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ORIGINAL ARTICLE

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Selection strategy for endoscopic necrosectomy approaches of infected walled-off pancreatic necrosis: Analysis of 101 patients from a single center with long-term follow-up

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Objectives: Endoscopic necrosectomy (EN) is a promising minimally invasive approach for treating infected walled-off pancreatic necrosis (WOPN). Multiple EN approaches are currently available, though criteria for selecting the optimal approaches are lacking. We aimed to propose a rational selection strategy of EN and to retrospectively evaluate its safety and effectiveness.

Methods: Altogether 101 patients who underwent EN for infected WOPN at a tertiary hospital between June 2009 and February 2023 were retrospectively included for analysis. Demographic characteristics, details of the EN procedures, procedure-related adverse events, and clinical outcomes were investigated.

Results: Among these 101 patients with WOPN, 56 (55.4%) underwent transluminal EN, 38 (37.6%) underwent percutaneous EN, and seven (6.9%) underwent combined approach, respectively. Clinical success was achieved in 94 (93.1%) patients. Seven (6.9%) experienced procedure-related adverse events, and seven (6.9%) died during the treatment period. During a median follow-up of 50 months, 5 (5.3%) of the 94 patients had disease recurrence, 17.0% (16/94) had new-onset diabetes mellitus, and 6.4% (6/94) needed oral pancreatic enzyme supplementation. The clinical success rate, procedure-related adverse event rate, and long-term follow-up outcomes were not significantly different among the three groups. High APACHE-II scores (≥15) and organ failure were identified as factors related to treatment failure.

Conclusions: A selection strategy for EN approaches, based on the extent of necrosis and its distance from the gastrointestinal lumen (using a threshold of 15 mm), is safe and effective for treating infected WOPN in both short-term and long-term outcomes.

KEYWORDS
infected walled-off pancreatic necrosis, percutaneous endoscopic necrosectomy, transluminal endoscopic necrosectomy

Jie Luo and Sheng Wei Zhang these authors contributed equally.

1 | INTRODUCTION

Acute pancreatitis (AP) is one of the most common digestive diseases that require hospital admission worldwide.[1] Most patients with AP manifest as mild-to-moderate symptoms and have a favorable prognosis; however, approximately 20%–30% of them develop acute necrotizing pancreatitis (ANP).[2,3] Walled-off pancreatic necrosis (WOPN), a late complication of ANP, typically develops at over 4 weeks following the onset of ANP.[4] Approximately one-third of the WOPN cases are associated with infection.[5] For those who survive the acute phase of AP, infection leads to a sharp increase in mortality rate of up to 30%.[6] Therefore, multidisciplinary strategies are warranted for the treatment of such cases.

Surgical necrosectomy has been regarded as a traditional approach for treating infected WOPN. However, it is associated with severe trauma and a high mortality, as some patients cannot tolerate abdominal open surgery and prolonged general anesthesia.[7] Alternative methods using a laparoscope, nephroscope, or mediastinoscope, such as video-assisted retroperitoneal debridement (VARD), have been introduced as less invasive therapies. However, the operability of these instruments around vital structures and their access to necrosis in deep regions or at angulation are limited, making the treatment of extensive multilocular necrotic collections with such modalities quite challenging.[8] With the development of endoscopic techniques, endoscopic necrosectomy (EN) has been increasingly applied as an optimal treatment for infected WOPN. Randomized controlled trials (RCTs) compared the efficacy of endoscopic approaches with that of surgical therapy for infected WOPN, showing a preference of endoscopic treatment.[9–11] Previous meta-analyses have revealed that endoscopic interventions are superior to surgery in terms of the length of hospital stay and the incidence of major complications.[12,13] Remarkably, different operative approaches of EN have been developed over the past decade, mainly including transluminal endoscopic necrosectomy (TEN), percutaneous endoscopic necrosectomy (PEN), and combined endoscopic necrosectomy (CEN), showing varied superiorities and shortcomings in different situations.

To our knowledge, previous studies have mostly focused on the efficacy of one single EN approach, and a selection strategy for appropriate EN approach has not been reported yet. In this study, we aimed to determine the selection strategy of EN for infected WOPN based on the characteristics of the necrotic collections.

2 | PATIENTS AND METHODS

2.1 | Ethics

This study was conducted in accordance with the Declaration of Helsinki (Brazil, 2013), and was approved by the Medical Ethical Committee of the Second Affiliated Hospital (Xinqiao Hospital) of the Army Medical University (no. 2024-002-01). Written informed consent was waived due to the retrospective study design.

2.2 | Study design and patient enrollment

This was a single-center retrospective observational study. Patients who underwent EN for infected WOPN at Xinqiao Hospital, Army Medical University (Chongqing, China) between June 2009 and February 2023 were recruited in the study. Inclusion criteria of the patients were: (a) patients admitted for AP during the study period, regardless of their age; (b) confirmed diagnosis of infected WOPN; and (c) underwent EN, including TEN, PEN, and CEN, due to the lack of significant clinical improvement after conservative medical treatment and drainage. Exclusion criteria were: (a) with insufficient clinical data for analysis; (b) with no evidence of infection or with sterile necrosis; (c) confirmed diagnosis of chronic pancreatitis; (d) patients who did not undergo EN, or those who underwent EN in other hospitals; and (e) automatically discharged during the treatment period. The flowchart of patient enrollment is shown in Figure 1.

According to the revised Atlanta criteria,[4] the diagnosis of AP was confirmed when meeting at least two of the following three criteria: (a) acute onset of persistent, severe epigastric pain often radiating to the back, which is consistent with AP; (b) serum amylase or lipase activity at least 3 times higher than the upper limit of normal (ULN); and (c) radiographic evidence of AP on contrast-enhanced computed tomography (CECT), magnetic resonance imaging (MRI) or transabdominal ultrasound. WOPN was defined as a collection of pancreatic/peripancreatic necrosis completely encapsulated with an inflammatory wall, which typically formed approximately 4 weeks after the onset of AP. Infection was confirmed based on a positive culture of fine-needle aspiration (FNA) or drainage fluid or the presence of gas bubbles in necrotic tissues on CECT.[4] Significant clinical improvement of infected WOPN after drainage was confirmed when the patient had the following manifestations: (a) apparent improvement of clinical symptoms (eg, resolution of chills and high fever); (b) effective infection control as evidenced by blood biochemical results, such as decreased white blood cell (WBC) count and C-reactive protein (CRP); and (c) significant reduction of WOPN cavity size to less than 3 cm or complete resolution of the necrotic cavity on CT.[6,14,15]

Data of the eligible patients, including demographic and clinical characteristics, details of the EN procedure, procedure-related adverse events, and long-term complications were collected.

