Can Percutaneous Cholecystostomy Be a Definitive Treatment in High Risk Acute Cholecystitis Patient? A Retrospective 10 Years Outcome

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Background: *Although, cholecystectomy is a definitive treatment in acute cholecystitis patient but is high risk for surgery patient. Therefore, percutaneous cholecystostomy (PC) was the alternative treatment. However, after the treatment, most patients still are unfit for interval cholecystectomy. The outcomes of these patients after PC with gallbladder in situ are unclear.*
Objective: *The aim of the present study is to assess the efficacy and clinical outcome on AC patients that underwent PC placement.*
Material and Method: *A retrospective study of all the patients treated with PC for acute cholecystitis in Ramathibodi Hospital, between 2006 and 2016 was conducted. The data was collected from medical records.*
Results: *Sixty high-risk acute cholecystitis patients were successful treated with PC. Fifty-seven patients (95%) had their conditions improved and could be discharged home about two weeks after PC. Three patients (5%) died in hospital. Forty-one patients (68.3%) were definitively treated with PC (GB in situ) and six patients (14.6%) had recurrent biliary symptoms. Median time of recurrence was 135.5 days. Twelve patients (20%) underwent cholecystectomy after PC and four patients(6.7%) were lost to follow-up. Six (10%) patients had immediate complications after PC such as intra-abdominal collection, minimal bile leakage, or PC displacement.*
Conclusion: *PC could be an alternative interim treatment as a less invasive method of treating the acute process to avoid extra morbidity and mortality of cholecystectomy under the emergency setting in high-risk acute cholecystitis patients. After the PC tube was removed, the gallbladder can be left in situ with a low recurrence rate of biliary event.*

Keywords: *Percutaneous cholecystostomy, Cholecystitis, Cholecystectomy*

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Acute cholecystitis (AC) is an inflammatory disease of the gallbladder, and more than 90% of AC cases are associated with gallstones. Cholecystitis represents one of the most common emergency admissions in surgical practice[1].

Cholecystectomy has been the gold standard treatment for AC. With the advent of laparoscopic cholecystectomy, early surgery is considered safe and cost effective for the management of AC[1].

However, high-risk surgical patients with co-existing illnesses may have pathological changes in cardiovascular, cerebrovascular, pulmonary, and renal functions, resulting in increased morbidity and mortality after surgery[6].

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Because of the increased risks of emergency surgery in elderly people, percutaneous cholecystostomy (PC) has been proposed as replacement for cholecystectomy in high-risk surgical patients[3].

Most of them were treated with PC. The management of high-risk patients with AC is still controversial and no consensus on the issue of elective cholecystectomy has been reached.

The aim of the present study is to retrospectively assess the efficacy and clinical outcome after AC patients who underwent PC placement.

Material and Method

Between 2006 and 2016, 60 patients with acute cholecystitis were managed by PC at Ramathibodi Hospital. Medical records were retrospectively reviewed. Patients were identified using diagnosis and procedure codes from ICD-10, ICD-9 through the institution's electronic medical records coding database.

An acute cholecystitis is an inflammatory

disease of the gallbladder with/without gallstone. The diagnosis based on clinical signs of fever, right upper quadrant abdominal pain and imaging such as abdominal ultrasound or computed tomographic findings. Patients managed with surgery at first were excluded from the study.

All cholecystostomy tube were inserted percutaneously by interventional radiologists and gallbladder was identified by ultrasonography.

The management of patients with cholecystostomy tube, included timing of removal and decision regarding cholecystectomy, was based on attending doctor's preference after discussing with patients' relatives.

Demographic data, co-morbidity, Charlson comorbidity index, patient status, imaging for diagnosis, severity grading according from Tokyo guideline, laboratory test, length of stay, time with PC, time of recurrent symptom, and management was collected.

Statistical analysis

We used STATA version 14 (StataCorp LP 4905 Lakeway Drive College Station, Texas 77845-4512, USA) for data analysis. Categorical data were shown as number and percentage. Continuous data were reported as mean, interquartile range, and standard deviation. The statistical analysis was carried out using Chi-square test and Fisher's exact test for categorical data. The continuous data was analyzed by Wilcoxon Mann-Whitney test. Logistics regression was used to analyze associated factor about cholecystectomy group and recurrence group.

