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« Percutaneous Drainage versus Emergency Cholecystectomy for the treatment of Acute Cholecystitis in Critically ill patients: Does it matter? »

THESE

préparée sous la direction du Docteur Jean-Marie Calmes
avec la co-direction du Professeur Nicolas Demartines
avec la collaboration des Professeurs Alban Denys
et Markus Schäfer

et présentée à la Faculté de biologie et de Médecine de
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par

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Madame le Professeur Stephanie Clarke
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RESUME DE THESE

Contexte de l'étude

Le but de cette étude est de comparer le drainage percutané (DP) et la chirurgie d'urgence (CU) de la vésicule biliaire (VB) pour le traitement de la cholécystite aigüe lithiasique/alithiasique dans un groupe homogène de patients gravement malades et hospitalisés aux soins intensifs (SI).

Patients et méthode

Entre les années 2001 et 2007, tous les patients successivement traités par DP ou CU pour cholécystite aigüe aux SI ont été rétrospectivement analysés. Les cas ont été collectés à partir d'une base de données prospective. Le DP était effectué par voie trans-hépatique et la chirurgie par voie ouverte ou laparoscopique. L'état général des patients et la dysfonction des organes étaient évalués par deux scores validés (SAPS II et SOFA, respectivement). L'analyse des données s'est portée sur les complications à court terme (morbidité, mortalité hospitalière) et à long terme (récurrence des symptômes) après drainage ou chirurgie en urgence.

Résultats

Quarante-deux patients (âge médian 65 ans, 32-94 ans) ont été inclus dans l'étude ; 45% ont eu une CU (10 laparoscopies, 9 voies ouvertes) et 55% un DP (n=23) de la vésicule biliaire. Le DP et la CU ont eu des taux de succès respectifs de 91 et 100% pour la résolution du sepsis lié à la cholécystite aigüe. Après drainage et chirurgie de la VB, la dysfonction des organes secondaire au sepsis s'est résolue dans les 3 jours. Malgré le drainage, deux patients ont nécessité une cholécystectomie en urgence pour cholécystite gangréneuse. Le taux de conversion de la laparoscopie à la voie ouverte était de 20%. La morbidité majeure était de 0% après drainage et 21% après chirurgie en urgence (p=0.034). Finalement, la mortalité hospitalière était similaire (13% après DP vs. 16% après CU, p=1.0) et uniquement liée aux co-morbidités des patients. La récurrence des symptômes liés à la VB n'est apparue que chez des patients initialement drainés pour cholécystite lithiasique.

Conclusions

Chez les patients gravement malades des soins intensifs, le drainage percutané et la chirurgie en urgence de la VB sont tous deux efficaces pour la résolution d'un sepsis lié à une cholécystite aigüe. Cependant, la chirurgie d'urgence est associée à une morbidité majeure accrue et l'approche par laparoscopie n'est pas toujours réalisable. Le drainage percutané de la VB est donc une modalité de traitement valable, mais nécessite à distance de l'épisode aigu une cholécystectomie par laparoscopie, surtout après une cholécystite lithiasique.

