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# Better Treatment Strategies for Patients with Acute Cholecystitis and American Society of Anesthesiologists Classification 3 or Greater

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**Purpose:** Laparoscopic cholecystectomy is the best treatment choice for acute cholecystitis. However, it still carries high conversion and mortality rates. The purpose of this study was to find out better treatment strategies for high surgical risk patients with acute cholecystitis. Materials and Methods: Between January 2002 and June 2008, we performed percutaneous cholecystostomy instead of emergency cholecystectomy in 44 patients with acute cholecystitis and American Society of Anesthesiologists (ASA) classification 3 or greater. This was performed in 31 patients as a bridge procedure before elective cholecystectomy (bridge group) and as a palliative procedure in 11 patients (palliation group). Results: The mean age of patients was 71.6 years (range 52-86 years). The mean ASA classifications before and after percutaneous cholecystostomy were  $3.3 \pm 0.5$  and  $2.5 \pm 0.6$ , respectively, in the bridge group, and  $3.6 \pm 0.7$  and  $3.1 \pm 1.0$ , in the palliation group, respectively. Percutaneous cholecystostomy was technically successful in all patients. There were two deaths after percutaneous cholecystostomy in the palliation group due to underlying ischemic heart disease and multiple organ failure. Resumption of oral intake was possible  $2.9 \pm 1.8$  days in the bridge group and  $3.9 \pm 3.5$  days in the palliation group after percutaneous cholecystostomy. We attempted 17 laparoscopic cholecystectomies and experienced one failure due to bile duct injury (success rate: 94.1%). The postoperative course of all cholecystectomy patients was uneventful. Conclusion: Percutaneous cholecystostomy is an effective bridge procedure before cholecystectomy in patients with acute cholecystitis and ASA classification 3 or greater.

Key Words: Percutaneous cholecystectomy, acute cholecystitis, American Society of Anesthesiologists classification

### INTRODUCTION

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This is an Open Access article distributed under the terms of the Creative Commons Attribution Non-Commercial License (http://creativecommons.org/ licenses/by-nc/3.0) which permits unrestricted noncommercial use, distribution, and reproduction in any medium, provided the original work is properly cited. Laparoscopic cholecystectomy (LC) is the treatment of choice, even in acute cholecystitis.<sup>1,2</sup> However, there is still a high rate of open conversion and mortality in patients with high surgical risk, especially when emergency cholecystectomy is necessary.<sup>3,4</sup> Nevertheless, we need to treat them definitely as early as possible, because 10 to 30 percent of patients with acute cholecystitis develop life threatening complications such as empyema, gangrene and perforation.<sup>5</sup>

For the last decade, percutaneous cholecystostomy (PC) has been proposed and accepted as an alternative to emergency cholecystectomy.<sup>69</sup> However, even recent publications dealing with the efficacy or effectiveness of PC did not provide us clear guideline for PC in acute cholecystitis.

Since there is no clear guideline for PC and critical pathway developed for patients with acute cholecystitis, primary care doctor and surgical trainee in the emergency center have dilemma to select a good candidate patients for emergency cholecystectomy or PC.

Since 1963, American Society of Anesthesiologists (ASA) classification has been simple, reliable and evidence based method to evaluate surgical risk after general anesthesia.<sup>10</sup> Moreover, most of clinicians are familiar with ASA classification in real clinical situation. We decided to perform PC instead of emergency cholecystectomy in patients with acute cholecystitis and ASA classification 3 or greater, whether it was for a bridge procedure before cholecystectomy or palliative purpose. Because surgical risk after general anesthesia in patients with ASA classification 3 is 1.7%<sup>10</sup> which is unacceptable mortality rate after cholecystectomy, we need to setup better strategies for high risk patients in our institution.

We report a 6.5-year prospective experience with PC in patients with acute cholecystitis and ASA classification (Table 1) 3 or greater.

# MATERIALS AND METHODS

#### Patients and methods

Between January 2002 and June 2008, 622 patients were presented with acute cholecystitis. We applied ASA classification to these patients to evaluate surgical risk. The patients who had ASA classification below 3 were allocated to elective or emergency surgery and the patients who had ASA classification 3 or greater were allocated to PC as a bridge procedure before elective cholecystectomy (bridge group) and as a palliative procedure (palliation group) depending on clinical situation.

