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Review

Endoscopic management of walled-off pancreatic necrosis

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Walled-off pancreatic necrosis (WON) can develop in the late phase of necrotizing pancreatitis. When the WON is accompanied by an infection in the necrotic bed, it becomes a life-threatening complication. Open necrosectomy with drainage has been the standard treatment; however, it is associated with a significant morbidity and high mortality. Therefore, minimally invasive therapeutic alternatives are in demand. Recently, a new treatment algorithm for necrotizing pancreatitis, known as the step-up approach, has been proposed. The initial report on it consisted of percutaneous drainage followed by, if necessary, a minimally invasive retroperitoneal necrosectomy. However, the endoscopic step-up approach, which consists of EUS-guided transluminal drainage followed by, if necessary, endoscopic necrosectomy, was later introduced. Recent studies have suggested that an endoscopic step-up approach might be more advantageous than a minimally invasive surgical step-up approach. A lumen apposing metal stent (LAMS) with a cautery-enhanced delivery system is currently preferred over the conventional plastic stents for endoscopic interventions, because it decreases the technical difficulty of the procedure and may obviate the need for an adjunctive debridement procedure. However, some recent findings suggest that LAMS could be associated with a higher risk of stent-related complications than conventional plastic stents, especially in patients with long-term placement. Therefore, early removal of LAMS at 3 weeks post-intervention is proposed if the WON is resolved on CT examination. Thus, endoscopic interventions have emerged as a key player in the management of WON. However, multidisciplinary treatment approaches should be considered because the endoscopic approach has limitations in treating complicated WON..

Key words: endoscopic ultrasound, lumen apposing metal stent, necrosectomy

INTRODUCTION

ACUTE PANCREATITIS, AS per the revised Atlanta classification,[1] can be subdivided into interstitial edematous pancreatitis (mild type) and necrotizing pancreatitis (severe type). In addition, the pancreatic and peripancreatic fluid collection (PFC), following acute pancreatitis, can also be subdivided into four categories: acute peripancreatic collection and pancreatic pseudocyst develop in the early and late phase of interstitial edematous pancreatitis, respectively. Both collections are composed of only fluid. In contrast to these PFCs, necrotizing collections such as an acute necrotic collection (ANC) and walled-off necrosis (WON) may develop following necrotizing pancreatitis. In the early phase, the collection, containing variable amounts of fluid and necrotic tissue, is termed an ANC. WON is a mature, encapsulated collection of pancreatic and/or peripancreatic necrosis and has a well-defined inflammatory wall. The maturation and progression of the ANC to the WON usually occurs more than 4 weeks following the onset of the necrotizing pancreatitis.

The mortality rate in patients with WON, accompanied by infections in the necrotic bed, is in the range 20–30%.[2] Surgical interventions, including open necrosectomy and drainage, have been widely performed as a standard treatment; however, they are also associated with a high morbidity (13–53%) and mortality (6–34%).[3] In addition, these patients require an extensive recovery period. These limitations have led to investigations of alternative techniques to treat WON. Recently, minimally invasive therapeutic alternatives have been attempted to combat WON. Minimally invasive treatments include percutaneous catheter drainage, video-assisted retroperitoneal debridement (VARD), endoscopic ultrasound (EUS)-guided transluminal drainage, and endoscopic necrosectomy.

MINIMALLY INVASIVE TREATMENTS

Percutaneous catheter drainage

IMAGE-GUIDED PERCUTANEOUS catheter drainage, the primary treatment of infected pancreatic necrosis, was initially described in 1998.[4] In a large prospective multicenter cohort study, 35% of patients managed by primary percutaneous catheter drainage did not require any

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further interventions.[5] A systematic review of 11 studies, including a total of 384 patients, also showed that more than half of the patients were successfully treated with percutaneous catheter drainage alone.[6] In addition, two randomized control trials (RCTs) comparing various approaches in the management of symptomatic WON demonstrated that percutaneous drainage alone was successful in 35% and 51% of patients, respectively.[7,8]

VARD

The VARD is a hybrid of the sinus tract endoscopy and open lumbar approach. By using a 5-cm subcostal incision, the previously placed percutaneous catheter drain is inserted into the retroperitoneal necrotic cavity. The superficial necrosis is removed under direct vision, followed by further debridement under videoscope assistance.[9]

