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Percutaneous Cholecystostomy is a Reasonable Alternative for the Treatment of Acute Cholecystitis in Critically Ill Patients: a Single Center Analysis

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Abstract. *Background / objective.* Laparoscopic cholecystectomy is a safe procedure and the treatment of choice for acute cholecystitis. As an alternative treatment option in critically ill patients percutaneous cholecystostomy (PC) is performed.

Methods. Retrospective review of patients who had undergone PC from 2008 to 2017 at the Department of Surgery, Hospital of Lithuanian University of Health Sciences Kaunas Clinics. Patients were reviewed for demographic features, laboratory tests, ASA class, complications, outcomes, hospital stay and mortality rate.

Results. Fifty-four patients were included in the study. Forty patients (74%) were ASA III and ten patients (18.5%) – ASA IV. Statistically significant decrease in white blood cell count (from 14.26±6.61 to 8.65±5.15) and C-reactive protein level (from 226.22±106.60 to 51.91±63.70)

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following PC was observed. The median hospital stay was 13.06 (range 2–68) days and 30-day mortality rate 13%. There were no deaths directly related to procedure. For eleven patients (20.4%) delayed cholecystectomy was scheduled.

Conclusions. PC is a reasonable treatment option for high-risk patients with acute cholecystitis and co-morbidities. It can be used as a temporizing treatment option or as a definitive treatment with a low number of delayed cholecystectomies.

Key words: acute cholecystitis, cholecystostomy, cholecystectomy, laparoscopic cholecystectomy.

Perkutaninė cholecistostomija – alternatyva, gydant sunkiomis gretutinėmis ligomis sergančius ligonius, kuriems diagnozuotas ūminis cholecistitas

Santrauka. Įvadas / tikslas. Laparoskopinė cholecistektomija yra saugi operacija ir pirmo pasirinkimo gydymo metodas, gydant sergančiuosius ūminiu cholecistitu. Sunkiomis gretutinėmis ligomis sergančius pacientus, kuriems diagnozuojamas ūminis cholecistitas, galima gydyti suformuojant perkutaninę cholecistostomą.

Metodai. Atliktas retrospektyvinis tyrimas, į kurį įtraukti pacientai, 2008–2017 m. gydyti Lietuvos sveikatos mokslų universiteto ligoninės Kauno klinikų Chirurgijos klinikoje. Tiriamiesiems buvo suformuota perkutaninė cholecistostoma. Tirti ir vertinti pacientų demografiniai duomenys, laboratoriniai rodikliai, analizuota ASA klasė, komplikacijos, išeitys, gydymo trukmė ir mirštamumas.

Rezultatai. Tyrime dalyvavo 55 pacientai. 47 pacientai (74 %) atitiko ASA III klasę, 10 pacientų (18,5 %) – ASA IV klasę. Suformavus perkutaninę cholecistostomą, pastebėtas statistiškai reikšmingas leukocitų skaičiaus (nuo 14,26±6,61 iki 8,65±5,15) ir C reaktyvinio baltymo koncentracijos (nuo 226,22±106,60 iki 51,91±63,70) sumažėjimas. Vidutinė gydymo trukmė – 13,06 (intervalas 2–68) dienų. Ankstyvas mirštamumas (30 dienų) siekė 13 proc. Mirčių, tiesiogiai susijusių su atlikta procedūra, nefiksuota. 11 pacientų (20,4 %) taikyta planinė cholecistektomija.

Išvados. Perkutaninė cholecistostomija yra tinkama alternatyva didelės rizikos pacientams, kuriems diagnozuotas ūminis cholecistitas, gydyti. Šis gydymo metodas gali būti taikomas tiek kaip tarpinis, tiek kaip galutinis gydymo metodas.

Reikšminiai žodžiai: ūminis cholecistitas, cholecistostomija, cholecistektomija, laparoskopinė cholecistektomija.

Introduction

Acute cholecystitis is (AC) usually related to a syndrome of right upper quadrant pain, fever, and leukocytosis associated with gallbladder inflammation that is usually caused by gallstones. Gallstones are found in about 10% to 15% of the adults in Western countries [1]. Through the last few decades, AC remains as one of the most frequent reasons for admission to surgical departments in Western region according to the fact that the population ages. It is noticeable that mortality of AC increases from 2.8% in the general population to 11.4% in those over 80 years of age [2].

For many years laparoscopic cholecystectomy (LC) was described as a safe, relatively simple procedure and the treatment of choice for AC [3]. However, early cholecystectomy has higher morbidity and mortality rate, reaching up to 19% in high-risk elderly patients, which is strongly associated with comorbidities [4, 5].