2.3 | EN procedures

A multidisciplinary team (MDT) comprising expert gastroenterologists, endoscopists, radiologists, and intensivists engaged in the determination of optimal management strategy for infected WOPN. General care and drug use of the patients were given in accordance with the related guidelines, with antibiotics chosen based on drug sensitivity and bacterial culture results.[16,17] All patients underwent CECT before

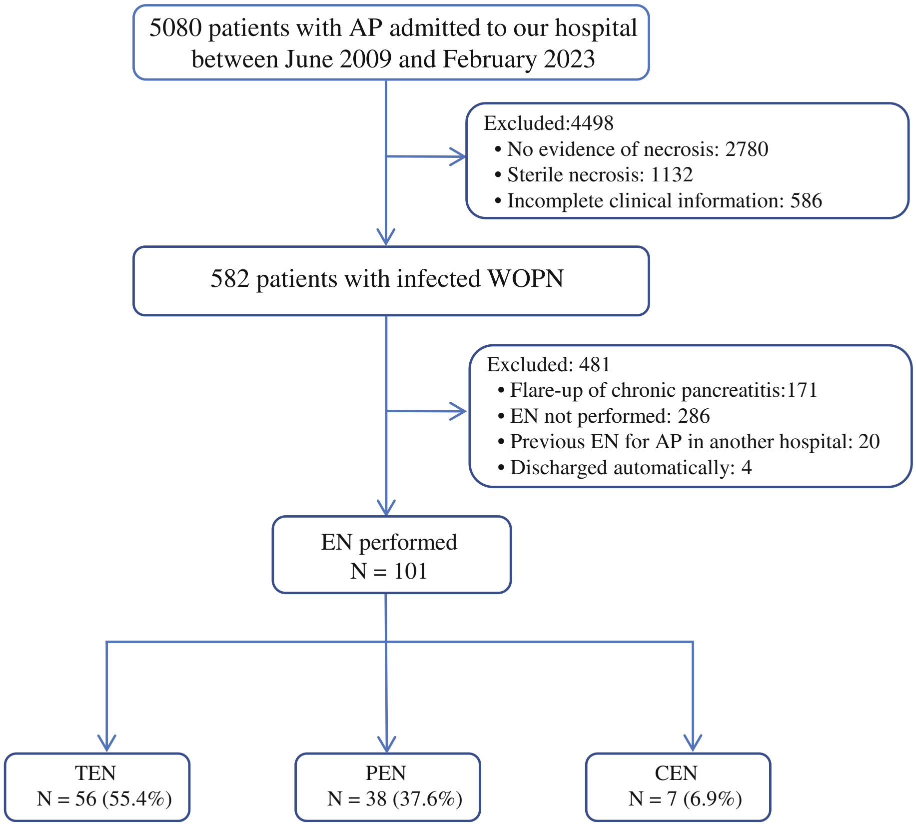

FIGURE 1 Flow diagram of patient enrollment. AP, acute pancreatitis; CEN, combined endoscopic necrosectomy; EN, endoscopic necrosectomy; PEN, percutaneous endoscopic necrosectomy; TEN, transluminal endoscopic necrosectomy; WOPN, walled-off pancreatic necrosis.

the EN procedure to determine the range and location of infected WOPN. The EN approach was then determined based on the following principles. If the distance between the gastrointestinal (GI) lumen and the necrotic collection was 15 mm or less,[18,19] TEN was performed. When this distance exceeded 15 mm and the collection was close to the body surface, PEN was performed. While CEN was performed in patients with extensive necrosis that was close to both the GI lumen and the body surface. The shortest route between the puncture site and necrotic cavity through which vital structures were avoided was ensured (Figure 2).

All the EN procedures were conducted by experienced endoscopists who had performed more than 500 minimally invasive endoscopic procedures for over 5 years to ensure a high level of proficiency in endoscopic techniques.

2.3.1 | Transluminal drainage and TEN

General anesthesia was administrated for all patients before the procedure. Puncture was subsequently performed using a conventional 19-G endoscopic ultrasound (EUS) needle (Boston Scientific, Marlborough, MA, USA). The optimal puncture site was determined under EUS guidance after the extent of the collection was evaluated by CT scan, so as to avoid intervening blood vessels and maintaining the shortest distance between the GI tract and the necrotic cavity (Figure 3A,B). A guidewire was then introduced into the necrotic cavity through the needle after the inner stylet was removed, and the tract was then dilated. Double pigtail plastic stent (10 Fr, 3 cm in length; Boston Scientific) or self-expandable metal stent (1.6 cm in diameter, 3.0 cm in length; Micro-Tech, Nanjing, Jiangsu Province, China) was placed for drainage. If a significant clinical improvement could not be achieved after drainage, TEN was then performed. During the TEN procedure, the sinus tract was further dilated with a large balloon (12–18 mm in diameter; Boston Scientific) several days after plastic stent placement (Figure 3C,D). A forward-viewing endoscope (GIF-Q260J; Olympus, Tokyo, Japan) was then inserted through the sinus tract into the necrotic collection, and debridement was carried out using snares (loop width 13–27 mm), assisted by nets and clips (all from Boston Scientific), together with lavage with normal saline for the removal of necrotic materials[20–22] (Figure 3E–G). The operation was repeated several times until all necrotic materials were removed. Resolution of the lesion was assessed via postoperative CT images (Figure 3H, Supplementary Videos S1 and S2).

