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Voermans, R.P.

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4

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Endoscopic transmural debridement of symptomatic organized pancreatic necrosis

Rogier P. Voermans
Mariëlle C. Veldkamp
Erik A. Rauws
Marco J. Bruno
Paul Fockens

ABSTRACT

Background: Surgical management of pancreatic necrosis is associated with significant morbidity and mortality. Several weeks after an episode of a necrotizing pancreatitis, necrosis can become organized. By the time necrosis becomes organized, endoscopic therapy has the potential to offer an alternative treatment to surgery.

Objective: To evaluate safety and efficacy of endoscopic debridement of organized pancreatic necrosis.

Design: Retrospective cohort study.

Setting: Tertiary referral center

Patients: All consecutive patients between January 2003 and July 2006 who underwent this novel endoscopic approach were included.

Interventions: Treatment started with a cystoenterostomy or a cystogastrostomy. The next steps consisted of balloon dilatation up to 18 mm, advancement of an endoscope into the retroperitoneal cavity; and endoscopic debridement of the collection under direct endoscopic vision. Debridement was repeated every two days until most necrotic material was evacuated. In addition, nasocystic catheter irrigation was performed manually with saline solution 6 to 8 times a day.

Main outcome measurements: Clinical success, number of endoscopic procedures, and complications.

Results: Twenty-five patients were identified, who had undergone debridement of 27 collections. In 11, 13, 2, and 1 collections 1, 2, 3, and 4 endoscopic debridement procedures, respectively, were performed. There was no mortality. Severe complications that required surgery occurred in 2 patients: hemorrhage in 1 case and perforation of cyst wall in the other. During a median follow up of 16 months (range 3-38 months), the overall clinical success rate with resolution of the collection and related symptoms was 93% (95%-CI: 77-98%).

Limitations: Retrospective study.

Conclusion: In this study we showed that endoscopic debridement is an effective and relatively safe minimally invasive therapy in patients with symptomatic organized pancreatic necrosis. Further comparative studies are warranted to define its definitive role in the management of these patients.

INTRODUCTION

Acute pancreatitis can be associated with a variety of complications. Pancreatic necrosis is among the most severe complications and is defined as diffuse or focal areas of nonviable pancreatic parenchyma, which is typically associated with peripancreatic fat necrosis.^{1, 2} Infected necrosis is generally accepted as a strong indication for surgery.²⁻⁹ The aim of treatment in those with infected pancreatic necrosis is to remove all necrotic tissue and to provide drainage for the remaining debris to facilitate resolution of the collection. Surgical management of pancreatic necrosis is associated with high morbidity (19-62%) and mortality (6%-28%).^{3, 5-7, 10} Surgical treatment of sterile necrosis is controversial.^{3, 4, 6-9, 11, 12} The majority of patients with sterile necrosis can be successfully treated without intervention.^{3, 4, 7-9, 11} Indications for intervention in sterile pancreatic necrosis are deteriorating organ failure despite maximal support, or symptoms as intractable abdominal pain, inability to tolerate oral feeding, weight loss, progressive jaundice, and subfebrile temperature or persistent fever despite several weeks of conservative treatment.^{3-9, 12, 13} Mortality and complication rates of surgical treatment are similar for infected and sterile necrosis.^{5, 6}

Several weeks after an episode of severe acute necrotizing pancreatitis, necrosis can become organized.¹⁴ The term organized pancreatic necrosis was introduced to distinguish poorly demarcated acute tissue necrosis from an encapsulated, well-defined collection of pancreatic juice and debris.^{2, 3, 15} By the time necrosis becomes organized, endoscopic therapy has the potential to offer an alternative treatment for surgery. Another option is drainage with radiologically placed percutaneous catheters. This, however, is not effective when thick necrotic material is present within the cavity.¹⁶ Transmural endoscopic drainage has become the treatment of choice for uncomplicated pseudocysts.^{2, 17-21} However, standard endoscopic drainage of necrotic collections has been reported less successful and is often considered contraindicated.^{2, 18, 19} By adding endoscopic debridement to the standard technique of transmural drainage, we started to treat patients with symptomatic organized pancreatic necrosis endoscopically. Because few data have been published of endoscopic debridement of pancreatic necrosis,²²⁻²⁴ we have performed a retrospective study to evaluate safety and efficacy of this treatment.

