



Percutaneous cholecystostomy for severe (Tokyo 2013 stage III) acute cholecystitis

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Abstract

Purposes To evaluate the impact of percutaneous cholecystostomy (PC) on severe acute cholecystitis (AC).

Methods According to the ICD-9 classification, we retrospectively retrieved medical records of patients discharged with a diagnosis of AC from January 2007 to December 2016 at our hospital. Patients were then stratified according to the Tokyo 2013 (TG 13) AC severity criteria. Grade III AC was diagnosed according to the TG 13 criteria. Indications for PC were failure of optimal medical treatment within 48 h, worsening of clinical condition within early medical treatment, patients unfit for upfront surgery and patient's preference. Ascites was considered a contraindication to PC while coagulopathy was considered a minor contraindication. Primary end points were: clinical improvement, morbidity and related mortality. Secondary endpoints were AC recurrences and elective laparoscopic cholecystectomies (LS). Response was evaluated by clinical and blood test improvement. Morbidity was evaluated according to the Dindo–Clavien scale.

Results A total of 117 eligible patients were diagnosed as grade III AC. Of these, 29 (24.7%) underwent PC. The procedure was completed in all cases. Overall morbidity rate was 20.6%. Main complication was the drainage dislodgement due to involuntary patient's movement. Overall mortality was 17.2% but no causes of death were dependent upon the procedure. Clinical improvement was reported in 95.5% of surviving patients.

Conclusion This study confirms that PC is a valuable tool in the treatment of severe AC. Randomized trials are needed to clarify the criteria for patient selection and to optimize the timing for both cholecystostomy and cholecystectomy.

Keywords Acute cholecystitis · Gallbladder abscess · Gallstones · Percutaneous drainage

Introduction

Acute cholecystitis (AC) is the most frequent complication of cholelithiasis. It is reported to occur in as many as 20% of patients with symptomatic gallstones [1]. Due to the high prevalence of cholelithiasis, AC is one of the most frequent causes of urgent admission at surgical departments [2]. The gold standard for AC treatment is laparoscopic cholecystectomy (LC). However, in case of acute inflammation, this condition shows high morbidity and mortality rate as high as 30% [3]. Patients presenting with clinical features of severe AC with sepsis and signs of organ damage account for the 5–10% of all those admitted for AC [4]. This particular condition significantly increases operative risk for

both complications and death [5]. Moreover, in western countries there is an increasing number of elderly patients presenting at emergency departments with AC associated with pre-existing huge comorbidities that is well recognized to further increase risk of complications and death; all these conditions are often considered as a contraindication for upfront surgery. For septic or comorbid patients, the goal of treatment should be primarily the control of the septic status [6]. In the 1980s, Radder [7] first described ultrasound (US)-guided percutaneous drainage of the gallbladder to treat a gallbladder empyema. Since then, many studies have reported on percutaneous gallbladder drainage in different subsets of patients. With the development of newer technologies, other accesses have been proposed and evaluated for AC drainage, such as US-guided percutaneous access (transhepatic or direct), endoscopic access via the biliary tree, or transduodenal US-guided cholecystoduodenostomy. Rationale for drainage is to remove the causes of the sepsis and help the patient improve. In 2013, the Tokyo

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Consensus Meeting officially recommended gallbladder drainage as a tool for treating severe AC and this statement has been recently empowered by the Tokyo consensus 2018 [6, 8]. Nonetheless, there is still a lack of perspective studies with the statistical power as to definitely clarify the role and timing of PD in severe AC patients. We report our experience on a retrospective series of percutaneous transhepatic cholecystostomy (PC) for grade III AC patients treated over a 10-year period.