2.3.2 | Percutaneous drainage and PEN

Ultrasonography, CT, or X-ray examination was performed to evaluate the range and location of the lesion and to avoid vital organs and adjacent blood vessels (Figure 4A). Skin and subcutaneous tissues were locally anesthetized layer by layer with 2% lidocaine. An 18-G puncture needle (Cook Medical, Bloomington, IN, USA) was inserted into the necrotic cavity (Figure 4B), and the puncture site was dilated using the Seldinger technique over a 0.035-inch stiff guidewire (Cook Medical). A percutaneous transhepatic

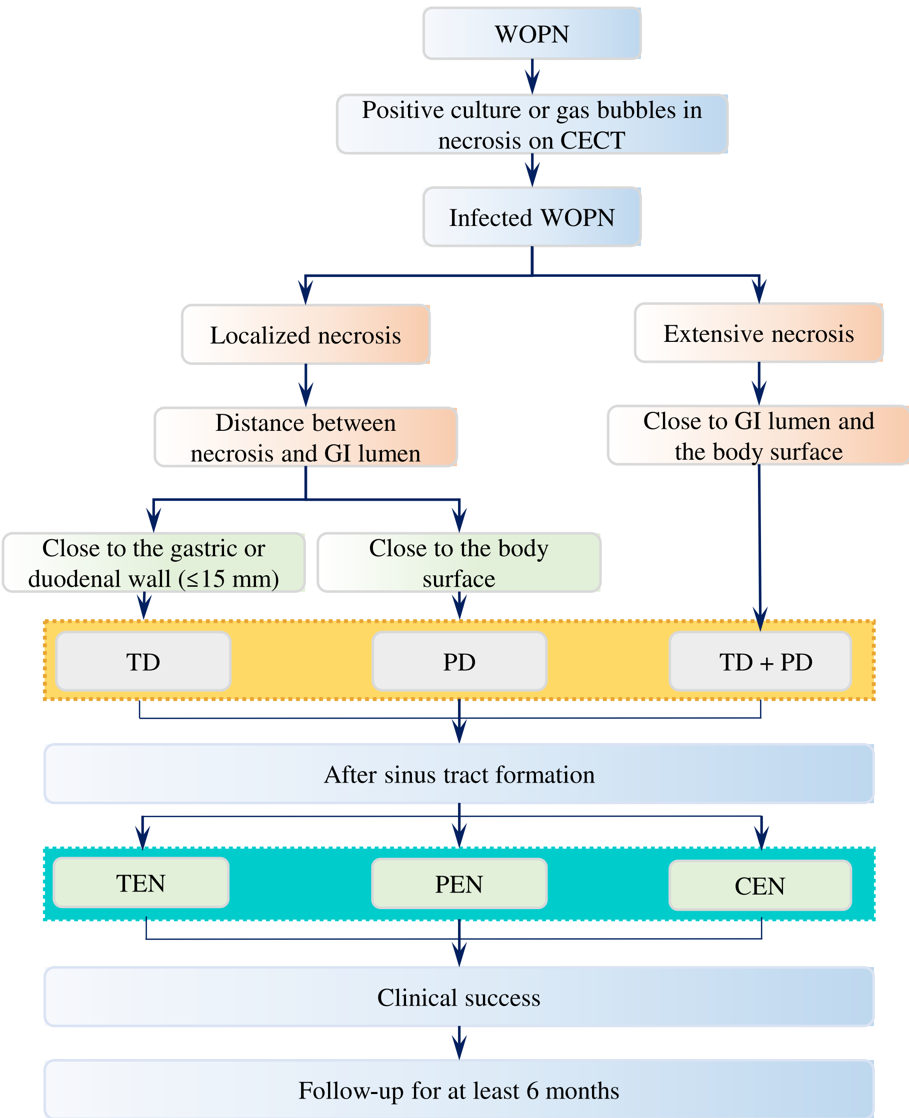

FIGURE 2 Selection strategy for endoscopic necrosectomy approaches. CECT, contrast-enhanced computed tomography; CEN, combined endoscopic necrosectomy; GI, gastrointestinal; PD, percutaneous drainage; PEN, percutaneous endoscopic necrosectomy; TD, transluminal drainage; TEN, transluminal endoscopic necrosectomy; WOPN, walled-off pancreatic necrosis.

cholangial drainage (PTCD) catheter (10–12 Fr; Cook Medical) was then placed for drainage. If a significant clinical improvement was not observed after drainage, PEN was performed under general anesthesia. During the PEN procedure, the catheter was removed first and balloon dilatation of the sinus tract was performed (Figure 4C). An esophagogastroduodenoscope was advanced into the necrotic collection, and the necrotic materials were removed by snares (loop width 13–27 mm; Boston Scientific), assisted by nets and clips, and irrigation with normal saline[23–25] (Figure 4D–G). The PEN procedure was repeated until all necrotic materials were removed. Resolution of the lesion was assessed via postoperative CT images (Figure 4H, Supplementary Videos S2 and S3).

2.3.3 | CEN

A combined transluminal and percutaneous approach was used when multiple extensive necrotic collections were present adjacent to both the body surface and the GI lumen.

2.4 | Outcomes

The primary outcomes included the technical and clinical success of EN for infected WOPN, and AP-related death during the treatment period. Technical success was defined as the successful completion of the EN procedure without any major technical complications such as rupture of the necrotic cavity and severe bleeding. Clinical success was defined as the remission of clinical symptoms and complete resolution of the necrotic cavity.[26,27] The secondary outcomes were treatment failure, procedural-related adverse events (including bleeding from the necrotic cavity, GI fistula, and septic shock), and long-term follow-up outcomes including the evaluation of long-term complications such as new-onset diabetes mellitus (DM), pancreatic endocrine or exocrine insufficiency and regional portal hypertension. New-onset DM was defined as the use of oral antidiabetic drugs or insulin within 6 months after discharge. Pancreatic exocrine insufficiency was defined as the requirement of oral pancreatic enzyme supplementation to treat clinical symptoms and signs of steatorrhea 6 months after discharge. Both of the conditions were not present before the onset