METHODS

Patients

After approval by the local medical ethics committee, all consecutive patients who underwent endoscopic debridement of organized pancreatic necrosis in our hospital between January 2003 and July 2006 were identified from our prospective endoscopy database (Endobase, Olympus Medical System Europe, Hamburg Germany). No

endoscopic debridement procedures had been performed before 2003. From the database we identified all pancreatic fluid collections that were transmurally entered with an endoscope. Procedural data and treatment outcome were collected from endoscopy and hospital records, and by telephone follow-up of patients. Data that were collected included information regarding the underlying disease, the size and location of the collections, the indication for drainage, drainage technique, complications, the number of endoscopic procedures, and follow-up of cyst resolution.

Technique of initial EUS-guided drainage

Patients, under conscious sedation with midazolam and/or fentanyl, were examined in the prone position. Prophylactic antibiotics were routinely administered and were continued for at least 3 days after procedure. In all patients the treatment was started by creating a cystoenterostomy or cystogastrostomy (endoscopic or surgical). In the case of prior surgery, endoscopic treatment was started with dilatation of surgical anastomosis and endoscopic debridement .

The endoscopic drainage through the gastric or duodenal wall was EUS-guided by using a therapeutic EUS-scope (Olympus, GF-UCT140 or GIF-UCT160; Olympus). The feasibility of endoscopic drainage was assessed with EUS by measuring the distance between the fluid collection and gastric or duodenal wall. The optimal drainage site was chosen, ensuring a minimum distance and avoiding vessel interposition by use of color-flow Doppler. The collection was punctured with a 19-gauge EUS-needle (Cook Endoscopy, Winston-Salem, NC, USA) (Fig 1). After withdrawal of the stylette, the cyst content was aspirated to confirm the correct position of the needle in the cavity. Next, a standard 0.035-inch guidewire was introduced through the 19-gauge needle into the collection, after which the needle was removed (Fig. 2). An 8 mm biliary dilation balloon (Hurricane, Boston Scientific, Boston, Mass, USA) or a 10F cystotome (Cook) was introduced over the wire



Figure 1: EUS-image, showing puncturing of organized pancreatic necrosis. The needle is seen exiting form the dot at the upper side of the image into the necrotic collection.



Figure 2: Fluoroscopy image, showing a guidewire placed into a large retroperitoneal collection.

to enlarge the cystostomy opening. Multiple 7F, double-pigtail stents were inserted into the collection and a nasocystic catheter (NCC) was left in place alongside the stents. The NCC was manually flushed with a saline solution 6-8 times a day.

Technique of endoscopic debridement

All debridement procedures started with removal of the NCC and all but 1 of the transmural stents. The remaining stent was used as a visual guide to the opening of the cavity. The next step consisted of balloon dilation of the track under radiologic guidance up to 18 mm and entering the cavity with a therapeutic gastroscope (GIF-1T160 or GIF-1T140; Olympus) for inspection (Fig. 3A). At the endoscopist's discretion, a Dormia basket (Olympus), a Roth net (US Endoscopy, Mentor, Ohio, USA) or a polypectomy snare was used to remove necrotic tissue (Fig. 3B). As much necrotic tissue was removed as possible, until a vital, pink, easily bleeding wall became visible (Fig. 4). At the end of each procedure multiple 7F, double-pigtail stents were inserted into the collection. If necrosis was still present, but the procedure was terminated, because of patient discomfort,

