Current state of percutaneous cholecystostomy: indications and management

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Acute calculous cholecystitis is a common surgical problem. Although laparoscopic cholecystectomy is the standard therapy for these patients, some may not be suitable candidates for surgery owing to serious comorbidities, high surgical risk, or severity of the cholecystitis and its local and systemic consequences. In selected cases, percutaneous cholecystostomy may be an alternative to surgery; however, there are no definite recommendations for patient management after this technique is performed. Surgery may be not an appropriate treatment for such patients for the rest of their lives. This review discusses the main indications of percutaneous cholecystostomy and its management based on the findings of recently published literature.

Keywords:
Percutaneous cholecystostomy, acute calculous cholecystitis, Charlson Comorbidity Index, indications, management

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Introduction

Acute cholecystitis (AC) is one of the most common gastrointestinal system emergent conditions faced by surgeons and the second source of complicated intra-abdominal infections [1]. It is the most common complication of cholelithiasis, and management of some patients remains a matter of debate. AC may be calculous or acalculous. Cystic duct obstruction due to gallstone or sludge is the main cause of acute calculous cholecystitis (ACC). The degree and duration of the cystic duct obstruction determine the severity of gallbladder inflammation. Secondary bacterial infections with enteric organisms accompany ACC in 20% of patients. After gallbladder wall edema and congestion (first phase, 2–4 days), hemorrhage and necrosis of the gallbladder wall occurs, and this leads to gangrene, perforation, and biliary peritonitis (second phase, 3–5 days). On day 6 or later after the onset of symptoms, chronic or purulent phase starts. It is characterized by leukocyte infiltration, necrotic tissue, and suppuration with pus and gross infection. Finally, this purulent tissue is replaced by granulation tissue named as subacute cholecystitis [2].

Laparoscopic cholecystectomy (LC) is the ideal treatment for patients with AC admitted within the first 72 h from the onset of symptoms. Approximately 120 000 LCs are performed annually. Early surgery is favored over delayed surgery when feasible [3,4]. Technical difficulties, an increased conversion rate to open surgery, and risk of bile duct injury were the main concerns for delayed surgery in AC. However, a meta-analysis performed by Cao *et al.* [3] demonstrated that early surgery has a decreased risk of wound infections, a shorter total hospital stay, and decreased costs, but no difference in mortality rates, bile duct injury, bile leaks, and conversion rates, although a longer hospital stay and increased costs attended two admissions from the delayed group [3]. Interval cholecystectomy is recommended in medically treated patients with AC at admission after 6–8 weeks after onset, although PC may be a definitive treatment for high-risk surgical patients [5,6].

In 2007, the Tokyo Guidelines (TG) were established for diagnosis and grading of AC, which were revised in 2013 and 2018. According to TG 2013, local signs, systemic signs, and imaging findings comprise the main parameters for diagnosis of AC. Depending on pathologic examination, diagnostic accuracy ranged from 60.4 to 94%. Sensitivity and specificity of TG13 for diagnosis of AC were 91.2 and 96.9%, respectively [5]. As a result of the findings of these validation studies, TG13 diagnostic criteria were unchanged for TG18 [6].

Grading of severity of AC in TG13 is a predictive factor for prognosis of AC [5]. Mortality rate, conversion to open surgery, length of hospital stay, complications, intraoperative complications, and

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severity of pathological findings were all found to correlate with grade of severity [7]. Grading of severity of AC in TG13 was validated in many studies, and as it is significantly associated with vital prognosis, its use has been accepted in TG18 [7,8].

When AC is suspected in a patient, we try to make a definite diagnosis depending on the diagnostic criteria, assess the severity of the disease using severity assessment criteria, and evaluate surgical risks (Table 1). In evaluating surgical risks, the Charlson Comorbidity Index (CCI) (Table 2) and American Society of Anesthesiologists physical status (ASA-PS) classification are used [8]. For grades I and II patients, TG18 recommends early LC, if the patient meets CCI less than or equal to 5 and ASA-PS less than or equal to 2 criteria; if the patient does not meet these criteria, medical treatment and/or gallbladder drainage is indicated. For grade III patients, LC is indicated with strict criteria, such as favorable organ failure, negative predictive factors with CCI less than or equal to 3 and ASA-PS less than or equal to 2, and being treated in an experienced center. If surgery is not suitable for these patients, early gallbladder drainage is indicated [9,10].

