



# Management of high-surgical-risk patients with acute cholecystitis following percutaneous cholecystostomy: results of an international Delphi consensus study

Antonio Pesce, MD, PhD, FACS<sup>a,\*</sup>, Camilo Ramírez-Giraldo, MD<sup>b,\*</sup>, Nikolaos-Achilleas Arkoudis, MD<sup>c</sup>, George Ramsay, MD<sup>d</sup>, Georgi Popivanov, MD<sup>e</sup>, Kurinchi Gurusamy, MD<sup>f</sup>, Natalia Bejarano, MD<sup>g</sup>, Maria Irene Bellini, MD<sup>h</sup>, Massimiliano Allegritti, MD<sup>i</sup>, Jacopo Tesei, MD<sup>j</sup>, Alessandro Gemini, MD<sup>k</sup>, Augusto Lauro, MD<sup>h</sup>, Matteo Matteucci, MD<sup>k</sup>, Antonio La Greca, MD<sup>l</sup>, Valerio Cozza, MD<sup>l</sup>, Federico Coccolini, MD<sup>m</sup>, Marco Cannistra<sup>l</sup>, MD<sup>n</sup>, Carlo Boselli, MD<sup>o</sup>, Piero Covarelli, MD<sup>o</sup>, Gianluca Costa, MD<sup>p</sup>, Paolo Bruzzzone, MD<sup>q</sup>, Giovanni Domenico Tebala, MD<sup>l</sup>, Simona Meneghini, MD<sup>h</sup>, Vito D'Andrea, MD<sup>h</sup>, Andrea Mingoli, MD<sup>h</sup>, Eugenio Cucinotta, MD<sup>r</sup>, Antonia Rizzuto, MD<sup>s</sup>, Mauro Zago, MD<sup>t</sup>, Paolo Prosperi, MD<sup>u</sup>, Massimo Buononato, MD<sup>v</sup>, Gioia Brachini, MD<sup>h</sup>, Roberto Cirocchi, MD<sup>j,o</sup>

**Background:** The management of high-surgical-risk patients with moderate to severe acute cholecystitis is challenging in clinical practice. Early laparoscopic cholecystectomy is considered the gold standard for patients who do not respond to conservative treatment. However, for those unfit for surgery due to high risk, alternative treatment options, such as percutaneous cholecystostomy (PC), are available. There are no clear guidelines regarding the management of patients following PC. The primary aim of this study was to propose indications for PC in high-surgical-risk patients with acute cholecystitis and to establish management strategies for gallbladder drainage, either as a bridge to surgery or as a definitive treatment, according to available literature.

**Materials and methods:** After a targeted literature review, International and Italian experts in the field from the Italian Society of Research in Surgery (SIRC) and the Italian Society of Emergency Surgery and Trauma (SICUT) were consulted to provide their evidence-based opinions on the topic. Statements were proposed during subsequent rounds using the Delphi methodology. Ten statements were provided, and the final agreement is presented in this study.

**Results:** Patients with moderate acute cholecystitis, a Charlson Comorbidity Index (CCI)  $\geq 6$ , and American Society of Anesthesiologists-Performance Status (ASA-PS)  $\geq 3$  who fail conservative treatment should undergo laparoscopic cholecystectomy as the first-line approach. For those with severe acute cholecystitis at high-surgical risk, percutaneous cholecystostomy is recommended to relieve symptoms within 24–48 hours. Once the infection is controlled, we should assess which patients may be candidates for interval laparoscopic cholecystectomy. For patients selected for surgery, laparoscopic cholecystectomy is recommended at least six weeks after PC placement. In patients not suitable for surgery, such as those with CCI  $\geq 6$  and ASA-PS  $\geq 4$ , percutaneous cholecystostomy should remain in place for at least three weeks, after which, following radiographic confirmation of biliary tree patency, the tube may be removed.

**Conclusions:** This consensus, developed through a multidisciplinary collaboration of interventional radiologists, gastroenterologists, and surgeons, provides a clear and practical guide for managing high-risk surgical patients with acute cholecystitis.

**Keywords:** acute cholecystitis, bridge to surgery, definitive treatment, high-surgical risk, interval cholecystectomy, percutaneous cholecystostomy, radiological approach, timing, trans-tube cholangiography

