* test) were employed for statistical comparisons. Nominal variables are expressed as frequencies and percentages. The χ^2 test with Yates continuity correction for the

two-way contingency table was used for statistical comparisons. Fisher's exact test was used in the case of a small expected frequency. Data were considered significant at a P value <0.05 .

Results

The mean period between the onset of POPF and endoscopic therapy was 7.1 months (range, 1–24 months). EUS-TD was successfully performed without complications in all six cases (rate of technical success, 100%) (Table 2). The size of the fistula decreased remarkably (average reduction rate, 81.2%; range, 46.8–100%) in the five POPF patients. The MPD diameter in case 6 improved after MPD stenting. In all six cases, the serum amylase level was lower after drainage (before drainage: 413 U/L; 1 week after drainage: 65 U/L), reflecting decreased pancreatic duct pressure. One patient (case 1) developed a growth in the cavity by occlusion of the indwelling stent 2 months after the first drainage; this case underwent a stent exchange using a conventional endoscopic approach. No recurrences (mean follow-up, 7.5 months; range, 1–27 months) were observed in the remaining five cases. Table 3 compares the characteristics of the patient treated by EUS-TD and percutaneous drainage. EUS-TD and percutaneous drainage each had a final technical success rate of 100%. The short- and long-term clinical success rates of EUS-TD were both 100%, and those of percutaneous drainage were 61.1% and 83%, respectively. These rates did not differ significantly between techniques (short-term clinical success rate, $P = 0.091$; long-term clinical success rate, $P = 0.403$). However, the time until clinical success was significantly shorter with EUS-TD (5.8 days) than with percutaneous drainage (30.4 days; $P = 0.0013$).

Follow-up

After discharge, all patients were followed-up by laboratory investigations and CT. Transmural stents were not retrieved, even after fluid collection was completed. Endoscopic treatment was repeated in the event of stent occlusion. No POPF recurrence was observed during the follow-up time (mean follow-up, 17.7 months; range, 1–47 months).

Discussion

A pancreatic fistula is as an abnormal communication between the pancreatic duct and another non-epithelized cavity containing pancreas-derived, enzyme-rich fluid [3, 12], which occurs mainly after pancreatic resection and trauma. Pancreatic juice may spread throughout the pleura or peritoneum and induce severe inflammation and autodigestion of peripancreatic and retroperitoneal tissues. A pancreatic pseudocyst, which develops after acute pancreatitis or accompanying chronic pancreatitis, is a localized collection of fluid rich in amylase and other pancreatic enzymes and enclosed by a non-epithelized, hard and thick wall [3, 12]. However, differentiating a POPF from a pancreatic pseudocyst is difficult in some situations. A POPF represents failure of healing and/or sealing of a pancreatic-enteric anastomosis and a leak of pancreatic juice into the peritoneal or retroperitoneal cavity.

POPF is treatable by endoscopic, surgical, and/or percutaneous drainage. Endoscopic transpapillary drainage of the MPD for a pancreatic fistula communicating with the MPD is a relatively easy, well established, first-step for patients with POPFs [14, 15]. However, the transpapillary approach can occasionally be difficult owing to distortion of the duodenum caused by postoperative changes. When distal pancreatectomy is performed, a transpapillary approach should be considered. However, we did not undertake any endoscopic transpapillary approaches during the period of this retrospective study. Of the six cases, cases 1–3, 5 and 6

underwent pancreaticoduodenectomy or hepatopancreatoduodenectomy. Although only case 4 underwent a distal pancreatectomy, we performed EUS-TD because POPF were readily visualized by EUS. EUS-TD has been successfully performed for POPFs associated with a complete MPD rupture caused by trauma, pancreatoenteric anastomotic breakdown, and occlusion of a pancreatoenteric anastomosis after pancreatic surgery [13, 16, 17]. The present report demonstrates that drainage of pancreatic fistulas and MPD by EUS-TD through the gastrointestinal tract was effective and safe in all six cases. EUS-TD allows access to relatively small and non-bulging pancreatic fistulas and provides visualization of the blood vessels to reduce the risk of bleeding [18, 19]. EUS-TD also permits internal drainage of pancreatic fluid into the gut, and direct fistula formation between the POPF space and the gut can facilitate POPF closure in one step. In contrast, percutaneous drainage may lead to the formation of a permanent external fistula in 5–10% of cases [4]. Percutaneous drainage also sometimes requires two or more procedures in a multistep conversion from external to internal drainage and necessitates a longer hospital stay compared with EUS-TD. Disconnected pancreatic duct syndrome (DPDS) is an anatomic situation defined by a lack of ductal continuity between viable secreting pancreatic tissue and the gastrointestinal tract. The visible upstream pancreas continues secretion without an intact drainage system. The physiologic abnormality of DPDS results in myriad complications, including pancreatic pseudocysts, pancreatic ascites, pancreatic fistula, and others [20]. In our study, we believed that differences in the mechanism of POPF were caused by the methods of surgical anastomosis used. The patients with pancreatojejunostomy would demonstrate POPFs caused by anastomotic breakdown (case 1–3,5) or complete rupture (case 4), whereas a case with pancratogastrostomy would develop stasis of the pancreatic juice caused by occlusion of the anastomosis (case 6). EUS-TD to the