Percutaneous cholecystostomy (PC) is the most commonly used technique for gallbladder drainage in the current practice for selected patients [11]. It has been shown that PC may be a safe option for the treatment of some patients with AC. In the USA, about 7000 PCs are performed annually; of these, approximately two-thirds of PC patients remain unsuitable for LC. Two factors determine the need for PC: gallbladder pathology and patient-born risks. The first depends on the presence of gallstones or lack of, severity of inflammatory reaction, and time passed since the onset of symptoms. The second entails surgical risks determined by the scoring systems previously mentioned [12].

In this review, we discuss the main indications of PC, the results of this technique, and management of AC patients after PC, with a focus on grades II and III patients.

Table 1 Acute cholecystitis classification based on severity of the disease (Tokyo Guidelines 13)[a]

Grades	Definition
I (mild)	No organ dysfunction
	Does not meet criteria for grade II or III
II (moderate) degree of local inflammation makes the operation difficult	Elevated WBC count (>18 000/mm^3)
	Duration of complaints >72 h
	Palpable tender mass in the right upper quadrant
	Marked local inflammation (gangrenous cholecystitis, pericholecystic abscess, hepatic abscess, biliary peritonitis, and emphysematous cholecystitis
III (severe) inflammation causes systemic organ dysfunction	Cardiovascular dysfunction: hypotension requiring treatment with dopamine ≥5 lg/kg per min, or any dose of norepinephrine
	Neurological dysfunction: decreased level of consciousness
	Respiratory dysfunction: PaO_2/FiO_2 ratio <300
	Renal dysfunction: oliguria and creatinine >2.0 mg/dl
	Hepatic dysfunction: PT-INR >1.5
	Hematological dysfunction: platelet count <100 000/mm^3

[a]Modified from Okamoto *et al.* [8].

Indications of percutaneous cholecystostomy

In radiology literature, the main indication for percutaneous cholecystostomy is defined as AC whether calculous or acalculous. Approximately 95% of PCs are performed for this indication. Other indications are only valid when direct access to biliary tract cannot be performed via endoscopic or percutaneous transhepatic biliary route, for example, acute cholangitis, a need to dilate biliary strictures, or stenting for malignant lesions [13].

Table 2 Charlson Comorbidity Index[a]

Assigned weights for diseases[b]	Conditions
1	Myocardial infarction
	Congestive heart failure
	Peripheral vascular disease
	Cerebrovascular disease
	Dementia
	Chronic pulmonary disease
	Connective tissue disease
	Peptic ulcer disease
	Mild liver disease
	Diabetes mellitus (uncomplicated)
2	Hemiplegia
	Moderate or severe chronic kidney disease
	Diabetes mellitus with end-organ damage
	Any solid tumor
	Leukemia
	Malignant lymphoma
3	Moderate or severe liver disease
6	Metastatic solid tumor
	AIDS

[a]Modified from Okamoto *et al.* [8]. [b]The total equals the score.

From the surgical point of view, indications for PC are mostly described under the title of treatment of ACC. When we mention indications of PC, we are in fact talking about treatment of ACC. Accordingly, we must first discuss treatment of AC in detail.

Treatment of AC depends on disease severity. In addition to this, a patient's condition, comorbidities, and surgical risk determine their treatment strategy.

Based on disease severity, treatment of grade I patients is LC after onset of the disease, if CCI and ASA-PS are, respectively, 5 and class II or less, but if CCI is more than 5 and ASA-PS is more than class II, initial medical treatment must be performed and after improvement, LC [8].

Grade II patients are given supportive care and antibiotics immediately, and if advanced LC technique is available, and the patient has CCI less than or equal to 5 and ASA-PS less than or equal to II, early LC should be considered. If a patient's inflammatory findings do not improve after medical treatment, urgent or early gallbladder drainage must be considered. However, if inflammatory findings resolve after medical treatment, but patient has CCI more than 5 and/or ASA-PS more than II, delayed LC must be considered [8].

Grade III AC means that organ dysfunction accompanies AC, as shown in Table 1. Early or urgent LC may be considered under intensive care treatment, if the patient meets the criteria of CCI less than 4 and ASA-PS less than 3, favorable organ failure, and non-negative predictive factors and being treated in an experienced center. If the patient does not meet these criteria, gallbladder drainage is indicated. Cholecystectomy is indicated after clinical improvement [8,14].

For grades II and III patients who do not improve with medical therapy or are high risk for surgery, PC may be performed. We can list the indications of PC as follows:

(1) Failure to improve after medical treatment.
(2) Severe sepsis or systemic inflammatory response syndrome.
(3) Advanced age.
(4) Gallbladder empyema.
(5) Refusing surgery.
(6) Suspected necrosis or perforation of gallbladder.
(7) Use of systemic anticoagulation.
(8) Late presentation [15–20].

