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ORIGINAL ARTICLE

Endoscopic transgastric versus surgical necrosectomy in infected pancreatic necrosis☆

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Summary Surgical necrosectomy, but is still associated with a high morbidity. Indications of the endoscopic route, a new less invasive technique are not defined yet. To compare characteristics and clinical outcome of patients treated by the two techniques, a bi-centric retrospective comparison of 21 patients treated by surgical necrosectomy in one center (group S) with 11 patients treated in another center by endoscopic transgastric necrosectomy (group E) was performed. Clinical severity scores were significantly higher in group S although CT severity score did not differ between groups. Acute postoperative complications including pancreatic fistula occurred more frequently in group S (86% vs. 27%, $P = 0.002$). ICU and hospital length of stay were higher in group S (84 vs. 4 days; $P = 0.008$ and 58 vs. 15 days; $P = 0.005$ respectively). Long-term complication did not differ between groups. Compared to surgery, endoscopic necrosectomy exhibited lower rate of complications and reduced hospital length of stays. Endoscopic transgastric necrosectomy appears as a safe and effective procedure and has to be included in the therapeutic algorithm of infected pancreatic necrosis.

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Introduction

The incidence of acute pancreatitis (AP) is increasing, up to 0.7 hospitalizations for 1000 habitants in the US [1]. In 80% of the patients, AP is mild and self-limiting, but up to 20% of the patients may run a severe necrotizing course, responsible for substantial morbidity and a mortality rate up to 27% [2]. The major cause of death is infection of necrosis [3], which is associated with a poor prognosis with reported mortality rates of 15% [4] to 39% [5]. The gold standard for the treatment of infected necrosis used to be surgical necrosectomy through laparotomy until quite recently [6—10]. This procedure provides a wide access to infected necrosis [10,11], but is highly invasive and associated with reported morbidity rates of 34 to 95% and mortality rates of 11 to 39% [12,13]. During the two latter decades, the treatment of necrotizing pancreatitis has dramatically evolved with emerging less invasive new techniques including retroperitoneal approach [14], laparoscopy [15], interventional radiology [16,17] and endoscopy [18]. These ''mini-invasive'' techniques are today either alternative or complementary approaches to classical surgery. Their use may allow to postpone surgery in order to optimize the necrosectomy [19] or even to reduce surgical indications. Thus, a recent randomized Dutch study [20] demonstrated the benefit of gradual strategy using first percutaneous drainage associated with a targeted antibiotherapy followed by delayed surgical mini-invasive necrosectomy in patients whose status did not improve after drainage. Endoscopic transgastric necrosectomy may constitute a valuable alternative to surgical necrosectomy since several non-comparative studies reported impressively good results of endoscopic route [18,21—23].

This work aimed at comparing both the clinico-biological characteristics of treated patients and their outcome after surgical open and endoscopic transgastric necrosectomies respectively used in two French referral centers.

Patients and methods

Patients

From May 2005 to September 2011, patients hospitalized in two referral centers with infected acute necrotizing pancreatitis requiring necrosectomy were included. At the time of the study, neither the practicians, nor the equipment for endoscopic necrosectomy were available in the first center which performed surgical anterior necrosectomies. At the same time, the second center which was the first French one to use endoscopic necrosectomies adopted this new technique when possible. Patients treated by surgical necrosectomy in the first center (group S) were here compared to patients treated in the second center with endoscopic transgastric necrosectomy (group E). Infected necrosis was defined by either a positive culture of peripancreatic necrosis, harvested by fine needle aspiration (FNA) or by the presence of gas bubbles in the area of pancreas on a CT scan study associated with a septic status. In both centers, proved infected necrosis was considered as an indication to necrosectomy and debridement.

For this bi-centric retrospective observational study using anonymized information, informed consent was not required by French law (Act N. 78-17 of 6 January 1978 on data processing, data files and individual liberties).

Treatment protocols

In both centers, patients were treated according to the French consensus conference guidelines for intensive care management of acute pancreatitis [8,18]. Surgical necrosectomies were performed in the first center by various senior surgeons through bi-subcostal incision according to previously reported technique [24]. A cholecystectomy was associated to necrosectomy. Post operative continuous irrigation of the necrotic sites was performed through large three channels helicoidal drains (large bore 36 French 3 channeled soft silicon spiralled drain) placed at post operative day 14 after the removal of the capillary drainage (Mikulicz gauze packs).