<sup>a</sup>Department of Surgery, Azienda Unità Sanitaria Locale Ferrara, University of Ferrara, Lagosanto (FE), Italy, <sup>b</sup>Hospital Universitario Mayor – Méderi, Bogotá, Colombia, <sup>c</sup>Research Unit of Radiology and Medical Imaging, 2nd Department of Radiology, Medical School, National and Kapodistrian University of Athens, Athens, Greece, <sup>d</sup>Health Services Research Unit, University of Aberdeen, Aberdeen, United Kingdom, <sup>e</sup>Department of Surgery, Military Medical Academy, Sofia, Bulgaria, <sup>f</sup>Division of Surgery and Interventional Science, University College London, London, United Kingdom, <sup>g</sup>Hepato-Bilio-Pancreatic Surgery Unit, General and Digestive Surgery Service, Hospital Universitari Parc Taulí, Universitat Autònoma de Barcelona (UAB), Sabadell, Barcelona, Spain, <sup>h</sup>Department of Surgery, Sapienza University of Rome, Rome, Italy, <sup>i</sup>Interventional Radiology Unit, AOSSP Santa Maria di Terni, Terni, Italy, <sup>j</sup>Department of Digestive and Emergency Surgery, “S. Maria” Hospital, Terni, Italy, <sup>k</sup>Department of Medicine and Surgery, University of Milan, Milan, Italy, <sup>l</sup>Department of Trauma and Emergency Surgery, Fondazione Policlinico Universitario A. Gemelli IRCCS, Rome, Italy, <sup>m</sup>General, Emergency and Trauma

Surgery, Pisa University Hospital, Pisa University, Pisa, Italy, <sup>n</sup>Chirurgia Generale, Ospedale S. Giovanni di Dio, Crotone, Italy, <sup>o</sup>Department of Medicine and Surgery, University of Perugia, Perugia, Italy, <sup>p</sup>Dipartimento di Scienze della Vita, della Salute e delle Professioni Sanitarie, Università degli Studi Link Campus University, Roma, Italy, <sup>q</sup>Department of General and Specialist Surgery, Sapienza University of Rome, Rome, Italy, <sup>r</sup>Department of Human Pathology of the Adult and Evolutive Age “Gaetano Barresi,” Section of General Surgery, University of Messina, Via Consolare Valeria, Messina, Italy, <sup>s</sup>Department of Medical and Surgical Sciences, Magna Græcia University, Catanzaro, Italy, <sup>t</sup>General Surgery Department, Lecco Hospital, Lecco, Italy, <sup>u</sup>General, Emergency and Minimally Invasive Surgery Unit, Careggi University Hospital, Florence, Italy and <sup>v</sup>Department of General and Emergency Surgery, S. Maria della Stella Hospital, Località Ciconia, Orvieto (TR), Italy.

AP and CR contributed equally to this article. AP and CR are listed as co-first authors due to comparable contributions to study.

## Background

Early laparoscopic cholecystectomy is considered the gold standard for patients with acute cholecystitis. Current guide-lines from the World Society of Emergency Surgery (WSES)<sup>[1]</sup> suggest performing surgery within 7 days of hospital admission and within 10 days of symptoms onset, while the Tokyo Guidelines 2018 (TG18)<sup>[2]</sup> recommends surgery within 24–72 h of symptom onset. However, for critically ill patients or those unfit for surgery due to high-surgical risk, drainage treatment options such as percutaneous cholecystostomy (PC) may be beneficial<sup>[2]</sup>. Therefore, stratifying frail and high-surgical risk patients is essential for planning optimal management. The American Society of Anesthesiologists (ASA) score and the Charlson Comorbidity Index (CCI) are well-known tools that are very useful in daily clinical practice<sup>[3–5]</sup>. Percutaneous cholecystostomy is generally considered a safe and effective procedure for draining the gallbladder in patients who are not candidates for surgery or who require temporary symptom relief. Cholecystostomy often relieves pain caused by distension and helps reduce inflammation. It is particularly beneficial for gallbladder obstructions, such as stones lodged in the gallbladder neck accompanied by hydrops or empyema. However, it can be disadvantageous in cases of gangrenous cholecystitis. Moreover, like any medical procedure, it carries risks, including infection, bleeding, and catheter-related complications<sup>[6,7]</sup>. Furthermore, there are no clear guidelines regarding the management of patients following PC.

The primary aim of this consensus conference was to propose indications for PC in high-surgical-risk patients with a diagnosis of moderate to severe AC and to establish management strategies for gallbladder drainage, either as a bridge to surgery or as definitive treatment, according to available scientific evidence.

## Methods

In October 2023, the Italian Society of Research in Surgery (SIRC) and the Italian Society of Emergency Surgery and Trauma (SICUT) organized a joint consensus conference and established a Promoting Committee that included members from both scientific societies. This consensus conference adhered to the standards set by the Consensus Development Program of the United States' National Institutes of Health (NIH) and the guidelines of the Italian national system. The conference employed the classic Delphi method, a qualitative research approach designed to gather and refine expert opinions to achieve strong group consensus<sup>[8,9]</sup>. The conference chairs and Promoting Committee selected members for the expert

\*Corresponding Authors. Address: Department of Surgery, Azienda USL of Ferrara – University of Ferrara, Via Valle Oppio, 2 – 44023 Lagoneto (FE), Italy. Tel.: +39 3286680943. E-mail: nino.fish@hotmail.it (A. Pesce); Hospital Universitario Mayor Méderi - Universidad del Rosario, Calle 24 #29 – 45, Bogotá, Colombia. Tel.: +57 320 677 0474. E-mail: ramirezgiraldocamilo@gmail.com (C. Ramírez-Giraldo).