Results

Sixty patients with acute cholecystitis were treated with PC in Ramathibodi Hospital between January 2006 and October 2016. Fifty-seven (95%) patients improved after PC and could be discharged home about two weeks after PC. Three (5%) patients died from venous thromboembolism (VTE), cirrhosis with hepato-renal syndrome, and severe sepsis. Four (6.7%) patients were lost to follow-up.

Twenty percent of patients (12/60) underwent elective cholecystectomy after clinical improvement and 68.3% of patients (41/60) had their gallbladder left in situ.

In patients group of GB in situ, median time with PC tube was 56.5 days. The recurrent symptoms rate was 14.6% (6/41). Median time of recurrence was 135.5 days.

Median time of follow-up in GB in situ group and cholecystectomy group were 29 months 10 days and 51 months 22.5 days, respectively.

Six (10%) patients had immediate complications after PC such as intra-abdominal collection, minimal bile leakage, or PC displacement. Two patients who underwent cholecystectomy had complication related cholecystectomy such as intra-abdominal bleeding and intra-abdominal collection.

Table 1 summarized the demographic data of these patients. Thirty-two (53.3%) patients were male with a mean age of 78.5 years. Twenty (33.3%) patients had acalculous cholecystitis and 40 (66.7%) patients had scalculous cholecystitis. Thirty-seven patients (61.7%) were categorized as severity grade II per the Tokyo guidelines. Most of the patients (33/60, 55.5%) were ASA class 4. Most of the patients (60%) underwent US for diagnosis. Mean of Charleston's comorbidity index was 7. PC was technically successful in all patients.

Discussion

The efficacy of PC for AC patients in this study (95%) show that it was suitable for unfit patients. The complication rate was 14.6% and no technical related mortality. We concluded that the results supported the safety of PC in our hospital, which is similar to previous studies[1-5,20].

In our study, 10% (6/60) of patients had complications such as intra-abdominal collection, minimal bile leakage, or PC displacement. However, the number of patients who underwent PC in our study were small. Chou et al collected 202 patients and reported about the complications. They found that some patients had a lower procedure-related bleeding rate, bile leakage, gut obstruction, malposition, and catheter-related infection[19].

In patients groups of GB in situ, other series[1-8] reported low rates (0% to 14%) of recurrent cholecystitis or biliary symptoms requiring cholecystectomy, and concluded that PC might be a definitive treatment. The interval cholecystectomy in these high-risk patients might not be necessary, which is with our study that shows recurrent biliary symptoms at 14.6%.

The optimal time at which the catheter should be removed after PC treatment for AC remains controversial. Some authors advocate a minimum treatment duration of six weeks[4]. Most patients underwent cholecystocholangiogram before the PC tube was removed.

After the PC tube was removed, the

Table 1. Comparison between patients who underwent cholecystectomy and gallbladder in situ