The diagnosis of acute cholecystitis was established on the basis of clinical and laboratory findings. Patients who had more than two of the following findings were defined as having acute cholecystitis: fever  $> 37.5^{\circ}$ C, pain for more than 48 hours, gallbladder wall thickness > 4 mm, and abdominal distension, pericholecystic abscess. Assignment of the ASA classification was carried out by two anesthesiologists, one of which at least was a consultant. The ASA classification system used in this paper is shown in Table 1.

ASA classification 3 or greater was defined depending on significant comorbidities. Significant cardiac comorbidity included severe ischemic heart disease (as evidenced by coronary angiography, history of frequent/unstable angina or myocardial infarction within 6 months of presentation), dysrhythmias causing hemodynamic instability, or clinical and/or echocardiographic evidence of poor ventricular function. Significant respiratory disease included a respiratory condition causing clinically evident respiratory distress, hypoxemia, or a peak expiratory flow rate of less than 40% expected. Renal impairment was defined by the presence of an elevated serum creatinine level despite adequate fluid resuscitation. Significant central nervous system disease included a neurological condition preventing patients from attending to their personal activities of daily living, or a history of cerebrovascular accidents.11 We defined biliary sepsis-induced leucopenia, thrombocytopenia and/or hypotension with response to pressor drugs as an ASA classification 3 and hemodynamic instability not respond to pressor drugs and/or mental change as an ASA classification 4.

We evaluated patient characteristics, complication rates after PC, ASA classification change before and after PC, resumption of oral intake after PC, and the success rate of LC. PC was performed under sterile conditions using ultrasound guidance. After local anesthesia was achieved with 1% subcutaneous lidocaine, a 10 F or 8.5 F nephrostomy, cope loop, or multipurpose catheter was placed in the gallbladder, using the Seldinger exchange technique, and secured in place. The transperitoneal route was used in 17 patients, while the transhepatic route was used in 27 patients. Aspirated material was sent to the clinical laboratory for culture. This study was approved by the Ethics Committee, Yeungnam University Medical Center, Daegu, Korea.

### Statistical analysis

Results are reported as means  $\pm$  SDs. Differences were tested using the Chi-square test. *p* values less than 0.05 were

Table 1. American Society of Anesthesiologists (ASA) Classification

Ι	Patient with no limitation of activities; they suffer no symptoms from ordinary activity.
Π	Patients with slight, mild limitation of activity; they are comfortable with rest or with mild exertion.
III	Patients with marked limitation of activity; they are comfortable only at rest.
IV	Patients who should be at complete rest, confined to bed or chair; any physical activity brings on discomfort and symptoms occur at rest.
V	Moribund patient not expected to survive 24 hrs with or without an operation.

considered statistically significant.

# RESULTS

Forty-four patients (7.1%) among 622 patients with acute cholecystitis had ASA classification 3 or greater. We performed PC as a bridge procedure before elective chole-

Disease	No. of patients (%)
Malignancy	3 (3)
Pulmonary	32 (32.3)
Vascular	3 (3)
Renal	6 (6.1)
Cardiac	6 (6.1)
Ischemic heart disease	14 (14.1)
Hypertension	17 (17.2)
Diabetes mellitus	11 (11.1)
Other	7 (7.1)
Total	99

cystectomy (bridge group) in 31 patients and as a palliative procedure in 11 patients (palliation group). There were 2 deaths after PC in the palliation group due to underlying disease (ischemic heart disease and multiple organ failure). We believe that these deaths were not related with PC or biliary sepsis.

The mean patient age at the time of PC was 71.6 years (range 52-86 years). The mean age of the bridge group was 70.7  $\pm$  10.5 years, and that of the palliation group was 73.1  $\pm$  8.8 years. Surgical risk factors in enrolled patients are described in Table 2. The indications for PC were significant patient comorbidity with high anaesthetic risk (n = 38) and biliary sepsis (n = 6). The mean ASA classifications before and after PC were 3.3  $\pm$  0.5 and 2.5  $\pm$  0.6 in the bridge group; and 3.6  $\pm$  0.7 and 3.1  $\pm$  1.0 in the palliation group, respectively (Table 3). PC was technically successful in all patients (success rate: 100%), with 4 complications (rate: 9.1%; one case of PC site infection and 3 cases of PC site bleeding). However, all complications responded well to conservative treatment.

