Annals of Gastroenterology (2025) **38,** 564-569

Trends and outcomes of endoscopic ultrasound-guided drainage and pancreatic necrosectomy for acute necrotizing pancreatitis

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Abstract

Background Use of endoscopic ultrasound (EUS)-guided interventions has resulted in an expanding domain of non-surgical endoscopic methods for treating acute necrotizing pancreatitis (ANP). We examined the current trends and outcomes of EUS-guided drainage and endoscopic necrosectomy in the United States.

Methods This observational retrospective study used the Nationwide Inpatient Sample database (2016-2020) to identify adult patients with ANP who underwent endoscopic necrosectomy, based on ICD-10-CM codes. Univariate and multivariate logistic regression, and linear models were used to examine the outcomes of ANP in patients who underwent endoscopic necrosectomy in comparison to patients who had no such interventions.

Results Among 11,212 ANP cases identified, 493 (4.4%) underwent endoscopic necrosectomy. The patients' mean age was 49.6 years and they were predominantly male (66.8%). There was a steady increase in ANP admissions (542 to 3180) and endoscopic necrosectomy (0% to 5.8%) from 2016-2020. Endoscopic intervention had lower odds for systemic inflammatory response syndrome (P=0.038), but higher odds for venous thromboembolism (P=0.006). Hospital costs (P<0.001), charges (P<0.001), and length of hospital stay (LOS) (P<0.001) were greater for patients with endoscopic intervention. Procedural adverse events were rare (5.9%), and were associated with significantly greater LOS (P=0.004), higher hospital costs (P=0.018) and charges (P=0.004), but no difference in mortality (P=0.899).

Conclusions Endoscopic necrosectomy for ANP increased from 2016-2020 and was associated with low risk for adverse events or mortality, but greater LOS and costs compared to conservative non-interventional management. Further research is required to optimize patient selection and address the economic implications.

Keywords Acute pancreatitis, necrotizing pancreatitis, pancreatic necrosis, endoscopic necrosectomy, endoscopic ultrasound-guided drainage

Ann Gastroenterol 2025; 38 (5): 564-569

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Conflict of Interest: None

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Received 26 March 2025; accepted 1 July 2025; published online 11 August 2025

DOI: https://doi.org/10.20524/aog.2025.0987

Introduction

Acute pancreatitis (AP) represents a prevalent gastroenterological disease on a global scale [1]. The incidence of AP in the United States has been reported as 600-700 cases per 100,000 individuals [2]. Although interstitial edematous pancreatitis predominates, 10-20% of cases involve pancreatic necrosis [3-7]. Approximately 30% of patients with acute necrotizing pancreatitis (ANP) experience the development of infected necrotizing pancreatitis, resulting in mortality rates of up to 40% in the presence of sepsis [3,8].

Historically, the management of pancreatic necrosis relied heavily on open necrosectomy, a procedure associated with substantial morbidity and a high risk of complications [9]. Over the past 3 decades, however, there has been a significant shift towards minimally invasive approaches, including endoscopic

ultrasound (EUS)-guided transmural drainage and direct endoscopic necrosectomy [10]. The trend is now firmly towards these minimally invasive methods, favoring endoscopic drainage or debridement guided by ultrasound [4,5,11,12]. Several experts agree that EUS has become the preferred method, given its advantages—which include, for example, a reduced risk of developing complications such as pancreatico-cutaneous fistula [4]. Since its first description in 1996, endoscopic transmural therapy for pancreatic necrosis has evolved into a safer and more effective therapeutic option, with fewer complications [4,13].

Although EUS-guided drainage and necrosectomy for necrotizing pancreatitis appears to be a promising treatment, it is worth recognizing that the procedure is not without risk. It has several limitations, including the necessity of performing the procedure under anesthesia. Furthermore, access to the target area may be challenging if there is a deep retroperitoneal extension, and there is a risk of damaging vasculature during the procedure [14]. Moreover, EUS-guided intervention alone is sometimes insufficient to resolve pancreatic fluid collections, so that additional interventions, such as percutaneous catheter drainage or surgery, may be needed [7,14].

This study aimed to evaluate the current trend and outcomes of EUS-guided drainage and necrosectomy for ANP, using the largest inpatient dataset in the United States. We sought to determine how the growing use of endoscopic interventions has influenced clinical and economic outcomes for ANP.