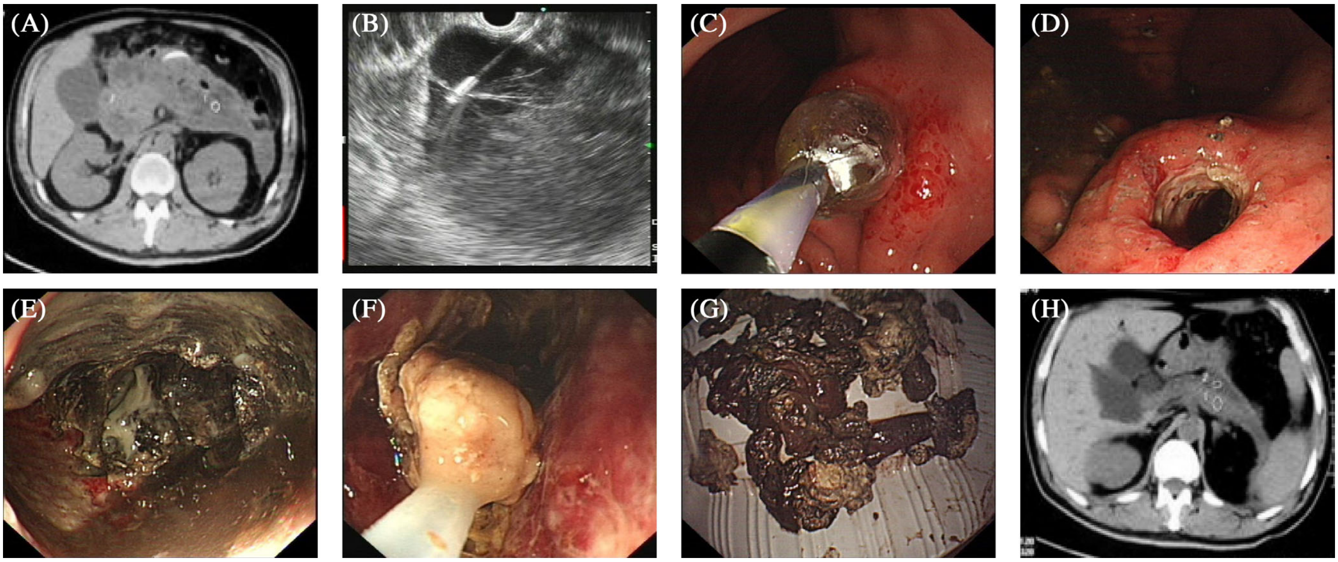

FIGURE 3 Transluminal endoscopic necrosectomy procedure. (A) A representative computed tomography (CT) image of walled-off pancreatic necrosis. (B) Endoscopic ultrasound-guided puncture. (C,D) Endoscopic view of dilatation of the transgastric tract to the necrotic cavity. (E–G) Advancement of the endoscope into the necrotic cavity and removal of necrotic materials. (H) Postoperative CT image showing complete resolution of the lesion.

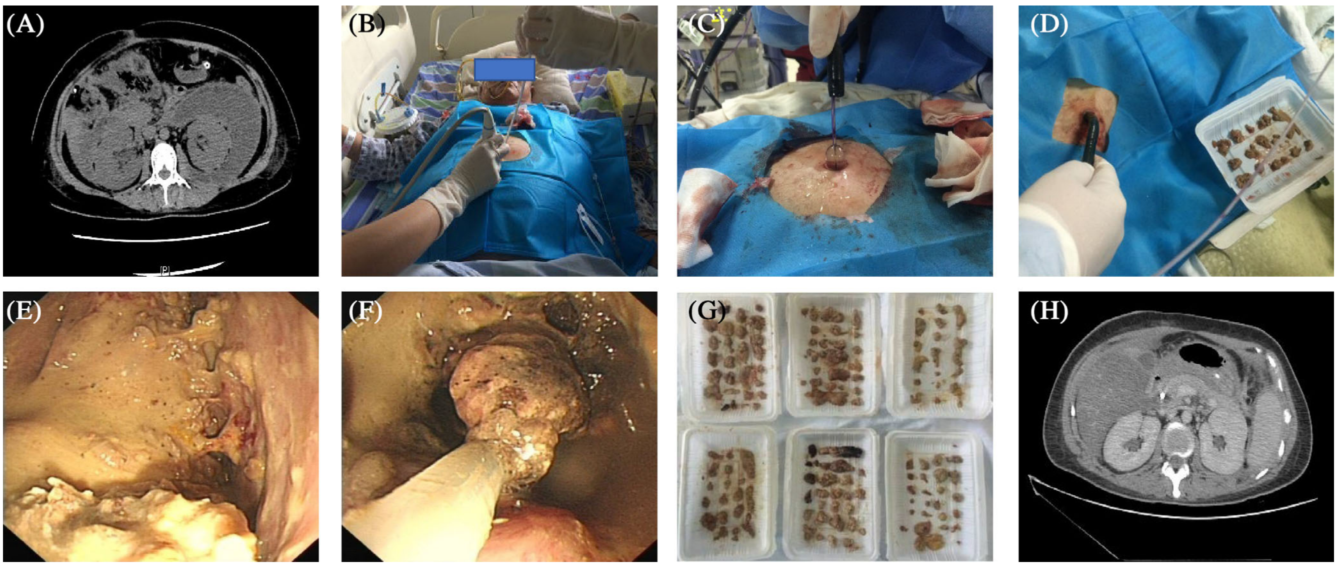

FIGURE 4 Percutaneous endoscopic necrosectomy procedure. (A) Computed tomography (CT) image of walled-off pancreatic necrosis. (B) Ultrasound-guided puncture. (C) Dilatation of the percutaneous tract to the necrotic cavity. (D–G) Endoscopic removal of necrotic materials. (H) Postoperative CT image showing complete resolution of the lesion.

of AP.[28] Treatment failure was defined as the requirement for open surgical intervention or patient's death.[29] Follow-up started on the day of patient's discharge until August 1, 2023 by a trained physician via short messages or telephone call, together with a review of their medical records. The patients were asked to visit the Outpatient Department of our hospital at 1, 3, and 6 months after discharge, and semiannually thereafter. The follow-up data, including pancreatic ultrasonography or CT findings, blood and urine amylase tests, blood biochemical tests (such as liver and kidney function tests, blood glucose, etc) were recorded in case report forms specifically designed for the trial.

2.5 | Statistical analysis

The Shapiro–Wilks test was used for normality testing of the quantitative variables. Normally distributed quantitative variables were presented as mean ± standard deviation, whereas those with non-normal distribution were presented as median and range. Categorical variables were presented as numbers and percentages or frequencies. Student's *t*-test and the Mann–Whitney *U*-test were used to compare the differences in normally and non-normally distributed quantitative variables, respectively. While the chi-square and Fisher's exact tests

TABLE 1 Baseline demographics of the patients and details of the endoscopic necrosectomy (EN) procedures.

