REVIEW

Current Status of Direct Endoscopic Necrosectomy

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ABSTRACT

The management of pancreatic necrosis has evolved. Sterile necrosis is now managed conservatively. Intervention is generally required for infected necrosis but is now deferred until four weeks after disease onset in order to permit encapsulation and demarcation of the necrotic collection. Demarcation facilitates necrosectomy and reduces complications related to the drainage and debridement procedures. The approach to pancreatic necrosectomy has evolved from primary open necrosectomy to minimally-invasive radiologic, surgical and endoscopic procedures. Direct endoscopic necrosectomy is a minimally-invasive technique that was introduced in recent years for the treatment of infected walled-off necrosis. A stoma is created endoscopically between the gastric lumen and the walled-off collection. An endoscope is then inserted directly into the cavity to perform endoscopic necrosectomy. This is followed by short-term placement of double pigtail transgastric stents and nasocystic catheter for post-procedural irrigation and drainage. This review will summarise the current status of direct endoscopic necrosectomy.

Keywords: Endotherapy, Necrotising pancreatitis, Walled-off pancreatic necrosis

BACKGROUND

Severe necrotising pancreatitis occurs in 15–20% of patients with acute pancreatitis with the potential for considerable morbidity and significant mortality[1]. Over the course of time, these patients may develop walled off pancreatic necrosis (WOPN) which is characterised by a thickened wall between the necrotic area and adjacent viable tissue. Within the necrotic region, a variable amount of liquefactive necrosis may occur with the resultant collection being a variable mixture of solid and fluid components[2]. Interventions are generally not needed and even contraindicated in sterile necrosis, as there is a risk of creating iatrogenic infection in a sterile collection which increases morbidity and mortality[3]. For infected necrosis, intervention is generally required in addition to the use of antibiotics such as carbapenems.

OPTIONS FOR INTERVENTIONS IN INFECTED PANCREATIC NECROSIS

In order to minimise morbidity and increase the treatment success rate of any intervention, it should be delayed to approximately 3–4 weeks after the onset of disease in order to allow encapsulation and demarcation of the infected necrotic collections. Demarcation facilitates necrosectomy and reduces complications related to drainage and debridement procedures[4,5]. The traditional intervention for infected pancreatic necrosis has been primary open surgical necrosectomy (ON) to remove all necrotic material. However, this may result in significant morbidity (complication rate 34–95%) and mortality (11–39%) as well as long-term pancreatic exocrine insufficiency[4,6–13]. A recent multi-centre randomised controlled study randomly assigned 88 patients with necrotising pancreatitis and suspected or confirmed infected necrotic tissue to undergo ON or a step-up approach to treatment. The step-up approach consisted of percutaneous drainage followed, if necessary, by minimally-invasive retroperitoneal necrosectomy. It was found that the minimally-invasive step-up approach, as compared with ON, reduced the rate of the composite end point of major complications or death (40% vs. 69%,

P = 0.006)[14]. This study supported the concept that minimally-invasive therapeutic interventions were viable options.

Minimally-invasive techniques of necrosectomy avoid open laparotomy and involve debridement via retroperitoneal, laparoscopic or endoscopic approaches. The infected area remains compartmentalised during the intervention such that contamination of tissue planes and the peritoneal cavity are avoided. They may reduce the risk of fistulas, bleeding, and wound complications that are associated with open explorations and which commonly required multiple re-explorations[15].

Direct endoscopic necrosectomy (DEN) is an extension of the concept of endoscopic transgastric drainage of walled-off pancreatic fluid collections such as pseudocysts and abscesses. Endoscopic ultrasound (EUS) guided transgastric stenting is now regarded as the technique of choice for the drainage of symptomatic pancreatic pseudocysts (PC), due to a lower morbidity compared to surgical and percutaneous drainage, and similar efficacy as surgery[16–18]. In EUS-guided transgastric drainage, a small communication is created endoscopically between the gastric lumen and the fluid collection for the insertion of transgastric stents to drain the fluid collection. During DEN, this stoma between the gastric lumen and WOPN is dilated to 15–18mm endoscopically. An endoscope is inserted directly into the cavity to perform endoscopic necrosectomy. This is followed by short-term placement of double pigtail transgastric stents and nasocystic catheter for post-procedural irrigation and drainage. Comparative studies showed that unlike the case of PC, where the clinical success rate for endoscopic drainage ranged from over 90% to almost 100%, transgastric drainage alone for infected WOPN had a success rate as low as 25%–45%[19,20]. A retrospective study compared DEN with conventional endoscopic transgastric drainage for the treatment of WOPN. Successful resolution was accomplished in 88% who underwent DEN versus 45% who received standard transgastric drainage (P <0.01), without a change in the total number of procedures. Complications associated with DEN were limited to mild peri-procedural bleeding which occurred at a similar rate as conventional transgastric drainage[20].

