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Early cholecystectomy may be performed in patients with Tokyo Guideline 2018 grade III acute cholecystitis who have risk factors

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Abstract

Aim: The preferred treatment for acute cholecystitis (AC) is early cholecystectomy (EC). There are several risk factors increasing the risk of mortality for EC in Tokyo Guideline 2018 (TG18) grade III AC; and therefore, percutaneous cholecystostomy (PC) is recommended in these patients. However, the effect of these risk factors on mortality in patients having undergone EC has not been sufficiently investigated to date.

Materials and Methods: In our clinic, 206 patients with AC were treated between 2015 and 2020. Thirty-one adult patients with TG18 grade III AC were included into the study. The patients were divided into two groups as EC group (n=11) and PC group (n=20). Comparisons were made between EC and PC, and the effects of risk factors on mortality were examined.

Results: All patients had a score of ≥III according to American Anesthesiologists Association (ASA). The Charlson comorbidity index (CCI) was ≥4 in 72.4% of the patients, and 32.4% of patients had negative predictive factors (NPF: neurological and respiratory dysfunction, and also a total bilirubin value of ≥2 mg/dL on admission). Mortality was seen in 12 patients. Compared to patients with PC, higher definitive treatment ($p<0.001$), less re-admission ($p<0.001$) and less mortality ($p=0.01$) were seen in patients with EC. Major complications (Clavien-Dindo classification >II) and length of hospital stay were similar in both groups ($p=0.60$, $p=0.39$; respectively).

Conclusion: This study showed that EC may be performed in patients with TG18 grade III AC who have risk factors. TG18 guidelines should be re-evaluated for risk factors for EC.

Introduction

Acute cholecystitis (AC) is one of the most common surgical emergency diseases. The preferred treatment is cholecystectomy in eligible patients for surgery [1]. However, due to high postoperative morbidity and mortality rates and longer hospital stay, it is difficult to treat patients with severe AC [1,2]. Cholecystectomy is not always recommended in these patients [3-5]. Tokyo Guidelines (TG) was established to help guide the stratification and management of the severity of AC in high-risk patients [6]. For TG18 grade I and II, early cholecystectomy (EC) is recommended in patients eligible for surgery, while percutaneous cholecystostomy (PC) is recommended for patients not suitable for surgery [7]. However, EC can be performed in a small number of patients with grade III AC defined as end organ dysfunction, and PC is generally recommended in these patients [7]. Several risk factors have been identified that cause an increase in mortality risk for EC in TG18 grade III AC, such as American Anesthesiologists Association (ASA) score ≥3, Charlson comorbidity index (CCI) ≥4, and negative predictive factors (NPF) [7]. However, the effect of risk factors on mortality in patients having undergone EC has not been sufficiently confirmed until today. Several studies have shown that cholecystectomy may be performed even in these patients who have risk factors, with rates of lower complications and mortality and shorter hospital stay [8,9]. The aim of this study was to compare the results of EC and PC.

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Materials and Methods

In our clinic, 206 patients with AC were treated between January 2015 and January 2020. Thirty-one patients with TG18 grade III AC who had risk factors were included into study. A patient with TG18 grade III AC but had no risk factors was excluded from the study. The patients were divided into two groups as EC group (patients on whom surgery was performed within seven days after onset of AC symptom, n=11) and PC group (patients on whom PC was performed after admission, n=20). Age, sex, presence of comorbidity, ASA score, CCI, NPF, laboratory and imaging findings, EC and PC treatments, additional treatments, complication, re-admission, length of hospital stays, and mortality were recorded. Comparisons were made between EC and PC. Median follow-up time was eight (1-60) months. The primary output variable was mortality. Since the study was retrospective, the sample size was not calculated. This retrospective study was approved by the local ethics committee (decision number: 2020/70). Informed consent was not obtained for the study.