Materials and methods

Patient population

Medical records from patients admitted to our hospital in either the surgical or medical departments with a diagnosis of AC from January 2007 to December 2016 were retrospectively evaluated. Patients with concomitant common bile duct stones and acute pancreatitis as well as those with incomplete or unclear medical records were excluded. The remaining records were then stratified according to the Tokyo 2013 acute cholecystitis severity criteria. According to the guidelines, AC was diagnosed in the presence of at least two major criteria (biochemical, clinical, and radiologic). Grade III AC was diagnosed in the presence of at least one of the items listed in Table 1. Patients with grade III AC were selected for the present study, steps for patient selection are resumed in Fig. 1. Their medical records were evaluated for symptoms at presentation, clinical features, treatment, length of hospitalization, outcome, morbidity, and 30-day mortality. Primary end points of the study were clinical improvement, morbidity and related mortality. Secondary endpoints were AC recurrences, elective laparoscopic cholecystectomies (LC). Response was evaluated by clinical improvement and by improvement of blood tests. Complications were defined according to the Clavien–Dindo scoring system [9].

Treatment and response assessment

At our institution, the standard treatment options for AC patients are upfront laparoscopic cholecystectomy unless

contraindication for surgery is ruled out. Patients with grade III AC, Charlson's score lower than 5 and symptom duration < 72 h are offered urgent cholecystectomy as long as contraindications to surgery are ruled out. Other patients are offered nihil per os (NPO), aggressive intravenous hydration, intravenous broad-spectrum antibiotics, and analgesics. Conservative treatment is maintained for patients showing clinical and laboratory improvement within 48 h, emergency PC is proposed for patients who fail to improve at 48–72 h of optimal medical treatment according to the decision made after a consultation among the surgical and anesthesiological teams and the patient. Ascites was considered a contraindication to PC while coagulopathy was considered a minor contraindication unless it could be corrected by frozen fresh plasma or prothrombin concentrate administration. PC is performed under local anesthesia and mild sedation by US-guided percutaneous access. All procedures are performed by the same experienced surgeon or skilled interventional radiologist. After performing a control echography for confirming the diagnosis and choosing a catheter insertion line, under US visualization, a 16-gauge needle is inserted into the gallbladder, and the fluid is partially aspirated and cultured. An ultra-stiff guidewire is then placed into the gallbladder lumen, and a 10 French pigtail catheter is inserted into the gallbladder and stitched to the skin. A 10-min US control is performed to rule out immediate complications. The drainage is usually left in place open for at least 2 weeks; then, it is closed and removed immediately before cholecystectomy or after 4–6 weeks. No trans-catheter colangiographies were routinely obtained. The response was assessed according to the improvement of symptoms and clinical signs: white blood cell count on days 1 and 3 post-treatment and plasma C-reactive protein (CRP) as measured on days 3 and 5 post-treatment.

Statistical analysis

Categorical data are expressed as counts and proportions, and continuous data are expressed as means and standard deviations. Categorical variables are compared by Fisher's exact test, and continuous variables are compared by Wilcoxon's rank-sum test. All data have been analyzed using the GraphPad software. A p value < 0.05 was considered statistically significant.

Results

From January 2007 to December 2016, a total of 1218 patients were admitted to our hospital in both the medical and surgical departments with a diagnosis of AC. Of these, 792 (65%) were females and 426 were males. The patients' median age was 58.4 years. All patients' medical

Table 1 Criteria for grade III AC diagnosis

Cardiovascular impairment	Hypotension requiring dopamine or norepinephrine infusion
Neurological impairment	Confusional state
Respiratory impairment	PaO ₂ /fIO ₂ ratio < 300
Renal impairment	Oliguria, serum creatinine > 2 mg/dL
Hepatic impairment	INR > 1.5
Hematological dysfunction	Platelets count lower than 100,000 mm ³