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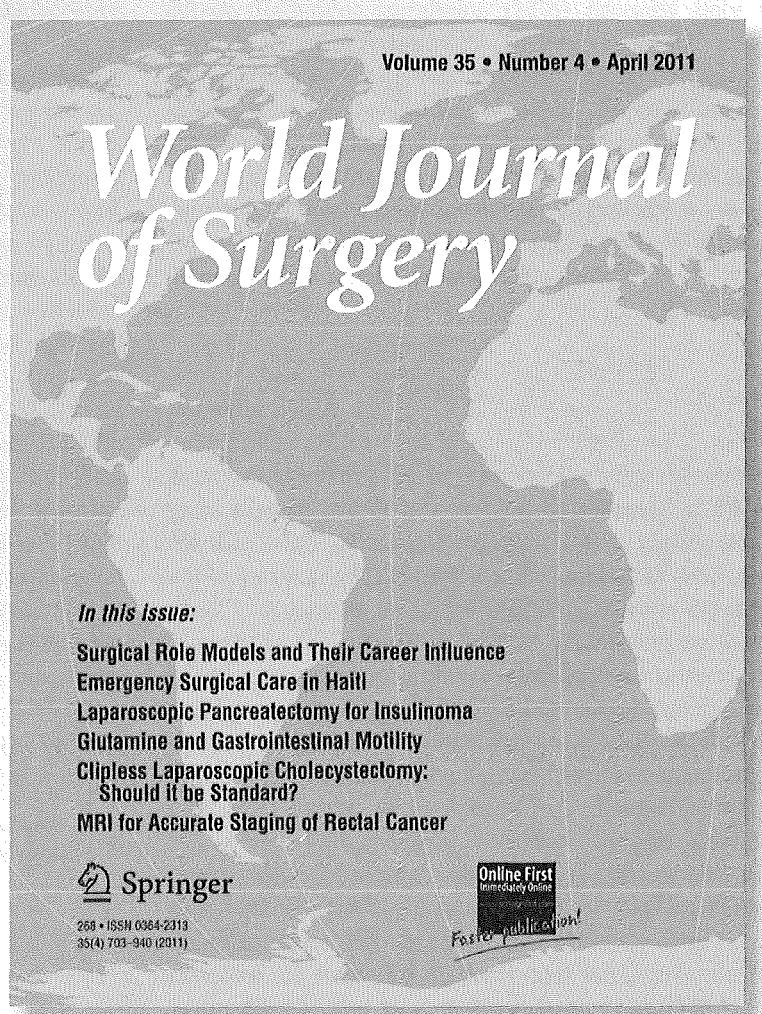

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Percutaneous Drainage versus Emergency Cholecystectomy for the Treatment of Acute Cholecystitis in Critically Ill Patients: Does it Matter?

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Abstract

Background The aim if this study was to compare percutaneous drainage (PD) of the gallbladder to emergency cholecystectomy (EC) in a well-defined patient group with sepsis related to acute calculous/acalculous cholecystitis (ACC/AAC).

Methods Between 2001 and 2007, all consecutive patients of our ICU treated by either PD or EC were retrospectively analyzed. Cases were collected from a prospective database. Percutaneous drainage was performed by a transhepatic route and EC by open or laparoscopic approach. Patients' general condition and organ dysfunction were assessed by two validated scoring systems (SAPS II and SOFA, respectively). Morbidity, mortality, and long-term outcome were systematically reviewed and analyzed in both groups.

Results Forty-two patients [median age = 65.5 years (range = 32–94)] were included; 45% underwent EC (ten laparoscopic, nine open) and 55% PD ($n = 23$). Both patient groups had similar preoperative characteristics. Percutaneous drainage and EC were successful in 91 and 100% of patients, respectively. Organ dysfunctions were similarly improved by the third postoperative/postdrainage days. Despite undergoing PD, two patients required EC due to gangrenous cholecystitis. The conversion rate after laparoscopy was 20%. Overall morbidity was 8.7% after PD and 47% after EC ($P = 0.011$). Major morbidity was 0% after PD and 21% after EC ($P = 0.034$). The mortality rate was not different (13% after PD and 16% after EC, $P = 1.0$) and the deaths were all related to the patients' preexisting disease. Hospital and ICU stays were not different. Recurrent symptoms (17%) occurred only after ACC in the PD group.

Conclusions In high-risk patients, PD and EC are both efficient in the resolution of acute cholecystitis sepsis. However, EC is associated with a higher procedure-related morbidity and the laparoscopic approach is not always possible. Percutaneous drainage represents a valuable intervention, but secondary cholecystectomy is mandatory in cases of acute calculous cholecystitis.