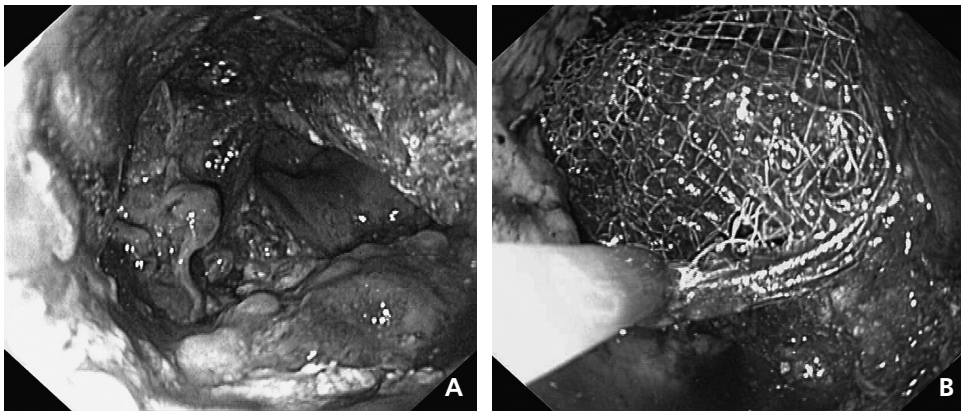


Figure 3: **A**, Endoscopic image, showing cavity with yellowish necrotic material. **B**, Endoscopic image showing, a large piece of necrotic material extracted by a Roth net. (For color figures, see page 256)

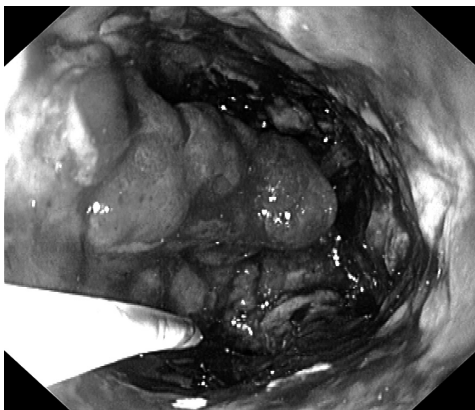


Figure 4: Endoscopic image showing a vital, pink, easily bleeding wall after final endoscopic debridement procedure. (For color figures, see page 256)

then an NCC was placed as well. Endoscopic debridement was repeated every 2 to 3 days until all solid necrotic and purulent material had been evacuated. In case some residual necrosis was present, but not as a solid mass, no extra debridement procedure was planned, but after 2 to 6 days, the NCC was injected with contrast medium under radiography. If no residual debris was visualized, then the NCC was removed while at least 3 transmural stents remained in place. After 6 weeks, abdominal imaging was performed to ensure that the collection had resolved before the transmural stents were removed. If a collection was still present, then the stents were exchanged electively and left in place for another 6 weeks. All the endoscopic drainage and debridement procedures were performed by 1 of 3 experienced interventional endoscopists (MB, ER, PF).

Follow up

Follow up data were obtained through chart review of outpatient clinic visits. The long-term prospective outcome of all patients was obtained by telephone contact with each patient. Patients were questioned about the recurrence of symptoms of abdominal pain, difficulty eating, fever, and general lack of well being. At the same time, they were asked if any additional abdominal imaging investigations were performed outside our hospital; if so, then the images were acquired from the local hospital.

Statistics

The primary outcome parameter is clinical success, defined as resolution of the collection and related symptoms. Secondary outcomes were the number of endoscopic debridement procedures, complications, and length of hospital stay. Complications were defined as any event leading to an additional surgical, radiological or endoscopic intervention within 30 days after the endoscopic procedure (with exclusion of endoscopic debridement procedures). The duration of the follow up, hospital stay, stent placement, and NCC placement were calculated, starting from the first endoscopic debridement procedure. Quantitative data are expressed as median plus range.

RESULTS

Patients

A total of 25 patients (13 women, 12 men), with a median age of 58 years, who had undergone endoscopic debridement of 27 collections, were identified from the database. The characteristics of patients are summarized in table 1.

All patients had acute necrotizing pancreatitis, and, in all, necrosis became organized after several weeks. The collections were drained a median of 84 days (21-385) after the onset of pancreatitis. When endoscopic debridement was performed, complaints were abdominal pain (88%), fever or subfebrile temperature (69%), nausea and vomiting

Table 1. Patients and collections characteristics

| Patients (n=25) and collections (n=27) | |
|-----------------------------------------------|------------|
| Age, median, y (range) | 58 (31-77) |
| Sex, male, n (%) | 12 (46) |
| Etiology pancreatitis, n (%) | |
| Gallstones | 10 (40) |
| Alcohol | 5 (20) |
| Other | 3 (12) |
| Idiopathic | 7 (28) |
| Collection size, median, cm (range) | 10 (4-20) |
| Collection location, n (%) | |
| Pancreatic head | 10 (37) |
| Pancreatic body | 11 (41) |
| Pancreatic tail | 4 (15) |
| Bursa omentalis | 2 (7) |

(27%), and progressive jaundice (22%). Organized pancreatic necrosis was diagnosed by contrast-enhanced computed tomography (CECT) (Figs. 5A and B) or magnetic resonance imaging (MRI) and confirmed with EUS. In 4 patients the necrosis had not been visualized on earlier CECT and was confirmed with EUS during intended standard endoscopic drainage.