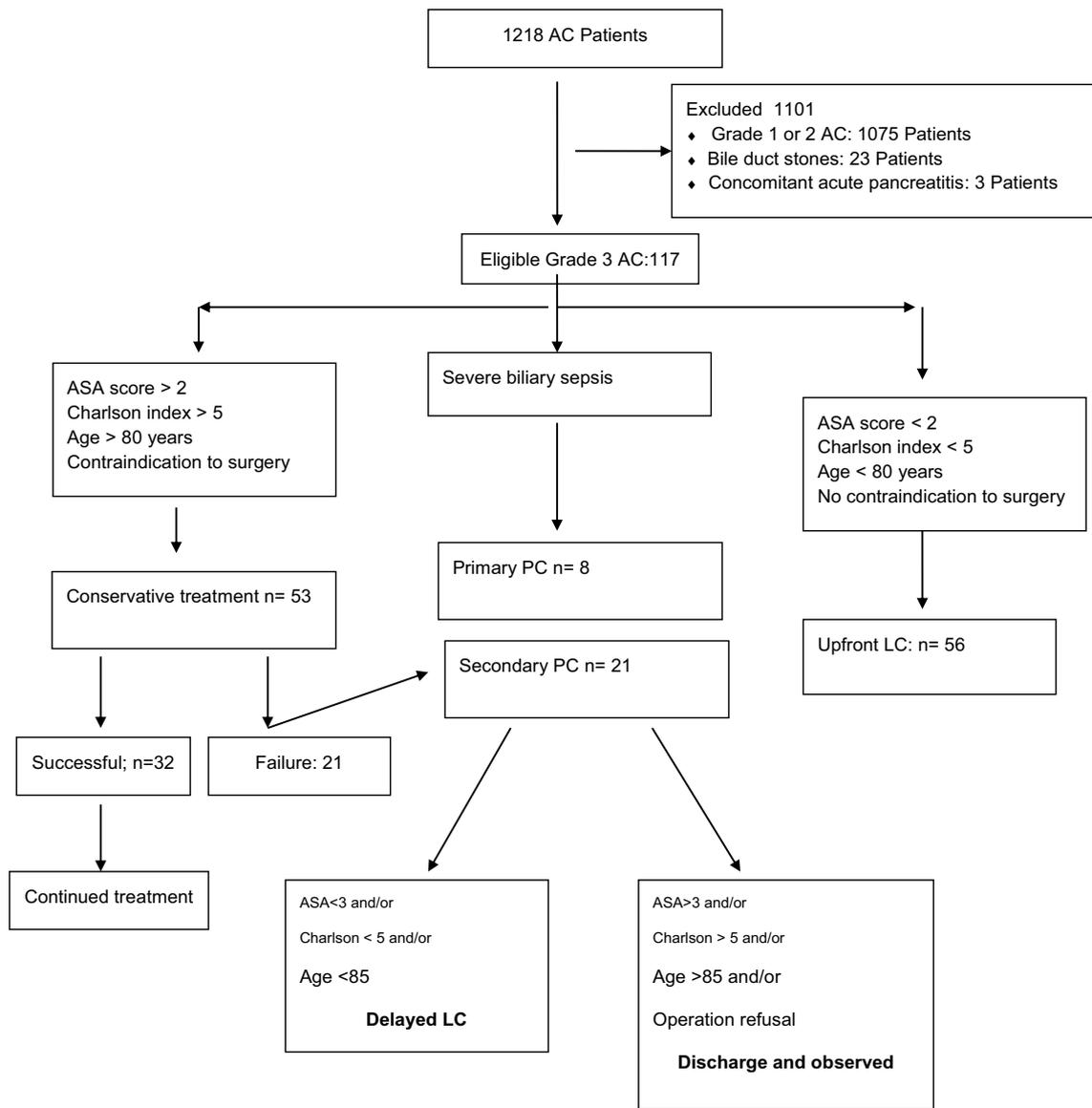


Fig. 1 Decision-making algorithm for grade 3 AC patients

records were reviewed, and they were stratified into AC grades according to the Tokyo 2013 guidelines (TG13). A total of 143 (11.7%) patients were diagnosed as grade III AC. Of these, 26 were excluded owing to the concomitant presence of bile duct stones and cholangitis (23 patients), and concomitant acute pancreatitis (3 patients). The medical records of the remaining 117 patients were complete, and none of them were excluded. Of these 117 patients, 88 (75.2%) were females and 29 were males. The patients' mean age was 75.25 ± 11.17 years (median age 76.5 years, range 44–93 years). Of these, 56 (47.8%) underwent urgent laparoscopic cholecystectomy, 32 (27.3%) received only medical treatment, and the remaining 29 (24.7%) underwent percutaneous drainage of the gallbladder. A complete