As an alternative treatment option for critically ill or elderly patients percutaneous cholecystostomy (PC) was developed – a less invasive procedure involving gallbladder drainage tube placement and decompression [6, 7]. The first PC was performed in a jaundiced patient in 1979 by Elyaderani and Gabriele and since that time several studies reported the efficacy and safety of the procedure [4, 8]. PC is also used as a bridge to a safer elective cholecystectomy after patients recover from acute symptoms [9–11]. There is data showing that PC is better tolerated than LC in elderly septic or otherwise critically ill patients and could be used as the first-line treatment for AC [6]. Tokyo Guidelines 2013 and Tokyo Guidelines 2018 included PC as a possible treatment in critically ill patients diagnosed with Grade II or Grade III AC [12, 13]. However, this option remains controversial because there is lack of well-designed clinical trials, that could confirm treatment guidelines for critically ill patients with AC [10, 13–17].

The aim of our study was to evaluate the clinical outcomes and possible benefits of ultrasound guided percutaneous cholecystostomy in the treatment of acute cholecystitis for high risk patients.

Material and methods

This was a retrospective single center cohort study. Data collection was performed at the Department of Surgery, Lithuanian University of Health Sciences using specially developed and maintained database from 01-03-2008 to 31-12-2017. During this period 634 consecutive patients were diagnosed with acute chole-cystitis. The diagnosis was based on updated Tokyo Guidelines for Acute Cholangitis and Acute Cholecystitis TG13 [13]. The definite diagnosis of AC was made if at least one item from each of the following three groups was found: (1) Local signs of inflammation (Murphy's sign, right upper quadrant mass/pain/tenderness); (2) Systemic signs of inflammation (fever, elevated CRP level, elevated WBC count); (3) Imaging findings characteristic of AC (abdominal ultrasound and/or computed tomography). Fifty-four (n = 54) patients met the following criteria and were included in the study: [1] patients older than 18; [2] patients with acute cholecystitis; [3] performed percutaneous cholecystostomy. Included patients were graded into three severity grades (Grade I – Grade III) according to the Tokyo Guidelines [18]. Medical records were reviewed for data collection including demographic features, laboratory tests, comorbidities, ASA class, postoperative outcomes (complications, duration of hospital stay, 30-day mortality rate). The Kaunas Regional Biomedical Research Ethics Committee approved the study (protocol no. BEC-MF-204) and allowed the use of publicly unavailable database.

Percutaneous cholecystostomy

Indications for percutaneous gallbladder drainage instead of laparoscopic or open surgery were older age, comorbidities and grading according to the Tokyo guidelines (TG13 and TG18) [12, 13]. The decision was made by the responsible surgeon and anesthesiologist. The PC was performed using an aseptic technique and local anaesthesia under ultrasound guidance by the surgeon with experience in performing ultrasound guided procedures. Puncture of the gallbladder was through the transhepatic route using Seldinger's technique. Due to possibly lower number of postoperative bile leaks transhepatic approach was chosen in most cases. Pigtail catheter (6 to 11 Fr) was placed into the gallbladder after dilating the canal. Aspirated bile was cultured. The catheter was secured to the skin for continuous drainage and was left in place for several weeks or until it stopped producing any bile content [19]. On the 2nd-3rd postoperative day, before the discharge from the hospital and/or the removal of the catheter cholangiogram was performed in order to evaluate if the cystic duct was patent and if there was a free passage of contrast media to the duodenum [16].

Statistical analysis

Statistical analysis was performed using SPSS software version 22 for Windows (SPSS Inc., Chicago, USA). Results shown in the texts, and graphs are expressed as median (range) or mean \pm standard deviation (SD). A P-value less than 0.05 was considered statistically significant (P < 0.05).

Results

The demographics and medical history data are summarized in Table 1. Ultrasonography was performed for all patients, while CT scan in 19 (35.2%) cases. Forty-seven (87%) patients were diagnosed with acute calculous cholecystitis. Based on Tokyo guidelines [10, 13, 14, 18] 37 patients were graded as Grade II (moderate cholecystitis) and 17 patients as Grade III (severe cholecystitis) with no patients with Grade I (mild cholecystitis). The mean time between onset of symptoms (acute right upper quadrant pain, fever) and hospitalization was 124.52±142.04 hours. Almost all the patients (85.2%) had comorbidities. The majority of them (64.8%) had cardiopulmonary diseases, while 4 patients (7.4%) had cancer of various locations (Table 1). The gallbladder

drainage was performed by surgeon under ultrasound guidance within 1 day after hospitalization with the mean duration time of 25.39 ± 6.62 minutes. The clinical symptoms of AC improved in all patients after the PC. White blood cells (WBC) count and CRP levels significantly decreased and showed a positive clinical response (P < 0.05) (Table 2). There were no significant differences between patients classified with Grade II and Grade III AC and between patients with acalculous and calculous AC (Table 3 and Table 4).