Fluid resuscitation was initiated in patients diagnosed with AC, and prophylactic antibiotics and analgesic were administered. Endoscopic retrograde pancreatography (ERCP) was performed in patients who had choledocholithiasis or cholangitis on imaging findings, and percutaneous drainage (PD) was performed in patients who had pericholecystic abscess. The decision on treatment (EC or PC) was made by the patient's attending surgeon. PC was performed by an interventional radiologist using an 8–10 pigtail catheter (Dawson-Mueller Drainage Catheter, Cook, Bloomington, IN) guided by USG and fluoroscopy through the transhepatic route. Microbiological samples were not taken from the bile fluid of the patients. Drainage catheter was washed with 10 mL of saline daily. EC was performed by open technique within seven days after onset of AC symptom. Patients who were readmitted for new episode of cholecystitis during the follow-up period were evaluated for medical treatment, PC or surgical treatment. Delayed cholecystectomy was recommended to patients who had a successful PC.

Definitions

AC diagnosis was made based on the clinical presentation of the patients (RUQ abdominal pain, fever, Murphy's sign), laboratory findings (elevated white blood cell (WBC) count and C-reactive protein (CRP) level), and imaging findings (thickening of the gallbladder (GB) wall, pericholecystic fluid collection, enlarged GB) [10]. All patients with AC were classified into three groups according to the severity grade of TG18: grade I (inflammatory changes in GB and no associated organ dysfunction), grade II (elevated WBC, a palpable tender mass, and/or marked local inflammation, with no associated organ dysfunction), and grade III (including end organ dysfunction (Table 1)) [11]. ASA score was used for surgical risk [12]. CCI was used for comorbid conditions of the patients [13]. Treatment success after PC and EC was defined as resolution of symptoms and fever, and normalization of CRP levels and WBC counts. Complications were classified according to the Clavien-Dindo classification [14]. Re-admission was defined as re-hospitalization within 30 days due to postoperative complications in patients on whom EC had been performed or at any days after having been discharged due to recurrence of AC in patients on whom PC had been performed. Mortality was defined as 30 days postoperatively for patients on whom EC had been performed and as any day due to biliary complaints for patients on whom PC had been performed.

Table 1. Tokyo Guideline 2018 grade III acute cholecystitis.

Grade III acute cholecystitis is associated with dysfunction of any one of the following organs/systems:		
1	Cardiovascular dysfunction	Hypotension requiring treatment with dopamine $\geq$5 µg/kg per min, or any dose of norepinephrine
2	Neurological dysfunction	Decreased level of consciousness
3	Pulmonary dysfunction	PaO_2/FiO_2 ratio <300
4	Renal dysfunction	Oliguria, creatinine >2.0 mg/dl
5	Hepatic dysfunction	PT-INR >1.5
6	Hematological dysfunction	Platelet count < 100.000/mm^3

Statistical analysis

SPSS software version 22 (IBM Corp., Chicago, IL, USA) was used for statistical calculations. Shapiro–Wilk test was used to test normality prior to statistical calculations. Fisher's Exact test and Mann–Whitney U test were used for categorical and continuous variables. A p value of < 0.05 was considered statistically significant in all analyses.

Results

Thirty-one patients were included into study (Table 2). Median age of the patients was 77 (42-96) years. Hypertension (64.5%), Type 2 Diabetes Mellitus (35.5%), chronic obstructive pulmonary disease (32.3%), congestive heart failure (29.0%), and cerebrovascular accident (25.8%) were the most frequent comorbidities. All patients had an ASA score of $\geq$III. CCI was $\geq$4 in 72.4% of the patients, and 32.4% had NPF. Imaging findings revealed acute calculous cholecystitis in 23 patients, gangrenous cholecystitis in six patients, acute acalculous cholecystitis in two patients, choledocholithiasis in two patients, cholangitis in one patient, and pancreatitis in one patient. ERCP was performed in two patients who had choledocholithiasis, and PD was performed in one patient with pericholecystic abscess. While seven patients who had undergone PC were re-hospitalized because of AC recurrence, no patients who had undergone EC were hospitalized. Mortality was seen in 12 patients.

PC was performed in 20 patients who had AC. Median PC duration was 13 (2-84) days. Complications developed in two (10.0%) patients during PC treatment (Table 3). Seven patients (35.0%) were re-hospitalized due to AC recurrence. PC revision was performed in one patient who developed PC-catheter occlusion, and six patients received antibiotic treatment. While EC was not performed in any patient with PC, delayed cholecystectomy was performed in two patients. Surgical treatment could not be performed

Table 2. Patients demographics.