A recent systematic review describes that if a patient is considered high risk for surgery, whether due to medical illnesses or systemic consequences of AC, we must keep PC in mind for these patients [15].

However, there are some unclear points in TG18. For example, if surgery has not been performed in a grade II patient because of CCI more than 6 or ASA-PS more than 3, TG18 advises performing LC after clinical improvement. However, a six-point CCI can include permanent medical problems, including leukemia or congestive heart failure ; as such, how can a patient become low surgical risk after a waiting period of, for example, 6–8 weeks? Even if inflammatory changes and related organ failures improve by the end of week 6, a patient will still remain high risk for surgery, and surgery will be contraindicated because of their high CCI or ASA-PS score. In TG18, observation is described as an alternative to delayed LC for grade III patients [8]. However, what should we do in the case of grades I and II patients with a poor performance status at the end of the waiting period for delayed cholecystectomy? Observation can be a good alternative for such patients who are unmentioned in TG18.

Risk factors used for selecting a treatment strategy for acute cholecystitis

The CCI, ASA-PS, and predictive factors are the main parameters used for determining the treatment strategy of AC. The CCI categorizes a patient's comorbidities based on International Classification of Diseases codes. Each comorbidity has a weight depending on mortality rate. The total of all weightings gives a single score (Table 2).

The ASAs physical status is an index that provides understanding of a patient's health status before surgery.

In TG13, any of the system dysfunctions, including cardiovascular, neurologic, respiratory, renal, hepatic, or hematologic systems, was accepted as a contraindication to surgery in patients with AC. LC is also contraindicated in these patients [5]. However, in a multicentric retrospective study, Endo and colleagues demonstrated that jaundice, neurologic dysfunction, and respiratory dysfunction were predictors of 30-day mortality. Without these factors, no differences were found in mortality rates between the cholecystectomy and cholecystectomy after gallbladder drainage groups, although when one of these factors was present, mortality increased

significantly in the cholecystectomy group. The study also showed CCI and low BMI as predictive factors of 30-day mortality rates in grades I and II patients [21]. Endo and colleagues concluded that for grade III patients with no negative predictive factors, cholecystectomy can be performed without increasing mortality. Based on these findings, TG18 defines neurological dysfunction, respiratory dysfunction, and jaundice (total bilirubin $\geq$2 mg/dl) as negative predictive factors, and renal and cardiovascular dysfunction as favorable organ system failure or non-negative predictive factors, as they can be mostly corrected by initial treatment [8].

Optimal timing for percutaneous cholecystostomy

The timing of PC depends on response to medical therapy for patients who are not candidates for surgery at admission. Chou and colleagues compared the results of PCs performed within less than 24 and more than 24 h. They demonstrated that the early PC group had significantly less bleeding due to the procedure (P=0.018) and a shorter hospital stay (P=0.001). In the early group, the main indications for PC were sepsis and local rupture of gallbladder, whereas in the late group, the indications for PC were progressive abdominal pain and persistent fever. Mortality was higher in the early group, but the difference was not significant (7.3 vs. 5%, P=0.572), and the cause of mortality was not procedure related [22]. Chou and colleagues concluded that early PC may be more suitable for patients with sepsis, septic shock, fever, and gallbladder rupture.

In another study, Bickel and colleagues showed that the conversion to open surgery rate is significantly lower in early PC performed patients (<48 h) compared with the late group (>48 h), based on time from onset of pain (8.3 vs. 33.3%, P=0.09). When comparing readmissions, the rate was 16 and 40.4% in the early group and late group, respectively (P=0.047). The authors also concluded that early PC reduces inflammatory process and resulting adhesions and fibrosis [23].

Based on these findings, we propose that when a surgeon decides not to operate on a patient with AC owing to comorbidities or severity of acute illness, the PC procedure may be performed at an early period of admission (within 24–48 h). Accordingly, evaluation of a patient's response to medical therapy must be done within 24 h. Some authors advise evaluating a patient's response at the end of the third or fourth dose of antibiotics [24].

Management of cholecystostomy tube

There is no clear data about the management of cholecystostomy tubes. Questions including whether the tube should be clamped after improvement of a patient's condition, or the tube kept open until cholecystectomy, or if cholangiography should be performed before clamping the tube, even when to perform cholecystectomy, and to whom, are still not clearly answered in the literature. Most of the studies are retrospective, and there are no comparative data for each parameter.