Introduction

Acute cholecystitis (AC) represents a very common surgical disease that is best treated by removal of the gallbladder. Most patients are admitted with acute calculous cholecystitis (ACC), whereas acute acalculous cholecystitis (AAC) occurs as a complication of severe preexisting diseases in critically ill patients [1, 2]. During the last two decades, laparoscopic cholecystectomy has almost completely replaced the open approach, and it represents the current standard of treatment for acute and chronic cholecystitis [3, 4]. Even complicated cases under emergency conditions can be safely operated on laparoscopically [5]. While the vast majority of cases can be considered uncomplicated, some patients develop cholecystitis sepsis that requires intensive care medicine and distinct treatment options taking into account the patient's poor general condition. In particular, patients with AAC have markedly increased mortality rates ranging from 22 to 71% [1, 2].

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In order to avoid the surgical trauma of a cholecystectomy and its related morbidity in critically ill patients, different conservative and interventional strategies have been developed recently. One such strategy is percutaneous drainage (PD) of the gallbladder to remove the infected bile as the infectious source of biliary sepsis.

Since first reported in 1980 [6], several series have demonstrated the feasibility of PD in high-risk patients with AC-related sepsis [7–21]. However, there are only scarce data comparing PD to emergency surgery, i.e., laparoscopic cholecystectomy. This lack of data is related to various factors. There is no generally accepted definition of high-risk patients. Often, age or the American Society of Anesthesiology (ASA) score is used as a surrogate parameter instead of a precise assessment of organ failure to define critical illness. In addition, many surgeons and anesthetists still prefer open cholecystectomy in high-risk patients. Finally, biliary sepsis caused by AC in critically ill patients is a rather rare event, and randomization of patients may probably never be achieved.

The aim of the current study was to compare PD of the gallbladder to emergency cholecystectomy (EC) in a well-defined patient group with biliary sepsis related to AC after failed conservative treatment. Procedure-related morbidity and mortality as well as long-term outcome were of primary interest.

Patients and methods

Patients

From January 2001 to December 2007, PD or EC was performed in 42 patients with biliary sepsis caused by ACC and AAC. All patients were critically ill according to the definitions used as mentioned below, and treatment in the ICU at the University Hospital of Lausanne (Switzerland) was mandatory for resuscitation. Patients with additional cholangitis or pancreatitis were excluded.

Patients were identified from prospective databases of the Departments of Intensive Care Medicine and Visceral Surgery. Their medical charts and radiological and pathological reports were carefully reviewed to extract data and outcome parameters. Data were documented on a separate data sheet developed a priori for each patient.

The severity of disease at the time of cholecystitis sepsis was assessed using the Simplified Acute Physiology Score II (SAPS II) [22–24]. This score includes the type of admission (medical or surgical), preexisting chronic disease, Glasgow coma scale, age, blood pressure, heart rate, fever, urine output, white blood cell count (WBC), electrolytes values, bilirubin level as parameters; it is a well-accepted and well-used risk score for ICU patients. As SAPS scores of 15 or greater are associated with a high predictive mortality rate in surgical ICU patients [25], we used this value as a cutoff to define high-risk patients.

Diagnosis of acute cholecystitis and sepsis

The diagnosis of AC was based on the patient's history, clinical signs (i.e., positive Murphy's sign, fever, pain in the right upper quadrant), laboratory finding (CRP > 10 mg/l, WBC > 10 g/l), and positive computed tomography (CT) and/or ultrasound (US) imaging. Acute cholecystitis was considered on imaging if there was greater than 10-cm enlargement of the anteroposterior gallbladder axis and gallbladder wall thickening greater than 3 mm. The diagnosis of gangrenous cholecystitis (GC) was based on histopathological analysis of the gallbladder.

Sepsis was defined as infection causing hypotension that requires colloids or catecholamines supports, and/or with one or more dysfunctional organs [26].

Assessment of organ dysfunction

The sequential organ failure assessment (SOFA) score was used to assess the severity of organ dysfunction in all patients with sepsis caused by AC. In order to document the clinical course, organ dysfunction was assessed at the time of diagnosis of AC, 3 and 7 days after PD or EC. The SOFA score is a validated score that is widely used to describe organ dysfunction/failure in critically ill patients [27, 28]. It includes cardiovascular, renal, hepatic, respiratory, and neurologic parameters [27, 28].