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## HIGHLIGHTS

- The management of high-surgical-risk patients with moderate to severe acute cholecystitis is challenging in clinical practice.
- Early laparoscopic cholecystectomy is considered the gold standard for patients who do not respond to conservative treatment. However, there are still no clear guidelines regarding the management of patients following percutaneous cholecystostomy.
- This study proposes management strategies for gallbladder drainage, either as a bridge to surgery or as definitive treatment for high-surgical-risk patients with acute cholecystitis, based on available scientific evidence and a multidisciplinary consensus of international experts on the topic.
- The results of this consensus may offer a straightforward and safe guide for surgeons and radiologists when managing high-risk surgical and frail patients with moderate to severe acute cholecystitis.

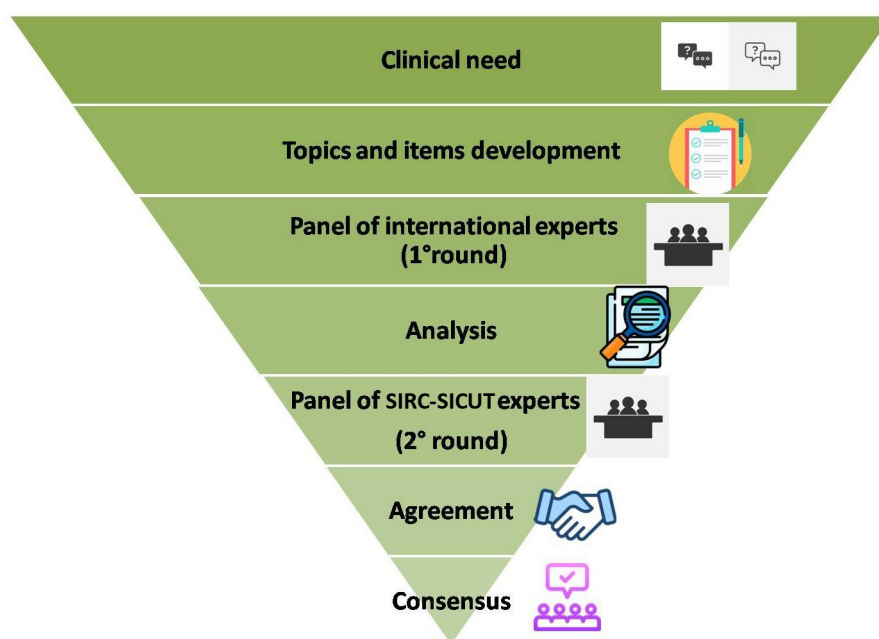
panels, determined the topics, and developed items for expert evaluation.

A targeted review of the literature was performed using the following primary search strategy: “cholecystitis,” “acute,” “abdominal,” “infection,” “resuscitation,” “adult,” “hemodynamic instability/stability,” “critical,” “unfit,” “surgery,” “management,” and “follow-up,” combined with AND/OR. No search restrictions were applied. The search included published abstracts of clinical trials, consensus conferences, comparative studies, guidelines, multicenter studies, systematic reviews, meta-analyses, original articles, and randomized controlled trials.

Subsequently, international and Italian experts in the field, from the Italian Society of Research in Surgery (SIRC) and the Italian Society of Emergency Surgery and Trauma (SICUT), were consulted to provide their evidence-based opinions on the topic and the proposed statements during the Delphi rounds. We included in this consensus specific experts, primarily critical care surgeons, followed by interventional radiologists and gastroenterologists from high-volume centers. First, the conference chairs and the Promoting Committee identified the following strategic objectives:

- Number of Rounds: 3
- Panel Size (Number of Expert Panelists): 120
- Required Agreement Level for Statements (2nd and 3rd Rounds): ≥ 80%

In February 2024, the first round was conducted to gather opinions from international expert panelists; during this phase, closed-ended questions were converted into open-ended ones. The questionnaire was sent to 60 international experts, achieving a response rate of 73.3%. Responses from this first round were independently evaluated by two external reviewers and subsequently reported to the Promoting Committee, which used the findings to develop revised statements for the second round. In the second round (June 2024), expert panelists were asked to rate their level of agreement with each statement on a Likert scale. A new questionnaire with ten closed-ended