TECHNIQUE OF DIRECT ENDOSCOPIC NECROSECTOMY

1. Patient Selection

Appropriate patient selection is crucial. The criteria include: 1) duration of fluid collection greater than four weeks; 2) well-formed wall surrounding the collection; 3) WOPN accessible endoscopically; 4) located within 1cm of the gastric wall; 5) Symptomatic. Contraindications include: 1) presence of coagulopathy that cannot be corrected; 2) endoscopically inaccessible sites; 3) sterile necrosis; 4) predominantly solid necrosis with minimal liquefaction.

2. Procedural Details

The author's preference is to perform DEN as a staged procedure with initial EUS-guided transgastric stenting and irrigation (a transduodenal approach is theoretically and technically feasible, but since most collections are accessible through a transgastric approach, the discussion will focus on the transgastric route which is easier as there is more space to manoeuvre). The stoma is dilated progressively to 15–18m to allow passage of the endoscope into the cavity for endoscopic necrosectomy. The intent is to reduce the risk of perforation which may otherwise occur if the stoma is dilated to 18mm at the index endoscopy.

a. The patient is positioned in the left lateral position. A combination of intravenous midazolam and fentanyl is used to provide conscious sedation. Generally, general anaesthesia or propofol sedation is not required since the procedural time in experienced hands is about 20–30 minutes. For patients who cannot tolerate sedation, intravenous propofol or general anaesthesia may be required. A therapeutic linear echoendoscope with a working channel diameter of 3.7mm (GF-UCT160, Olympus, Tokyo, Japan) is used to visualise the infected collection across the gastric wall. With Doppler ultrasound guidance, the collection is punctured using a 19 gauge fine needle aspiration (FNA) needle (EUSN-19-T, Cook Endoscopy, Winston-Salem, NC, USA) (fig. 1). Pus is aspirated and sent for culture. Contrast is injected through the FNA needle to outline the collection to ensure that it is contained.

b. A 0.035 inch guide wire is inserted through the needle into the collection under fluoroscopic guidance. The puncture tract is sequentially

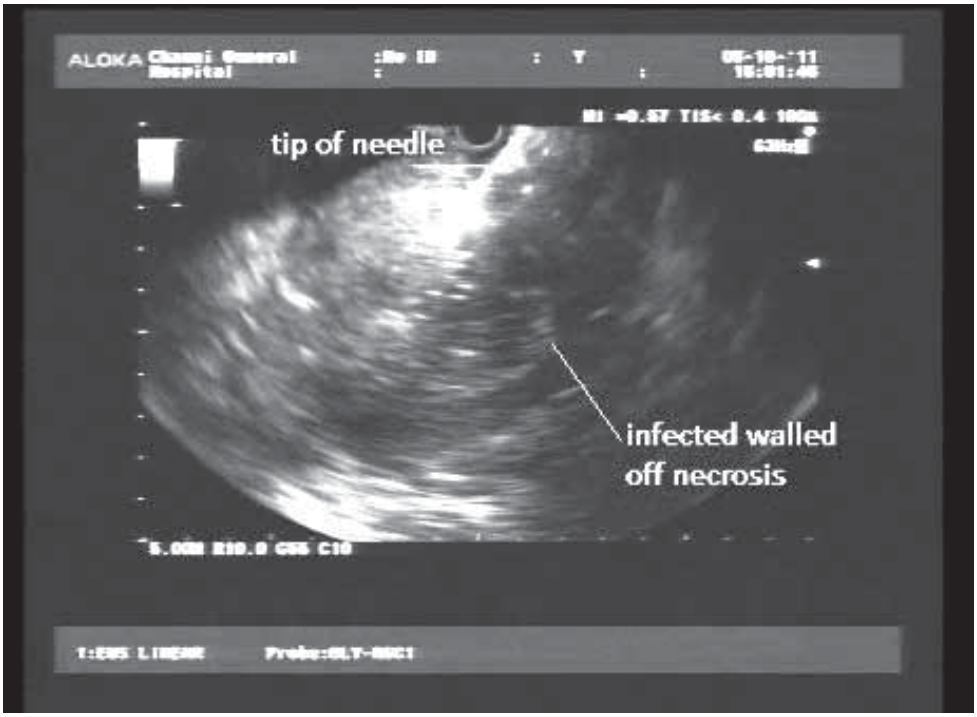

Fig. 1. The walled-off pancreatic necrosis is punctured by a 19 gauge needle under endoscopic ultrasound guidance.