overview of demographics, clinical features, instrumental diagnostics, comorbidities and ASA score of the three groups is given in Table 2. Of the 29 PC patients, 16 were females and 13 were males. The patients' mean age was 74.59 ± 11.39 years (median 75 years, range 44–91 years). Seven patients had acalculous cholecystitis, and the remaining ones had gallstones. The mean Charlson index was $7.14 \pm 2.0.7$ (range 2–13). The mean ASA score was 2.62 ± 0.73 (range 2–4). The pre-procedural serum value of PCR was 270.21 ± 108.71 mg/L (median 260 mg/L, range 88–473 mg/L); that of the white blood cell count was 20421 ± 12930.41 mm³ (median 18,400 mm³, range 4500–70,000 mm³).

Table 2 Demographics, clinical presentation, diagnostics and comorbidities of patients

	PCD	Medically treated	Primary LC	Overall
Patients (<i>N</i>)	29	32	56	117
Age (mean \pm sd)	74.59 \pm 11.39	76.17 \pm 13.28	64.39 \pm 12.18	75.25 \pm 11.17
Symptoms				
RUQ pain, <i>n</i> (%)	26 (89.6%)	28 (87.5%)	51 (91%)	105 (89.7%)
Fever, <i>n</i> (%)	24 (82.7%)	28 (87.5)	49 (87.5)	101 (86.3)
Nausea/vomiting, <i>n</i> (%)	18 (62%)	22 (68.7%)	37 (66%)	77 (65.8%)
RUQ tenderness	14 (48.2%)	18 (56.2%)	41 (73.2%)	73 (62.3%)
Murphy's sign (%)	11 (37.9%)	9 (28.1%)	44 (78.5%)	64 (54.7%)
Calculous AC	22 (75.8%)	32 (100%)	56 (100%)	110 (94.0%)
Acalculous AC	7	0	0	7
Laboratory				
WBC count (mean \pm sd)	20,421 \pm 12,930	20,200 \pm 11,440	21,070 \pm 11,850	20,610 \pm 12,000
CRP	270 \pm 108	259 \pm 123	277 \pm 101	263 \pm 103
Radiology				
Diagnostic AUS	29/29	32/32	54/56	115/117
CT scan	ne	ne	3/3	3/3
Cardiovascular impairment	9 (31%)	12 (37.5%)	0	21 (17.9%)
Neurological impairment	7 (24.1%)	16 (50%)	5 (8.9%)	28 (23.9%)
Respiratory impairment	8 (27.5%)	16 (50%)	0	24 (20.5%)
Renal impairment	10 (34.4%)	22 (68.7%)	16 (28.5%)	48 (41.0%)
Hepatic impairment	9 (31%)	9 (28.1%)	1 (1.7%)	19 (16.2%)
Hematological dysfunction	13 (44.8%)	19 (59.3%)	0	32 (27.3%)
Need for ICU	6 (20.6%)	11 (34.3%)	2 (3.5%)	19 (16.2%)
Charlson score < 5	0	0	56	56 (47.8%)
Charlson score > 5	29 (100%)	32	0	61 (52.2%)
ASA 1	0	0	18 (32.1%)	18 (15.3%)
ASA 2	0	0	31 (55.3%)	31 (26.4%)
ASA 3	17 (58.6%)	11 (34.3%)	6 (10.7%)	34 (29.0%)
ASA 4	12 (41.4%)	21 (65.6%)	1 (1.7%)	34 (29.0%)

RUQ right upper quadrant, AC acute cholecystitis, WBC white blood cells, CRP C-reactive protein, AUS abdominal ultrasounds, CT computerized tomography, ICU intensive care unit

In the 29 PC patients, the main symptoms at presentation were pain (96%), fever (83%), and nausea/vomiting (63%). One patient presented with septic shock with multiple organ failure (MOF); this patient was under mechanical ventilation for a severe blunt thoracic trauma.