Treatment algorithm (Fig. 1)

All patients admitted with sepsis caused by ACC or AAC were seen primarily by the surgeon or internist on call. Critically ill patients were immediately transferred to the ICU and treatment was started by using standard resuscitation with fluid/catecholamine support and broad-spectrum antibiotics. For critically ill patients who developed AC sepsis while in the ICU for other pathologies, the surgeon on call was always involved in the primary assessment of the patient. ICU patients were regularly reviewed by an interdisciplinary team, including surgeons, intensivists, and, if necessary, interventional radiologists and anesthesiologists. If there was no clinical improvement within 12–24 h, EC or interventional gallbladder drainage was discussed within the interdisciplinary team. The final decision on the type of intervention to use was made by the senior surgeon on call based on the patient's condition and the availability of interventional radiology within 6 h.

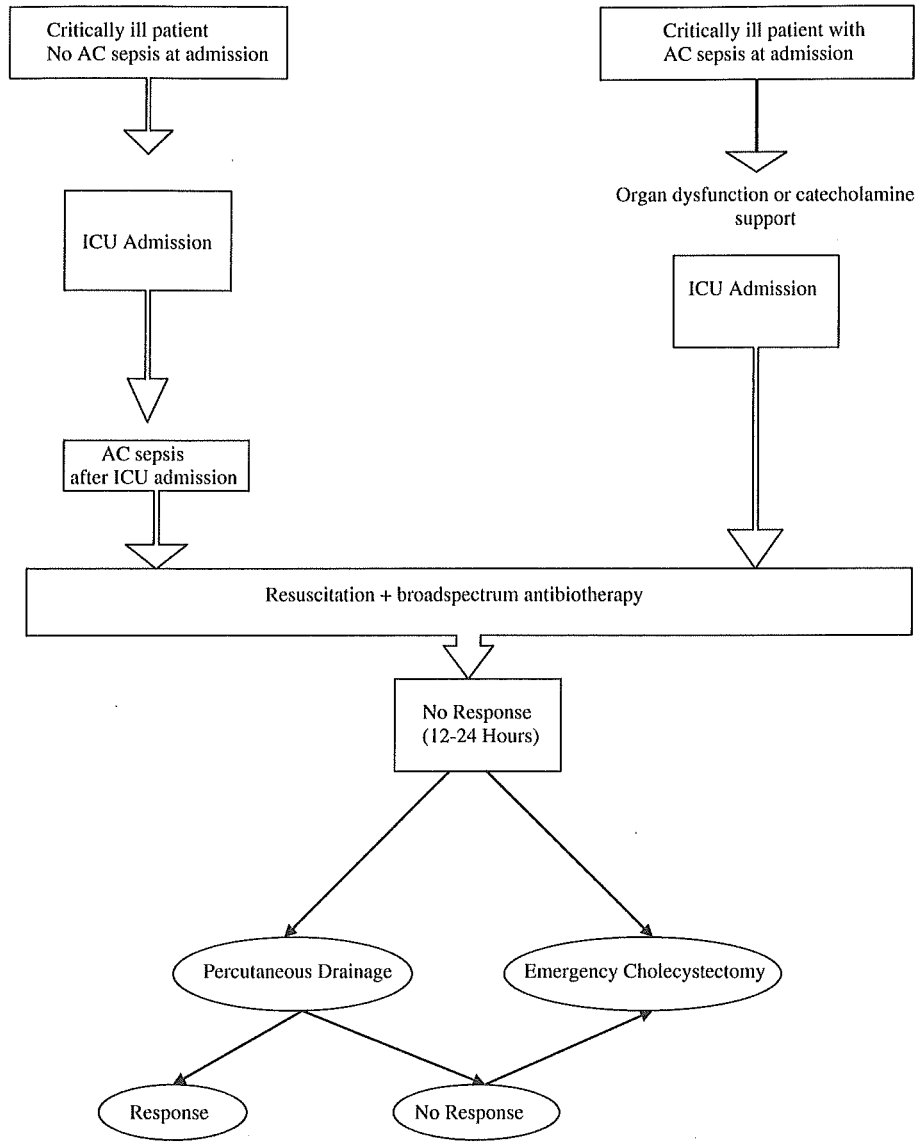

Fig. 1 Treatment algorithm

Percutaneous drainage of the gallbladder

Unless patients were already intubated, all procedures were performed under local anesthesia. Biliary tract imaging and interventions were done on a dedicated system in a standard fashion. Following percutaneous transhepatic puncture of the gallbladder under US or CT guidance, an 8-Fr Autolock catheter (Boston Scientific, Natick, MA, USA) was inserted using the standard Seldinger technique.

Complications related to the procedure were evaluated using the Society of Interventional Radiology classification system for complications by outcome [29]. Major complications were defined as any procedure-related morbidity requiring either radiological or emergency surgical intervention, or death of a patient. Mortality was defined as any death that occurred during the PD procedure up to 90 days after hospital admission.

Positive response to PD was defined as improvement in clinical signs (reduction of abdominal tenderness, fever, and, in the case of severe sepsis, of catecholamine perfusion) and/or organ dysfunction within 12 h after the procedure. If these criteria were not met and provided that no other cause of sepsis was found, EC was mandatory to treat PD failure. The criteria for catheter removal were resolution of sepsis and a patent cystic duct after transcatheter cholecystography [30]. After drain removal, the transhepatic channel was occluded with a hemostatic device (Gelfoam, Pfizer) in all cases.

Emergency cholecystectomy

Laparoscopic cholecystectomy was always attempted if there were no contraindications for a minimally invasive approach. While open cholecystectomy was performed by