Boules and colleagues reviewed the data of 380 patients with cholecystostomy tubes. Of these, 244 patients had PC only, 125 patients had cholecystectomy after PC, and 11 patients had reinsertion of the tube. The mean age was 65.3±14.2 years, and CCI was 3.2±2.1 in this study. The readmission rate was 3.7% after PC tube placement. The mortality rate was 60.7% in the PC-only group. Elective cholecystectomy could be performed in 32.9% of patients, of whom LC could be performed in 56.8% cases. The average time between PC to surgery was about 15 weeks. The tube-related complication rate was 22.6%, the most common complication being tube dislocation [16].

Bundy and colleagues reviewed the results of 324 patients. The technical success was 100%, the mortality rate was 29%, and elective cholecystectomy could be performed in 29.6% of patients. Complication of cholecystostomy tube was seen in 9% [18]. In another study, the mortality rate was reported as 4.7%. This lower rate was explained by excluding patients with acalculous cholecystitis in that study. The catheter was removed within a median time of 12 days but the range was too variable (0–193). Routine cholangiography was performed after tube insertion until demonstrating the passage of contrast material to the duodenum. Cholecystectomy was not advised if contrast has not passed to the duodenum [17].

Molavi and colleagues reported the results of 140 patients. The mortality rate was not mentioned. Elective cholecystectomy had been performed in 31.4% of patients, most of which was LC. Readmission owing to catheter-related complications was 15%, and for recurrent cholecystitis, it was 7.1% [25].

Joliat and colleagues had evaluated the results of 105 elderly patients with AC. A total of 28 patients were treated with PC, but about one-third of patients required emergent cholecystectomy due to failure of PC. Mortality was 5.5% in this group. The authors compared antibiotic alone and PC group in patients with AC who were treated conservatively. Morbidity and length of hospital stay were greater for the latter group [19].

Aroori and colleagues reviewed the results of 53 patients with PC. The main indications were presence of multiple comorbidities, sepsis, and patient refusal of surgery. Elective cholecystectomy could be performed in 45.2% of patients. The authors routinely evaluated the catheter via cholangiogram after sepsis resolved and kept the tube in place until the operation either clamped or open [20].

When comparing elderly and nonelderly patients who had received PC, the authors found that the overall survival rate of recurrent cholecystitis in patients who had not undergone definitive therapy (cholecystectomy) did not differ between the two groups. In the elderly group, PC resulted in shorter hospital stays and morbidity compared with cholecystectomy. Cholecystectomy could be performed in 61.2% of patients. In this study, mortality was due to comorbidities but not PC insertion [26]. Patients who had undergone interval cholecystectomy had fewer recurrent biliary events (7%) compared with the noninterval cholecystectomy group (21%) in patients with PC. For the latter group, cholecystectomy was performed only in the case of persistent symptoms. Recurrent biliary events were seen in 6.8 and 21.1% in the cholecystectomy group and noncholecystectomy groups, respectively, in a cohort of 288 patients [27].

Younger patients were more likely to receive interval cholecystectomy [27–29]. When patients with calculous and acalculous AC treated with PC were compared, no difference was found in terms of complications and mortality between these groups [30]. Severity of AC, duration of antibiotics, and PC treatment were related to an increased risk of recurrence [30]. Ongoing SIRS at 72 h after PC was found to be associated with mortality [29] (Table 3).

In 2018, Elsharif and colleagues published a systematic review regarding PC and its management. They evaluated the results published before 2017 of 46 different series of patients from 20 different centers. Only two of them were a prospective study. The median duration of drainage ranged from 7 to 49 days. In 33% of the studies, the catheter was removed after cholangiographic evaluation. The mortality rate was highly variable (0–35.8%). This high mortality was mostly owing to including patients with acalculous cholecystitis in these series. Surgery could be performed in 0 to 100% (mean 37.8) of patients. Timing of surgery was at least 5 weeks later than PC tube insertion time in most of the studies. Conversion to open surgery rate was 2.8–37.5% [15].