In the second center, the transgastric endoscopic necrosectomies were performed by two senior endoscopists. All treated patients had at least one accessible necrotic site in the lesser sac, close to the stomach. After evaluation of the extent of necrosis, endoscopic ultrasound guidance was used to visualize and determine the optimal puncture site. Under echoendoscopic and fluoroscopic guidance, the posterior gastric wall was punctured using a 19 Gauge needle and a guide wire was inserted in the necrotic cavity. Then the cystogastrostomy was performed using an electrocautery cystotome and the tract was dilated by balloon. The endoscope was passed through the stomach in the necrotic cavity, where necrosectomy was performed with a dormia basket. Necrosectomy was as complete as possible at the end of a long first procedure. A naso-cystic drain was left in the necrotic cavity and a naso-gastric tube was placed for postoperative irrigations and gastric aspiration respectively and maintained until complete detersion of the necrosis [25]. Double pigtails stents were left for drainage between the cavity and the stomach for at least 6 months. If present on US endoscopic examination, main bile duct lithiasis was treated in the same time with ERCP and endoscopic sphincterotomy. A pancreatic stent was inserted if pancreatic duct rupture was suspected or in case of alcoholic pancreatitis with pancreatic duct stones or stenoses.

Studied variables

Variables were extracted from patient medical charts and recorded. The severity of pancreatitis was assessed by the Ranson's scoring system [26], APACHE II scoring system [27] and the simplified acute physiology score (SAPS II score) [28]. All CT scan examinations were reviewed jointly by a surgeon and a radiologist and the Balthazar CTSI (Computed Tomography Severity Index) [29,30] was calculated.

Endpoints

The primary endpoint was the hospital length of stay. Secondary studied endpoints included preoperative clinico-biological patients' characteristics and post procedure

Table 1 Baseline characteristics of the patients.

	Group E Endoscopic necrosectomy $n = 11$	Group S Surgical necrosectomy $n = 21$	*P* value
Age, median [IQR]	51 (42—57)	52 (47—60)	0.61
Male sex, (*n* [%])	9 (82)	14 (67)	0.44
ASA class on admission (*n* [%])			
I Healthy status	1 (9)	3 (14)	
II Mild systemic disease	5 (45)	16 (76)	0.06
III Severe systemic disease	5 (45)	2 (9)	
Diabetes (*n* [%])	2 (18)	4 (19)	0.90
Obesity (BMI > 35) (*n* [%])	4 (36)	9 (38)	0.76
> 1 cardiovascular risk factors (*n* [%])	8 (73)	14 (66)	0.90

complications. Pancreatic fistula were defined according to the ISGPF classification [31].

Statistical analysis

Data are expressed as median and range for quantitative variables and numbers (percentages) for qualitative variables. The Mann-Whitney U test and Fisher's exact method were used for quantitative and qualitative variables respectively. A *P* value less than 0.05 was considered as statistically significant. An online available software was used (http://lib.stat.cmu.edu/R/CRAN). (R Development Core Team, R Foundation for Statistical Computing) for statistical analysis.

Results

Patients' characteristics

During the study period, 103 patients were admitted for acute necrotizing pancreatitis in the first center and 44 in the second. In the first center, 21 patients (20.3%) underwent surgical necrosectomy (group S) In the second center, 11 patients (23.3%) underwent endoscopic transgastric necrosectomy (group E), including one patient with previous surgical necrosectomy performed in another referring center and two patients were treated surgically because of no accessible necrosis site by transgastric route and were excluded from this study.

Baseline characteristics of the two groups of patients are depicted in Table 1. The median age, ASA score and sex ratio were similar between the two groups. There was no difference between groups in terms of obesity, diabetes or cardiovascular risk factors.

Infection of necrosis was demonstrated by positive cultures in 19 out of 21 (90%) patients in group S and in 10 out of 11 (91%) patients in group E. The causes of acute pancreatitis did not differ between the two groups and were mainly biliary and alcoholic. Time elapsed since onset of symptoms was similar. Five patients in each group underwent a previous drainage under TDM Prior to necrosectomy, 13 (60%) patients in group S had organ failure versus 1 (9%) patient in group E ($P < 0.0.1$) (Table 2).