The indications for endoscopic debridement were persistent symptoms of sterile organized pancreatic necrosis despite several weeks of conservative treatment in 8 cases (29.6%); suspicion of primary infected necrosis in 5 (18.5%); and secondary infected necrosis after earlier standard endoscopic drainage in 14 cases (51.9%). In the latter

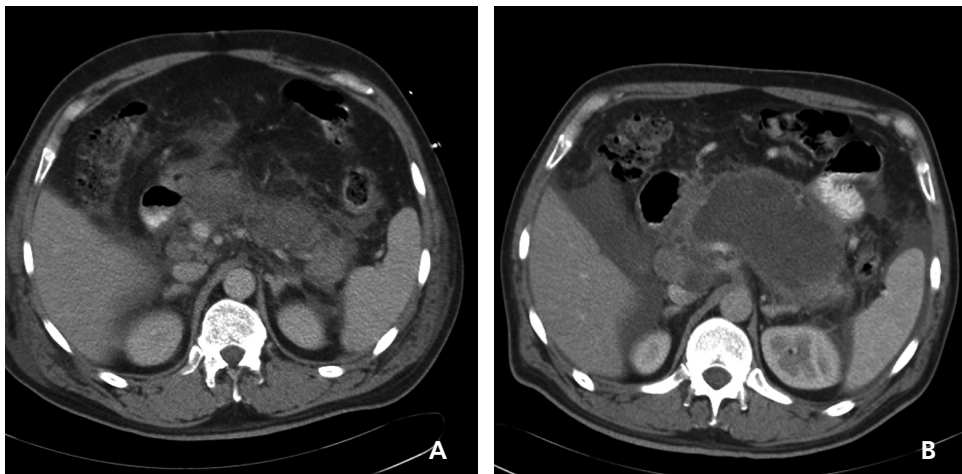


Figure 5: **A**, Abdominal CECT, showing extensive pancreatic necrosis. **B**, Abdominal CECT scan of the same patient 6 weeks later, showing the pancreatic necrosis is organized during these weeks and suitable for endoscopic transluminal debridement.

subgroup, 11 collections were secondary infected after endoscopic drainage and 3 after surgical drainage. Infection of organized pancreatic necrosis was suspected on clinical findings as fever, abdominal pain, and leukocytosis.

Details of endoscopic procedures

In all cases, treatment was started with transmural drainage of the collection: endoscopic in 24 and surgical in 3 patients. Transgastric drainage was performed in 23 (85%) and transduodenal in 4 cases (15%). In 11 (41%), 13 (48%), 2 (7%), and 1 (4%) cases, 1, 2, 3, and 4 endoscopic debridement procedures, respectively, were performed. Planned endoscopic debridement procedures were performed 1 to 2 days after first drainage; in case of secondary infected necrosis (after endoscopic drainage) after a median of 3 days (range 1-11 days).

The median duration of stenting was 62 days (range 42-206 days) with a median of 3 stents (range 2-10 stents). One patient did not require transmural stents, because a large spontaneous fistula and surgical cystoenterostomy were already present, and all necrotic debris was evacuated during the first endoscopic debridement procedure. Stent exchanges without endoscopic debridement were carried out once in 5 patients and twice in 1 patient. In 6 cases, the stents were changed electively when the collection had not resolved 6 weeks after the last endoscopic debridement procedure. Because of occluded stents, 1 patient developed fever 1 week after the last endoscopic debridement procedure for which stents were subsequently exchanged. The median duration of NCC placement after the first debridement procedure was 3 days (range 1-10 days). In 5 patients, no NCC was placed because all necrotic material was already evacuated during the first endoscopic debridement procedure.