dilatation of the MPD was successful in our study. However, Kahaleh *et al.* [21] reported that EUS-TD of the MPD dilatation failed in 28.5% of postsurgical patients. Therefore, EUS-guided pancreatic duct drainage remains difficult, especially in the postoperative situation. If recurrence develops after EUS-TD of the dilated MPD, surgery should be considered, despite its higher morbidity and mortality than nonsurgical approaches [22].

Only one patient (case 1) developed a relapse of pancreatic fluid collection due to stent occlusion and underwent a second EUS-TD for a stent exchange. Although several reports have indicated the recurrence of pancreatic fluid accumulation following stent removal after endoscopic transmural drainage, in most patients with a pancreatic fistula who undergo EUS-TD, stent removal is performed routinely within 2 weeks of fistula resolution on imaging [6, 23]. The recurrence rate of a pancreatic fistula that requires further endoscopic, surgical, or percutaneous drainage varies from 10% to 30%, and recurrence often occurs within 1 year after treatment [6, 7, 10]. A previous randomized controlled trial regarding stent removal after successful endoscopic transmural drainage of a pancreatic fistula caused by acute pancreatitis or chronic pancreatitis showed that stent retrieval was associated with a higher recurrence rate [24]. In this study, during a median follow-up period of 14 months, no patients in the persistent stent placement group had POPF recurrence, whereas five of the 13 patients (38.4%) in the stent retrieval group did have POPF recurrence. This result suggests that by maintaining the stent in place, the cystenterostomy tract may remain patent. This patency could be caused by the stent, which acts as a wick and maintains communication between the pancreatic fistula and the stomach. Prolonged transmural stent placement has been adapted as a strategy to prevent recurrence of POPF [24, 25]. Although Varadarajulu *et al.* pointed out the risk of stent migration, they reported placement of a permanent indwelling stent by EUS-TD [26].

Furthermore, the appropriate period for stent placement and optimal stent diameter are controversial and yet to be determined. Nevertheless, we consider that a stent remaining in its proper position reduces the recurrence rate.

In our study, the period to clinical success was significantly shorter with EUS-TD than with percutaneous drainage. In two previous studies [27, 28], a higher failure rate was associated with percutaneous drainage of pancreatic pseudocysts (58%) compared with surgical treatment (7%) [27], and surgical and endoscopic interventions for pancreatic pseudocysts were equally safe and effective compared with percutaneous drainage [28]. Thus, EUS-TD can be considered a first-line therapy for a pancreatic fistula detectable by EUS when conservative management is ineffective. When EUS-TD cannot be performed, percutaneous drainage or surgical drainage can be considered to manage POPF.

No major complications following EUS-TD were noted in our study. Previous studies have reported complications such as perforation, bleeding, and pancreatitis, although most were not serious [10, 11]. As major hemorrhage, a rare occurrence during EUS-TD, would require surgery, EUS-TD should be performed only in tertiary care centers [17].

The limitations of the present study include its retrospective design, the small number of patients studied, and the evaluation of subjects from a single center. Larger studies are needed to further understand the current situation of POPF drainage.

In conclusion, EUS-TD is a technically feasible and apparently safe alternative to percutaneous or surgical drainage for POPF. EUS-TD can be considered as a first-line therapy for POPFs visible by EUS.

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Figure legends

Fig. 1. Flow diagram of the study participants. Abbreviations: AC, ampullary carcinoma; BDC, bile duct carcinoma; DP, distal pancreatectomy; EUS-TD, endoscopic ultrasound-guided transmural drainage; GBC, gallbladder cancer; HPD, hepatopancreaticoduodenectomy; IPMN, intraductal papillary mucinous neoplasm; MCN, mucinous cystic neoplasm; NET, neuroendocrine tumor; PC, pancreatic carcinoma; PD, pancreaticoduodenectomy; POPF, postoperative pancreatic fistula; SPR, segmental pancreatic resection.

Fig. 2 Endoscopic ultrasound-guided transmural drainage (EUS-TD) technique.

