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CONSENSUS CONFERENCE

Acute cholecystitis management in high-risk, critically ill, and unfit-for-surgery patients: the Italian Society of Emergency Surgery and Trauma (SICUT) guidelines

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Abstract
Dealing with acute cholecystitis in high-risk, critically ill, and unfit-for-surgery patients is frequent during daily practice and requires complex management. Several procedures exist to postpone and/or prevent surgical intervention in those patients who temporarily or definitively cannot undergo surgery. After a systematic review of the literature, an expert panel from the Italian Society of Emergency Surgery and Trauma (SICUT) discussed the different issues and statements in subsequent rounds. The final version of the statements was discussed during the annual meeting in Rome (September 2022). The present paper presents the definitive conclusions of the discussion. Fifteen statements based on the literature evidence were provided. The statements gave precise indications regarding the decisional process and the management of patients who cannot temporarily or definitively undergo cholecystectomy for acute cholecystitis. Acute cholecystitis management in high-risk, critically ill, and unfit-for-surgery patients should be multidisciplinary. The different gallbladder drainage methods must be tailored according to each patient and based on the expertise of the hospital. Percutaneous gallbladder drainage is recommended as the first choice as a bridge to surgery or in severely physiologically deranged patients. Endoscopic gallbladder drainage (cholecystoduodenostomy and cholecystogastrostomy) is suggested as a second-line alternative especially as a definitive procedure for those patients not amenable to surgical management. Trans-papillary gallbladder drainage is the last option to be reserved only to those unfit for other techniques. Delayed laparoscopic cholecystectomy in patients with percutaneous gallbladder drainage is suggested in all those patients recovering from the conditions that previously discouraged surgical intervention after at least 6 weeks from the gallbladder drainage.

Keywords Acute cholecystitis · Critical · Unfit · Surgery · Mortality · Morbidity · Comorbidities · Decision · Intensive care · Unstable · Sepsis · Septic shock

Background

Acute cholecystitis (AC) is a frequent and sometimes challenging disease. It is related to several causative events. The prevalence of gallstone disease increases with age. For this reason, an increasing number of elderly patients present with gallstone disease [1]. Independently from the age, some patients may not be initially or definitively candidates for surgical intervention. This may be due to frailty, comorbidities, or a specific severity of intraabdominal infection compromising the general status of the patient. In these patients, especially when they are at risk for developing sepsis, septic shock, and organ failure, treatment may become mandatory and gallbladder drainage may be a valid option [2].

Stratifying the frail, high-risk, critical, and unfit-for-surgery patients is mandatory to plan their best management. Numerous classification systems and scores exist. They

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are utilized to assess anesthesiologic risk factors (ASA), morbidity and mortality rates after surgery (P-POSSUM), 10-year survival rates based on comorbidities [Charlson Comorbidity Index (CCI) scores], and severity criteria of critical patients (APACHE II). Several studies exist where one or more of these scores are utilized. However, they are not homogeneously applied. At present, no agreement exists to establish pre-operative, intra-operative, and post-operative morbidity and mortality risks related to AC and its surgical management. The same issue exists for alternative procedures to surgery [EUS-guided gallbladder drainage (EUS-GBD), percutaneous gallbladder drainage (PT-GBD), and transpapillary gallbladder drainage (TPA-GBD)].

Patients' stratification must encompass both clinical scores and patient's condition (clinical and surgical).

Non-surgical drainage is an alternative option that can be used either as a bridge for subsequent surgery or as a definitive treatment in patients who remain unfit for surgery [3, 4]. In surgically high-risk patients with AC, non-surgical management should be considered only in patients without evidence of gallbladder perforation or biliary peritonitis [2, 5, 6]. In the case of a patient admitted to a low-skilled or low-resource setting whenever she/he is in need of complex management, transferring the patients to a referral center should be considered.

Even if widely utilized and effective, gallbladder drainage in AC is still underregulated and lacking clear indications about its use. The present paper aims to propose the Italian Society of Emergency Surgery and Trauma (SICUT) indications in the management of AC in high-risk, critically ill, and unfit-for-surgery patients.

Notes on the use of the statements

These statements are evidence based, with the grade of recommendation also based on the evidence. They present the diagnostic and therapeutic methods for optimal management of acute cholecystitis in high-risk, critically ill, and unfit-for-surgery patients. The practice indications promulgated in this work do not represent a standard of practice. They are suggested plans of care, based on the best available evidence and the consensus of experts, but they do not exclude other approaches as being within the standard of practice. For example, they should not be used to compel adherence to a given method of medical management, i.e., which method should be finally determined after taking account of the conditions at the relevant medical institution (staff levels, experience, equipment, etc.) and the characteristics of the individual patient. However, responsibility for the results of treatment rests with those who are directly engaged therein, and not with the consensus group.

Methods

A computerized search was done in different databanks (MEDLINE, SCOPUS, and EMBASE) and citations were included for the period between January 2005 and July 2022 using the primary search strategy: cholecystitis, acute, abdominal, infection, resuscitation, adult, hemodynamic instability/stability, critical, unfit, surgery, management, follow-up combined with AND/OR. No search restrictions were imposed. The dates were selected to allow comprehensive published abstracts of clinical trials, consensus conferences, comparative studies, congresses, guidelines, government publications, multicenter studies, systematic reviews, meta-analysis, large case series, original articles, and randomized controlled trials. Case reports and small cases series (less than 20 patients) were excluded. Narrative review articles were also analyzed to determine other possible studies.