Characteristics	Patients (n = 101)
Gender, n (%)	
Female	38 (37.6)
Male	63 (62.4)
Age, years (mean ± SD)	43.5 ± 11.5
Charlson comorbidity score (median [range])	1 (0–5)
Etiology, n (%)	
Hypertriglyceridemia	38 (37.6)
Alcohol	16 (15.8)
Gallstone	26 (25.7)
Others[a]	21 (20.8)
ASA classification, n (%)	
<Grade 3	56 (55.4)
≥Grade 3	45 (44.6)
Baseline disease severity	
APACHE II score ≥15, n (%)	15 (14.9)
White blood cell count, $\times 10^9$/L (median [range])	10.3 (1.8–29.5)
Gastrointestinal fistula, n (%)	20 (19.8)
Intestinal fistula	17 (16.8)
Gastric fistula	1 (1.0)
Biliary fistula	1 (1.0)
Pancreatic fistula	1 (1.0)
Sepsis, n (%)	11 (10.9)
Organ failure, n (%)	21 (20.8)
ICU admission, n (%)	74 (73.3)
CT findings	
Number of necrotic cavity, n (%)	
Single	40 (39.6)
Multiple	61 (60.4)
Main location of necrotic cavity, n (%)	
Head and neck	13 (12.9)
Body and tail	51 (50.5)
Entire pancreas	37 (36.6)
Location of the lower margin of necrotic cavity, n (%)	
Peripancreatic region	44 (43.6)
Below the lower margin of the left kidney	21 (20.8)
Extension to the pelvic cavity	36 (35.6)
Size of necrotic cavity, cm (median [range])	
Long axis	13.0 (5.5–30.0)
Short axis	8.0 (2.0–26.0)
Time from AP onset to initial drainage, days (median [range])	38 (9–126)
EN approaches, n (%)	
Transluminal	56 (55.4)
Percutaneous	38 (37.6)

(Continues)

TABLE 1 (Continued)

Characteristics	Patients (n = 101)
Combined	7 (6.9)
Number of EN sessions (median [range])	2 (1–10)

Abbreviations: AP, acute pancreatitis; APACHE, Acute Physiology and Chronic Health Evaluation; ASA, American Society of Anesthesiologists; CT, computed tomography; ICU, intensive care unit; SD, standard deviation.

[a]Including post-endoscopic retrograde cholangiopancreatography, postoperation, malignancy, and idiopathic, etc.

were used to evaluate the group differences in categorical variables. A *p* value of less than 0.05 indicated statistical significance. All the statistical analyses were performed using SPSS 27.0 (IBM, Armonk, NY, USA).

3 | RESULTS

3.1 | Characteristics of the patients and details of the EN procedures

Altogether 101 patients who underwent EN for infected WOPN between June 2009 and February 2023 at our hospital were retrospectively included in the study. The baseline characteristics and procedural details are listed in Table 1. The mean age of the patients was 43.5 ± 11.5 years, and 62.4% of them were men. Hypertriglyceridemia (37.6%) and gallstone (25.7%) were identified as the major etiologies of AP in these patients. The median Charlson comorbidity index score was 1 (range 0–5), indicating that the comorbidities were less severe. The Acute Physiology and Chronic Health Evaluation (APACHE)-II score was used to comprehensively assess illness severity, and 15 (14.9%) patients had an APACHE-II score ≥15. Twenty (19.8%) patients presented with GI fistulas, 11 (10.9%) with sepsis, and 21 (20.8%) with organ failure before the procedure. The median long axis of the WOPN was 13.0 cm (range 5.5–30.0 cm), and the median short axis was 8.0 cm (range 2.0–26.0 cm) on CT scan. Necrosis extending to the pelvic cavity was observed in 36 (35.6%) patients. Drainage was performed after a median of 38 days (range 9–126 days) from the onset of AP. The operative approaches were selected based on the extent of necrosis and the distance between the necrotic collection and the GI lumen (whether the distance was >15 mm or not) or the body surface. Finally, 56 (55.4%) patients underwent TEN for WOPN, 38 (37.6%) received PEN, and 7 (6.9%) received CEN, respectively. The patients underwent a median of two EN sessions (range 1–10 sessions).

3.2 | Outcomes

Clinical outcomes of the patients who underwent EN are summarized in Table 2. The technical success rate was 100% among all 101

TABLE 2 Outcomes of patients who underwent endoscopic necrosectomy.

Outcomes	Patients (n = 101)
Primary outcomes, n (%)	
Technical success[a]	101 (100)
Clinical success[b]	94 (93.1)
Death[c]	7 (6.9)
Secondary outcomes, n (%)	
Procedure-related adverse events	7 (6.9)
Bleeding from the necrotic cavity	3 (3.0)
Pancreatic fistula	1 (1.0)
Colonic fistula	1 (1.0)
Septic shock	2 (2.0)
Other outcomes	
Postoperative fever, n (%)	47 (46.5)
Mild (38.0–38.4°C)	4 (4.0)
Moderate (38.5–38.9°C)	14 (13.9)
Severe (39.0–40.0°C)	29 (28.7)
Hospitalization, days (median [range])	59 (14–181)
Cost, CNY (median [min–max])	226 640 (28 105–1 476 090)
Events during long-term follow-up (n = 94)	
Follow-up duration, months (median [range])	50 (6–155)
New-onset diabetes mellitus, n (%)	16 (17.0)
New-onset pancreatic exocrine insufficiency, n (%)	6 (6.4)
Regional portal hypertension, n (%)	3 (3.2)
Death,[d] n (%)	2 (2.1)
Recurrence, n (%)	5 (5.3)

[a]Technical success was defined as successful completion of the procedure without any major technical complications.
[b]Clinical success was defined as remission of clinical symptoms and complete resolution of the necrotic cavity.
[c]Death related to acute pancreatitis during the treatment.
[d]Death unrelated to the procedure or acute pancreatitis during the follow-up period. One patient died of liver cancer 20 months after discharge and the other died of pancreatic cancer 10 months after discharge.

patients, while clinical success was achieved in 94 (93.1%) of the patients. No open surgical intervention was required. Seven (6.9%) patients experienced AP-related death during the EN treatment; among them, six died of severe septic shock, and the other died of fatal bleeding. Data of these seven patients are summarized in Supplementary Table S1.