Materials and methods

Study design and data source

Patients were selected from the Nationwide Inpatient Sample, which is the largest publicly available, inpatient, all-payer database in the United States. The data set for each year contains more than 7 million hospital stays, which are a 20% stratified sample of over 4000 nonfederal acute care hospitals in more than 40 states of the United States, and is representative of 95% of hospital discharges nationwide. A principal diagnosis, defined as the primary discharge diagnosis, as well as up to 40 other secondary diagnoses (depending on the selected year) are included in the data set. The data set also includes codes for up to 40 procedures performed during the hospital stay. In addition, it allows the determination of the length of hospital stay, (LOS) and total hospitalization costs and charges, as well as indicating the desired outcome measures. All the analyzed data for this retrospective cohort study were extracted from the database for the years 2016-2020.

Study population

Patients in the Nationwide Inpatient Sample data set for the year 2016-2020 with an International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) diagnostic code for acute necrotizing pancreatitis (Supplementary Table 1A) were identified. All adult patients with acute necrotizing pancreatitis who underwent EUS-guided drainage and necrosectomy (referred to hereafter simply as endoscopic necrosectomy), based on ICD-10-CM codes (Supplementary Table 1A), were included in the analysis. Patients who underwent percutaneous drainage (ICD-10 codes: 0F9G30Z, 0F9G3ZX, 0F9G3ZZ) or surgical necrosectomy (ICD-10 codes: 0F9G00Z, 0F9G0ZX, 0F9G0ZZ) were excluded from the outcome analysis in our study cohort.

Variable definition

The patients' general characteristics included demographics such as age, sex, ethnicity, median income in zip code, and insurance type. Each patient's vital status at the conclusion of their hospital stay, the total days of hospitalization, and total hospitalization charges and costs were also extracted from the database. To account for patient comorbidities, the Deyo adaptation of the Charlson comorbidity index was used, which is a validated tool for large database analysis.

Aims

The primary outcome was to determine the rate of patients admitted for acute necrotizing pancreatitis who underwent endoscopic necrosectomy for each year between 2016 and 2020. Secondary outcomes compared the differences in clinical outcomes between patients who had endoscopic necrosectomy and those who did not undergo interventions, in terms of the rate of pancreatitis complications (systemic inflammatory response syndrome [SIRS], acute kidney injury [AKI], acute respiratory distress syndrome [ARDS], venous thromboembolism [VTE], and shock), utilization of additional interventions, such as endoscopic retrograde cholangiopancreatography (ERCP) and cholecystectomy, LOS, inpatient mortality, and hospital expenditures (subdivided into total hospitalization charges and hospital costs). The occurrence of procedural adverse events was also examined.

Statistical analysis

Patients with acute necrotizing pancreatitis were stratified according to whether or not they underwent endoscopic necrosectomy during hospitalization. Categorical variables were compared using Pearson's chi-square test and continuous variables using a standard *t*-test. Multivariate logistic regression was used to examine the outcomes of acute necrotizing pancreatitis in patients who had endoscopic necrosectomy in comparison to patients who did not undergo interventions, adjusting for statistically significant covariates. The adjusted odds ratio (aOR) and 95% confidence interval [CI] were reported for each variable, with statistical significance set at $P<0.05$. Multivariate linear regression was used to determine

the adjusted additional mean (aMean) of the LOS, hospital cost and charges, adjusting for statistically significant covariates. Analyses were performed using SAS version 9.4 (SAS Institute, North Carolina, US).

Results

A total of 11,212 patients with ANP were identified, of whom only 493 (4.4%) underwent endoscopic necrosectomy. The mean age was 49.6 years and 66.8% were male. Supplementary Table 1B shows descriptive data for the overall study population.

There was a steady increase in ANP admissions from 2016 to 2020 (from 542 to 3180). Endoscopic necrosectomy cases increased from 0 (0%) in 2016 to 184 (5.8%) in 2020 (Table 1).

Table 2 shows the baseline characteristics of patients who underwent endoscopic interventions. Patients who underwent endoscopic necrosectomy were more likely to be older (51.1 vs. 49.6 years, P=0.04) or have private insurance (45.6% vs. 37.2%, P=0.002). Patients who underwent endoscopic drainage were more likely to have infected necrosis (46.9% vs. 20.3%, P<0.001). There were no differences based on sex, ethnicity, income or Charlson comorbidity index.