EUS-guided drainage and endoscopic necrosectomy

Endoscopic drainage of the PFC has been attempted since the 1980s.[10] The transmural puncture of the PFC was originally attempted blindly via the gastric or duodenal wall. Therefore, the procedure was possible only in cases where the lesion bulged into the gastric or duodenal lumen. Subsequently, an EUS-guided drainage technique was initially attempted by Grimm *et al.* in 1992.[11] This technique enabled the secure and safe puncture of the PFC, even when it had not bulged into the gastrointestinal lumen. Two RCTs, involving only pancreatic pseudocysts, confirmed the superiority of this technique over the conventional endoscopic approach (success rates in RCT-1 100% vs 33% and RCT-2 94% vs 72%).[12,13]

In 1996, Baron *et al.*[14] first described the effective removal of infected necrotic pancreatic tissue by endoscopic transmural drainage and lavage to treat WON. Later, Seifert *et al.*[15] described the direct endoscopic necrosectomy (DEN) technique, which involved the direct entry of the endoscope into the necrotic cavity with subsequent removal of necrotic tissue using endoscopic accessories. Since then, numerous studies have shown the efficacy of DEN in combating WON. The Asian consensus statements on the endoscopic management of WON reviewed 38 published studies involving 697 patients. The resolution of the WON cavity was obtained in 82.6% of the patients. The DEN-related complications were also reviewed in 37 studies with 633 patients. The morbidity and mortality associated with DEN were 27.3% and 4.4%, respectively. The primary complication was bleeding (12.6%), which could occur during either balloon dilation of the fistula or necrosectomy. Perforation (4.4%) was the second most frequent complication. Air embolism was a lethal complication that was observed in 0.8% of cases.[16] Therefore, both Asian and European guidelines strongly recommended the use of CO_2 instead of air for insufflation during the DEN procedure to reduce the risk of air embolism.[16,17]

INDICATIONS AND TIMING OF INTERVENTIONS

THE ENDOSCOPIC INTERVENTIONS are essentially performed to treat infected WON. The indications for these endoscopic interventions also include sterile WON with symptoms, such as abdominal pain, nausea, vomiting, and nutritional failure, or with associated complications including gastrointestinal luminal obstruction, biliary obstruction, recurrent acute pancreatitis, or fistulas.[17,18]

Delayed intervention is currently preferred over early intervention in cases of infected pancreatic necrosis, because early intervention is associated with an increased morbidity and mortality. Postponing interventions by more than 29 days following hospitalization is significantly associated with a decrease in the mortality rate.[5,19] The current guidelines recommend that the necrosectomy is optimally delayed by 4 weeks and performed earlier only when there is an organized collection and a strong indication.[18] However, early intervention is sometimes required in the case of an infection that cannot be controlled by conservative treatment in the presence of organ failure. Recent studies have demonstrated the feasibility and safety of early endoscopic interventions (drainage with or without subsequent necrosectomy) in these cases.[20–22]

STEP-UP APPROACHES

IN A MULTICENTER RCT, the Dutch Pancreatitis Study Group compared the outcomes of a standard open necrosectomy to that of a step-up approach, which consists of percutaneous drainage followed by, if necessary, a minimally invasive retroperitoneal necrosectomy. Data obtained from this RCT showed that major complications, such as new-onset multiple-organ failure or multiple systemic complications including perforation of a visceral organ, enterocutaneous fistula, or bleeding, or death occurred less frequently with the step-up approach as compared to open necrosectomy (40% vs 69%; $P = 0.006$), and 35% of patients in the step-up group were only treated with the percutaneous drainage.[7] The Dutch Pancreatitis Study Group also analyzed the long-term outcomes and showed that a significantly lower proportion of patients in the step-up group, as compared to those patients treated with standard open necrosectomy, had incisional hernias (23% vs 53%; $P = 0.004$), pancreatic exocrine insufficiency (29% vs 56%; $P = 0.03$), or endocrine insufficiency (40% vs 64%; $P = 0.05$). Thus, a less invasive step-up approach demonstrated superiority over open necrosectomy without an increased risk of reintervention during long-term follow-up.[23]

Currently, both endoscopic and minimally invasive surgical step-up approaches are widely accepted as treatment modalities for combating WON.[18] In summary, the endoscopic step-up approach consists of EUS-guided transluminal drainage followed by, if necessary, DEN, while the surgical step-up approach consists of percutaneous catheter drainage followed by, if necessary, VARD (Fig. 1).