**Figure 1.** Schematic representation of the stepwise Delphi methodology, which used to achieve consensus.

questions was sent to 30 expert panelists from the Italian Society of Research in Surgery (SIRC) and the Italian Society of Emergency Surgery and Trauma (SICUT), achieving a response rate of 90%. In the second round of discussion, the number of experts decreased due to the fact that the interested local experts would be the same ones attending most likely the third round in person during the congress conference. Moreover, only the experts who completed the previous round have been invited to participate in the subsequent rounds. After each round, the manuscript and statements were revised and improved. The final version was discussed during the 126th Joint Congress of the Italian Society of Surgery (SIC) and the SIRC National Congress on 15 October 2024, in Rome, Italy. During this discussion, the statements were considered accepted if they reached at least 80% consensus. The *Woodclap platform* was used for final agreement through real-time interaction: speakers presented each statement, and participants provided instant feedback using their devices (smartphones, tablets, or laptops). Votes were categorized as “agree,” “neutral,” or “disagree” according to the Likert scale method. The percentage of agreement was recorded immediately; in case of disagreement, the statement was modified following discussion. The stepwise Delphi methodology used to achieve consensus is illustrated in Fig. 1. A summary of the final statements is presented in Fig. 2. A practical flow-chart for the management of high-surgical-risk and frail patients with moderate to severe AC was also proposed and shown in Fig. 3.

## Results

### Indications to percutaneous cholecystostomy

**Statement 1:** *Laparoscopic cholecystectomy should be considered as the first option in patients with moderate AC, according to the 2018 Tokyo Guidelines, who have failed conservative*

*treatment, with a CCI  $\geq 6$  and an American Society of Anesthesiologists-Physical Status (ASA-PS)  $\geq 3$ , particularly if gangrenous or emphysematous cholecystitis is suspected.*

*PC should be considered as a second choice.* (The percentage of agreement for both statements was 93%.)

Moderate AC (Grade II) is defined by the Tokyo Guidelines 2018 as cholecystitis that exhibits certain clinical features suggesting a more severe infection than mild (Grade I) but without the critical organ dysfunction observed in severe (Grade III) cases. According to the TG18 criteria<sup>[1]</sup>, moderate (Grade II) AC includes patients who meet any of the following conditions: elevated white blood cell count (WBC)  $> 18,000/\text{mm}^3$ ; palpable tender mass in the right upper quadrant of the abdomen; duration of symptoms for more than 72 h; or marked local inflammation identified on imaging, such as pericholecystic fluid, abscess formation, or gangrenous changes in the gallbladder. We acknowledge the importance of clearly defining the appropriate timing for surgery in high-risk surgical patients who do not respond to antibiotic therapy. We suggest that the decision to proceed with cholecystectomy should be made within 72 hours of initiating antibiotics if there are no signs of clinical or biomolecular improvement. This is based on evidence indicating that a delay beyond this timeframe may increase the risk of complications, including disease progression and a more complex surgical course<sup>[1,2]</sup>.

Patients with moderate AC are best treated with laparoscopic cholecystectomy<sup>[1,9,10]</sup>. Surgery provides better outcomes and the medical costs are significantly lower than those of PC<sup>[9,10]</sup>. The multicenter randomized controlled CHOCOLATE clinical trial in 2018 confirmed that laparoscopic cholecystectomy reduces the rate of major complications (infectious and cardiopulmonary complications within one month), recurrent biliary disease and length of hospital stay compared with percutaneous cholecystostomy in high surgical



	Statements
<b>Indications to percutaneous cholecystostomy</b>	<i>Laparoscopic cholecystectomy should be considered as the first option in patients with moderate acute cholecystitis (AC), according to the 2018 Tokyo Guidelines, who have failed conservative treatment, with a Charlson Comorbidity Index (CCI) <math>\geq 6</math> and an American Society of Anaesthesiologists Physical Status (ASA-PS) <math>\geq 3</math>, particularly if gangrenous or emphysematous cholecystitis is suspected. Percutaneous cholecystostomy (PC) should be considered as a second choice.</i>
	<i>Percutaneous cholecystostomy should be considered in patients with severe AC, according to the 2018 Tokyo Guidelines, who have failed conservative treatment, with a Charlson Comorbidity Index (CCI) <math>\geq 6</math> and an American Society of Anaesthesiologists Physical Status (ASA-PS) <math>\geq 3</math>.</i>
<b>Timing for percutaneous cholecystostomy</b>	<i>When percutaneous cholecystostomy is chosen for the management of acute cholecystitis, it should be done as soon as the patient's clinical conditions allow, preferably within 24-48 h.</i>
<b>Approach for percutaneous cholecystostomy</b>	<i>The transhepatic and transperitoneal routes are both acceptable, depending on the expertise of the single center and local policies.</i>
<b>Management of percutaneous cholecystostomy</b>	<i>Trans-tube cholangiography is strongly suggested in patients with recurrent abdominal pain and suddenly reduced amount of bile drainage and in the presence of tube dislodgement suspicion.</i>
	<i>The performance of a "clamping test" is not mandatory. It is essential to carry out a trans-tube cholangiography to assess the patency of the biliary tree, and, if it is patent, the cholecystostomy tube can be removed; otherwise, it should be continued.</i>
	<i>Routine trans-tube cholangiography may be performed before removal at least 3 weeks (to allow for a mature tract) after PC placement to confirm the patency of the biliary tree, in cases of failed clamping test (if performed).</i>
<b>Percutaneous cholecystostomy as definitive treatment without Interval Cholecystectomy</b>	<i>PC may be a definitive treatment without delayed interval cholecystectomy in AC patients who are unfit for surgery: CCI <math>\geq 6</math> and/or ASA-PS <math>\geq 4</math>.</i>
<b>Early interval cholecystectomy</b>	<i>Early interval cholecystectomy (&lt;30 days) is associated with an increased risk for postoperative complications and more difficult surgery.</i>
<b>Delayed interval cholecystectomy</b>	<i>If delayed laparoscopic cholecystectomy is planned, the PC should be left in situ until surgery, at least 6 weeks after PC placement.</i>