Tables 3 and 4 show the univariate and multivariate analysis outcomes, respectively, of patients undergoing endoscopic interventions. Patients who underwent endoscopic necrosectomy had a lower likelihood of experiencing SIRS (4.0% vs. 7.3%; aOR 0.60, 95%CI 0.37-0.97; P=0.038), but a higher likelihood of VTE (10.9% vs. 7.3%; aOR 1.57, 95%CI 1.14-2.16; P=0.006). No differences were noted in the rates of other complications of ANP, including AKI (P=0.23), ARDS (P=0.67), shock (P=0.74), or in-hospital mortality (P=0.07).

In terms of additional interventions (Tables 3 and 4), patients who underwent endoscopic necrosectomy for ANP were significantly more likely to undergo ERCP (27.0% vs. 8.0%; aOR 4.16, 95%CI 3.29-5.25; P<0.001), but less likely to undergo surgical interventions (cholecystectomy: 2.7% vs. 9.5%; aOR 0.21, 95%CI 0.12-0.39; P<0.001).

In terms of resource utilization (Tables 3 and 4), patients who underwent endoscopic necrosectomy incurred higher hospital costs ($67,443 vs. $38,305; aMean $28,904, 95%CI $21,213-$36,594; P<0.001) and hospital charges ($261,895 vs. $156,768; aMean $103,631, 95%CI $71,828-$135,433; P<0.001), and had longer hospital stays (20.5 vs. 12.3 days;; aMean 8.1, 95%CI 6.6-9.6; P<0.001).

Procedural adverse events occurred in 29 (5.9%) patients who underwent endoscopic necrosectomy, including 12 (2.4%) infections, 7 (1.4%) hemorrhages and 10 (2.0%) perforations (Supplementary Table 2). As shown in Table 5, procedural adverse events were associated with a significantly longer hospital stay (aMean 14.4, 95%CI 4.6-24.2; P=0.004), higher hospital costs (aMean $53,147, 95%CI $9,178-$97,116;

Table 1 Trends in acute necrotizing pancreatitis (ANP) admissions and endoscopic intervention (N=11,212)

Year	ANP admissions	Endoscopic necrosectomy cases	% of ANP admissions undergoing endoscopic necrosectomy
2016	542	0	0
2017	2161	32	1.5
2018	2613	131	5.0
2019	2716	146	5.4
2020	3180	184	5.8

Table 2 Baseline characteristics of patients with acute necrotizing pancreatitis who underwent endoscopic necrosectomy (N = 11,212)

Variable	No endoscopic necrosectomy (N=10,719)	Endoscopic necrosectomy (N=493)	P-value[a]
Age (years)	49.6	51.1	0.0412
Male sex	66.92%	63.49%	0.1143
Ethnicity			0.0773
Caucasian	65.86%	69.44%	
African American	12.73%	9.56%	
Hispanic	14.19%	13.31%	
Asian	2.72%	2.29%	
Native American	1.26%	0.62%	
Other	3.24%	4.78%	
Income			0.0803
1 (0-25th percentile)	27.81%	25.05%	
2 (26th to 50th percentile (median)	26.36%	23.19%	
3 (51st to 75th percentile)	25.26%	29.19%	
4 (76th to 100th percentile)	20.56%	22.57%	
Charlson Comorbidity Index			0.8416
0	36.45%	36.71%	
1 – 2	46.7%	45.4%	
3>	16.81%	17.85%	
Insurance			0.0020
1 Medicare	24.28%	23.53%	
2 Medicaid	25.44%	21.91%	
3 Private insurance	37.24%	45.64%	
4 Self-pay	8.99%	5.68%	
5 No charge	0.69%	0.20%	
6 Other	3.36%	3.04%	
Necrosis type			<0.001
Infected	20.3%	46.9%	
Non-infected	79.7%	53.1%	

[a]Chi square for categorical variables, t-test for continuous variables, statistically significant (P<0.05)

Table 3 Univariate outcomes of patients with acute necrotizing pancreatitis who underwent endoscopic necrosectomy† (N=10,424)