Variable	All patients (n = 54)	
Age (median (range))	77 (53–93)	
Male	34 (62.96)	
Time to hospitalization (hours)	124.52±142.04	
Imaging		
Ultrasonography	54 (100)	
CT scan	19 (35.19)	
Comorbidities		
Cardiopulmonary	35 (64.81)	
Diabetes mellitus	6 (11.11)	
Chronic renal failure	7 (12.96)	
Cancer	4 (7.41)	
Other	12 (22.22)	
None	6 (11.11)	
ASA score		
Ι	0 (0)	
II	4 (7.41)	
III	40 (74.07)	
IV	10 (18.52)	
Tokyo classification		
Grade I (mild)	0 (0)	
Grade II (moderate)	37 (68.52)	
Grade III (severe)	17 (31.48)	
Length of hospital stay (days)	13.06 (2–68)	
Mortality (30-days)	7 (12.96)	

Table 1. Patients' characteristics and severity grading n (%)

CT - computed tomography; ASA - The American Society of Anaesthesiologists physical status classification system

Table 2. Improvement of inflammatory markers

	Upon admission	After PC	Р
WBC	14.26±6.61	8.65±5.15	0 < 0.05
CRP	226.22±106.60	51.91±63.70	0 < 0.05

WBC - white blood cells; CRP - C-reactive protein; PC - percutaneous cholecystostomy

Bile cultures were negative in 14 patients (26%), for 3 patients (5.6%) the cultures were not taken. Most common bacteria found in bile samples were *Escherichia coli*, *Enterococcus faecalis*, *Klebsiella oxytoca* and *Enterococcus faecium*. Nearly all patients (94.4%) received antibiotics prior the procedure. The combination of Cefuroxime and Metronidazole was the most often used combination of antibiotics before the procedure. After the procedure, 54 patients (100%) received antibiotics. The antibacterial treatment was based on the results of bacterial culture. In most cases (72.2%) combination of Cefuroxime and Metronidazole was given. Gallbladder catheter insertion was technically successful in all 54 patients.

	Grade II	Grade III	Р
Age (median (range))	77 (53–93)	77 (60–93)	0.967
Male	20 (54.05)	14 (82.35)	0.046
Length of hospital stay (days)	14.16±13.15	10.64±4.11	0.287
ASA score			
Ι	0 (0)	0 (0)	_
II	4 (11)	0 (0)	_
III	29 (78)	11 (65)	0.701
IV	4 (11)	6 (35)	0.634
CRP upon admission	222.64±119.18	233.63±77.66	0.755
CRP after PC	42.07±45.09	72.89±90.19	0.123
WBC upon admission	14.17±6.21	14.44±7.70	0.905
WBC after PC	8.43±3.57	9.14±7.80	0.669
Mortality	3 (8)	4 (24)	0.121

Table 3. Comparison between patients classified with Grade II and Grade III acute cholecystitis n (%	ween patients classified with Grade II and Grade III acute ch	nolecystitis n (%)
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ASA – The American Society of Anaesthesiologists physical status classification system; WBC – white blood cells; CRP – C-reactive protein; PC – percutaneous cholecystostomy

	Acalculous	Calculous	Р
Age (median (range))	76 (61–89)	77 (53–93)	0.826
Male	6 (85.71)	29 (62)	0.188
Length of hospital stay (days)	10.57±2.51	13.42±11.93	0.534
ASA score			
Ι	0 (0)	0 (0)	_
II	0 (0)	4 (9)	-
III	7 (100)	33 (70)	0.783
IV	0 (0)	10 (21)	_
CRP upon admission	234.18±105.12	225.17±108.13	0.861
CRP after PC	41.69±45.46	53.40±66.26	0.678
WBC upon admission	10.65±4.50	14.63±6.73	0.257
WBC after PC	6.03±0.94	8.96±5.36	0.232
Mortality	0 (0)	7 (15)	0.282

Table 4. Comparison between patients diagnosed with acalculous and calculous acute cholecystitis n (%)

ASA – The American Society of Anaesthesiologists physical status classification system; WBC – white blood cells; CRP – C-reactive protein; PC – percutaneous cholecystostomy

Twelve patients (22.2%) developed post-procedural complications including septic shock (n = 2) and bile duct stricture that resulted in clogged stent (n = 1). Both patients with septic shock died during the postoperative period. Other complications included atrial fibrillation (n = 5, 9.26%), and pneumonia 7.41% (n = 4, 7.41%) which resulted in acute respiratory failure.