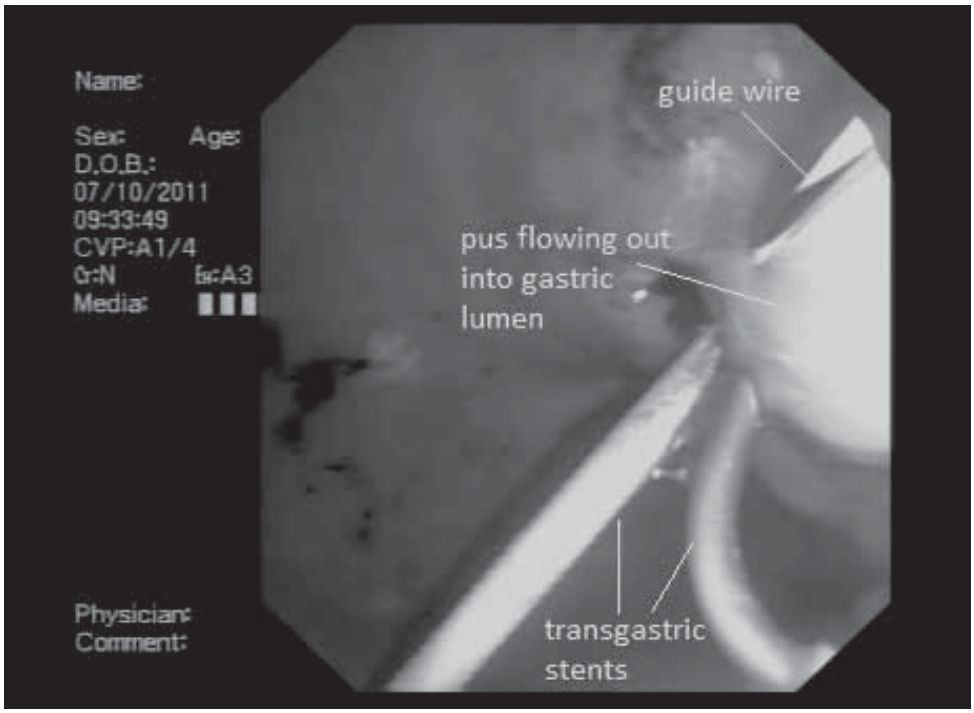

Fig. 2. After balloon dilatation of the stoma, pus is seen flowing out into the gastric lumen from the infected collection. The two previously inserted transgastric stents are in place.

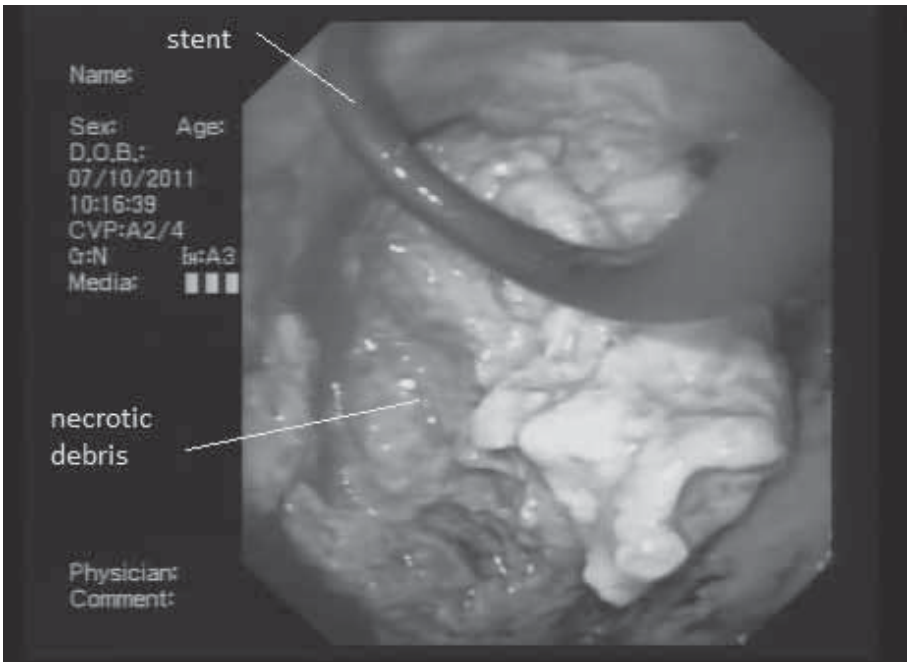

Fig. 3. Endoscopic view of the necrotic debris within the walled off necrosis.