Variable	No intervention (N=9975)	Endoscopic necrosectomy (N=449)	P-value[a]
SIRS	7.31%	4.01%	0.0080
AKI	0.15%	0.45%	0.1296
ARDS	1.85%	1.78%	0.9107
VTE	7.29%	10.91%	0.0042
Shock	0.72%	0.67%	0.8953
ERCP	8.01%	26.95%	<0.001
Obesity	9.82%	10.24%	0.7699
Cholecystectomy	9.52%	2.67%	<0.001
Costs	$38,305	$67,443	<0.001
Charges	$156,768	$261,895	<0.001
LOS	12.3	20.5	<0.001
In-hospital mortality	5.12%	3.79%	0.2076

[a]Chi square for categorical variables, t-test for continuous variables, statistically significant (P<0.05)

†Excluding percutaneous or surgical necrosectomy

SIRS, systemic inflammatory response syndrome; AKI, acute kidney injury; ARDS, acute respiratory distress syndrome; VTE, venous thromboembolism; ERCP, endoscopic retrograde cholangiopancreatography; LOS, length of hospital stay

Table 4 Multivariate outcomes of acute necrotizing pancreatitis in patients who underwent endoscopic necrosectomy†

Variable	aOR[a]	95%CI	P-value
SIRS	0.597	0.367-0.971	0.0375
AKI	2.595	0.539-12.502	0.2344
ARDS	1.164	0.558-2.431	0.6856
VTE	1.565	1.137-2.155	0.0060
Shock	1.225	0.372-4.035	0.7385
ERCP	4.156	3.288-5.254	<0.001
Obesity	1.109	0.802-1.532	0.5311
Cholecystectomy	0.214	0.119-0.385	<0.001
In-hospital mortality	0.615	0.364-1.040	0.0697
	aMean[a]	95%CI	P-value
LOS	8.1	6.6-9.6	<0.001
Costs	$28,904	$21,213-$36,594	<0.001
Charges	$103,631	$71,828-$135,433	<0.001

[a]Adjusted for age, insurance status and infected necrosis

†Excluding percutaneous or surgical necrosectomy

aOR, adjusted odds ratio; CI, confidence interval; aMean, adjusted mean difference; SIRS, systemic inflammatory response syndrome; AKI, acute kidney injury; ARDS, acute respiratory distress syndrome; VTE, venous thromboembolism; ERCP, endoscopic retrograde cholangiopancreatography; LOS, length of hospital stay

Table 5 Outcomes of patients with acute necrotizing pancreatitis who experienced procedural adverse events after endoscopic necrosectomy (N=493)

Variable	aOR (95%CI)[a]	P-value
In-hospital mortality	0.876 (0.113-6.805)	0.8989
	aMean (95%CI)[a]	P-value
LOS	14.4 (4.6-24.2)	0.0039
Costs	$53,147 ($9,178-$97,116)	0.0178
Charges	$233,765 ($74,132-$393,397)	0.0041

[a]Adjusted for morbidity (Charlson–Deyo Index)

aOR, adjusted odds ratio; CI, confidence interval; aMean, adjusted mean difference; LOS, length of hospital stay

P=0.018) and hospital charges (aMean $233,765, 95%CI $74,132-$393,397; P=0.004), but no difference in in-hospital mortality (P=0.899).

Discussion

In recent years, there has been a marked increase in ANP admissions, paralleled by a shift toward minimally invasive management techniques, such as EUS-guided drainage and pancreatic necrosectomy [9,11-14]. This shift highlights the advantages of EUS-guided approaches over traditional surgery, particularly in terms of lower complication rates and shorter recovery times [15]. As endoscopic approaches become more prevalent, examining and analyzing related outcomes is important to identify gaps for improvement. Despite its growing use, research on ANP outcomes following EUS-guided drainage and endoscopic necrosectomy remains limited. Our observational study includes a relatively large sample of ANP patients who were managed with endoscopic necrosectomy, supporting its safety and efficacy when available, albeit with some clinical and economic implications for the patient.