Attempt to place a drainage into the gallbladder was successful in all the 29 attempted cases. The mean duration of the procedure was 13.45 \pm 3.48 min (range 10–23 min). No post-procedural bleeding was ever observed. A percutaneous transperitoneal access was chosen in three cases, and transhepatic access was chosen in the remaining cases.

The main complications were one case of biliary fistula with choleperitoneum requiring emergent cholecystectomy (3.4%), four drainage dislocations, and one abdominal wall abscess. The dislocations occurred at, respectively, 3, 18, 27, and 49 days after the procedure; in one case, the drainage was repositioned, and the others were asymptomatic and required no further drainage. The patient presenting

with the abdominal wall abscess secondary to partial dislocation underwent urgent cholecystectomy and drainage of the abscess. The 30-day mortality was 17.2% (5 out of 29 patients). Death occurred at 1 day in two cases, 2 days in one case, 16 days in one case, and 18 days in one case. The causes of death were MOF in three cases, pulmonary thromboembolism in one case, and acute cardiac failure in one case. In univariate analysis, the presence of MOF upon admission was the only predictor of death.

In the 24 patients who survived, the mean 1-day post-procedure white blood cell count was 9954.17 \pm 5212.09 mm³ (median 8820 mm³, range 3000–29,700 mm³) and the mean 3-day CRP was 93.83 \pm 65.25 mg/L (median 69.5 mg/L, range 16–249 mg/L). When compared to the pre-procedural data, we found a strongly significant statistical difference for both white blood cells ($p < 0.0005$) and CRP ($p < 0.0001$). Cultured samples showed bacterial growth in 18 of 24 cases. The most frequent growth was *E. coli* (11 cases, 61.1%)

followed by *P. Auriginosa* (3 cases), *Enterobacter cloacae* (2 cases), and *Acinetobacter baumannii* and *Streptococcus gordonii* (1 case each). All patients were initially administered broad-spectrum intravenous antibiotics that were eventually substituted based on an antibiogram report. The antibiotics course was switched to oral administration as soon as possible, and it continued for 11.50 ± 2.43 days (median 12 days, range 8–14 days).

The mean hospital stay for the 24 patients was 9.38 ± 4.31 days (median 8 days, range 4–23 days); this was significantly longer than that for the operated patients (mean 6.31 ± 1.60 days, median 6 days, range 4–10 days; $p < 0.0001$) but almost equal to that for non-operated patients (mean 11.22 ± 4.22 days; median 10 days, range 2–23 days, $p = 0.76$). Four patients stayed in the ICU for 2, 3, and 7 days owing to septic shock and MOF. The antibiotic therapy duration was significantly shorter in the operated patients (mean 6.94 ± 1.01 days, median 6 days, range 6–8 days) compared to both conservatively treated patients (mean 11.13 ± 2.24 days, median 12 days, range 8–14 days; $p < 0.0001$) and PC patients (mean 11.21 ± 1.64 days, median 11 days, range 9–14 days; $p < 0.0001$). No statistically significant difference was found when comparing conservatively treated patients with PC patients ($p = 0.97$).

Data regarding hospital stay, duration of antibiotic therapy, delayed cholecystectomy and complications from the three groups are shown in Table 3. In total, 28 of 47 (59.5%) patients had a delayed cholecystectomy; this included 12 of 24 patients with initial PC and 16 of 23 patients with initial conservative treatment. The mean time to operation was 53.57 ± 12.10 days (median 53 days, range 37–88 days) for PC and 54.08 ± 11.26 days (median 53 days, range 47–59 days) for conservatively treated patients. All procedures were laparoscopic, and no conversions to laparotomy and biliary complications were observed. Of the remaining 19 patients (12 with initial PC and 7 with initial conservative

treatment), 10 were excluded from surgery for ASA 4 score or Charlson index > 5 ; 7 for having acalculous cholecystitis; and 2 for patient’s refusal of surgery.

Two patients offered upfront surgery suffered from intra-operative biliary lesions, 1 Strasberg A and 1 Strasberg E2 (6.5%), vs. no lesion in patients treated with delayed surgery from both the remaining groups. Moreover, the conversion to laparotomy rate was 12.5% in the upfront surgery patients versus 0% in the delayed surgery group. However, both data sets were not statistically significant.