**Figure 2.** Summary of the ten final proposed statements that achieved at least 80% agreement.

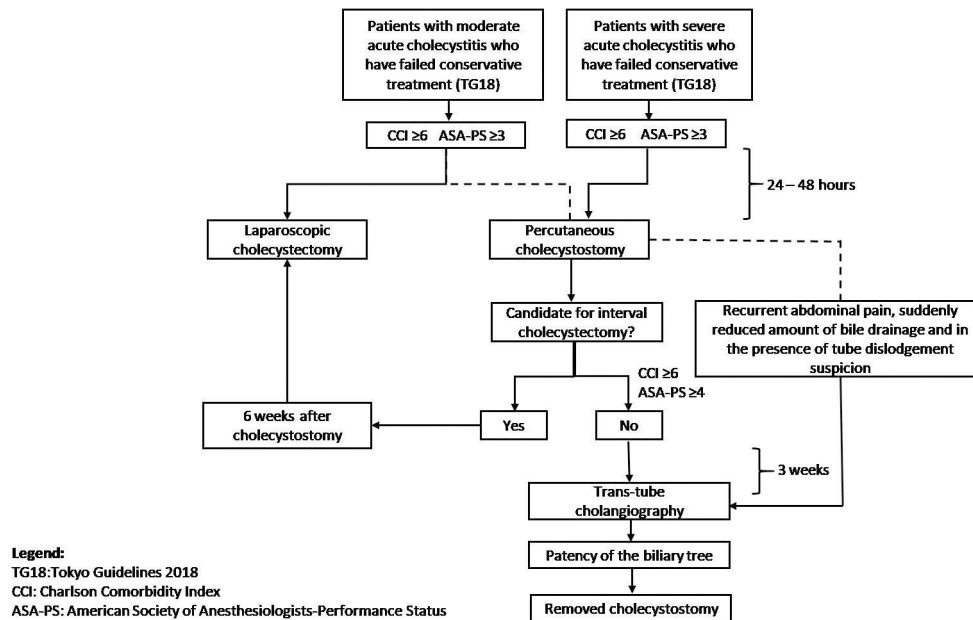
risk patients with AC<sup>[10]</sup>. In the CHOCOLATE study, the high risk was defined as an APACHE II (acute physiology assessment and chronic health evaluation II) score of 7 or more. In this consensus the expert panel decided to use CCI  $\geq 6$  and ASA-PS  $\geq 3$  to define patients' surgical risk, as these criteria are more commonly used and straightforward in daily clinical practice.

LC is generally considered safe in these patients, while percutaneous cholecystostomy should only be used in cases where the patient is truly unfit for surgery, given the complications associated with cholecystostomy, such as tube dislodgment, recurrence of biliary disease, and negative impacts on quality of life. Pavurala, *et al*<sup>[3]</sup> reported that, by analyzing a large Nationwide Readmission Database in Ohio (USA), approximately 2% of all

patients with acute calculous cholecystitis needed percutaneous cholecystostomy. However, the majority ( $n = 1971$ ; 60%) of patients who received this supposedly temporary gallbladder drainage did not undergo subsequent cholecystectomy within one year. Moreover, percutaneous cholecystostomy is not recommended as the first approach in cases with suspected gangrenous cholecystitis or biliary peritonitis.

**Statement 2:** *Percutaneous cholecystostomy should be considered in patients with severe AC, according to the 2018 Tokyo Guidelines, who have failed conservative treatment, with a CCI  $\geq 6$  and an ASA-PS  $\geq 3$ .* (The percentage of agreement was 98%.)