Importantly, our findings indicate that endoscopic necrosectomy was associated with a lower likelihood of SIRS: of the 493 patients who underwent endoscopic necrosectomy, 4.0% were noted with SIRS, compared to 7.3% in those who did not undergo intervention (P=0.008). The tendency of endoscopic interventions for ANP to reduce the proinflammatory response (SIRS) was demonstrated by Bakker *et al*, when they compared endoscopic transgastric and surgical necrosectomy for infected necrotizing pancreatitis [16]. They used linear-array endoscopic ultrasound to visualize the extent of the necrosis. Their findings revealed a difference in the proinflammatory response between the groups, with interleukin-6 levels being higher in the surgical group but lower in the endoscopic group, with the largest difference seen 24 hours post-intervention (P=0.005). New-onset multiple organ failure, a common complication in AP, did not occur in the endoscopic group (P=0.03) [16]. These findings underscore the potential clinical

relevance of endoscopic necrosectomy in minimizing the AP-induced inflammatory response and subsequent organ failure, a critical factor in long-term morbidity and mortality associated with AP. However, the observational design of our study does not support causal inference, and it is therefore possible that patients who had already developed SIRS may have been excluded from undergoing endoscopic intervention.

Interestingly, patients treated with endoscopic necrosectomy in our study were observed to have a statistically significant higher rate of VTE, possibly due to instrumentation of a necrotic/inflamed pancreas, immobilization during recovery and prolonged hospitalization. Prothrombotic effects associated with AP-related inflammation have been documented [17]. For example, a study that examined murine models demonstrated that murine AP resulted in a transient hypercoagulable state that peaked 24 h after induction of pancreatitis, then returned to baseline by 72 h [18]. Furthermore, patients with ANP have a 2.5-fold risk of VTE, and a 3-fold risk of pulmonary embolism compared to AP without necrosis [19]. Our study seems to suggest that this risk may be higher following endoscopic necrosectomy for ANP compared to ANP without intervention. This finding might underscore the need for preventive measures, such as prophylactic anticoagulation, and careful monitoring for VTE occurrence in this clinical setting. Although the patients who underwent endoscopic interventions tended to be older on average (51.1 vs. 49.6 years), the average age of the study population was relatively young (<50 years).

EUS-guided drainage and endoscopic necrosectomy are considered to be relatively safe, with our study observing a relatively low adverse event rate of 5.9%, including complications such as infection, hemorrhage and perforation. Although not associated with greater mortality, these adverse events may be associated with prolonged hospitalizations and increased healthcare costs. Similarly, Singh *et al*, who identified EUS-guidance as the preferred choice for encapsulated collections, found that, while effective, the procedure carries potential complications, such as bleeding, gastrointestinal perforation, stent migration and air embolism, although the probability is low [20]. EUS-guided drainage techniques and lumen-apposing metal stents have substantially reduced complication rates, reinforcing the safety and efficacy of EUS-guided necrosectomy [21]. Additionally, a randomized trial that compared endoscopic and surgical step-up approaches for infected necrotizing pancreatitis found no significant differences in complications or mortality between the groups, but the endoscopic group required fewer reinterventions during the initial 6-month follow-up period [22].

Finally, our study highlights the healthcare costs related to EUS-guided intervention. This intervention may be associated with a longer hospital stay and greater expense compared to conservative non-interventional management. The longer LOS may correlate directly with the degree of pancreatic necrosis, and possibly the interval for walled-off necrosis to be amenable to endoscopic drainage [23]. A greater extent of pancreatic necrosis in ANP correlates with higher costs and the need for multiple necrosectomy interventions [24], which may explain the greater economic costs noted in our study. It is also worth noting that the occurrence of post-procedure adverse events, as observed in our study, or the need for close monitoring afterwards, may also contribute to a longer hospital stay and greater economic costs. However, in comparison to percutaneous and surgical necrosectomy, endoscopic necrosectomy has been shown to be associated with significantly lower mortality, fewer adverse events, shorter LOS and lower cost [25].