Variable	GB in situ (n = 41)	Cholecystectomy (n = 12)	*p*-value	95% CI
Age, mean (SD)	78.17 (11.30)	72.92 (9.16)	0.147	73.94 to 80.01
Male, n (%)	19 (46.34)	8 (66.67)	0.215	
Diagnosis, n (%)				
Calculous cholecystitis	26 (63.41)	9 (75.00)	0.353	
Acalculous cholecystitis	15 (36.59)	3 (25.00)		
DM, n (%)	24 (58.54)	7 (58.33)	0.990	
HT, n (%)	33 (80.49)	9 (75.00)	0.479	
DLP, n (%)	13 (31.71)	2 (16.67)	0.264	
Heart, n (%)	15 (36.59)	4 (33.33)	0.561	
CKD & ESRD, n (%)	11 (26.83)	0	0.041	
ASA class, n (%)				
Class 3	19 (46.34)	6 (50.00)	0.540	
Class 4	22 (53.66)	6 (50.00)		
Charlson comorbidity index	7 (6 to 9)	6 (5.5 to 7.5)	0.019	6.99 to 8.07
Severity grading				
Tokyo guideline 2013, n (%)				
Mild	16 (39.02)	6 (50.00)	0.497	
Moderate	25 (60.98)	6 (50.00)		
WBC, mean (SD)	16,502 (7,989)	16,570 (7,970)	0.979	14,338 to 18,697
Creatinine, median (IQR)	1.21 (0.98 to 2.21)	1.14 (0.82 to 1.37)	0.349	0.95 to 4.16
AST, median (IQR)	42 (22 to 60)	34 (28 to 83.5)	0.663	40.81 to 69.15
ALT, median (IQR)	32 (25 to 44)	33 (29 to 67)	0.551	34.85 to 54.21
GGT, median (IQR)	85 (58 to 135)	103 (84 to 168.5)	0.313	79.45 to 193.68
ALP, median (IQR)	97 (72 to 146)	86.5 (48.95 to 134.5)	0.425	96.12 to 157.08
Alb, median (IQR)	27 (22 to 32)	27.25 (23.5 to 31)	0.999	24.73 to 29.09
TB, median (IQR)	0.90 (0.70 to 1.50)	1 (0.70 to 1.85)	0.949	1.07 to 2.91
DB, median (IQR)	0.50 (0.30 to 0.80)	0.60 (0.35 to 1.20)	0.447	0.60 to 2.09
INR, median (IQR)	1.24 (1.12 to 1.41)	1.40 (1.20 to 1.87)	0.101	1.30 to 1.54
Platelet, median (IQR) $x10^3$	249 (188 to 311)	218 (182 to 245)	0.298	224.89 to 275.52
Length of stay, median (IQR)	13 (7 to 20)	14.50 (7.5 to 19)	0.991	12.93 to 20.76
Total ATB iv day, median (IQR)	12 (5 to 8)	13 (7 to 18)	0.798	11.60 to 19.31
Time PC (day), median (IQR)	56.5 (40 to 96)	51 (30.5 to 89.5)	0.539	55.02 to 81.94
Complication, n (%)				
No	35 (85.37)	10 (83.33)	0.999	
Yes	6 (14.63)	2 (16.67)		

management of high-risk patients is still controversial and there is no consensus on the issue of elective cholecystectomy. In elderly patients with comorbidity, surgery can result in serious complications and even mortality. However, routine elective cholecystectomy is preferred as these patients represent a high-risk population because of advanced age and/or significant medical comorbidities. Therefore, further episodes of biliary sepsis could carry mortality rate risks as high as with elective cholecystectomy. In our study, 12 patients who underwent elective cholecystectomy had 16.6% (2/12) complication and no mortality. E. Atar et al has reported a post-surgery morbidity rate of 5.6%, and a mortality rate of 2.8%[18].

Another point about efficacy of PC such as the timing of PC insertion in AC patient was not collected in our study but the timing may be one of the key success factor of infection treatment. S. Zarour et al reported that the timing of PC (less than 24 hours or more than 24 hours after admission) did not affect AC resolution or drain-related complications[17,18]. The clinical data assessment should be performed in the future study. There are several limitations in our study. This was a retrospective design, but there was some controlled in a cross-over study of some clinical and laboratory test parameters. The series of patients who

Table 2. Chronic underlying medical problems

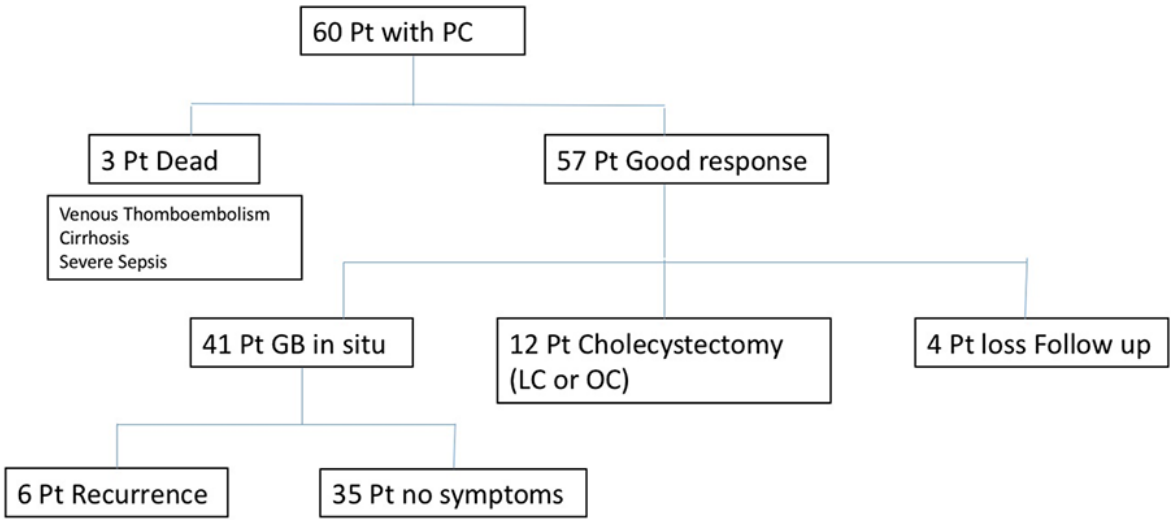
Chronic underlying medical problems	Percent
Diabetes mellitus	53.3
Heart disease	35
Cerebrovascular disease	31.7
Chronic renal failure	21.67
Bed ridden status	19
Malignancy	15
Liver cirrhosis	6.7