The average hospital stay after PC was  $14.3 \pm 14.5$  days in the bridge group and  $16.0 \pm 17.1$  days in the palliation

#### Table 3. Comparison of Bridge Group and Palliation Group

	Bridge group		Palliation group	
Age	$70.7 \pm 10.5 \text{ yrs}$		$73.1 \pm 8.8 \text{ yrs}$	
A S A	Before PC	After PC	Before PC	After PC
ASA	$3.3\pm0.5$	$2.5\ \pm 0.6$	$3.6\pm0.7$	$3.1\pm1.0$
Hospital stay	$14.3 \pm 14.5 \text{ days}$		$16.0 \pm 17.1 \text{ days}$	
Resumption of oral intake	$2.9 \pm 1.8 \text{ days}$		$3.9 \pm 3.5$ days	

PC, percutaneous cholecystostomy; ASA, American Society of Anesthesiologists.



Fig. 1. Flow chart of outcomes in 44 patients with acute cholecystitis undergoing percutaneous cholecystostomy. PC, percutaneous cholecystostomy; LC, laparoscopic cholecystectomy; OC, open cholecystectomy.

group. Resumption of oral intake was possible at  $2.9 \pm 1.8$  days after PC in the bridge group and at  $3.9 \pm 3.5$  days after PC in the palliation group, except for in 2 patients who died due to underlying diseases (Table 3). We tried 17 LCs at  $25.1 \pm 19.8$  days after PC and failed in one case due to bile duct injury (success rate: 94.1%). The mean hospital stay after LC was  $5.1 \pm 1.8$  days, and the mean operative time for LC was  $101.6 \pm 36.8$  minutes, which was not longer than that for LC in the setting of acute cholecystitis in our hospital. The postoperative course of all patients who underwent LC and open cholecystectomy was uneventful.

In the bridge group (n = 31), 3 patients who declined surgery were reallocated to the palliative group. Elective cholecystectomy was performed in 28 patients, including laparoscopic (16 patients) and open (12 patients) cholecystectomy (Fig. 1).

In the palliation group (n = 14), 3 patients were lost in our follow up program and 4 patients were dead due to esophageal cancer bleeding, ischemic heart diseases and disseminated malignancy at 27th, 36th, 132th and 148th days after PC. In the remaining 7 patients, we performed tubography through the PC tube to see the cystic duct function. We removed PC tube at  $141 \pm 91$  days after PC without complication in 5 patients, including 3 patients with acalculous cholecystitis. Despite of minor symptoms, they survived without acute severe cholecystitis at 23.8  $\pm$ 15.4 months. One of two patients, who did not have patent cystic duct, received repeat PC at 6 months after spontaneous removal and the other patient survived at 24 months after removal with collapsed chronic cholecytitis.

## DISCUSSION

In contrast to physicians in the early era of laparoscopic cholecystectomy (LC), most of current surgeons agree that LC is also the treatment of choice in acute cholecystitis with similar operation time, shorter hospital stay and complication rate, compared with open cholecystectomy. Nevertheless, there have been two issues concerning the high rate of mortality and open conversion after LC in high risk patients with acute cholecystitis.<sup>34,12-16</sup>

We focused on two points in determining the better strategy for treating high risk patients with acute cholecystitis. First, we evaluated surgical risk factors to reduce mortality and sought how to circumvent the septic process and pain. Second, we sought how to reduce open conversion rate.

We believe that mortality after LC derives usually from underlying comorbidities and sepsis. Even though there are various methods to evaluate critically ill patients, ASA classification is a well established and evidence-based method for determining surgical risk after general anesthesia. Furthermore, most of clinicians, especially surgeon and primary care doctors in emergency center, are familiar with that. We know that ASA class 3 and 4 patients have mortality rates of 1.7% and 4.3%, respectively.<sup>10</sup> Before the era of LC, surgeons noted an approximately 0.5% mortality rate after open cholecystectomy.<sup>17,18</sup> Hence, if a procedure carries a mortality rate above 0.5%, alternative treatment should be considered.