Severe AC (Grade III), according to the Tokyo Guidelines (TG18), is characterized by acute cholecystitis associated with



**Figure 3.** A practical flowchart illustrating the management approach for high-surgical-risk and frail patients with moderate to severe acute cholecystitis.

organ dysfunctions (cardiovascular, respiratory, neurological, renal, hepatic, or hematological) due to systemic inflammation. This is the most serious form of cholecystitis and requires urgent, often intensive, medical intervention. In specific subgroups of patients with high-surgical risk, with a CCI  $\geq 6$  and an ASA-PS  $\geq 3$ , particularly those experiencing sepsis or septic shock due to severe AC, general anesthesia could significantly increase their instability<sup>[1]</sup>. Administering general anesthesia in such cases can worsen hemodynamic instability, increase the risk of organ failure, and elevate postoperative complications. The TG18 guidelines define neurological dysfunction, respiratory dysfunction and hepatic alterations as negative predictive factors in Grade III AC and they are associated with increased surgical mortality rates within 30 days of surgery<sup>[1]</sup>. Moreover, this category of patients has a higher probability of being admitted to the intensive care unit (ICU), which could represent a significant contraindication to immediate surgery. For high-surgical-risk patients, the key is to stabilize sepsis and organ dysfunction before considering surgical interventions that require general anesthesia. Early recognition and alternative interventions such as PC can significantly improve outcomes<sup>[11–14]</sup>. So, early gallbladder drainage should be considered if it is not possible to control the infection with conservative medical treatment (antibiotics and general supportive care) in high-surgical-risk patients.

### Timing for PC

**Statement 3:** When PC is chosen for the management of AC, it should be done as soon as the patient's clinical conditions allow, preferably within 24–48 h. (The percentage of agreement was 98%.)

When considering patients with high-surgical risk who are not fit for surgery, the placement of PC should be performed as soon as the patient's clinical condition allows. The optimal timing of PC is still a subject of debate. Chou, *et al*<sup>[15]</sup> reported on 209 consecutive patients, finding that early PC (within

24 hours) reduced hospital stay and procedure-related bleeding without increasing the mortality rate. In this study, the patients were divided into two groups based on the median time of PC placement: the early group (less than 24 hours) and the late group (more than 24 hours). The main indications for PC were sepsis and septic shock. The timing of PC must be related to the patient's clinical condition and discussed with anesthetists if the patients are admitted to the ICU. The procedure can also be performed under local anesthesia and sedation. In an observational retrospective study over 10 years of experience, Horn, *et al*<sup>[16]</sup> reported a low 30-day mortality rate (4.7%) for critically ill patients with AC. However, early PC (within 48 h compared to 3–6 days) seems to decrease the likelihood of delayed laparoscopic cholecystectomy (LC) conversion rates, regardless of the time interval to delayed LC<sup>[17]</sup>; this is possibly due to halting the propagation of the inflammatory process, fibrotic changes and their consequences<sup>[17]</sup>. Based on the available literature, once the decision regarding the necessity of draining the severely inflamed gallbladder is established, it is recommended to perform the procedure early, preferably within 24 to 48 h, considering the expertise of the radiology department at each center.

### Approach for PC

**Statement 4:** The transhepatic and transperitoneal routes are both acceptable, depending on the expertise of the single center and local policies. (The percentage of agreement was 80%.)

The two main routes for performing a PC are the transhepatic and transperitoneal approaches<sup>[18,19]</sup>. The transhepatic route involves passing through liver tissue to reach the gallbladder, which is why it is thought to carry a higher risk of bleeding complications. Nevertheless, it is believed to have a lower likelihood of bile leakage, increased safety in cases involving interposed bowel and significant ascites, improved catheter stability, and the potential to accelerate the maturation of the formed tract. In contrast, the transperitoneal route provides direct

access to the gallbladder without causing any damage to the liver. Therefore, it is commonly preferred for patients with liver disease and/or coagulopathy, as well as for those with acute acalculous cholecystitis following major cardiovascular surgery, who are typically on anticoagulant or antiplatelet therapy. However, it is important to recognize that the lack of liver tamponade in the transperitoneal method may be associated with a higher probability of bile spillage, which can lead to biliary peritonitis. Recent studies<sup>[20,21]</sup> have found no statistically significant differences in complication rates between the transhepatic and transperitoneal routes for PC. Importantly, an even more recent multicenter study<sup>[22]</sup> found the transperitoneal route to be safer than the transhepatic route, reporting a lower incidence of bleeding complications, fewer recurrences of acute cholecystitis, and fewer hospital readmissions. However, it is possible in only 1/5th of the cases because the lack of a free transperitoneal window (adherent duodenum, colon, or fistula respectively).

The operator's choice of anatomical approach for PC may also be influenced by the technique used (trocar or Seldinger) and vice versa<sup>[23]</sup>. For example, the multiple steps required with the Seldinger technique increase the risk of bile spillage during over-the-wire exchanges, which could be more significant if the transperitoneal approach is chosen due to the absence of liver tamponade. Additionally, when using the trocar technique, the larger diameter of the catheter may increase the risk of hemorrhagic complications, especially when traversing the liver parenchyma.

Therefore, although recent studies<sup>[24,25]</sup> have found both the trocar and Seldinger techniques for PC to be equally effective and safe, until larger patient cohorts are evaluated in more extensive trials, the transperitoneal approach may be more appropriate with the trocar technique, while the transhepatic approach may be better suited for the Seldinger technique<sup>[23,26]</sup>. Nevertheless, the route should be based on a case-by-case assessment, considering the anatomical structures and the patient's condition.