using a subcostal incision, a 4-trocar technique was the standard approach for a laparoscopic cholecystectomy. In all cases, the gallbladder was removed *in toto*, i.e., no subtotal cholecystectomy was performed. Intraoperative cholangiography was only selectively performed. Specimens were sent for routine pathological examination.

Complications related to surgery were assessed using a validated classification score [31]. Major complications were classified as grade III–V and referred to any life-threatening morbidity requiring either surgical or radiological intervention or patient death. Mortality was defined as any death occurring during the surgical procedure up to 90 days after hospital admission. All surgical interventions were performed and supervised by one of the five senior staff surgeons.

Statistics

Categorical values were expressed as percentage. Continuous variables were expressed as mean, standard deviation, median, and range. Fisher's exact test and Wilcoxon's test were used for statistical evaluation, and $P < 0.05$ was considered statistically significant.

Results

Patients

There were 34 men and 8 women [median age = 65.5 - years (range = 32–94)] included in the current study. While 19 (45%) patients underwent EC, the remaining 23 (55%) patients had interventional PD of the gallbladder. Both patient groups had similar characteristics, particularly age, SAPS scores, and preexisting comorbidities (Table 1).

Although sepsis caused by AC was the main reason for admission to the ICU for 11 of 23 patients with PD (48%) and for 9 of 19 patients with EC (47%), the remaining patients developed AAC or ACC in the ICU as a complication of an underlying disease (Table 2). The initial median SOFA scores at the time of cholecystitis sepsis diagnosis were 4.5 (range = 1–15) for the PD group and 8 (range = 1–18) for the EC group, with no statistically significant difference ($P = 0.29$).

Interventional versus surgical treatment

In accordance with our treatment algorithm, percutaneous gallbladder drainage was technically successful in all 23 patients who were scheduled for PD. In 21 of 23 patients (91%), cholecystitis sepsis rapidly resolved, with clinical improvement within 24 h and improvement in organ dysfunction within 3 days as reflected by significantly reduced SOFA scores (Fig. 2). In two patients with ACC (9%), interventional treatment failed and EC was mandatory. Both patients underwent laparoscopic cholecystectomy with an uneventful postoperative course. Histopathological assessment revealed GC in both cases. Overall, drains were removed after a median time of 7 days (range = 3–21 days), and two patients were discharged at home with the catheter in place.