Table 2 Characteristics of the pancreatitis.

	Group E Endoscopic necrosectomy $n = 11$	Group S Surgical necrosectomy $n = 21$	*P* value
Cause of pancreatitis *n* (%)			0.36
Biliary	5 (45)	6 (29)	
Alcohol abuse	4 (36)	6 (29)	
Other	2 (18)	9 (43)	
Infected necrosis *n* (%)	10 (91)	19 (90)	0.99
Time since onset of symptoms days, median (range)	22 (9—74)	21 (3—120)	0.76
Previous procedure *n* (%)	5 (45) 3 CT drainages 2 Endoscopic drainages	5 (24) 5 CT drainages	0.25
Fever *n* (%)	9 (82)	10 (48)	0.13
Ascitis *n* (%)	4 (36)	8 (38)	1
Pleural effusion *n* (%)	5 (45)	6 (29)	0.44
Organ Failure *n* (%)	1 (9)	13 (60)	0.007

CT drainages: percutaneous drainages performed under computed tomography guidance; Organ Failure: need for mechanical ventilation or inotropic catecholamine support or hemofiltration or hemodialysis.

Table 3 Disease severity scores.

	Group E Endoscopic necrosectomy $n=11$	Group S Surgical necrosectomy $n=21$	*P* value
Ranson score [24]	3 (1—7)	6 (5—8)	< 0.001
CTSI [27]	8 (5—8)	6 (5—6)	0.41
APACHE II score [25]	9 (5—11)	12 (10—16)	0.007
SAPS 2 score [26]	27 (19—28)	39 (29—44)	< 0.001

Results are given as: median (range).

Severity disease scores

Ranson, SAPS II and APACHE II scores were significantly higher in group S compared to group E [26]. Conversely, the radiological severity of pancreatitis graded by CTSI did not differ (Table 3). Nevertheless, the distribution of peripancreatic collections was not comparable in both groups. A collection was always present in lesser sac close to the gastric posterior wall, but all patients presenting necrosis in the mesentery's root belong to group S ($P=0.0006$).

Endoscopic necrosectomies

One patient required three successive necrosectomies, all others were treated by one single procedure. One patient underwent a complementary percutaneous drainage. Stent obstruction occurred in one patient and stent migration in another one. In both cases the stent was replaced during an additional endoscopic procedure. One patient exhibited a colic perforation diagnosed during the procedure that was medically treated by antibiotics and percutaneous drainage.

Surgical necrosectomies

In 21 patients who underwent a surgical necrosectomy, Mikulicz gauze pads were placed in 18 cases (87%). A feeding jejunostomy was constructed in 12 patients (57%) and a loop ileostomy in 10 patients (47%) to divert a colon of dubious viability. Two patients underwent a splenopancreatectomy because of splenic infarction or rupture. One right colectomy and one ileal resection were necessary because of bowel necrosis discovered intra operatively. Because of either excessive fascial tension or an abdominal compartment syndrome, 8 out of 21 patients (38%) underwent exclusive cutaneous closure.

Outcome

Hospital length of stay was significantly shorter for patients in group E. Median hospitalization stay in ICU (Intensive Care Unit) was 30 days in group S and 9 days in group E ($P=0.008$). Median total hospitalization stay was 74 days in group S versus 32 days in group E ($P=0.006$). The rate of post necrosectomy organ failure did not differ between the two groups. Eighteen patients in group S suffered from one or more complications whereas only 3 patients from group E had a complicated course ($P=0.002$) (Table 4). Three patients died postoperatively in group S (14.3%) from multiple organ failure and none in group E ($P=0.53$). Five patients in group S needed relaparotomy, three for hemoperitoneum (two died) and two for enterocutaneous fistula. No pancreatic fistula occurred in group E whereas 8 patients in group S exhibited a pancreatic fistula ($P=0.03$) whose two needed endoscopic treatment by pancreatic stenting. Nine patients

Table 4 Postoperative complications.