A Computed tomography scan of the abdomen showing a postoperative pancreatic fistula (arrowhead) that developed 24 months after surgical resection. **B** EUS image of a pancreatic fistula (arrowhead) showing a 71-mm hypoechoic area and introduction of a needle (dotted arrowhead). **C, D, E, F** Fluoroscopic images of EUS-TD. A fine aspiration needle was used to puncture the fistula under EUS guidance. A guidewire was introduced through the needle and was coiled within the fistula cavity under fluoroscopic guidance. Dilatation was performed using a dilatation catheter. After dilatation, a 7 Fr double-pigtail stent was inserted into the fistula.

Table 1. Characteristics of patients with a postoperative pancreatic fistula before endoscopic treatment.

Case	Age (yr)/Gender	Disease	Operation	Reconstruction	Location of POPF	POPF grade	Size of POPF (mm)	Duration from Operation to EUS-TD (months)
1	50/M	PC	PD	PJ	Anastomosis of PJ	B	39	6
2	79/M	PC	PD	PJ	Anastomosis of PJ	B	21	1
3	66/M	BDC	HPD	PJ	Anastomosis of PJ	B	71	24
4	75/M	PC	DP	(–)	Pancreatic body (cut end)	B	77	4
5	69/M	BDC	HPD	PJ	Anastomosis of PJ	B	75	5
6	49/M	AC	PD	PG	Dilatation of MPD*	B	6	3

AC, ampullary carcinoma; BDC, bile duct carcinoma; DP, distal pancreatectomy; EUS-TD, endoscopic ultrasound-guided transmural drainage; HPD, hepatopancreaticoduodenectomy; MPD, main pancreatic duct; PC, pancreatic carcinoma; PD, pancreaticoduodenectomy; PG, pancreatogastrostomy; PJ, pancreatojejunostomy; POPF, postoperative pancreatic fistula.

* Case 6 had a dilatation of the pancreatic duct by occlusion of pancreatogastrostomy. The value indicates the MPD diameter.

Table 2. Clinical course of patients with a postoperative pancreatic fistula before and after EUS-TD.

Case	Indwelling stent size	Number of EUS-TD procedures	Resolution of POPF	Period of clinical success (days)	Recurrence of POPF	Size of POPF or MPD (mm)		Serum amylase (U/l)		Follow up (months)
						Before drainage	1 week after drainage	Before drainage	1 week after drainage	
1	7 Fr-40 mm	2	Yes	4	Yes*	44	0	1710	76	47
2	7 Fr-40 mm	1	Yes	5	No	21	0	242	57	28
3	7 Fr-40 mm	1	Yes	7	No	71	0	142	64	21
4	7 Fr-40 mm	1	Yes	7	No	77	36	71	55	5
5	7 Fr-40 mm	1	Yes	7	No	75	13	139	62	1
6	5 Fr-50 mm	1	Yes	5	No	6**	2.5**	175	78	3

EUS-TD, endoscopic ultrasound-guided transmural drainage; MPD, main pancreatic duct; POPF, postoperative pancreatic fistula.

*Case 1 developed a growth in the cavity by occlusion of the indwelling stent 2 months after the first drainage and underwent stent exchange by a conventional endoscopic approach.

**The value of case 6 indicates the MPD diameter.

Table 3. Characteristics of the patients with a postoperative pancreatic fistula treated with EUS-TD and percutaneous drainage

Characteristic	EUS-TD	Percutaneous drainage	<i>P</i> value
Number of cases, <i>n</i>	6	18	NS
Male/Female, <i>n</i>	6/0	11/7	NS
Mean age, years	67.8	66.9	NS
Initial operation, <i>n</i>			
PD/HPD	3/2	10/3	NS
DP	1	5	NS
PF location, <i>n</i>			
Anastomosis of PJ	4	16	NS
Pancreatic body	2	2	NS
POPF grade/no. of cases	B/6	B/11, C/7	
Median PF diameter (range), cm	4.9 (0.6–7.7)	7 (3–14.7)	NS
Technical success, <i>n</i> (%)	6 (100)	18 (100)	NS
Short-term clinical success, <i>n</i> (%)	6 (100)	11 (61.1)	NS
Long-term clinical success, <i>n</i> (%)	6 (100)	15 (83)	NS
Time till clinical success (range), days	5.8 (4–7)	30.4 (15–57)	0.001
Complications, <i>n</i>	0	0	NS

DP, distal pancreatectomy; HPD, hepatopancreaticoduodenectomy; NS, not significant; PD, pancreaticoduodenectomy; PJ, pancreatojejunostomy; POPF, postoperative pancreatic fistula.