While ten patients underwent laparoscopic cholecystectomy, there were another nine patients who had primary open cholecystectomy. The indications for a primary open approach in that latter group were previous abdominal surgery ($n = 2$), trauma patients ($n = 3$), septic shock ($n = 2$), an unclear mass in the pancreatic head ($n = 1$), and severe heart failure with extracorporeal cardiac assistance ($n = 1$). Three patients in the laparoscopic group were converted to open (conversion rate = 16%) due to severe adhesions impairing adequate visualization and extreme friability of tissues making further dissection hazardous. Biliary sepsis was resolved in all patients and

Table 1 Preoperative characteristics of patients

	PD group	EC group	*P*
N	23	19	
Age (years)	65(37–86)[a]	63(32–85)[a]	0.85
Male/female (*n*)	18/5	16/3	0.53
ACC/AAC (*n*)	11/12	13/6	0.22
SAPS II score at the time of cholecystitis diagnosis	34(15–71)[a]	31(15–72)[a]	0.55
Comorbidities (*n*)	47	24	
Cardiomyopathy	12	5	0.12
Renal insufficiency	5	5	0.25
Diabetes	8	2	0.08
Obesity	6	2	0.26
COPD	6	3	0.43
Hypertension	10	7	0.34

ACC/AAC acute calculous cholecystitis/acute acalculous cholecystitis, *SAPS* simplified acute physiology score

[a] Median values (range)

Table 2 Indications for ICU admission

	PD group ($n = 23$)	EC group ($n = 19$)
Acute cholecystitis sepsis	11	9
Cardiac failure	4	1
Abdominal trauma	2	3
Others[a]	6	6

[a] Urosepsis, lung carcinoma, agranulocytosis, post esophagectomy, cervical fasciitis, post pulmonary lobectomy, post abdominal aortic aneurysm replacement, post lung transplantation

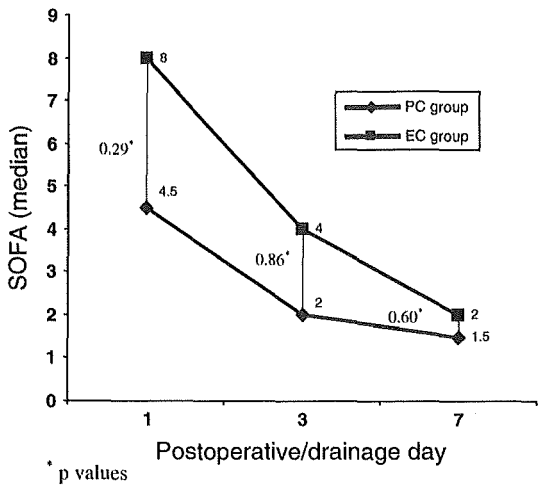

Fig. 2 Evolution of SOFA (Sequential Organ Failure Assessment) score at the time of acute cholecystitis diagnosis (day 1) and days 3 and 7 after PC or EC; *P values

organ dysfunction improved after 3 days as shown by decreased SOFA scores (Fig. 2).

Complication rates, mortality, and length of hospital stay (Table 3)

The overall complication rate was 8.7% (2/23) after PD and 47% (9/19) after EC ($P = 0.011$). There were no major complications related to PD. Minor complications consisted of one drain dislodgement and one abdominal wall hematoma. In the EC group, minor complications (grades I and II) included two paralytic ileus, two abdominal wall abscesses, and one cholangitis. Major complications (grades III–V) occurred in 21% (4/19) after EC. Severe bleeding from the gallbladder bed and high-output biliary leak in two patients each required open reoperation at postoperative day 1.

