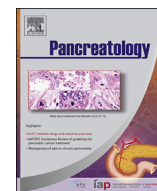




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## Original article

## Early dual drainage combining transpapillary endotherapy and percutaneous catheter drainage in patients with pancreatic fistula associated with severe acute pancreatitis

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## ABSTRACT

**Background:** The development of pancreatic fistula (PF) associated with pancreatic necrosis is of great concern in the management of severe acute pancreatitis (SAP). We expected that early recognition and intervention of PF combined with percutaneous catheter drainage (PCD) for pancreatic infection may improve SAP outcomes.

**Methods:** Fifteen consecutive patients with SAP were enrolled. Whenever feasible, fine-needle aspiration for fluid collection was performed to determine infection and amylase concentration. For infection and PF with amylase-rich fluid, PCD and transpapillary endotherapy (preferably naso-pancreatic drainage) were carried out as soon as possible. PCD was intensively managed by irrigating the sized-up and multiple large bore catheters.

**Results:** Infected fluid collection and PF were both detected in 13 (86.7%) patients. Pancreatic duct (PD) disruption ( $n = 6$ ) and organ failure ( $n = 5$ ) occurred exclusively in patients with amylase-rich collection  $\geq 10,000$  U/L. The median timing of PCD and endotherapy was 15.5 and 16.5 days, respectively. No serious complications or mortality resulted from intervention procedures other than stent occlusion in one (6.7%) patient. Surgical intervention due to uncontrollable infection and visceral organ injury was avoided. Fistula closure was achieved in 12 (92.3%) of 13 PF patients with a median duration of 45 days. Disease-related mortality occurred in one (6.7%) patient.

**Conclusion:** Amylase-rich fluid collection  $\geq 10,000$  U/L may be an indication for further endoscopic investigation of PD disruption. Early dual drainage combining pancreatic endotherapy and PCD is feasible and safe, and may improve treatment outcome.

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## Introduction

Severe acute pancreatitis (SAP) occurs in approximately 20% of acute pancreatitis patients, with a mortality of 20–60% [1,2]. The management of SAP is challenging, because of the dynamic changes in its critical course, difficulty in the estimation and prediction of its severity, and the diversity of treatment strategies. Recently, a minimally invasive “step-up” approach has been increasingly explored as a safe and practical strategy [3–6]. As the initial step, percutaneous catheter drainage (PCD) is carried out in a subset of patients who develop a collection of infected fluid or infected

necrosis to reduce the septic condition and the risk of organ failure. PCD can postpone or even obviate surgical necrosectomy in 35–55% of patients [2,7,8].

Necrosis of the pancreatic duct (PD) and/or pancreatic gland causes pancreatic fistula (PF), which occurs in one third of SAP patients [9,10]. Although the Atlanta classification has concentrated on the severity of pancreatic glandular necrosis [11], PF increases the hospital stay, morbidity, mortality and overall health-related expenditure of patients with pancreatic infection [10,12]. Persistent PF may develop following PCD, becoming a major obstacle to the step-up approach.

Based on these clinical aspects, the possibility of developing PF as well as pancreatic necrosis is of great concern in the management of SAP. In contrast to PCD as a well-established treatment

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method for pancreatic infective necrosis, the treatment of PF is not uniform. Traditionally, PF is managed by conservative means including total parenteral nutrition, and pancreatic secretion inhibitors such as glucagon, calcitonin, somatostatin or its long-acting analogue octreotide, however, its success rate is limited to 30–80% [4,5,13,14]. Upon failure of conservative treatment, surgery involving either bypass or resection is performed, however, significant morbidity and mortality are associated with operative treatment [2,15]. An alternative and effective strategy for uncontrolled PF is endoscopic estimation of the PD disruption and transpapillary drainage of the PD [16–31]. The rationale for transpapillary endotherapy involves drainage of the pancreatic juice, decreasing the PD-duodenal pressure gradient by pancreatic stenting across the papilla, and bridging transpapillary pancreatic stenting in the definitive management of communicating leaks. Although previous studies have focused on persistent and complicated PF after conservative-and/or surgical-treatments, current data regarding the consequences and safety profile of endotherapy in patients with newly developing PF during the early phase of SAP are scarce.

In this study, we describe our experience with SAP patients employing a systematic approach targeting infected pancreatic necrosis and PF utilizing PCD and transpapillary endoscopic drainage, respectively. We expected that early recognition and active induction of transpapillary endotherapy for developing PF in combination with PCD would confine the extension of PFs and inflammation leading to improved outcomes.