dilated using 6Fr and 7Fr Soehendra dilators (Cook Endoscopy, Winston-Salem, NC, USA) and balloon dilators (CRETM, Boston Scientific, Natick, MA, USA) to 10mm. The same therapeutic echoendoscope is used to perform the transgastric stenting. In some centres, especially when a smaller diagnostic echoendoscope is used, the echoendoscope is removed, and replaced with a duodenoscope over the guide wire. Although the duodenoscope has the advantages of a larger working channel of 4.2mm and an elevator, it is not necessary to change to a duodenoscope. Using a therapeutic echoendoscope will avoid the risk of losing the guide wire access and shorten the procedure time. Two double pigtail transgastric stents are then inserted for transgastric drainage of the infected collection (Both 10Fr or one 10Fr and one 8.5Fr in diameter). In the same setting, a 7FR or 10Fr nasocystic catheter may be inserted for the purpose of irrigation and drainage. The stents and drainage catheter are either inserted sequentially via repeated cannulation of the cavity with fluoroscopic guidance or via a double wire technique[16,21]. Inserting a single 10Fr stent (3.3mm diameter) across the working channel of the echoendoscope can be easily performed. However, if one were to insert two transgastric stents using a two-wire technique, then the first stent cannot be 10Fr and must be 8.5Fr, because the presence of two guide wires reduces the free space within the working channel.

c. The second session is performed after 24–48 hours. Endoscopy is repeated under conscious sedation with the patient in the left lateral position. For patients who cannot tolerate sedation or when a longer procedure time is anticipated, intravenous propofol or general anaesthesia may be used. From the author's personal experience, sedation alone is adequate since the procedure time should be less than an hour. The cystogastrostoma is cannulated, a guide wire is inserted into the collection, and a balloon catheter (CRETM, Boston Scientific, Natick, MA, USA) is used to dilate the stoma endoscopically up to 15–18 mm (fig. 2). A standard gastroscope is then inserted into the cavity. Saline irrigation, suctioning and debridement of necrotic material using Dormia baskets (fig. 3) and retrieval nets are performed until all necrotic debris were removed (fig. 4).

d. The number of sessions required for endoscopic necrosectomy may range from one to three or more sessions. These are repeated at time intervals of about 24–48 hours or longer, as required. At the completion of endoscopic necrosectomy, when

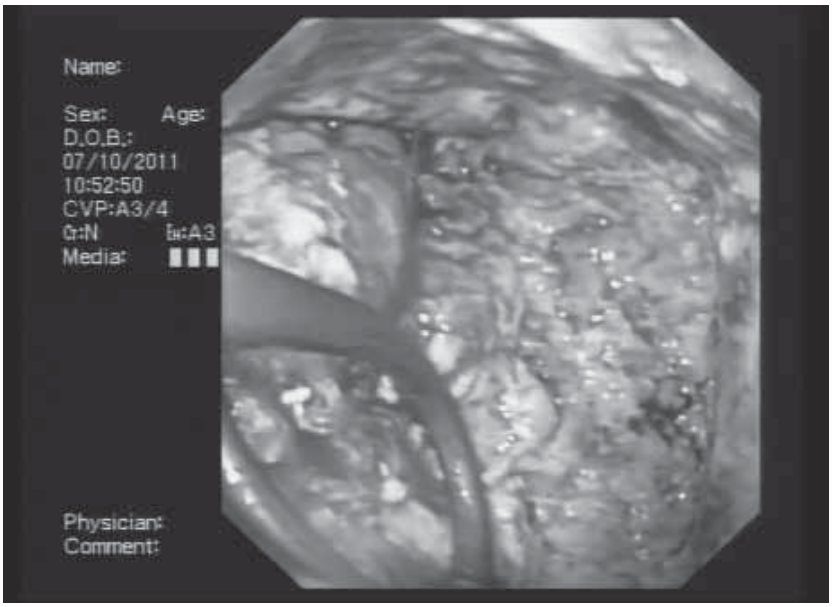

Fig. 4. An endoscopic view of the cavity after completion of endoscopic necrosectomy.

the pink granulating wall can be seen with no or minimal debris, two double pigtail transgastric stents are usually left in place to prevent re-accumulation of the fluid collection.

e. The stents are removed endoscopically once follow-up imaging, usually performed within two to three months, demonstrates cavity resolution.