The mean time for PC catheter removal in our study was 19.38 ± 12.16 days. The catheter was removed in 11 (20.4%) patients during initial hospitalization period. In the rest patients, the catheter was removed later, between 10 to 14 days, in outpatient clinic. Two patients (3.7%) removed the catheters by themselves during the hospitalization, because of mental disorders. In these cases, the catheters were reinserted without any additional complications. Clinical status and inflammation markers postoperatively improved in 39 patients (72.2%). One (1.9%) of these patients underwent surgery during the same hospital stay where open cholecystectomy was performed. The median length of hospital stay was 13.06 (range 2–68) days. The 30-day mortality rate was 13% (n = 7). The cause of death was acute cardiovascular failure (n = 7). No deaths were directly related to the procedure.

Discussion

Acute cholecystitis is one of the most frequent reasons for admission to surgical services in Western countries [8]. According to the updated Tokyo Guidelines, laparoscopic cholecystectomy is the gold standard in the treatment of AC. Although, there are still no reliable reports regarding optimal treatment for each severity grade [20], it is recommended that severe AC should be treated by gallbladder drainage and delayed chole-cystectomy after the patient's general condition improvement. Usually the management of AC is challenging because of the critically ill patients or patients with prolonged duration of symptoms. In these cases, PC is considered to be the treatment of choice because of quick relief of the symptoms, low complication and post-procedure mortality rate.

In our study we demonstrated a significant improvement of inflammatory markers and clinical status after the percutaneous gallbladder drainage with low 30-day mortality rate (13%). It was a definitive treatment in 43 (79.6%) patients and only in 11 patient's delayed cholecystectomies were performed.

Severe AC, old age and comorbidities are the main factors determining the treatment choice in these patients according to the previously published studies [21]. However, despite the published results [3, 22, 23], the management of high-risk patients with AC is controversial and no consensus on the issue has been reached yet. Some studies demonstrated that laparoscopic cholecystectomy is a time-tested method and still remains the gold standard for AC treatment [3]. Other studies introduce PC as a safe alternative treatment approach [22], especially useful when immediate cholecystectomy is unsafe [23]. There are several published studies comparing postoperative outcomes between early and late laparoscopic cholecystectomy following PC [24]. Jung et al. reported no difference between groups in comorbid conditions that could affect surgical outcome.

Our study was focused on the safety of the PC and the outcomes of critically ill patients after the procedure. According to numerous studies [8, 16, 20, 24] PC can be used as a temporizing measure or as a definitive treatment option with a low number of delayed cholecystectomies [2]. Among 54 cases in our study, clinical status significantly improved and laparoscopic cholecystectomy was performed for 11 patients (20.37%). The decision to schedule the delayed cholecystectomy was made after discussing these patients with anaesthesiologist.

The optimal time of the catheter removal after the treatment is also controversial. Most authors recommend maintaining the drain from 3 to 6 weeks before the removal to ensure resolution of inflammation and bile leak prevention [8, 19]. Although, there are studies presenting higher possibility of AC recurrence, if the catheter is removed later than 2 weeks from its placement [25, 26]. Our study results demonstrate that mean time of drainage was 19.38±12.16 days and it was determined individually for each patient. It is also mentionable that patients were usually discharged with a catheter in place. Decision to remove the catheter was made after the improvement of the patient's general condition and inflammatory markers.

Complications that occur in nearly 10% of cases include haemorrhage, haemobilia, pneumothorax or bile leaks depending on whether the approach was trans-hepatic or trans-peritoneal [1]. In the present study, low rate of early complications due to the catheter placement was seen. Clinical status deteriorated in 12 patients (22.2%) during the postoperative period due to septic shock, atrial fibrillation, pneumonia and acute respiratory failure developed. These results are comparable to the other studies [2, 8, 27]. Total mortality rate varies widely among the studies, from 3.8% to 59% [16, 19] through the last decade. The high total mortality rate in patients after the PC might be related to a high-risk because of older age, presence of comorbidities or complicated acute cholecystitis. In our study the 30-day mortality rate reached 13%. The cause of death was acute cardiovascular failure in all cases. However, no deaths were directly related to the procedure.

The main limitations of this study are a relatively small number of patients treated using PC in our hospital and possible selection bias due to retrospective design of the study. However, these numbers are similar to other published studies [5–7, 19, 27].

Conclusions

Our study supports PC as a reasonable low risk management option for high-risk (ASA III–IV) patients with acute cholecystitis and co-morbidities with a low rate of 30-day mortality [26, 28].

Disclosure of interest

The authors report no conflict of interest.

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