The appropriate management to circumvent the septic process and relieve pain in critically ill patients has been an another issue. Because some patients (10 to 30%) with acute cholecystitis develop life threatening complications such as empyema, gangrene or perforation,<sup>5</sup> a question still remains whether PC is superior to conservative treatment in high risk patients with acute cholecystitis. To the best of our knowledge, there has been only one prospective randomized study by Hatzidakis, et al.<sup>19</sup> Even though they reported similar response and mortality rate in both groups, PC was recommended when there was no response after 3 days of conservative treatment. We decided to perform PC in high risk patients because PC has been accepted as a good alternative to LC in that it avoids septic process and relieves pain. Eventually, we could have time to evaluate and treat combined comorbidities after PC.6,8,20-23

Many authors emphasized that the importance of an early definitive treatment in patients with acute cholecystitis, especially if an operation is attempted laparoscopically.<sup>14-16</sup> The longer LC is delayed, the more fibrosis and adhesion in operation field which makes operation difficult.

Before the start of this study, we clearly defined the definition of ASA classification in our institution with anesthesiologists (see materials and methods). We evaluated surgical risk of all patients with acute cholecystits, depending on ASA classification. During the study period, fortunately there was no mortality among 412 patients with ASA classification less than 3 who were allocated to surgery (emergency or elective). We performed PC in 44 patients with ASA classification 3 or greater and classified them as a bridge group (bridge to definite surgery) or palliation group, depending on clinical situation. Allocation to the palliative group was determined by the attending surgeon, based on life expectancy, medical comorbidities, patient and family desire. All surgeries in the bridge group were done under elective schedule as early as possible to reduce the open conversion rate.

In our present study, PC was associated with no mortality and low morbidity. We preferred a transhepatic approach, despite potential risks of pneumothorax, intrahepatic bleeding, hemobilia, and fistula formation, because this approach minimizes the risk of intraperitoneal bile leakage and colon injury. Resumption of oral intake was possible at  $2.9 \pm 1.8$  days after PC in the bridge group and at  $3.9 \pm 3.5$  days after PC in the palliation group. The mean ASA classifications before and after PC were  $3.3 \pm 0.5$  and  $2.5 \pm 0.6$ , in the bridge group, and  $3.6 \pm 0.7$  and  $3.1 \pm 1.0$  in the palliation group, respectively. Early oral intake and improvement in ASA classification suggest that PC is an effective alternative to emergency cholecystectomy.

Hospital stays after PC in this study were longer than those in other reports.<sup>21,24,25</sup> In Korea, patients tend to stay in the hospital longer because most hospital expenses are paid by the socialized Korean medical insurance system.

The rates of conversion to open surgery in earlier studies<sup>26-29</sup> were high (more than 10%), whereas the success rate of LC (94.1%) after PC in the current study was acceptable, and postoperative courses after LC and open cholecystectomy were uneventful. It is not unrealistic to expect that we can reduce open conversion rate by doing LC as early as possible, and Tsumura, et al.<sup>30</sup> reduced open conversion rate from 9.6% to 3.3% by LC after PC.

In palliation group, we tried to remove PC after tubography, and we were able to remove PC tube in 5 patients with patent cystic duct. For acalculos cholecystitis, there are studies that cholecystecomy is not required because acalculous cholecystitis did not recur after PC.<sup>31,32</sup> Sugiyama, et al.<sup>33</sup> and Van Steenbergen, et al.<sup>34</sup> reported that, after cessation of drainage, acute cholecystitis relapsed in 33% and 25% of their elderly patients with gallbladder stones, respectively. For patients with acute calculous cholecystitis who are not good candidate for surgery, we need to consider another treatment options such as contact dissolution therapy, endoscopic gallbladder stent and/or percutaneous lithotripsy.

In conclusion, better treatment strategies for high risk patients with acute cholecystitis are evaluation of surgical risk with ASA classification at first, and if ASA classification is 3 or greater, perform PC to reduce septic symptoms, to have time for evaluation and treatment of comorbidities, subsequently, allocate them to a bridge or palliative group depending on clinical decision, and try to definite surgery under elective schedule as early as possible in the bridge group.

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