RESULTS OF DIRECT ENDOSCOPIC NECROSECTOMY

Three non-comparative large case series have been published thus far and these will be further examined. These are a German multi-centre study (n = 93)[22] an American multi-centre study (n = 104)[23] and a large single centre case series from the German centre that pioneered this technique (n = 80)[24]. High clinical success rates ranging from 80–91% were achieved. The complication rate from the multi-centre German study was 26% and 30-day mortality rate was 7.5%[22]. In the American multi-centre case series, complications occurred in 14% and included five retrogastric perforations/ pneumoperitoneum (4.8%) which were managed non-operatively[23]. The initial experience with DEN in Singapore came from Changi General Hospital and it was recently published. In a series of eight cases, DEN was technically successful in all cases with no major complications. During follow-up, recurrence of collection occurred in one patient giving an overall clinical success rate of 87.5%[25].

There is a lack of comparative studies between DEN and surgical necrosectomy. To date, there is only one published randomised study that compared DEN with surgical necrosectomy. In this Dutch multi-centre randomised controlled study patients with signs of infected necrotising pancreatitis were randomly assigned to undergo endoscopic (n = 10) or surgical necrosectomy. Surgical necrosectomy consisted of minimally-invasive surgical techniques such as video-assisted retroperitoneal debridement (n = 6) or, if not feasible, laparotomy (n = 4). The primary endpoint was the post-procedural pro-inflammatory response as measured by serum Interleukine-6 (IL-6) levels. Secondary clinical endpoints included a composite of death or major morbidity (new-onset multiple organ failure, intra-abdominal bleeding, enterocutaneous fistula) and other morbidity (pancreatic fistula, new onset diabetes or use of pancreatic enzymes). It was found that DEN significantly reduced the post-procedural IL-6 levels compared with surgical necrosectomy. The composite clinical endpoint occurred less often after DEN (20% vs 80%; P = 0.03). DEN did not cause new-onset multiple organ failure compared to surgery (0% vs 50%; P = 0.03) and reduced the number of pancreatic fistulas (10% vs 70%; P = 0.02)[26]. A recent retrospective study compared minimally-invasive retroperitoneal necrosectomy (MINE) (n = 14) with DEN (n = 18) and ON (n = 30). There was no significant difference in the success rates but mortality was significantly

higher with surgical approaches (ON 63% vs. MINE 21% vs. DEN 6%, P <0.05). ON was also associated with significantly higher major complication rates compared to MINE and DEN[27]. Although comparative data between DEN and surgery are limited, the results of surgical series do provide further insight to the relative merits of DEN. The outcomes of surgical necrosectomy were reviewed recently[9,28]. Retroperitoneal necrosectomy was associated with an average major complication rate of 41% (range: 0–43%) and mortality rate of 16% (range: 0–27.3%). Laparoscopic necrosectomy had a major complication rate of 0–50% and mean mortality rate of 7% (range: 0–10.5%). In a recently published retrospective case series of retroperitoneal necrosectomy not included in the review, 32 patients were treated and mortality occurred in five patients (15.6%) due to multi-organ failure, and morbidity in 9.3% (2 colonic fistulas and 1 pancreatic fistula). The overall clinical success rate was 84.4% (27/32)[29]. It must be qualified that the patient numbers in the individual surgical series are small (retroperitoneal necrosectomy: numbers ranged from 1–47; laparoscopic necrosectomy: numbers ranged from 1–19) which may result in outcome bias. The success and complication rates of the DEN series[23-26] compares favourably with the results from the surgical series[9,28,29]. The Dutch Pancreatitis Study Group recently started the nationwide randomised TENSION-trial, in which the endoscopic step-up approach (endoscopic drainage followed by DEN) is compared with surgery. The primary endpoint is a composite of mortality and major morbidity (new onset organ failure, bleeding, perforation of a hollow organ or incisional hernia for which intervention is needed)[30]. This will provide further definitive data.

LIMITATIONS AND RISKS OF ENDOSCOPIC NECROSECTOMY

DEN is technically not feasible if there is minimal liquefaction of the pancreatic necrosis, with predominant solid debris. In such cases, when interventions are required, the main treatment option is surgical. The presence of splenic vein thrombosis by CT prior to intervention mandate extra precaution because of the possible occurrence of collateral vessels in the field of endoscopic transgastric access and in this context, Doppler ultrasound guidance using EUS during the initial puncture is particularly important. Another relative contraindication is the extension of the necrotic collection beyond the midline across the cava and aorta.