Parameters	n=31
Age (years) (median (min-max))	77 (42-96)
Gender (Male/Female)	16/15
Comorbidity (Yes, %)	29 (93.5)
Hypertension	20 (64.5)
Type 2 Diabetes Mellitus	11 (35.5)
Chronic obstructive pulmonary disease	10 (32.3)
Congestive heart failure	9 (29.0)
Cerebrovascular accident	8 (25.8)
Chronic renal failure	5 (16.1)
Coronary artery disease	4 (12.9)
Atrial fibrillation	3 (9.7)
Alzheimer disease	1 (3.2)
ASA score (n, %)	
III	9 (29.0)
IV	22 (71.0)
CCI (median (min-max))	6 (2-12)
Negative predictive factors (n, %)	10 (32.3)
Total bilirubin ≥2mg/dL	7 (22.6)
Pulmonary dysfunction	3 (9.7)
Neurological dysfunction	2 (6.5)
Labaratory values (median (min-max))	
Alanine transaminase (U/L)	49 (11-325)
Aspartate transaminase (U/L)	94 (15-462)
Alkaline phosphatase (U/L)	118 (2-1611)
Gamma-glutamyl transferase (mg/dL)	112 (15-543)
Total bilirubin (mg/dL)	0.8 (0.2-15.9)
C-reactive protein (mg/L)	25.5 (0.7-38.7)
Lokosit (x10^3/µl)	15.0 (3.3-36.8)
Imaging findings (n, %)	
Calculous cholecystitis	23 (74.2)
Acalculous cholecystitis	2 (6.5)
Gangrenous cholecystitis	6 (19.4)
Choledocholithiasis	2 (6.5)
Cholangitis	1 (3.2)
Pancreatitis	1 (3.2)
Additional treatment (n, %)	
ERCP	2 (6.5)
Percutaneous drainage	1 (3.2)
Type of treatment (n, %)	
Early cholecystectomy	11 (35.5)
PC	20 (64.5)
Early choleystectomy	
Open/Laparoscopy (n)	11/0
Operation duration (minute) (median (min-max))	80 (35-120)
Intraoperative blood loss (ml) (median (min-max))	50 (20-100)
PC duration (day) (median (min-max))	13 (2-84)
Delayed cholecystectomy after PC (n, %)	2 (6.5)

ASA: American Anesthesiologists Association, CCI: Charlson comorbidity index, ERCP: Endoscopic Retrograde Cholangiopancreatography, PC: Percutaneous cholecystostomy.

Table 3. Developing complications after early cholecystectomy and Percutaneous Cholecystostomy treatment in patients with Tokyo guideline 2018 grade III acute cholecystitis.

Clavien-Dindo classification	Early cholecystectomy n=7	Percutaneous cholecystostomy n=13
II	4	0
Atelectasis	2	0
Organ/space surgical site infection	1	0
Pneumonia	1	0
IIIB	1	0
Common bile duct injury	1	0
IVA	1	0
Respiratory failure	1	0
IVB	0	2
Acute renal failure	0	2
Septic shock	0	1
Sepsis	0	1
Disseminated intravascular coagulation	0	1
Multiorgan dysfunction syndrome	0	1
V	1	11
Septic shock	1	5
Sepsis	0	5
Pneumonia	0	2
Pulmonary edema	0	2
Multiorgan dysfunction syndrome	0	1
Cerebrovascular accident	0	1
Acute renal failure	0	1

in seven patients due to their comorbidities and patient preference after PC. Surgery could not be performed in 11 patients who were lost during PC treatment.

EC was performed in 11 patients with AC. Cholecystectomy was performed with open technique in all patients. Operation duration was 80 (35-120) minutes, and intraoperative bleeding loss was 50 (20-100) ml. T-tube drainage was performed in one patient due to intraoperative common bile duct injury. Postoperative complications developed in six (54.5%) patients (Table 3). No patient was re-hospitalized due to biliary complaints. Mortality occurred in one patient.