In patients with grades I and II ACC with CCI more than or equal to 6 and ASA-PS more than or equal to 3, and patients with grade III ACC with CCI more than or equal to 4 and ASA-PS more than or equal to 3, besides medical and supportive therapy, PC may be a life-saving procedure. Other indications for PC are advanced age, gallbladder empyema, late presentation, patient refusal of surgery, use of systemic anticoagulation, suspected necrosis or perforation of gallbladder, and inexperience of the surgeon (or center) in LC. It is recommended to make a decision about PC tube placement in patients with ACC within the early

Table 3 Studies reporting clinical results in percutaneous cholecystectomy performed patients

References	Patient number (*n*)	Mortality (%)	Complication (%)	Cholecystectomy (%)	Time to cholecystectomy (weeks)	Readmission for any reason	Cholangiographic evaluation
Boules *et al*. [16]	380	60.7	22.6	32.9	17	–	+
Bundy *et al*. [18]	324	29	9	29.6	–	–	+
Horn *et al*. [17]	278	4.7	37	31.8	–	23.5%	+
Molavi *et al*. [25]	140	–	–	31.4	–	22.1%	–
Joliat *et al*. [19]	28	3.5	29	64	At least six	5.2%	–
Aroori *et al*. [20]	53	9.3	–	45.2	At least six	18%	+
Lin *et al*. [26]	99	11.1	–	61.2	–	27.7%	–
Alvino *et al*. [27]	288	9.0	6.6	36	–	28%	–
Cooper *et al*. [28]	30	43.0	53	43.3	16	33%	–
Kim *et al*. [30]	144	–	4	33.6	16±7	6%	+
Wang *et al*. [31]	184	–	–	54.35	–	9.2%	–

period of disease (<48 h or at the end of the third or fourth dose of antibiotics), especially in septic (+/−shock) patients and patients with a ruptured gallbladder.

Of course, as in all invasive procedures, PC has some complications (4–37%), the most common being catheter displacement. Bile leak, peritonitis, and hemorrhage are other common complications. After inserting a PC tube, management is a bit controversial. First, clinicians have to wait until the septic condition of patient completely resolves. After clinical improvement, most centers evaluate the patency of cystic duct via cholangiogram. If contrast material passes to the duodenum, the catheter may be kept closed until elective cholecystectomy, recurrence of symptoms, or septic findings. Otherwise, if contrast material does not pass to the duodenum, or a blockage exists in the common bile duct, the catheter must be kept open. If stone is present in the common bile duct, clearance can be achieved through endoscopic retrograde cholangiographic interventions. Some authors advocate waiting at least 2–3 weeks for the formation of tract around the catheter to prevent bile leakage, etc., before retrieval of the catheter. Others kept in place until elective cholecystectomy. In fact, clinicians may not have strict rules for this, and so decisions may be given on an individual basis.

Other controversial points in management of PC-performed patients include whether or not to do cholecystectomy, and if so, the optimal timing for this. In a recently published clinical series, cholecystectomy could be performed in 29–64% of patients [29–32]. In almost all of the studies, cholecystectomy had been performed after a waiting period of at least 6–8 weeks. However, a significant portion of the patients could not be operated on owing to severe comorbidities or high surgical risk. This point is mentioned in TG18 for grade III patients, and for some, observation is advised instead of delayed cholecystectomy; however, for grades I and II patients, this point is missing. Observation may be an obligatory choice as well for grades I and II patients with severe comorbidities or high surgical risk, as determined by objective scoring systems (CCI and ASA-PS, etc.) at the end of the 6–8-week waiting period for delayed cholecystectomy. Some patients required early cholecystectomy after insertion of the PC tube, but this was owing to the failure of PC treatment or the patient's worsening clinical condition. Mortality in PC-performed patients with ACC is mostly due to severity of inflammation and resulting sepsis and organ failure, or severe comorbidities, and not to PC insertion.

Two factors determine the prognosis of patients with ACC: disease severity and patient comorbidities and surgical risk. In PC, we treat only the source of inflammation or infection but not a patient's chronic diseases or comorbidities. For this reason, determining the risk of surgery may be more important than grading of severity of ACC while planning the patient's treatment strategy at the first admission, and time of delayed cholecystectomy. In a recent study, we have demonstrated that plasma albumin level, ASA score, CCI, and American College of Surgeons' expected mortality rate can be used to predict mortality and decide on elective CCY [32].

In conclusion, PC is an alternative for ACC in selected patients. However, surgeons may be not able to perform cholecystectomy in all PC-performed patients. In other words, surgeons must accept the reality that ~60–70% of patients will never be operable for cholecystitis. This must not be seen as a negative fate of PC, but it is the fate of patient, for whom observation may be the only choice. Prospective randomized studies are needed to compare results of different approaches in patients with ACC with high surgical risk or grade of severity.

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Conflicts of interest
There are no conflicts of interest.

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