Endoscopic vs surgical step-up

Recently, an RCT compared the endoscopic step-up approach with the surgical step-up approach. The results showed that the endoscopic step-up approach was not superior to the surgical step-up approach in reducing major complications or death during a 6-month follow-up, but the rate of pancreatic fistulae and length of hospital stay were lower in the endoscopic step-up approach group.[8] More recently, another RCT compared the outcomes of endoscopic approaches to those of the minimally invasive surgical approach (laparoscopic or VARD). The results showed that the rate of complications and death during 6 months of follow-up was significantly lower in the endoscopic step-up approach group than in the minimally invasive surgery group (11.8% vs 40.6%; $P = 0.007$). The physical health scores for quality of life (QOL) at 3 months was better, and the mean total cost was significantly reduced in the endoscopic step-up approach group as compared to those of the minimally invasive surgery group.[24] A retrospective cohort study evaluating the long-term outcomes and health-related QOL in these patients demonstrated that the disease-related mortality and the occurrence of exocrine insufficiency and endocrine insufficiency were 3.7%, 32.5%, and 27.7%, respectively, over a mean follow-up period of 42.2 months. The health-related QOL of patients was relatively preserved; however, patients with exocrine insufficiency had a significantly poorer health-related QOL compared to healthy controls.[25] A recent meta-analysis showed that complications, such as new-onset multiple-organ failure, enterocutaneous fistula/perforations, and pancreatic fistulae, as well as the length of hospitalization were significantly lower following endoscopic interventions compared to those after minimally invasive surgical interventions.[26] These data are likely to promote the application of the endoscopic step-up approach in treating WON.

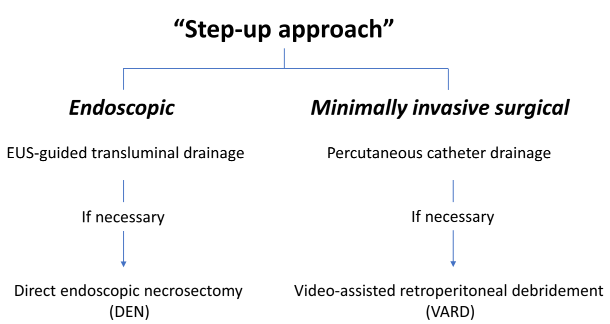

Figure 1 A flow chart of the step-up approaches.

LUMEN APPOSING METAL STENTS

MAINTENANCE OF A large open access is required to allow the evacuation of necrotic tissue, particularly to allow repeated DEN as per requirements. To achieve this purpose, multiple plastic stents (PSs) have been previously used. However, the lumen apposing metal stent (LAMS) is currently the preferred treatment modality (Fig. 2).[27] In addition, a LAMS with a cautery-enhanced delivery system decreases the technical difficulty of the procedure, avoids the need for tract dilation for stent insertion, has a short procedural time, and may obviate the need for adjunctive debridement procedures.

LAMS vs PS

Several studies have compared the efficacy and safety of LAMSs to those of PSs (Table 1).[28–36] The use of LAMS reduced the procedure duration,[28,30,35] and some studies demonstrated higher clinical success and lower adverse events with the use of LAMSs as compared to those when PSs are used.[31,36] Although LAMSs are much more expensive than PSs, a lower number of DEN sessions and decreased hospital stay associated with the LAMS procedure may render the overall cost comparable to that associated with PSs.[28–30] In a meta-analysis including 41 studies (2213 patients), metal stents were superior in treating WON as compared to PSs in terms of lower bleeding events, occlusion and perforation rates, and migration rates.[37] In contrast to the findings of the above study, another meta-analysis demonstrated that LAMSs and PSs had comparable clinical outcomes and adverse events in the management of WON.[38] Additionally, a recent study demonstrated that LAMSs were associated with a higher risk of pseudoaneurysm bleeding as compared to PSs.[34] RCT results, comparing LAMSs and PSs, recently showed that there was no significant difference in the total number of procedures, treatment success, clinical adverse events, readmission, length of hospital stay, and overall treatment costs between these two treatment options. However, significant stent-related adverse events were observed after more than 3 weeks following the LAMS intervention. These findings suggest that patients