While age, sex, presence of comorbidity, CCI ≥4, NPF, major complications (Clavien-Dindo classification >II), and length of hospital stay were similar in the EC and PC groups (p=0.13, p=0.21, p=0.15, p=0.07, p=0.26, p=0.60, p=0.39; respectively), ASA IV score was higher in the PC group (p=0.02). Compared to patients with PC, patients with EC had definitive treatment (10.0% vs 90.9%, p ˂0.001), less re-admission (0% vs 35.0%, p ˂0.001) and less mortality (9.1% vs. 55.0%, p=0.01) (Table 4).

Table 4. Comparison of early cholecystectomy with percutaneous cholecystostomy treatment in patients with Tokyo guideline 2018 grade III acute cholecystitis.

Parameters	Early Cholecystectomy n=11	Percutaneous Cholecystostomy n=20	p
Age (n, %)			0.13
≥70	5 (45.5)	15 (75.0)	
<70	6 (54.5)	5 (25.0)	
Gender (n, %)			0.21
Male	4 (36.4)	12 (60.0)	
Female	7 (63.6)	8 (40.0)	
ASA score (n, %)			0.02
III	6 (54.5)	3 (15.0)	
IV	5 (45.5)	17 (85.0)	
Comorbidity (n, %)	9 (81.8)	20 (100.0)	0.15
CCI (n, %)			0.07
≥4	6 (54.5)	18 (90.0)	
<4	5 (45.5)	2 (10.0)	
Negative predictive factors (n, %)	2 (18.2)	8 (40.0)	0.26
Total bilirubin ≥2mg/dL	2 (18.2)	5 (25.0)	
Neurological dysfunction	0 (0)	2 (10.0)	
Respiratory dysfunction	0 (0)	3 (15.0)	
Definitive treatment (n, %)			<0.001
Yes	10 (90.9)	2 (10.0)	
No	1 (9.1)	18 (90.0)	
Major complications (CDC >II)			0.60
Yes	2 (18.2)	2 (10.0)	
No	9 (81.8)	18 (90.0)	
Re-admission (n, %)			<0.001
Yes	0 (0)	7 (35.0)	
No	11 (100.0	2 (10.0)	
Stay in intensive care unit (n, %)			0.29
Yes	7 (63.6)	7 (35.0)	
No	4 (36.4)	13 (65.0)	
Lenght of stay (day) (median (min-max))	10 (4-38)	13 (5-67)	0.39
Mortality (n, %)			0.01
Yes	1 (9.1)	11 (55.0)	
No	10 (90.9)	9 (45.0)	

ASA: American Anesthesiologists Association, CCI: Charlson comorbidity index, CDC: Clavien-Dindo classification.

Table 5. Effect of age on mortality.

Parameters	Mortality n=12	No-mortality n=19	p
Age (n, %)			0.08
≥70	10 (83.3)	10 (52.6)	
<70	2 (16.7)	9 (47.4)	

Discussion

The gold standard treatment for AC is surgery. However, TG18 grade III AC is associated with dysfunction of end-organ, and its management still remains controversial [11]. In TG18 grade III AC, early LC is recommended for patients who meet the CCI ≤3 and ASA score ≤2. CCI ≥4, ASA score ≥3, and NPF (neurological or respiratory dysfunction and at the time of admission total bilirubin value ≥2 mg/dL) have been defined as factors increasing the risk of surgical mortality [7,11]. Therefore, PC is recommended for patients with risk factors [7]. PC has emerged as an alternative to definitive cholecystectomy, and PC has gradually increased with the use of TG [11,15]. However, PC is not a definitive treatment and may worsen clinical outcomes. Studies involving all grade I, II, and III AC patients have shown that PC treatment has lower definitive treatment, higher readmission and increased mortality rates [15-17]. Sanaiha Y et al. have also reported