Our study has important limitations. The retrospective design, which identified endoscopic interventions using ICD-10-CM codes, limits the ability to account for all patients who underwent endoscopic necrosectomy. As such, our study may under-report the prevalence of endoscopic necrosectomy in ANP admissions, given the potential for coding errors or missed coding. To our knowledge, there is a lack of validation studies for the procedure codes, but they have been used in previously published large database studies [25,26]. The observational retrospective study design also limits the ability to infer causality or account for the temporal relationship between endoscopic intervention and the onset of complications. Additionally, the severity of pancreatic necrosis, or the presence of organ failure, which have not been fully accounted for in our study, may have an impact on ANP outcomes apart from the endoscopic procedure itself; these results should therefore be interpreted in the context of these constraints. It is noteworthy that the outcomes of EUS-guided drainage and necrosectomy depend on multiple variables, including the extent of necrosis, patient comorbidities, and the timing of this procedure after ANP diagnosis. Notably, our study did not compare clinical outcomes between endoscopic necrosectomy and surgical or percutaneous drainage. These groups differ inherently in disease trajectory and severity. Therefore, additional research is recommended to provide additional context to the safety, efficacy and costs of endoscopic necrosectomy in comparison to other interventions for ANP. Nevertheless, as EUS-guided techniques continue to evolve, research specifically examining EUS-guided drainage and endoscopic necrosectomy outcomes is needed. Few studies on the endoscopic outcomes for ANP have been conducted, and those available are often limited by small sample sizes. This study contributes to the growing literature supporting this therapeutic approach as an effective intervention for ANP management, while emphasizing the need for optimized procedural timing, enhanced safety and vigilant patient monitoring to minimize complications and control healthcare costs. Future investigations should also explore predictive markers to refine patient selection and develop protocols that can minimize the economic burden of this intervention.

In conclusion, our study emphasizes an expanding role of EUS-guided interventions in the management of ANP. Specifically, the utilization of endoscopic necrosectomy for ANP increased during the study period and was associated with a low risk for adverse events or mortality, but a greater LOS and higher costs compared to conservative non-interventional management. Our study underscores the need for careful patient selection in order to achieve excellent clinical outcomes and reduce associated healthcare costs, as the technique becomes more widely used.

Summary Box

What is already known:

- Infected acute necrotizing pancreatitis (ANP) is associated with up to 40% mortality
- Traditional management of infected ANP relied heavily on open necrosectomy, but this was associated with substantial morbidity and a high risk of complications
- Endoscopic ultrasound-guided drainage and endoscopic necrosectomy have resulted in an expanding domain of non-surgical endoscopic methods for managing ANP

What the new findings are:

- The use of endoscopic necrosectomy for ANP increased from 2016-2020
- Patients undergoing endoscopic necrosectomy displayed lower odds of systemic inflammatory response syndrome, but higher odds of venous thromboembolism, a longer hospital stay, and higher hospital expenditures compared to patients without interventions

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Supplementary material

Supplementary Table 1 (A) International classification of diseases, tenth revision, clinical modification (ICD-10 CM) diagnostic and procedure codes

Diagnosis	ICD 10 code
Acute pancreatitis with necrosis (uninfected)	K85.91
Acute pancreatitis with necrosis (infected)	K85.92
Idiopathic acute pancreatitis with uninfected necrosis	K85.01
Idiopathic acute pancreatitis with infected necrosis	K85.02
Biliary acute pancreatitis with uninfected necrosis	K85.11
Biliary acute pancreatitis with infected necrosis	K85.12
Other acute pancreatitis with uninfected necrosis	K85.81
Other acute pancreatitis with infected necrosis	K85.82
Alcohol induced acute pancreatitis with uninfected necrosis	K85.21
Alcohol induced acute pancreatitis with infected necrosis	K85.22
Drug induced acute pancreatitis with uninfected necrosis	K85.31
Drug induced acute pancreatitis with infected necrosis	K85.32
Endoscopic necrosectomy	0F9G80Z 0F9G8ZX 0F9G8ZZ

Supplementary Table 1 (B) Descriptive summary of study population[†]

Total number of ANP patients	11,212
Endoscopic necrosectomy	493 (4.4%)
Percutaneous necrosectomy	540 (4.8%)
Surgical necrosectomy	277 (2.5%)
Mean age	49.6 years
Male sex	66.8%

[†]Patients who underwent percutaneous drainage or surgical necrosectomy were excluded from the outcome analysis of the study cohort

ANP, acute necrotizing pancreatitis; IR, interventional radiology

Supplementary Table 2 Occurrence of procedural adverse events in patients who underwent endoscopic necrosectomy (N=493)

Variable	Number of cases	Percent
Overall adverse events	29	5.9
Infection	12	2.4
Hemorrhage	7	1.4
Perforation	10	2.0