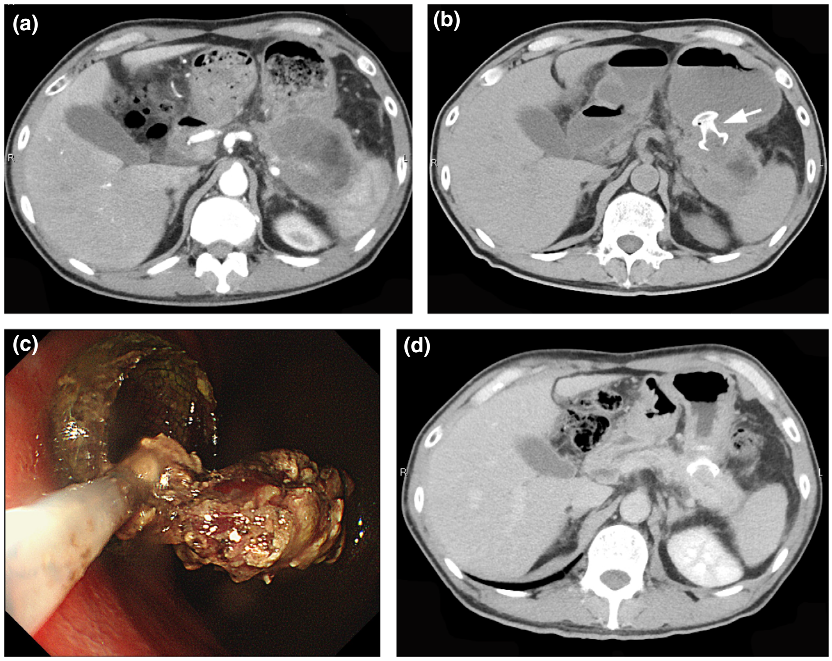

Figure 2 Endoscopic intervention using a lumen apposing metal stent. A CT image showing a Walled-off pancreatic necrosis (WON) in the tail of the pancreas (a). Following transgastric placement of a lumen apposing metal stent (Hot-Axios, Boston-Scientific, Natick, MA, USA) (b), endoscopic necrosectomy is performed using a polypectomy snare via the stent (c). The WON cavity is completely resolved after the treatment (d).

treated with LAMSs should undergo a CT scan after 3 weeks post-intervention.[35] Most recently, the efficacy and safety of a newly developed LAMS with less lumen-apposing force was evaluated in a prospective multicenter international study. As a result, the risk of stent-related adverse events was relatively low (6.8%). The authors suggested that the properties of the LAMS might reduce the risk of stent-related adverse events including a buried stent or stent induced bleeding.[39]

For a comprehensive understanding, more RCTs that include assessments of long-term outcomes and overall cost are necessary to conclude which stent provides better outcomes in the management of WON.

ADDITIONAL TECHNIQUES FOR COMPLICATED WON

Single and multiple transluminal gateway multiple drainage

THE CONVENTIONAL SINGLE transluminal gateway technique (SGT) using the transmural placement of single or multiple stents, with or without subsequent DEN, is usually sufficient to treat unilocular and uncomplicated WON. However, SGT is not always effective, especially in multiple and multiseptated complicated WON. In such cases, multiple transluminal gateway technique (MTGT) or single transluminal gateway transcystic multiple drainage (SGTMD) could be good options.[40,41]

Dual-modality approach

An endoscopic approach is currently used and preferable over percutaneous drainage, as it can avoid the risk of forming a pancreatocutaneous fistula. However, a dual-modality drainage technique, which combines the endoscopic drainage and the percutaneous drainage techniques, should be considered for treating WON with deep extension into the paracolic gutters and pelvis or for salvage therapy after endoscopic intervention or surgical debridement with residual necrosis burden.[18] It does not only facilitate drainage of such areas, but also allows for irrigation and clearance of necrotic materials. Several studies have demonstrated that the adjunctive use of percutaneous drainage and debridement can result in improved clinical outcomes.[42–44]

Management of disconnected pancreatic duct syndrome

Pancreatic duct disruption or disconnected pancreatic duct syndrome (DPDS) is sometimes accompanied by WON and is associated with a prolonged disease course. It often requires