	Group E Endoscopic necrosectomy $n=11$	Group S Surgical necrosectomy $n=21$	*P* value
Patient with ≥ 1 complications	3 (27)	18 (86)	0.002
Death	0 (0)	3 (14)	0.53
New onset organ failure	2 (18)	5 (17)	0.99
Bleeding	0 (0)	3 (14)[a]	0.53
Enterocutaneous fistula (requiring intervention)	0 (0)	2 (9)	0.54
Pancreatic fistula (all grades)	0 (0)	8 (38)	0.03
Pancreatic fistula grade C	0 (0)	2 (9)	0.54
Postoperative hernias	0 (0)	9 (43)	0.01
Bowel obstruction	0 (0)	4 (19)	0.27
Bowel perforation	1 (4.5)	0 (0)	0.34
Stent complication	2 (9)	0 (0)	0,11

New onset organ failure = organ failure which was not present 24 h before procedure. (% in brackets).
[a] Including 2 deaths.

Table 5 Long-term pancreatic complications.

	Group E Endoscopic necrosectomy $n=11$	Group S Surgical necrosectomy $n=21$	*P* value
Diabetes *n* (%)	1 (9)	4 (19)	0.98
Use of pancreatic extracts *n* (%)	3 (27)	4 (19)	0.64
Pseudocysts *n* (%)	3 (27)	6 (29)	0.29

(43%) from group S were re-operated for late postoperative hernias.

With a median follow-up of 483 days, there was no difference between the two groups in terms of pancreatic sequellae including development of pseudocysts, diabetes onset or need for pancreatic enzymes (Table 5).

Discussion

The surgical treatment of severe acute pancreatitis has significantly evolved in the last two decades with the advent of minimally invasive surgery [32—35]. Today, International Association of Pancreatology guidelines favour mini-invasive endoscopic or percutaneous drainage as the first step in the treatment of necrotizing pancreatitis, followed by necrosectomy only if required because of ongoing septic status despite targeted antibiotherapy [34]. The approach to be used to perform these delayed necrosectomies remains controversial. Thus, the American and European guidelines do not currently precise the best modality of drainage [7—9,32—34].

Our study compares two radically different practices used during the same period in two surgical tertiary centers. Necrosectomy was indicated in about 20% of patients in both groups that is comparable to previously reported series [3]. The median delay between the pancreatitis onset of three weeks was comparable in the two groups and in accordance with current guidelines [8]. The 90% rate of infected necrosis was comparable to previous surgical series [36,37] and is the witness of the strict adherence of both centers to current guidelines for the management of severe pancreatitis. At last, CT-graded severity of pancreatitis was also comparable. It can be therefore assumed that the treated necrosis were equally extended and mature in both groups.

Endoscopic transgastric necrosectomy, compared to open surgical necrosectomy, appears to reduce both overall stay and ICU stay, as well as the rate of post necrosectomy complications including pancreatic fistula. This better outcome of endoscopy might result from the lower invasiveness of endoscopic debridment compared to surgical necrosectomy. Thus, endoscopic necrosectomy allows preservation of the abdominal accessory respiratory muscles and avoids the impairment of the diaphragmatic function induced by laparotomy [38,39]. Moreover, the initial debridment is usually less extensive than in surgical necrosectomy, the long lasting naso-cystic irrigation of the necrotic cavity achieving complete necrosectomy [40]. It allows decompression of the septic necrotic cavity without upfront extensive necrosectomy, reported to be beneficial in the Dutch ''step-up approach'' [20]. Nevertheless, our series seems to differ from previously reported ones by the extension of the endoscopic debridment performed at the first procedure, requiring very rarely iterative procedures. A mean of 2 to 4 procedures have been indeed reported to complete necrosectomy in most published series [18,22]. This difference in the number of endoscopic procedures may be explained by the variability of techniques and therapeutic intents. A ''one shot'' procedure was adopted in the second center for the endoscopic necrosectomy as previously promoted by others whereas many centers prefer [41] repeated partial but very short necrosectomy. The one shot procedure does not seem to induce deleterious systemic inflammatory response but requires a very perseverant skilled operator and long lasting availability of endoscopic and anaethetic resources as in an operating theater. Further studies are needed to determine the best strategy.

This endoscopic approach differs from the formal surgical necrosectomy aiming to completely remove all infected necrotic tissue. This extended surgical necrosectomy frequently triggers a systemic inflammatory response syndrome (SIRS) requiring intensive intra and postoperative hemodynamic support [42]. It also might lead to unnecessary removal of inflammatory but still viable pancreatic tissue. Moreover, the invasiveness of surgical approach with long lasting drainages might have favoured the occurrence of postoperative hemorrhage, observed in 14% of the surgical group, leading to death in two cases, and never observed in the endoscopic group. At last, frequent delayed complications of surgical necrosectomy such as bowel obstruction and postoperative hernias complicated long-term outcome of 62% of surgically treated patients but were avoided in the endoscopically treated group.