## Materials and methods

### *Patients and definitions*

Fifteen consecutive patients (men = 8: women = 7; mean age, 66.0 years [range, 35–92 years]) with pancreatic fluid collections (PFCs) associated with SAP were admitted to the Department of Gastroenterology of the Shizuoka General Hospital (Shizuoka, Shizuoka, Japan), Hamamatsu Rosai Hospital (Hamamatsu, Shizuoka, Japan), or Shinshiro Municipal Hospital (Shinshiro, Aichi, Japan) between January 2005 and February 2014. The clinical and radiological records were reviewed retrospectively during this period. SAP was defined by the Japanese severity scoring system based on a combination of the clinical severity and computed tomography (CT) grade [32]. Ranson scores were also assessed [33]. Organ failures were defined as functional insufficiency requiring intensive supports, i.e., continuous catecholamine infusion after adequate resuscitation, mechanical ventilation, and renal replacement therapy (hemodialysis) for cardiovascular, respiratory and renal failures, respectively. All patients signed consent forms, and the study was approved by the Ethical Committee of Medical Research.

### *Treatment strategy*

Our strategy for SAP has been principally composed of non-surgical interventions and was quite similar to a recently reported staged multidisciplinary “step-up” approach [3–6]. In short, all the patients were initially treated by medical treatment including vigorous fluid resuscitation, antibiotics and total parental or jejunal nutrition in the early phase of acute pancreatitis. Somatostatin analogues and arterial infusion of antibiotics were not used. To estimate the degree of fluid collection and pancreatic necrosis, a contrast-enhanced CT (CECT) was performed within 3 days after onset of the disease. Thereafter, patients with persisting organ failure, signs of sepsis, or deterioration in clinical status underwent additional CECT and/or ultrasonography (US). Whenever PFCs and

peripancreatic necrosis were found and paracentesis was feasible, US- or CT-guided fine needle aspiration (FNA) was performed to measure amylase concentration, gram staining, and culture. A PCD was placed when bacteria-proven or amylase-rich fluid was aspirated and/or when infectious complication of the patient's clinical course continued.

We performed PCD under US- or CT-guidance as early as possible, and PCD was intensively managed by irrigating the sized-up and multiple large bore catheters. In short, after aspiration of as much fluid as possible, the drainage tube was sized up to more than 10 Fr at the first trial. We used one or more catheters as needed. At least one catheter is placed in the peripancreatic or retroperitoneal spaces for irrigation and extraction of necrotic collections, whereas others might be placed into the paracolic or peritoneal cavity for decompression of the seroperitoneum. PCD catheters in the peripancreatic or retroperitoneal regions were irrigated with 10–20 mL of saline twice daily. The efficacy of PCD was evaluated under fluoroscopic examination every week. If the PCD was inadequate, upsizing to 20–30 Fr or repositioning of the catheter and/or placement of additional catheter(s) were conducted. The upsized or mutually-communicating large bore catheters were intensively irrigated with 200–500 mL of saline twice a day.

The presence of PF was defined as output of any measurable volume of fluid with an amylase content of > threefold greater than the serum amylase level [34]. In cases of amylase-rich fluid collection by FNA and persistent symptoms longer than a few days after PCD, the PD anatomy and disorders were examined using endoscopic retrograde pancreatography (ERP). PD disruption was defined as extravasation of contrast media from the main PD or its branch during ERP. We aimed to bypass the site of the duct disruption in patients in whom the site of the leak was identified. The preferred position of PD drainage was to place a tube in the manner of bridging or covering the PD disruption. If bridging was not possible, a transpapillary internal tube was placed with the proximal tip in the fluid. In case 5, a short transpapillary stent was temporally placed to secure the pancreatic flow and reduce intraductal pressure. A 5 Fr naso-pancreatic drain (NPD) (Olympus, Tokyo, Japan) or 5 Fr pancreatic stent (Cook Endoscopy, Winston-Salem, NC, USA) was selected to drain the main PD.

Closure of the fistula was defined as the absence of amylase-rich discharge or leakage confirmed by pancreatography examination.

### *Amylase levels in PFCs*

Major PF frequently coexists with organ failure and may need critical care for associated infection and sepsis [2,35], whereas minor PF is spontaneously resolved without any interventions. Patients with major PD should be screened to plan subsequent interventions. We speculated that increased amylase levels in PFCs may reflect major PF or PD disruptions and be possible criteria for ERP and endotherapy. Thus, we plotted PFC-amylase levels and ERP findings to determine the amylase cut-off levels for PD disruptions. Thereafter, we examined the clinical, laboratory and radiological features in the patients with higher-amylase-PFCs compared to those with lower amylase levels.

### *Literature review*

To develop our strategy, a MEDLINE search was performed for similar studies reporting the results of transpapillary endoscopic treatment for acute pancreatitis-related PF. Search terms were “pancreatic fistula” AND “endoscopy”. Cross references from the identified studies were also searched. Only studies published in the English language were included.

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