were treated over a large span of time was rather small. The decision to perform PC instead of cholecystectomy depended on the attending physician's preference.

In conclusion, PC could be an alternative interim treatment as a less invasive method of treating the acute process thereby avoiding extra morbidity and mortality of cholecystectomy under emergency setting in high-risk acute cholecystitis patients. After the PC tube was removed, gallbladder can be left in situ with lower recurrence rate of biliary event.

Table 3. Factors that associated with recurrent symptoms patients group

Variable	Non-recurrence (n = 35)	Recurrence (n = 6)	*p*-value	95% CI
WBC, mean (SD)	16,175 (7,291.03)	21,100 (11,647.22)	0.146	14,642 to 18,693
Creatinine, median (IQR)	1.21 (0.91 to 2.21)	1.21 (0.82 to 2.2)	0.892	1.08 to 3.89
AST, median (IQR)	44 (28 to 68)	36.5 (24 to 61)	0.605	44.23 to 70.14
ALT, median (IQR)	34.5 (26 to 49)	51 (29 to 77)	0.475	38.03 to 56.27
GGT, median (IQR)	87.5 (58 to 143)	12.5 (74 to 154)	0.721	85.08 to 186.98
ALP, median (IQR)	97 (71.141)	159.5 (80 to 186)	0.175	101.89 to 157.27
Alb, median (IQR)	27.15 (23 to 31.7)	27.1 (21 to 38)	0.786	25.09 to 29.09
TB, median (IQR)	0.95 (0.7 to 1.8)	1.05 (0.70 to 2)	0.980	1.24 to 3.39
DB, median (IQR)	0.50 (0.30 to 1)	0.50 (0.30 to 1)	0.970	0.75 to 2.21
INR, median (IQR)	1.26 (1.15 to 1.49)	1.47 (1.23 to 1.52)	0.195	1.34 to 1.56
Platelet, median (IQR) x10^3	216 (174 to 292)	300 (248 to 450)	0.072	220 to 268
Length of stay, median (IQR)	14 (8 to 23)	10.5 (5 to 20)	0.355	14.93 to 23.47
Total ATB iv day, median (IQR)	13.5 (7 to 22)	9 (5 to 20)	0.451	13.54 to 22.03
Time PC (day), median (IQR)	56.5 (34.89)	55.5 (34 to 110)	0.905	55.02 to 81.94



LC = laparoscopic cholecystectomy, OC = Open cholecystectomy

Fig. 1 Patient outcome.

What is already known on this topic?

Cholecystectomy has been the gold standard treatment for acute cholecystitis (AC). With the advent of laparoscopic cholecystectomy, early surgery is considered safe and cost effective for the management of AC. However, high-risk surgical patients with co-existing illnesses may have pathological changes in cardiovascular, cerebrovascular, pulmonary, and renal functions, resulting in increased morbidity and mortality after surgery. Percutaneous cholecystostomy (PC) has been proposed as a replacement for cholecystectomy. The management of high-risk patients with AC after PC removal is still controversial and no consensus on the issue of elective cholecystectomy or gall bladder in situ.

What this study adds?

This study retrospectively assesses the efficacy and clinical outcome after AC patients who underwent PC placement. After the PC tube was removed, the gallbladder can be left in situ with low recurrence rate of biliary event. PC could be an alternative treatment as a less invasive method of treating the acute process thereby avoiding extra morbidity and mortality of cholecystectomy under emergency setting in high-risk acute cholecystitis patients.