The overall 90-day mortality rate was 13% (3/23) after PD and 16% (3/19) after EC ($P = 1.0$). In the PD group, acute cardiac failure, stroke, and agranulocytosis with multiple organ failure in the context of a myeloma were the reasons for the postoperative deaths. In the EC group, multiple organ failure in the context of a myeloma, ischemic colitis secondary to an operated ruptured abdominal aortic aneurysm, and a duodenal fistula after an esophagectomy were the causes of death.

Mean ICU stay was 10.5 days (range = 2–71 days) and 3 days (range = 2–31 days) for the PD and EC group, respectively. Overall, the length of hospital stay was 25 days (range = 7–97 days) in the PD group and 23 days (range = 5–65 days) in the EC group. Neither length of ICU stay nor overall length of hospital stay were significantly different for the treatment groups ($P = 0.17$ and 0.39).

Table 3 Complication rates, mortality, and length of hospital stay

	PD group	EC group	*P*
N	23	19	
Overall complication rate	2(8.7%)	9(47%)	0.011
Minor complications[a]	2(8.7%)	5(26%)	0.21
Major complications[a,b]	0	4(21%)	0.03
90-day mortality	3(13%)	3(16%)	1.0
Overall hospital stay in days	25(7–97)	23(5–65)	0.39
ICU stay in days	10.5(2–71)	3(2–31)	0.17

[a] According to the SIR classification for PD and Dindo–Clavien classification for EC group

[b] Grade III-V according to the Dindo–Clavien classification for the EC group

Long-term follow-up

Four patients after primary successful percutaneous gallbladder drainage developed recurrent biliary symptoms during long-term follow-up (median follow-up = 16 months, range = 2–44 months). These symptoms included recurrent right-upper-quadrant pain ($n = 2$) and *de novo* AC without sepsis ($n = 2$). All four patients had previous ACC, whereby two patients revealed an impacted gallstone in the gallbladder infundibulum causing a cystic duct obstruction and the drain was left after hospital discharge. One patient underwent laparoscopic cholecystectomy 14 days after hospital discharge due to drain dislodgement; two other patients were treated successfully by laparoscopic cholecystectomy at the time of recurrence (2 and 12 months after hospital discharge). The final patient denied surgery after drain removal and was lost during the follow-up.

Discussion

This current study assessed the role of interventional percutaneous gallbladder drainage compared to EC for the treatment of AC sepsis in critically ill patients. To this end, 42 patients of a single center were retrospectively analyzed during a 7-year period. Both PD and EC were able to resolve quickly cholecystitis sepsis in 90-100% of the patients. Surgery was associated with an increased complication rate of 47% compared to interventional treatment (8.7%), but mortality rates did not show any difference.

The optimal treatment of AC with concomitant sepsis in critically ill patients has not yet been well defined. In particular, there is only limited evidence in the literature about whether PD or surgical removal of the gallbladder should be preferred. Both approaches are currently used, and specific indications on which approach to use are

mostly dependent on local experience and personal preferences. In addition, with the successful advance of laparoscopic surgery and modern interventional radiology, the role of open cholecystectomy has been increasingly challenged.

Percutaneous drainage of the gallbladder has been developed as a less invasive procedure compared to open cholecystectomy in critically ill patients with AC. From a technical point of view, it is a rather uncomplicated procedure with a low complication rate that is reported to range from 3 to 13% [7–21, 32, 33]. The complication rate in this current series was 8.7% with no major complication. This low complication rate is related to the fact that only experienced radiologists performed all the interventional procedures and intrahepatic tracts were systematically occluded after drain removal to prevent biliary leaks and bleeding. Mortality after PD was 13%, which did not differ from that of EC (16%) and the reported mortality in the literature that ranges from 0 to 11% (see Table 4). Of note, mortality is predominantly related to the severity of the underlying disease rather than the ongoing gallbladder sepsis. Those latter cases have to be considered as a failure of interventional treatment, and EC is mandatory. PD successfully resolved sepsis in all but two patients (success rate = 91%) in our series, which is within reported clinical success rates of 78–100% (Table 4). Both patients who needed an EC as a salvage procedure revealed GC. Similar findings have been already reported; thus, GC that occurs in 40–80% of patients with AAC and in 2–31% of patients with ACC [2, 20, 34–38] seems to be an important risk factor for PD to fail. It can therefore be assumed that the underlying diseases are more important for long-term survival than the type of intervention.