The good results of endoscopic transgastric necrosectomy should be compared to the promising results of minimally invasive necrosectomy [18]. Recently, a ''step-up approach'' demonstrated that percutaneous drainage prior to mini-invasive surgical necrosectomy reduced both indications of surgical necrosectomy and postoperative major complications [43]. Thus, only 65% of the patients undergoing first percutaneous drainage still needed delayed surgical necrosectomy. In our series, five patients in each group (respectively 45% in endoscopy group and 24% in surgery group) underwent percutaneous drainage prior to necrosectomy. It was not possible to demonstrate retrospectively the benefits of this first radiological drainage since strategy in both centers was based on systematic necrosectomy for infected necrosis.

One theoretical advantage of the open anterior surgical approach is its ability to debrid in one single procedure

all necrotic sites whatever their localization and even if they are not closed enough to the stomach to be drained endoscopically. However, retrospective analysis of pre-necrosectomy CT scans in the first center revealed that a retrogastric prepancreatic collection, which presence is mandatory to gain endoscopic access to pancreatic necrosis, was constantly present. Furthermore, in the second center only 2 patients among 13 (15%) were not eligible for endoscopic necrosectomy. Anterior approach also allows the treatment of associated visceral necrosis or splenic lesions observed in four patients. Other benefits of anterior surgical approach are possible cholecystectomy to treat simultaneously causative biliary gallstone and construction of a feeding jejunostomy to provide postoperative enteral feeding. However, the cholecystectomy can usually be delayed [8], main bile duct lithiasis can be treated by endoscopic procedures and naso-jejunal or naso-gastric tube can safely provide continuous enteral nutrition in acute pancreatitis [44,45].

The randomized comparative trial very recently reported, comparing endoscopic necrosectomy and open necrosectomy included only 10 patients per group and demonstrated a reduced post-procedural IL-6 seric levels after endoscopic transgastric necrosectomy. This reflects the reduced post-procedural incidence of SIRS observed with mini-invasive necrosectomies. There was no significant difference in mortality but morbidity was lower in endoscopically treated patients [46]. Apart from its randomized design, this pivotal study differs in several aspects from our study. Hence, all patients with surgical necrosectomy underwent prior percutaneous drainage while patients endoscopically treated did not. Noteworthy, three patients in our endoscopic group underwent prior percutaneous drainage under CT scan guidance that did not preclude later endoscopic necrosectomy with no exteriorization of gastric fistula through the percutaneaous drainage tract. Furthermore, surgical necrosectomies were performed through either retroperitonal or anterior approaches.

Because of its retrospective design our comparison of the two techniques is impaired by the higher severity of the patients surgically treated. Ranson, APACHE II and IGS II scores were thus higher in group S with associated extra pancreatic visceral injuries (2 bowel necroses, 2 splenic ruptures) and mesenteric root necrosis observed in group S but lacking in group E. This selection bias prevents to conclude on the superiority of a technique above another. It might account for the longer hospital stays observed in the surgical groups, although the technique itself, using prolonged capillary drainage of the necrotic sites, is largely contributing to these prolonged ICU and hospitals stays. The small size of our series is also a limitation, as in most retrospective series reporting various indications and techniques and of necrosectomy.

Since our study compares classical surgical necrosectomies performed through anterior abdominal route with endoscopic necrosectomy, no conclusion can be drawn here about the respective merits of minimally invasive surgical techniques performed through retroperitoneal uni- or bilateral approaches and endoscopic necrosectomies. A recently reported review stated that endoscopic necrosectomy and mini-invasive surgical necrosectomy share comparable results and seem superior to percutaneous drainage [47].

Further studies are necessary to define the respective indications of these various techniques of necrosectomy in severe necrotizing pancreatitis. They are likely to be not exclusive of each other and can be associated in a same patient, such as endoscopic completion necrosectomy performed after prior surgical debridement in one of our patients. All these techniques must be available in centers treating severe pancreatitis and offered to the patient on a case by case basis.

Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

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