DEN is a challenging procedure that should only be performed by experienced therapeutic endoscopists with surgical back-up. Severe complications such as perforation, bleeding and embolism may occur. These risks may be minimised by meticulous attention to appropriate patient selection and technical details. Cross-sectional imaging such as CT scan should confirm that the collection is encapsulated by a mature wall in close proximity with the gastric lumen before DEN is attempted. Any coagulopathy should be corrected. The author does not dilate the drainage tract larger than 10mm at the index endoscopy, preferring to dilate the diameter of the cystogastrostoma to 15-18mm at the second session in order to reduce the risk of perforation. During the process of endoscopic necrosectomy, one must avoid over-insufflation of the cavity with air, and perform gentle debridement using saline lavage and aspiration, baskets, soft snares and retrieval nets. The use of carbon dioxide, if available, for insufflation, rather than air, is advisable to minimise the risk of air embolism. One should restrict debridement to necrotic debris that has detached from the wall, rather than forcibly attempt to remove necrotic matter adherent to the wall. Treatment-related perforations may potentially be treated conservatively. In the American multi-centre case series, five retrogastric perforations/pneumoperitoneum (4.8%) occurred and these were managed non-operatively[23]. In the case of bleeding, less severe bleeding may be treated endoscopically or radiologically. However, severe bleeding from vascular laceration would require surgical treatment.

Collections may be endoscopically inaccessible. Adjunctive minimally-invasive surgical or percutaneous procedures may be required. Percutaneous drainage using large bore catheters have been used to manage symptomatic PC. However it is associated with variable success, a need for prolonged external drainage and occurrence of local complications including pancreatico-cutaneous fistulas. It is difficult for drainage catheters to adequately address the problem of solid debris within WOPN although this may be circumvented somewhat by the use of continuous saline irrigation through large bore catheters. Hence percutaneous drainage is

generally not considered a first line treatment option in centres where endoscopic expertise is available[17]. However external drainage still has an important role as adjunctive treatment for collections that cannot be accessed endoscopically or for patients who are not stable enough to undergo endoscopy or surgery. The technique of combined modality treatment (CMT), in which endoscopic transenteric stents were added to a regimen of percutaneous drains, was introduced to overcome the problem of chronic pancreatico-cutaneous fistulas. It was based on the clinical observation that patients with WOPN with a spontaneously fistula into the duodenum during percutaneous drainage had shorter, less complicated hospital courses and no pancreatico-cutaneous fistulae. In CMT, a controlled fistula between the necrotic fluid collection and the gastric or duodenal lumen is created by transenteric stenting at the beginning of percutaneous drainage. External drains are still necessary to lavage WOPN. A retrospective comparative study found that compared to percutaneous drainage alone, CMT resulted in significantly decreased length of hospitalization, duration of external drainage, and number of radiological imaging studies[31]. Compared to DEN, CMT avoids the need for large-diameter balloon dilation of the stoma and endoscopic passage into the retroperitoneum and theoretically may reduce the risk of haemorrhage, perforation and air embolism.

NEED FOR ADJUNCTIVE ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATOGRAPHY

Evaluation of the integrity of the pancreatic duct is necessary. Pancreatic fluid collections would recur in the presence of persistent pancreatic duct disruption or disconnected pancreatic duct syndrome[32]. Endoscopic treatment by stenting across the pancreatic duct disruption may facilitate healing and prevent recurrence[33]. When fistulas persist despite prolonged stenting, it may be possible to seal the fistula endoscopically using tissue glue[34,35]. In the case of disconnected pancreatic duct syndrome, it may be technically difficult to bridge the disruption endoscopically, and even when successful, surgery may still be required. A randomised trial suggested that long-term transgastric stenting in patients with disconnected pancreatic duct syndrome may be an alternative to surgery to prevent the recurrence of collection, but more data are needed, given the concerns of stent occlusion and infection[36].

CONCLUSION

The management paradigm of infected WOPN has shifted from open laparotomy to minimally-invasive treatment options. Current data suggest that DEN is a viable minimally-invasive treatment option when there is expertise to perform such advanced therapeutic endoscopic procedures. However, management has to be multi-disciplinary in nature and surgical and radiological interventions may still be required as adjunctive or salvage procedures. Ultimately, the choice between minimally-invasive surgical necrosectomy, DEN and CMT would depend on the centre's expertise and specific patient characteristics.

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