### Management of PC

**Statement 5:** *Trans-tube cholangiography is strongly suggested in patients with recurrent abdominal pain and suddenly reduced amount of bile drainage and in the presence of tube dislodgement suspicion.* (The percentage of agreement was 95%.)

Trans-tube cholangiography represents the best imaging method to confirm the correct position of the cholecystostomy, as well as cystic duct and common bile duct patency, although other imaging modalities, such as ultrasound (US) and abdominal computed tomography (CT), may be used in daily clinical practice to identify the location of the catheter<sup>[27–29]</sup>. Although these options are not ideal, they can be useful if cholangiography is not accessible for any reason (e.g., allergy to iodinated contrast medium, contraindications to radiation) or to address immediate concerns until cholangiography can be performed. Additionally, these modalities may help identify or exclude other causes of abdominal pain, such as complications related to PC.

**Statement 6:** *The performance of a “clamping test” is not mandatory. It is essential to carry out a trans-tube cholangiography to assess the patency of the biliary tree, and, if it is patent, the cholecystostomy tube can be removed; otherwise, it should*

*be continued.* (The percentage of agreement was 100%.)

The “clamping test” is not performed at every center, and clinical practice lacks a standardized procedure. Trans-tube cholangiography can accurately assess the patency of the biliary tree, including the cystic duct and common bile duct. It is important to note that the assessment of biliary tree patency should include both the cystic duct and common bile duct, with visualization of the duodenum. Regarding asymptomatic patients being considered for percutaneous cholecystostomy (PC) tube removal, most physicians perform cholangiography in combination with clamping tests, as both the patency demonstrated on the cholangiogram and tolerance to the clamping test are essential factors before removing the PC tube<sup>[18]</sup>.

**Statement 7:** *Routine trans-tube cholangiography may be performed before removal, at least 3 weeks (to allow for a mature tract,) after PC placement, to confirm the patency of the biliary tree, in cases of a failed clamping test (if performed).* (The percentage of agreement was 95%.)

There are currently no established guidelines regarding the timing of tube removal after PC placement. PC catheter removal is typically performed when cholecystostomy is considered a definitive treatment for very high-surgical risk patients. If the ultimate treatment is a delayed interval cholecystectomy, the catheter is often removed during surgery. Most patients require approximately 2–3 weeks for complete tract maturation when PC placement is done through the transhepatic route and a minimum of 3 weeks when performed via the transperitoneal route<sup>[19,29]</sup>.

In some institutions, fistulography under fluoroscopy or CT guidance might not be performed, and PC removal occurs after an uneventful catheter clamping test. Some authors suggest that biliary tract imaging may not be mandatory in patients with small-bore gallbladder catheters who have recovered from critical illness and have had catheters in place for 3–6 weeks<sup>[29]</sup>. Kamezaki, *et al*<sup>[30]</sup> even suggested earlier removal of the PC catheter (7–10 days) if three conditions are met: (1) the inflammation is subsiding, (2) the cystic duct and common bile duct are visible on cholangiography, and (3) no intraperitoneal leakage is detected.

### PC as a definitive treatment without interval cholecystectomy

**Statement 8:** *PC may be a definitive treatment without delayed interval cholecystectomy in AC patients who are unfit for surgery: CCI  $\geq 6$  and/or ASA-PS  $\geq 4$ .* (The percentage of agreement was 98%.)

PC may represent a definitive treatment in patients truly unfit for surgery with a CCI  $\geq 6$  and/or ASA-PS  $\geq 4$ . In this category of patients, the risk of perioperative mortality is significantly higher compared to the risk of cholecystitis recurrence. Avoiding surgery in this population reduces the risk of postoperative complications and mortality. However, we decided to elevate the ASA score to 4 to classify patients with very high-surgical risk. Additionally, PC may be a definitive treatment option for patients with acalculous acute cholecystitis or those with an expected survival of less than 2 years, as the risk of recurrence decreases<sup>[11,31,32]</sup>. Deciding to forgo interval cholecystectomy should involve a detailed discussion between the patient, their family, and the healthcare team, with a clear outline of the risks and benefits.

### Early interval cholecystectomy

**Statement 9:** *Early interval cholecystectomy (<30 days) is associated with an increased risk for postoperative complications and more difficult surgery.* (The percentage of agreement was 95%.)

Interval cholecystectomy should be performed in patients following a cholecystostomy to prevent recurrent episodes of cholecystitis, particularly in those with a longer life expectancy<sup>[33–35]</sup>. Several considerations must be taken into account when performing LC after a cholecystostomy. First, the underlying reason that prevented an early laparoscopic cholecystectomy must be resolved, which may take a few weeks. Second, in cases where cholecystostomy was performed via a transhepatic approach, the liver must epithelialize the tract to prevent bleeding upon removal. Third, the inflammatory process in the gallbladder should be well-controlled.