While relief of sepsis could be achieved in 90% of patients, four patients with ACC (17%) developed recurrent biliary symptoms during the long-term follow-up which required laparoscopic cholecystectomy. It has been reported recently that up to 40% of patients treated with PD needed secondary cholecystectomy, whereby the mortality rate was below 2% [33]. Welschbilig-Meunier et al. [20] promote prophylactic cholecystectomy only in patients drained for ACC. Our results seem to support that; however, our data lack statistical power to be affirmative. Therefore, primary cholecystectomy or scheduled resection after drainage is recommended to prevent biliary complications in the long-term course, particularly after ACC.

A laparoscopic attempt to remove the gallbladder was made in only ten patients (52%), and nine patients were considered for primary open cholecystectomy. Thus, open cholecystectomy has not yet replaced laparoscopy since patients with biliary sepsis requiring ICU treatment often are too sick. Moreover, intraoperative conversion to open cholecystectomy was needed in two patients (16%) due to inflammatory changes that impaired safe identification of biliary and vascular anatomy in the hepatic pedicle. Since EC is a life-saving procedure, an increased complication rate of 47% is probably to be expected. Nevertheless, all major complications, i.e., bleeding and biliary leaks,

Table 4 Review of the literature

	Year of publication	*N*	Mean age (years)	Calculous/ Acalculous	PD success (%)	90-days mortality due to AC[a] (%)	Recurrent symptoms (%)	EC (%)
Sugiyama et al. [7]	1998	38	85	25/13	95	?	33	0
Davis et al. [8]	1999	22	77	14/6	82	?	9	0
Ghahreman et al. [9]	1999	19	70	14/4	78	0	5	0
Patel et al. [10]	2000	53	63	39/14	83	11	0	0
Pessaux et al. [11]	2000	29	80	21/8	86	0	7	14
Chang et al. [12]	2000	24	65	16/7	83	4	8	0
Hatzidakis et al. [13]	2002	63	79	44/19	86	9.5	2	11
Spira et al. [14]	2002	55	74	?	98	0	18	4
Andren-Sandberg et al. [15]	2001	86	71	?	89	6	32	1
Granlund et al [16]	2001	51	71	28/23	90	0	21	2
Berman et al. [17]	2002	10	77	10/0	100	0	?	0
Byrne et al. [18]	2003	45	63	?	78	2	2	0
Li et al. [19]	2004	25	81	?	92	0	12	8
Welschbilig-Meunier et al. [20]	2005	65	78	49/16	90	1.5	25	3
Ha et al. [21]	2008	65	63	65/0	91	?	35	?
Present study	2010	23	65	11/12	91	0	19	8.7

[a] Acute cholecystitis (not confirmed by autopsy)

required early open reoperation. Gangrenous cholecystitis was found in four patients, three of whom underwent primary open cholecystectomy and one had a laparoscopic cholecystectomy that was converted to an open. Since the source of the biliary sepsis is removed, all patients improved clinically and no recurrent biliary symptoms occurred in the long term. Mortality after EC was 16%, but as in the PD group, it almost always was related to the patients' underlying diseases.

In conclusion, PD and EC are highly efficient in resolving cholecystitis sepsis in critically ill patients with severe AC. While mortality rates are similar, surgery is associated with significantly increased perioperative morbidity. Furthermore, a laparoscopic approach is not always possible. Percutaneous drainage represents a valuable intervention to treat cholecystitis sepsis, but it should be completed by a secondary cholecystectomy, particularly in patients with ACC.

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