Table 1 Comparison of LAMS with plastic stents in management of WON

Author (year)	Study design	Stents	*N*	Technical success (%)	Clinical success (%)	Adverse events (%)		Mortality (%)	Cause of death
Mukai (2015)	Retro	PS	27	100	92.6	18.5	3 bleeding, 1 mediastinal emphysema, 1 stent migration,	7.4	1 sepsis, 1 bleeding
		LAMS	43	100	97.7	7.0	1 perforation	0	—
Ang (2016)	Retro	PS	37†	100	94.6	13.5	1 perforation, 2 bleeding, 1 pneumoperitoneum, 1 infection	—	—
		LAMS	12†	100	100	0	None	—	—
Bang (2017)	Retro	PS	26	100	92.3	7.7	1 infection, 1 stent migration	0	—
		LAMS	13	100	92.3	15.4	2 stent migration	7.7	1 sepsis
Bapaye (2017)	Retro	PS	61	100	73.7	36.1	16 sepsis, 2 stent migration, 5 bleeding	6.5	4 sepsis
		LAMS	72	100	94.4	5.6	2 sepsis, 2 bleeding	4.1	2 sepsis, 1 pulmonary embolism
Siddiqui (2017)	Retro	PS	106	99.1	81	15.1‡	2 bleeding, 5 infection, 1 perforation, 6 others	0	—
		LAMS	86	97.7	90	12.3‡	6 bleeding, 1 infection, 3 perforation, 1 other	0	—
Abu Dayyeh (2018)	Retro	PS	36	100	75.0	—	Bleeding 20%. perforation 8%	6	—
		LAMS	58§	100	82.8	—	Bleeding 7%, perforation 2%	2	—
Brimhall (2018)	Retro	PS	152¶	90.1	90.1	17.8	5 bleeding, 5 perforation, 6 infection, 6 others	0.7	1 underlying illness
		LAMS	97††	92.8	91.8	24.7	15 bleeding, 2 infection, 6 others	1.0	1 underlying illness
Bang (2019)	RCT	PS	29	100	96.6	20.7	2 stent migration, 1 bleeding, 2 aspiration pneumonia, 1 pulmonary embolism	0	—
		LAMS	31	100	93.5	41.9	2 stent buried in the gastric wall, 4 bleeding, 3 biliary stricture, 1 stent migration, 3 unrelated to stent placement	0	—
Chen (2019)	Retro	PS	87	98.9	57.5	10.3	10 bleeding, 4 peritonitis, stent misdeployment,	—	—
		LAMS	102	100	80.4	9.8	2 perforation, 2 others‡‡	—	—

Retro, retrospective study; RCT, randomized controlled trial.
†Included a total of 31 cases with pancreatic pseudocyst (PPC).
‡Only early adverse events.
§Included 12 cases used tubular large-caliber (18 or 20 mm) self-expandable metal stents.
¶Included 36 cases with PPC
††Included 16 case with PPC.
‡‡Events are mixed in both groups.

other additional interventions, reinterventions, rescue-surgery, and a longer hospital stay.[45] Therefore, some centers perform imaging of the main pancreatic duct (MPD) by multi-detector row CT, magnetic resonance cholangiopancreatography, or endoscopic retrograde cholangiopancreatography prior to drainage of and/or stent removal from WON.[17] When the MPD disruption is partial (incomplete), transpapillary stenting bridging of the MPD disruption may be effective.[46,47] If the endoscopic interventions fails and a recurrent fluid collection occurs, surgery such as distal pancreatectomy and Roux-en-Y drainage can offer an alternative. However, diabetes occurs in most patients. If transpapillary stenting of a partial disruption fails or where there is complete disruption, EUS-guided MPD drainage can be considered. However, high quality data on this are scarce thus far.[17]

CONCLUSIONS

ENDOSCOPIC INTERVENTIONS HAVE emerged as a key player in the management of WON, and the endoscopic step-up approach is widely accepted as the first treatment choice. Currently, LAMSs are preferred over PSs, but LAMS interventions might increase the risk of stent-related complications. Therefore, more RCTs are required to determine which stent provides better outcomes in the management of WON. Furthermore, multidisciplinary treatment approaches should be considered when treating complicated WON.

CONFLICTS OF INTEREST

AUTHOR I.Y. AND Olympus Corp. (Tokyo, Japan) hold a patent for a stone retrieval basket. Another author has no COI to disclose.

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NONE.

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