Given these factors, we recommend waiting at least one month to ensure these conditions are met before performing a safe laparoscopic cholecystectomy. It has been observed that patients who undergo the procedure within 30 days may have a higher risk of mortality and complications<sup>[36,37]</sup>. In the study conducted by Woodward, *et al*, an adjusted relative risk of 1.09 (confidence interval: 1.02–1.33) was observed for the occurrence of surgical complications when interval cholecystectomy was performed within the first month following cholecystostomy<sup>[36]</sup>.

### Delayed interval cholecystectomy

**Statement 10:** *If delayed LC is planned, the PC should be left in situ until surgery, at least 6 weeks after PC placement.* (The percentage of agreement was 98%.)

The available evidence to assess the optimal timing for performing interval cholecystectomy is limited<sup>[37]</sup>. One of the main challenges in evaluating the data is the variability in the criteria used to determine the best time for surgery. However, it appears that an intermediate interval for cholecystectomy may be ideal. Performing the surgery too early poses the challenges previously discussed, while delaying it further has also been linked to an increased risk of complications<sup>[37]</sup>. Recently, Spaniolas, *et al*<sup>[37]</sup> evaluated interval cholecystectomies following cholecystostomy and found that performing the surgery within the first 7 weeks reduced the risk of bile duct injury, reoperation, readmission, image-guided intervention, endoscopic intervention, conversion to open surgery, or death. Similarly, Giannopoulos, *et al*<sup>[38]</sup>, when comparing interval cholecystectomy at  $\leq 8$  weeks versus  $>8$  weeks, found no significant differences in intraoperative outcomes (procedure duration, estimated blood loss, intraoperative events, conversion to open surgery, or intraoperative drain placement) or perioperative outcomes (emergency department visits, readmission, reoperation, bile leak, or reintervention). This statement addresses the dilemma of performing cholecystectomy within 7 days post-drainage, which reported better outcomes (relative risk, RR: 0.58, 95% confidence interval, 95% CI: 0.32–1.06) compared to a longer duration of percutaneous cholecystostomy (RR: 0.95, 95% CI: 0.50–1.81)<sup>[33]</sup>.

Sakamoto, *et al* found that the optimal timing for performing interval cholecystectomy was between 7 and 26 days, as it was associated with a reduction in morbidity and mortality. However, this study also has its limitations<sup>[38]</sup>. In the study by Noubani, *et al*<sup>[39]</sup>, the optimal timing for interval cholecystectomy was found to be between weeks 5 and 12, as it was associated with a shorter hospital stay. However, no difference was observed in

other outcomes, such as 30-day readmission, 30-day emergency department visits, or discharge destination<sup>[39]</sup>. Lastly, based on their findings, Woodward, *et al* recommend performing interval cholecystectomy between weeks 4 and 8<sup>[36]</sup>. With the current evidence, it is difficult to determine the optimal timing for interval cholecystectomy. We believe that performing the surgery in the intermediate period (6 weeks) may offer the best outcomes.

### Conclusions

Patients with moderate acute cholecystitis, a CCI  $\geq 6$ , and ASA-PS  $\geq 3$  who fail conservative treatment should undergo laparoscopic cholecystectomy as the first-line approach. For those with severe acute cholecystitis at high surgical risk, percutaneous cholecystostomy is recommended to relieve symptoms within 24–48 hours. Once the infection is controlled, candidates for surgery should undergo laparoscopic cholecystectomy at least six weeks after PC placement. For non-surgical patients, particularly those with CCI  $\geq 6$  and ASA-PS  $\geq 4$ , the cholecystostomy tube should remain for at least three weeks. After confirming biliary patency via imaging, the tube may be removed. However, in cases of recurrent pain, reduced bile drainage, or suspected tube dislodgement, trans-tube cholangiography should be performed to assess and reposition the tube if necessary. This consensus, developed through a multidisciplinary collaboration of interventional radiologists, gastroenterologists, and surgeons, provides a clear and practical guide for managing high-risk surgical patients with acute cholecystitis.

### Ethical approval

Not applicable, this is a Delphi consensus study.

### Consent

Not applicable.

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None.

### Author contributions

All authors: study concept and design, writing the paper, validation and supervision; A.P., A.L., V.D., R.C., C.R., A.G., M.M., M.I.B.: study concept, literature review, data analysis and interpretation. All authors: data analysis and interpretation.

### Conflicts of interest disclosure

All authors declare to have no conflict of interest.

### Research registration unique identifying number (UIN)

Not applicable.

### Guarantor

Dr. Antonio Pesce.

## Provenance and peer review

Not commissioned, externally peer-reviewed.

## Data availability statement

The data that support the findings of this study are available on request from the corresponding author.

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