Complications

Severe complications were seen in 2 patients (7%) and both required surgery. In 1 patient, arterial hemorrhage occurred from the gastrocystostomy after balloon dilatation of the track up to 18 mm at the time of the second debridement procedure. The hemorrhage was successfully managed by surgical intervention. Because the collection was not palpable anymore at the time of surgery, the cavity was not surgically marsipulized, and the necrotic collection was successfully further treated endoscopically. Another patient suffered a perforation of the cyst wall during lavage of the cavity under endoscopic view; emergency surgery was necessary, and, during this procedure, the collection of organized necrosis was managed as well.

Minor bleeding occurred in 8 patients (30%), in 6 cases during balloon dilatation and in 2 during debridement. Six of the minor bleedings stopped spontaneously; in 2 patients, clips were placed endoscopically during the procedure (in 1 case, within the collection; in the other in the tract of the gastrocystostomy). None of these patient required transfusion. There was no mortality.

Outcome

The median length of hospital stay was 5 days (range 1-45 days). During a median follow up of 16 months (range 3-38 months), the overall clinical success rate was 93% (95%-CI: 77-98%). Two patients developed a recurrent symptomatic pseudocyst, without necrosis. Both were managed conservatively. In 1 patient, the recurrent pseudocyst and related symptoms resolved spontaneously after 4 months. The other case concerned the patient in whom a perforation of the cyst wall occurred during endoscopic lavage and who had undergone surgical management of the collection. In consultation with the patient, it was decided to manage the recurrent pseudocyst conservatively. The symptoms subsided, but, after 20 months' follow up, the pseudocyst (diameter 5 cm) was still present.

DISCUSSION

In the last decade, endoscopic therapy has gained widespread acceptance in the treatment of pancreatic fluid collections. Transmural endoscopic drainage has become the treatment of choice for uncomplicated pseudocysts.^{2, 17-19} It is important to differentiate uncomplicated pseudocysts from acute peripancreatic fluid collections, pancreatic abscess, and organized pancreatic necrosis, because each requires a different modality and timing of treatment. Acute fluid collections frequently resolve spontaneously.¹⁴ In most cases of primary pancreatic abscesses, standard endoscopic drainage suffices, because they lack significant amounts of necrotic debris.^{1, 2} In recent reports, success rates varies from 74%-91%.^{21, 25-27} The presence of septations within the abscesses might be an indication to add endoscopic debridement to standard drainage.²⁷ In case of collections with necrotic debris, standard drainage is usually not sufficient.^{2, 18, 27, 28} Thick necrotic material can not be evacuated through 1 or multiple transmural stents. Necrotic debris that is not removed from the collection may hamper drainage, because stents become easily occluded. The presence of necrotic debris and ineffective drainage both promote secondary infection.^{2, 15, 29}

In the literature, a distinction is usually made between early diffuse necrosis and late organized necrosis.^{6-8, 30} Late organized pancreatic necrosis is more suitable for treatment, because the necrotic tissue is better demarcated from the viable pancreas.^{7-9, 30-32} In case treatment of symptomatic necrosis is indicated, it is recommended to postpone intervention at least 4 weeks after the initial attack of necrotizing pancreatitis.^{5-7, 12, 13, 32} During this time period, it is not uncommon that collections resolve spontaneously. It also provides a time frame for peripancreatic fluid collections with necrosis to become organized.^{4, 12}

Traditionally, pancreatic necrosis has been treated surgically. Surgical management of pancreatic necrosis is associated with high mortality (6%-28%) and morbidity (19-62%).³

^{5-7, 10} In 1 study, no difference in mortality and morbidity between early (< 6 weeks) and late (> 6 weeks) surgery was observed.⁶

The high clinical success rate (93%) and relatively low complication rate (7%) of our cohort confirm that endoscopic treatment of pancreatic necrosis seems an attractive less-invasive treatment modality. It has the potential to provide effective internal drainage with a rapid recovery time. However, often, multiple endoscopic interventions are needed to remove all pancreatic necrosis. It seems that the timing of intervention, when pancreatic necrosis has become organized, is an important prerequisite for successful endoscopic treatment. Before endoscopic debridement is planned, it is important that a well-delineated organized collection is confirmed on CECT or MRI.