One of seven patients treated with antibiotics alone experienced cholecystitis recurrence within 6 months, as did two patients from the non-operated PC group. However, these data were not statistically significant ($p = 0.54$). Two other patients from the PC group experienced recurrence at, respectively, 9 and 10 months from catheter removal.

Discussion

Grade III (severe) AC is defined as AC presenting with features of systemic inflammatory response [8], and it must be diagnosed in the presence of at least one of the signs shown in Table 1. Most guidelines recommend early cholecystectomy for AC [10–12]; however, in this acute setting, cholecystectomy has shown high morbidity and mortality rates [3, 13, 14]. Therefore, for these particular patients who are poorly suitable for surgery, PC was proposed. PC affords the following advantages: (1) it does not require general anesthesia; (2) it may be performed even bedside in an intensive care setting; (3) it requires very little time to perform; (4) it has a success rate exceeding 95%; (5) it carries a low complication rate; and (6) it may be an efficient bridge to elective surgery [15–19]. The gallbladder can be accessed through either transperitoneal or transhepatic routes. In our experience, we mostly prefer a transhepatic approach because

Table 3 Data of length of hospital stay, features of treatment and complications of patients from the three groups

	Conservative treatment	Laparoscopic cholecystectomy	PC
Length of hospitalization (days; mean \pm sd)	11.22 \pm 4.22	6.31 \pm 1.60	9.38 \pm 4.31
Antibiotic course (days; mean \pm sd)	11.13 \pm 2.24	6.94 \pm 1.01	11.21 \pm 1.64
Delayed cholecystectomy	16/23 (69.5%)	0	12/24 (50%)
Interval to cholecystectomy (days; mean \pm sd)	54.08 \pm 11.26	0	53.57 \pm 12.10
Complications	0	2 (6.25%) 1 Strasberg A biliary leak 1 Strasberg E2 biliary lesion	5 (20.8%) 1 biliary fistula 4 drainage dislocation
Conversion to laparotomy	0	4 (12.5%)	0
3-month recurrences	1 (4.3%)	0	1 (4.1%)
6-month recurrences	0	0	1 (4.1%)
2-year recurrences	2 (8.6%)	0	2 (8.3%)
30-day mortality	0	0	5 (17.2%)

it may prevent leakage and choleperitoneum and lower the complication rate. Horn et al. reported no statistical difference in the complication rate between the transperitoneal and transhepatic routes; however, they found a significant difference in recurrence rate in favor of the transhepatic route and, therefore, they reported an overall higher complication rate than that in published studies reporting on the transhepatic route [20–22]. Our series reports on 29 patients treated with PC for grade III TG13 AC. In our experience, the transperitoneal route was chosen in only 3 out of 29 cases. Notably, the only biliary fistula requiring emergency cholecystectomy occurred in a patient in whom the transperitoneal approach was chosen owing to liver disease with portal hypertension. In our experience, drainage dislocation occurred in four cases owing to the patient's accidental movements in three cases and the patient, who was suffering from severe dementia, removing the catheter in one case. As a result, we found that PC led to a very quick resolution of symptoms in most cases; this figure is similar to that reported in other published series [23], and this finding is confirmed by the statistically significant difference in serum CRP and WBC counts as compared to pre-procedure and 3 days after the procedure.

After recovery, all patients suitable for elective surgery were scheduled for laparoscopic cholecystectomy (LC), and the drain was kept in place until the day of operation, which is usually performed within 8 weeks. This is our current policy in such cases, and we have subsequently found no recurrences in this subgroup of patients. This is quite different from the data reported by others [24–26] that are consistent with a recurrence rate of 4–22%. These data are almost biased by the persistence of drainage that may have prevented recurrences and by the short interval of time elapsed from the acute episode to the planned operation. No recurrence was observed at a 3-month follow-up. Moreover, of the 12 patients treated with PC alone, after excluding the 7 with acalculous cholecystitis, 2 out of the remaining 5 (40%) showed late recurrence at, respectively, 9 and 10 months regardless of the duration of both the antibiotic course and the persistence of drainage. This figure is similar to that of patients treated with antibiotics alone (one out of seven). Furthermore, it is much higher than that in other reports, and it may be explained, in our opinion, mostly by the very limited sample size.