Potential conflicts of interest

None.

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การศึกษาประสิทธิภาพประโยชน์และความเสี่ยงของการใส่สายระบายถุงน้ำดี (Percutaneous cholecystostomy) ในผู้ป่วยถุงน้ำดีอักเสบเฉียบพลันที่มีความเสี่ยงสูงในการผ่าตัดถุงน้ำดี

พงศธร ตั้งทวี, ทรงเกียรติ อยู่คง, สมคิด มิ่งพฤฒิ

ภูมิหลัง: *ปัจจุบันการรักษามาตรฐานในโรคถุงน้ำดีอักเสบเฉียบพลัน คือการผ่าตัดถุงน้ำดีแต่ผู้ป่วยที่มีความเสี่ยงสูงต่อการผ่าตัดการรักษา ด้วยการระบายน้ำดีด้วยวิธีการเจาะระบายผ่านทางผนังหน้าท้องอาจเป็นการรักษาแบบชั่วคราววิธีหนึ่ง ผู้ป่วยที่สภาวะต่าง ๆ คงที่และปลอดภัยแล้วจึงจัดให้ผู้ป่วยผ่าตัดถุงน้ำดีต่อไปในเวลาที่เหมาะสมต่อไป อย่างไรก็ตามมีผู้ป่วยจำนวนหนึ่งที่ไม่ได้รับการผ่าตัดดังกล่าว ผลของการรักษานี้ยังไม่ชัดเจนว่าสามารถทำได้หรือไม่ การศึกษานี้ช่วยตอบคำถามดังกล่าวว่าการทำการเจาะระบายถุงน้ำดีผ่านผนังหน้าท้องเพียงอย่างเดียวนั้นสามารถทำได้เป็นมาตรฐาน*

วัตถุประสงค์: *เพื่อศึกษาประสิทธิภาพประโยชน์ และความเสี่ยงของการใส่สายระบายถุงน้ำดี (Percutaneous cholecystostomy) ในผู้ป่วยถุงน้ำดีอักเสบเฉียบพลันที่มีความเสี่ยงสูงในการผ่าตัดถุงน้ำดี*

วัสดุและวิธีการ: *ศึกษาแบบย้อนหลังจากเวชระเบียนผู้ป่วยของโรงพยาบาลรามาธิบดีระหว่างปี พ.ศ. 2549 ถึง พ.ศ. 2559*

ผลการศึกษา: *ผู้ป่วยจำนวน 60 ราย ชาย 32 ราย (ร้อยละ 53) หญิง 28 ราย (ร้อยละ 47) อายุเฉลี่ย 78.5 ปี ได้รับการใส่สายระบายถุงน้ำดี (Percutaneous cholecystostomy) เป็นผู้ป่วยอยู่ใน ASA class 3 จำนวน 27 ราย (ร้อยละ 44.5) และ ASA class 4 จำนวน 33 ราย (ร้อยละ 55.5) ผู้ป่วยมีอาการดีขึ้นภายหลังใส่สายระบายถุงน้ำดี 57 ราย (ร้อยละ 95) เสียชีวิตภายในโรงพยาบาลที่ไม่เกี่ยวกับการใส่สายระบาย 3 ราย (ร้อยละ 5) และพบภาวะแทรกซ้อนหลังใส่สายระบายถุงน้ำดี 6 ราย (ร้อยละ 10) หลังกลับบ้านมีผู้ป่วย 12 ราย (ร้อยละ 22.7) ได้รับการผ่าตัดถุงน้ำดี ผู้ป่วยไม่มาตามนัด 4 ราย และมีผู้ป่วย 41 ราย (ร้อยละ 68.3) ไม่ได้ผ่าตัดถุงน้ำดี (Gall bladder in situ) จากการติดตามผลในระยะเวลาเฉลี่ย 135.5 วัน มีผู้ป่วย 6 ราย (ร้อยละ 14.6) มีการกลับเป็นซ้ำของถุงน้ำดีอักเสบ*

สรุป: *การใส่สายระบายถุงน้ำดี เป็นวิธีการรักษาที่มีประสิทธิภาพ และปลอดภัยในการรักษาโรคถุงน้ำดีอักเสบเฉียบพลันในผู้ป่วยที่มีความเสี่ยงสูงต่อการผ่าตัดถุงน้ำดี*