However, some caution is warranted when interpreting our results. Because of selection bias, more complicated cases might have been treated surgically. For example, in contrast to our cohort of patients, most surgical studies described intervention in infected pancreatic necrosis early in the course when necrosis is less organized. In our cohort of patients, primary infection was suspected in only 5 cases.

In other series, success of endoscopic drainage of infected, as well as sterile pancreatic necrosis varies from 25 to 72%.^{2, 18} Several investigators suggested a more aggressive approach, including that endoscopic debridement would result in a higher success rate.^{17, 18, 25} Endoscopic debridement added to standard endoscopic drainage was intended to remove all necrotic tissue to facilitate resolution of the collection and was recently described in smaller series.^{22-24, 33}

In 1 report, 13 patients with infected pancreatic necrosis were treated with a median of 4 endoscopic procedures.²² Clearance of necrosis was not achieved by entering the cavity with an endoscope for debridement. Besides the fact that intervention was performed earlier in course of the disease and necrosis was infected in all cases, the difference in technique may explain the necessity of additional treatment modalities and their higher number of endoscopic procedures.

Seewald et al.²³ used endoscopic debridement to treat infected pancreatic necrosis in 5 patients with a success rate of 80%. Our report is, however, the largest cohort study of this endoscopic technique so far and the first that described a high clinical success rate with relatively few endoscopic procedures and without additional treatment modalities in all but two cases.

The largest population (n=43) of standard endoscopic drainage of organized pancreatic necrosis was reported by Baron et al.² The lack of tissue debridement may explain the lower success rate, higher recurrence and longer hospital stay. Initially 11 patients of our cohort underwent only standard endoscopic drainage, but developed secondary infected necrosis. We believe that if these patients were initially treated more aggressively including endoscopic debridement, they might have had a more rapid recovery. We are presently planning a prospective study to compare these two endoscopic techniques in the management of organized pancreatic necrosis.

Outflow obstruction of the pancreatic duct (stricture, stone) and pancreatic fistulae are a potential cause of recurrence.³⁴⁻³⁶ In the literature, it is suggested that an endoscopic retrograde pancreatogram (ERP) be performed in all patients with pancreatic or peripancreatic collections to evaluate the pancreatic duct.^{23, 37} In our hospital we perform an ERP before drainage if the pancreatic duct was dilated on abdominal imaging. In this series, 1 patient underwent an ERP, in which, despite of a pancreatic duct stricture, no fistula was visualized. This patient received a long-term stent placement of the pancreatic duct. The low percentage of recurrence (7%) confirms our clinical impression, which is in contrast with earlier studies³⁷, that it is not mandatory to perform an ERP in all patients with organized pancreatic necrosis.

The key to complete evacuation of necrotic material is the creation of a large access opening to the cavity. This allows insertion of a therapeutic gastroscope into the cavity to remove necrotic and purulent materials under direct endoscopic vision. There are multiple devices that can be used to remove tissue necrosis, including a flushing catheter, a polyp snare, a Dormia basket, or a Roth net. Although preferentially all necrotic material should be evacuated in a single session, current devices that are used for tissue debridement are not optimally suited for this purpose. A high frequency ultrasonic debridement device or a modification of a waterjet³⁸ may be helpful.

One or 2 days after the first stent placement, the tract was dilated up to 18 mm in diameter. We did not encounter any perforations during dilatation. Perforation did occur during lavage in 1 patient. Probably the endoscope was blocking the outflow tract of the cavity, as a consequence pressure became too high and the wall perforated. During surgery, a tear in the posterior cyst wall was observed. To prevent perforation, it is wise to remove all but 1 transmural stent; the remaining stent will function as a safety valve. The case mentioned was secondary to surgery, so no transmural stents were in situ.

In this study, we showed that endoscopic debridement is an effective and relatively safe minimally invasive therapy in patients with symptomatic organized pancreatic necrosis. Because randomized controlled trials comparing endoscopic and (minimally invasive) surgical management are not available, future studies are eagerly awaited to determine the definite role of endoscopic debridement. Although we showed that there seems to be an important role for endoscopy in the management of patients with organized pancreatic necrosis, it should not be forgotten that optimal treatment consists of an interdisciplinary approach by endoscopists, surgeons, and interventional radiologists.

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