higher readmission, complications, and mortality rates in patients with TG18 grade III AC undergoing PC [18]. In our study, definitive treatment rate was lower, readmission and mortality rates were higher in patients treated with PC compared to EC. Additionally, PC is associated with several problems. First, PC makes laparoscopic surgery difficult, significantly increasing the rate of conversion to open surgery [10]. Second, recurring symptoms are seen during the waiting period for interval cholecystectomy and re-intervention is required due to dislodgement or obstruction of the PC drainage tube [19,20]. Third, the optimal timing of surgery after PC is uncertain since PC is not a definitive treatment, and PC management and recurrence constitute an important problem in patients on interval cholecystectomy plan [21,22]. In our study, open surgical technique was used in all patients, so we could not evaluate this effect. Seven patients undergoing PC were re-hospitalized. Six patients received medical treatment, and PC catheter placement was performed again in one patient who developed PC catheter occlusion. We were able to perform surgical treatment on only two of the patients who had undergone PC. The interval between PC and surgical treatment was less than six weeks in these patients. The role of PC in TG18 may be overstated in patients with TG18 grade III AC who have risk factors. Therefore, we recommend that EC should be performed in these patients who have TG18 grade III AC if there is intensive care support and sufficient surgical experience.

The effect of risk factors on patients who have TG18 grade III AC on EC has not been adequately evaluated until today. Greca AL et al. could not found any difference between PC and EC in terms of morbidity, mortality, and length of stay in their series including grade III AC patients. However, risk factors were not clear in this study [23]. Kohga A et al. have shown that EC could be performed with 28.5% major complications, 3.5% readmission, and 0% mortality rates in patients with TG18 grade III AC. In their series, 21.4% of the patients had ASA ≥3, 89.2% had CCI ≥4, and 85.7% had NPF [9]. Moreover, Garces-Albir et al. have reported that even in patients with TG18 Grade I and II AC, length of hospital stay, readmission and mortality outcomes were worse in the PC group [24]. Our study showed that EC may be applied with higher definitive treatment, less re-admission, and lower mortality rates compared to PC in patients with TG18 grade III AC. Major complications (CDC >II) and length of hospital stay were similar in both groups. In our study, ASA score of all patients was 3 and above, the rate of patients with CCI ≥4 was 77.4%, and NPF rate was 32.3%.

Young age has been found to be a predictor for cholecystectomy after PC [25]. In our study, approximately half of the patients (45.5%) who underwent EC were 70 years and older, and mortality developed in only one. Whereas, the majority of patients (75.0%) who underwent PC were 70 years or older, and mortality developed in nine of these patients. In our study, although mortality risk was higher (83.3% vs 16.7%) over the age of 70 years, this was not statistically significant (p=0.08) (Table 5). Our study showed that EC may be performed safely in patients younger than 70 years of age who have risk factors. PC should be limited only to selected patients aged 70 years and over who have risk factors.

Our study has some limitations. First, it was a retrospective, single-center study. Second, population size was quite small, and NPF was present in 10 patients, with CCI less than 4 in seven patients. Third, early surgery time was considered the first seven days after onset of AC symptom. Fourth, cost analysis was not performed. Finally, age, ASA score, CCI and NPF ratio were higher in patients who had PC. Therefore, randomized controlled trials are needed to confirm the superiority of EC over PC in patients with grade III AC.

Conclusion

EC was found to be feasible and safety in patients with TG18 grade III AC, even if there are risk factors proposed in TG18. TG18 guidelines should be re-evaluated for risk factors for EC.

Ethics approval

All procedures performed in studies involving human participants were in accordance with the ethics standards of the local ethics committee (decision number: 2020/70), and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent

Not required in this study.

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Conflict of interest statement

The authors declare that they have no conflict of interest.

Author contributions

Concept - A.A., I.C., E.K., C.A., I.I., H.A.T., E.B., U.K.; Design - A.A., E.K., I.C., C.A., I.I., H.A.T., E.B., U.K.; Supervision – A.A., U.K.; Data Collection and/or Processing– A.A., I.C., E.K., C.A., I.I., H.A.T.; Analysis and/or Interpretation -A.A., U.K.; Literature Review - A.A., I.C., E.K., C.A., I.I., H.A.T., E.B., U.K.; Writing Manuscript - A.A; Critical Reviews - A.A., U.K.

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