The timing to cholecystectomy remains a debatable issue. In patients with grade I and II TG13 AC, early surgery is strongly recommended [10–12, 27]. However, patients presenting with severe AC and showing signs of systemic inflammatory response may be at high risk for general anesthesia and, therefore, for surgery. Moreover, TG13 guidelines do not consider any other clinical parameters such as delay from the onset of symptoms, patient's age, and comorbidities, this issue has recently been partially corrected by

the upgrade of TG 18 that considers grade 3 patients as generally unfit for upfront surgery with the exception of younger patients with ASA score lower than 2, no comorbidities and mild SIRS signs [6]; therefore, a large pool of patients is not suitable for upfront emergency surgery despite PC being available. Our policy when faced with severe AC is to treat the patient by aggressive fluid administration together with broad-spectrum antibiotics under hemodynamic continuous monitoring. Patients whose condition worsens or fails to improve clinically within 48 h are reevaluated by two experienced HBP surgeons and an anesthesiological team, and a decision is made depending on the patient's preference for either emergent LC or PC. Comorbid and ASA IV patients are scheduled for PC, whereas others are considered for emergent LC or PC. Decision-making always depends on the delay from the onset of symptoms, patient's age, presence of previous upper abdominal surgery, and, of course, the patient's preference. The rationale for PC is that it is a procedure with a very high success rate and low morbidity, it is fast to perform under local anesthesia, and it may serve as a very good bridge to elective cholecystectomy. The reported data for the conversion rate of LC in acute settings vary greatly in published series, ranging from 7 to 43% [13, 14, 21, 28–30]. This wide discrepancy mostly depends upon the experience of the surgical teams, with the rate in large hospitals with dedicated surgeons being low and that in minor centers being high. Moreover, very few of these studies have reported on AC severity. In our series, we had 6.5% conversion to open cholecystectomy with the same figure of intraoperative bile duct lesions versus no conversion and no lesions in patients having delayed cholecystectomy. Even if these data were not statistically significant and the small sample size may bias the results itself, we feel that delayed LC may have better results than early LC. This impression is confirmed by several studies reporting on the treatment of severe AC. Bickel et al. reported a 33.3% conversion rate in patients with severe AC treated with upfront surgery versus 8.3% for patients treated with bridging cholecystostomy [31]. Karakayaki et al. reported the same figure, and they additionally reported a lower intraoperative bleeding and complication rate [32]. Similar findings have been reported by other researchers [19, 33, 34]. Reported mortality rate after PC has a wide range from the null reported by some small series to 15% [35]; in our series mortality rate was as high as 17.2%, this figure appears to be higher than mostly reported by others, none of these studies considered the severity of AC as an evaluated variable. Recently published studies on management of severe AC report on PC-related morbidity and mortality [36–39]. Overall reported morbidity ranges between 0% and 20% with a mortality rate between 0 and 17.9%, some of these studies did not consider mortality as an end point. Overall mortality appears to be influenced much more by the critical patients' conditions than

the procedure itself. We believe that there are several reasons explaining this issue. All deaths, in both the present study and in the reported ones, occurred related to the septic shock from AC and pre-existing medical conditions as reported from Chou and Coll [40] that explored treatment options for severe AC with more extensive criteria in the definition of the disease. Furthermore, the criteria for selection of patients themselves may contribute to the high mortality rate by reserving PC mostly to patients with septic shock and/or with severe comorbidities and these both conditions are well known to be strongly associated with morbidity and mortality rates in most clinical studies. In conclusion, this study confirms that PC is a valuable tool in the treatment of grade III (severe) AC. A large sample and randomized clinical trials are urgently needed to clarify the criteria for patient selection and for optimizing the timing for both cholecystostomy and subsequent cholecystectomy.

Compliance with ethical standards

Conflict of interest All authors declare no conflict of interest in the present paper.

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