Procedure-related adverse events occurred in seven (6.9%) patients. Bleeding from the necrotic cavity was observed in three patients, one of whom died of hemorrhagic shock due to massive bleeding from the splenic arterial branch after an attempt using coil embolization under interventional radiologic guidance. Hemostasis was achieved with endoscopic intervention in one patient, and the remaining patient was successfully treated conservatively with hemocoagulase and somatostatin. Pancreatic fistula was observed in one (1.0%) patient and was treated with pancreatic duct stenting. One (1.0%) patient developed colonic fistula, which was managed under endoscopy. Two (2.0%) patients suffered from postoperative septic shock. In addition, 47 (46.5%) patients developed postoperative fever, among whom 29 (28.7%) had body temperatures exceeding 39.0 °C. The median length of hospital stay was 59 days (range 14–181 days), and the median medical cost was 226 640 CNY (range 28 105–1 476 090 CNY).

3.3 | Long-term follow-up

Long-term follow-up data were collected from 94 patients who experienced clinical success, with a median follow-up period of 50 months (range 6–155 months) (Table 2). Pancreatic portal hypertension was present in three (3.2%) patients. Sixteen (17.0%) patients developed DM due to damage to the pancreas resulting from pancreatitis and debridement, while six (6.4%) needed oral pancreatic enzyme supplementation. Detailed descriptions of the 16 patients who developed new-onset DM are summarized in Supplementary Table S2. Two patients (2.1%) died of non-procedure-related or non-AP-related events, one of whom died of liver cancer at 20 months after discharge and the other whose necrosis was induced by malignant obstruction of the pancreatic duct died of pancreatic cancer after 10 months. WOPN recurrence was reported in 5 (5.3%) patients at the 6-month follow-up, all of which were successfully resolved via endoscopic or percutaneous drainage.

3.4 | Comparison of clinical outcomes among different EN approaches

We further investigated whether the EN approaches correlated with the clinical outcomes of the patients. We noticed that there were no significant differences in the short-term clinical outcomes, procedure-related adverse events, and long-term follow-up events among the three groups (Table 3). Interestingly, significant intergroup differences were observed in terms of the number ($p < 0.001$), main location ($p < 0.001$), location of the lower margin ($p < 0.001$), and size (long axis) ($p = 0.018$) of the necrotic cavity.

3.5 | Potential factors associated with treatment failure

Potential factors associated with treatment failure were evaluated (Table 4). High APACHE-II scores (≥15) were significantly associated with treatment failure ($p = 0.009$). Patients who developed organ failure were also more likely to have treatment failure ($p = 0.004$).

4 | DISCUSSION

In recent decades, EN has emerged as the preferred treatment for WOPN and mainly includes TEN, PEN, and CEN. Among these

TABLE 3 Demographic and procedural characteristics and clinical outcomes according to endoscopic necrosectomy (EN) approaches

Characteristics	TEN (n = 56)	PEN (n = 38)	CEN (n = 7)	*p* value
Gender, n (%)				0.584
Female	19 (33.9)	17 (44.7)	2 (28.6)	
Male	37 (66.1)	21 (55.3)	5 (71.4)	
Age, years (mean ± SD)	44.9 ± 11.8	41.5 ± 11.6	43.0 ± 8.5	0.373
Etiology, n (%)				0.229
Hypertriglyceridemia	21 (37.5)	16 (42.1)	1 (14.3)	
Alcohol	8 (14.3)	7 (18.4)	1 (14.3)	
Gallstone	13 (23.2)	8 (21.1)	5 (71.4)	
Others[a]	14 (25.0)	7 (18.4)	0 (0)	
Charlson comorbidity score (median [range])	1 (0–5)	1 (0–4)	0 (0–2)	0.65
ASA classification, n (%)				0.705
<Grade 3	31 (55.4)	20 (52.6)	5 (71.4)	
≥Grade 3	25 (44.6)	18 (47.4)	2 (28.6)	
APACHE II score, n (%)				0.136
<15	51 (91.1)	29 (76.3)	6 (85.7)	
≥15	5 (8.9)	9 (23.7)	1 (14.3)	
White blood cell count, $\times 10^9$/L (median [range])	9.0 (1.8–24.9)	11.6 (4.7–29.5)	9.5 (2.0–11.7)	0.112
Gastrointestinal fistula, n (%)	13 (23.2)	4 (10.5)	3 (42.9)	0.083
Organ failure, n (%)	9 (16.1)	11 (28.9)	1 (14.3)	0.318
Sepsis, n (%)	4 (7.1)	7 (18.4)	0 (0)	0.176
ICU admission, n (%)	39 (69.6)	31 (81.6)	4 (57.1)	0.254
Necrotic cavity, n (%)				
Number				<0.001
Single	33 (58.9)	6 (15.8)	1 (14.3)	
Multiple	23 (41.1)	32 (84.2)	6 (85.7)	
Main location				<0.001
Head and neck	4 (7.1)	7 (18.4)	2 (28.6)	
Body and tail	40 (71.4)	10 (26.3)	1 (14.3)	
Entire pancreas	12 (21.4)	21 (55.3)	4 (57.1)	
Location of the lower margin				<0.001
Peripancreatic region	35 (62.5)	9 (23.7)	0 (0)	
Below the lower margin of the left kidney	7 (12.5)	12 (31.6)	2 (28.6)	
Extension to pelvic cavity	14 (25.0)	17 (44.7)	5 (71.4)	
Size (long axis)				0.018
<12 cm	30 (53.6)	10 (26.3)	2 (28.6)	
≥12 cm	26 (46.4)	28 (73.7)	5 (71.4)	
Time from pancreatitis onset to initial drainage, n (%)				0.069
<4 weeks	8 (14.3)	12 (31.6)	0 (0)	
≥4 weeks	48 (85.7)	26 (68.4)	7 (100)	
Clinical outcomes, *n* (%)				0.214
Success	54 (96.4)	34 (89.5)	6 (85.7)	
Failure	2 (3.6)	4 (10.5)	1 (14.3)	
Procedure-related adverse events, n (%)				
Bleeding from the necrotic cavity	2 (3.6)	1 (2.6)	0 (0)	0.649
Pancreatic fistula	0 (0)	1 (2.6)	0 (0)	0.446
Colonic fistula	0 (0)	1 (2.6)	0 (0)	0.446
Septic shock	0 (0)	2 (5.3)	0 (0)	0.274

TABLE 3 (Continued)

Characteristics	TEN (n = 56)	PEN (n = 38)	CEN (n = 7)	*p* value
Events during long-term follow-up, n (%)				
New-onset diabetes mellitus	11 (19.6)	5 (13.2)	0 (0)	0.431
New-onset pancreatic exocrine insufficiency	3 (5.4)	2 (5.3)	1 (14.3)	0.497
Regional portal hypertension	1 (1.8)	2 (5.3)	0 (0)	0.649
Recurrence	2 (3.6)	2 (5.3)	1 (14.3)	0.414

Abbreviations: APACHE, Acute Physiology and Chronic Health Evaluation; ASA, American Society of Anesthesiologists; CEN, combined EN; CT, computed tomography; ICU, intensive care unit; PEN, percutaneous EN; SD, standard deviation; TEN, transluminal EN.
[a]Including post-endoscopic retrograde cholangiopancreatography, postoperation, malignancy, and idiopathic, etc.

approaches, TEN is more widely accepted in clinical setting.[18,30] Nevertheless, TEN is only feasible for no more than two-thirds of the patients with WOPN.[31] Notably, lateral necrotic collection extending to the pelvic paracolic gutter cannot be accessed via TEN.[32] In addition, patients with respiratory distress may not tolerate repeated per-oral endoscopic procedures.[23] Percutaneous drainage is conventionally performed in these patients and thus provides an accessible route for subsequent PEN. The effectiveness of PEN has been verified in many case series and studies,[24,25,33–35] indicating that PEN might be used as a rescue therapy when TEN is not feasible. Nevertheless, the percutaneous approach confers an increased risk of infection and the development of pancreaticocutaneous or enterocutaneous fistula.[36]

In the current study we proposed a selection strategy for treating infected WOPN, in which TEN, PEN, and CEN were performed depending on the extent of necrosis and the distance between the necrotic collection and the GI lumen (using a threshold of 15 mm) or the body surface. In patients with necrosis located close to the gastric or duodenal wall (≤15 mm), TEN was performed to reduce the risk of infection and the development of pancreaticocutaneous fistula. For cases with necrosis extending to the paracolic gutter or located near the body surface, PEN is recommended to guarantee thorough debridement.

Based on previous reports listed in Supplementary Table S3,[9,15,21,23,29,35,37–44] only one single EN approach was used in most cases. The rate of successful endoscopic debridement for infected WOPN ranges from 70% to 100%. The rates of procedure-related complication and mortality were 9.5%–53% and up to 30%, respectively. In our study, 56 patients underwent TEN, 38 underwent PEN, and seven underwent CEN, respectively. Clinical success was achieved in 94 (93.1%) of our patients, and the mortality and procedure-related adverse event rates were both 6.9%. Thus, the complication rate in our study was relatively lower, which might be attributed to the use of a tailored therapeutic strategy, as each of the approaches contributed its strengths. For cases that are difficult to be managed by TEN, PEN may be a potential alternative, which allows a flexible endoscope to advance into different cavity extensions to perform a more effective removal of debris and avoid unnecessary harm to normal tissues. In particular, PEN was performed at the bedside in three of our patients with extremely poor health (ASA grade 4, with multiorgan failure). Surgical intervention was initially considered not feasible for these patients, as they depended on mechanical ventilation and could not tolerate general anesthesia, and it was impossible to transfer them to the operating center and radiological examination. Therefore, PEN at the bedside was reserved as the "last resort" therapy. As a result, two of our patients were successfully managed, one of whom died of severe sepsis. Notably, CEN was performed in seven patients, all of whom exhibited extensive, multiple necrosis. Consequently, clinical success was achieved in six of them, and only one patient experienced WOPN recurrence after 3 months. Regrettably, one patient died of severe infection and malnutrition. Among these patients, a single approach for complete debridement would be time-consuming. More importantly, the risks of residual necrosis and bleeding would be greatly increased.[6,30]

Additionally, as the endoscopic approach is a relatively novel technique, its long-term efficacy needs further investigation. A retrospective study in Denmark revealed that new-onset pancreatic endocrine insufficiency was developed in 36 (32%) patients following TEN for WOPN during a median follow-up of 4.3 years.[41] In a long-term follow-up study of the ExTENSION trial, which compared endoscopic with surgical step-up necrosectomy after a mean follow-up of 7 years, new-onset pancreatic endocrine insufficiency was observed in 19 (37%) patients.[43] Among the 94 of our patients who achieved clinical success, 16 (17.0%) developed new-onset DM and six (6.4%) suffered pancreatic exocrine insufficiency during a median follow-up of 50 months. A slightly lower proportion of our patients developed pancreatic dysfunction, possibly because that the route selected for endoscopic debridement was more rational, which therefore reduced the risks of damage to viable pancreatic tissues. Moreover, because of the anatomical proximity of the pancreas to the splenic vein, three (3.2%) cases of new-onset regional portal hypertension were noted; therefore, additional attention should be given to the splenic vein during surgery.

Notably, clinical success rate was high among patients who received different EN approaches, with 96.4% for TEN, 89.5% for PEN, and 85.7% for CEN, respectively. Furthermore, the EN approaches were not associated with short-term or long-term clinical outcomes or complications. These findings validate the rationality of our therapeutic strategy, which ensures that each patient undergoes the EN approach individually. In addition, significant intergroup differences were noted in the number, main location, lower margin, and size of the necrotic cavity. It is not surprising to observe such differences in these indicators, as patients undergoing PEN and CEN typically

TABLE 4 Factors associated with treatment failure.

Variables	Clinical success (n = 94)	Clinical failure (n = 7)	*p* value
Gender, n (%)			0.421
Female	34 (36.2)	4 (57.1)	
Male	60 (63.8)	3 (42.9)	
Age, years (mean ± SD)	43.5 ± 12.0	43.1 ± 5.7	0.933
Etiology, n (%)			0.473
Hypertriglyceridemia	35 (37.2)	3 (42.9)	
Alcohol	14 (14.9)	2 (28.6)	
Gallstone	24 (25.5)	2 (28.6)	
Others[†]	21 (22.3)	0 (0)	
Charlson comorbidity score (median [range])	1 (0–5)	1 (0–2)	0.666
ASA classification, n (%)			0.697
<Grade 3	53 (56.4)	3 (42.9)	
≥Grade 3	41 (43.6)	4 (57.1)	
APACHE II score, n (%)			0.009
<15	83 (88.3)	3 (42.9)	
≥15	11 (11.7)	4 (57.1)	
White blood cell count, $\times 10^9$/L (median [range])	10.0 (1.8–24.9)	12.4 (7.0–29.5)	0.112
Gastrointestinal fistula, n (%)	19 (20.2)	1 (14.3)	1.000
Organ failure, n (%)	16 (17.0)	5 (71.4)	0.004
Sepsis, n (%)	9 (9.6)	2 (28.6)	0.167
ICU admission, n (%)	68 (72.3)	6 (85.7)	0.671
Necrotic cavity, n (%)			
Number			1.000
Single	37 (39.4)	3 (42.9)	
Multiple	57 (60.6)	4 (57.1)	
Main location			0.118
Head and neck	12 (12.8)	1 (14.3)	
Body and tail	50 (53.2)	1 (14.3)	
Entire pancreas	32 (34.0)	5 (71.4)	
Lower margin			0.780
Peripancreatic region	41 (43.6)	3 (42.9)	
Below the lower margin of the left kidney	19 (20.2)	2 (28.6)	
Extension to pelvic cavity	34 (36.2)	2 (28.6)	
Size (long axis)			0.446
<12 cm	38 (40.4)	4 (57.1)	
≥12 cm	56 (59.6)	3 (42.9)	
Time from AP onset to initial drainage, n (%)			0.623
<4 weeks	18 (19.1)	2 (28.6)	
≥4 weeks	76 (80.9)	5 (71.4)	
EN approach, n (%)			0.214
Transluminal	54 (57.4)	2 (28.6)	
Percutaneous	34 (36.2)	4 (57.1)	
Combined	6 (6.4)	1 (14.3)	

Abbreviations: AP, acute pancreatitis; APACHE, Acute Physiology and Chronic Health Evaluation; ASA, American Society of Anesthesiologists; EN, endoscopic necrosectomy; ICU, intensive care unit; SD, standard deviation.
[†]Including post-endoscopic retrograde cholangiopancreatography, postoperation, malignancy, and idiopathic, etc.

exhibit larger and more extensive necrotic lesions, which also explains the reason why necrosis in these patients extends toward the body surface. Therefore, PEN and CEN should be given thorough consideration for patients with extensive pancreatic necrosis, necrosis extending to the pelvic cavity, necrosis ≥12 cm in size, and multiple necrotic cavities. In our study, the EN approaches were primarily selected based on the distance between the GI tract and/or the body surface and the necrotic cavity. Further evaluation of the aforementioned indicators is needed to standardize our selection criteria. This may provide better guidance for selecting the optimal EN approaches in specific clinical scenarios.

Although our therapeutic strategy had a high success rate, several patients did not respond to endoscopic interventions. Then we asked which patients were more likely to experience treatment failure and who might be more suitable for other treatment modalities. A recent study by Zhai et al[15] included patients who underwent TEN with lumen-apposing metal stents and identified paracolic gutter extension, high APACHE-II scores, and severe necrosis (>50%) as having negative effects on treatment success. A retrospective study by Jain et al[40] revealed that organ failure and extensive pancreatic necrosis were related to unsatisfactory outcomes in patients with infected necrotizing pancreatitis. In our study, organ failure was recognized to be associated with treatment failure, which aligned with a previous meta-analysis illustrating that the simultaneous presence of organ failure and infection was associated with a 2-fold increased risk of mortality in AP.[5] The APACHE-II scale was initially designed to predict hospital and ICU mortality and is now widely accepted as a severity index to evaluate the health status of patients with AP,[45] and an APACHE-II score ≥15 has been confirmed to be strongly related to treatment failure in the current study. The results suggested that comprehensive assessment is required before endoscopic management and that more aggressive interventions should be considered for these patients.

Notably, operator-related factors were considered to be not associated with treatment failure. Although postponed catheter drainage until at least 4 weeks after complete encapsulation of infected necrosis is recommended according to current guidelines,[16,46] early intervention is inevitable to control sepsis and prevent organ failure in patients with significantly deteriorated clinical status. Nevertheless, the risks of adverse outcomes following early endoscopic intervention remains controversial. A meta-analysis of 630 patients revealed that both early (<4 weeks) and standard (≥4 weeks) drainage of WOPN achieved similar technical and clinical outcomes.[47] Consistently, our study also revealed that the initial drainage time was not associated with the clinical outcome, indicating that early endoscopic intervention may be an optimal option for patients with clinical decompensation. Zhai et al[15] suggests that the extension of the lesion to paracolic gutter was a significant predictor of TEN failure. While our findings showed the opposite result. In cases whose necrosis extends into the paracolic gutter, it is technically difficult to be reached through the transluminal route, while both PEN and CEN allow for a comprehensive removal of necrotic materials. Consequently, our study revealed no correlation between the location of necrotic lesions and clinical outcomes of the patients, which directly attributed to our selection strategy. Moreover, consistent with previous studies, the size of the necrosis was found to be unrelated to treatment failure.[15,29,42] For large necrotic lesions, endoscopic techniques can be employed to perform multiple debridement procedures, thereby minimizing the impact of a second open abdominal surgery on patients. For one of our patients, complete resolution of the necrotic cavity was eventually achieved after a total of 10 EN sessions over 174 days, despite the necrotic area measuring 30 cm × 26 cm in size.

There were some limitations to this study. As this was a retrospective study with a study period of 13 years, bias could not have been avoided. However, based on the unified EN management standard, we found that the technical success rate was 100%, indicating that all patients underwent the EN successfully with no major complications related to the operation. Therefore, we believe that minor bias arising from operative instruments, basic drug use, and the experiences of the operators did not significantly impact the efficacy of the approaches. Moreover, due to compliance concerns among patients and practical reasons, we defined pancreatic insufficiency on the basis of the use of pancreatic enzyme supplements instead of objective analyses of exocrine insufficiency (eg, positive fecal elastase test). This might have led to an underestimation of the number of patients with long-term complications. A fecal elastase test can provide more definitive evidence for a precise diagnosis in these cases, which should be employed in further studies.

In conclusion, EN led to a favorable outcome for patients with infected WOPN. Selection of EN approach shall be based on the extent of necrosis and the distance between the necrotic collection and the GI lumen with a threshold of 15 mm, which enables the selection of optimal EN approach for patients with infected WOPN so as to improve the clinical success rate and to guide clinical practice.

CONFLICT OF INTEREST

All authors declare that there are no competing interests.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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