A systematic review of the literature was done according to PRISMA guidelines [7] (Fig. 1). Level of evidence (LoE) was graded as high, moderate, low, and very low. The grade of recommendation (GoR), graded as strong, moderate, and weak, was established keeping into consideration the GRADE model [8]. A group of experts in the field coordinated by a central coordinator was contacted to express their evidence-based opinion about the discussed topic and the proposed statements in subsequent online Delphi rounds. At each round, the manuscript was revised and improved. The definitive version was discussed during the SICUT National Congress in October 2022 in Rome, Italy. During the discussion, the statements were considered as accepted if at least 80% consensus was obtained. The final version about which the agreement was reached resulted in the present paper. A summary of the statements is reported in Table 1.

Patient definitions

The definition of a frail patient as the one with increased vulnerability and decreased physiological reserve, resulting from the age-associated accumulation of physiological deficits in multiple organs/systems [9], is vague and almost useless in stratifying the patients for surgery. In fact, all frail patients experience a reduced resilience to physiological insults as surgery or invasive procedures, preventing or impairing post-procedural recovery and the return to pre-existing functional level [9].

For this reason, the decision about how to manage these patients cannot be taken only on frailty criteria.

Patients may be stratified into:

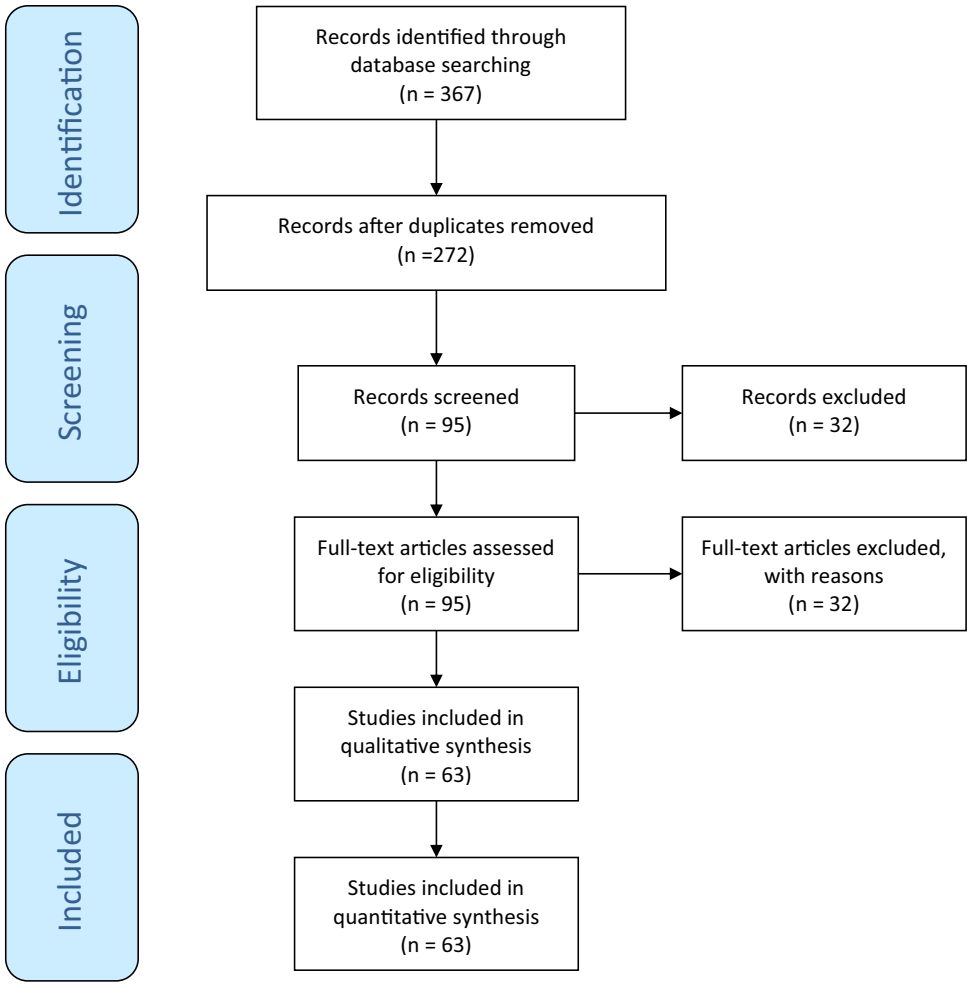

Fig. 1 PRISMA flowchart

High-risk patients

High-risk surgical patients may be defined as those who meet one or more of the following criteria: age ≥ 80 years, ASA ≥ grade 3, age-adjusted CCI score ≥ 4, and/or Karnofsky score < 50 [10–12].

Critically ill patients

Critically ill patients may be defined as those who present in septic shock, i.e., a subset of sepsis in which underlying circulatory and cellular/metabolic abnormalities are profound enough to substantially increase mortality. Patients with septic shock can be identified with persisting hypotension requiring vasopressors to maintain MAP of 65 mmHg and having a serum lactate level > 2 mmol/L (18 mg/dL) despite adequate volume resuscitation [13] associated with consequent organ or system dysfunction [14], and more in general those who present with hemodynamic instability [15]. Critically ill patients after adequate intensive management and resuscitation, once recovered from the critical conditions, may be classified otherwise depending on their clinical conditions.

Unfit-for-surgery patients

Patients were considered unfit for surgery if they satisfy at least one of the following criteria: age ≥ 80 years, ASA ≥ grade 3, age-adjusted CCI score ≥ 4, and/or Karnofsky score < 50 associated with severe or end-stage: liver cirrhosis, degenerative or malignant disease, hematologic disorders, or any other severe disease/comorbidity preventing the possibility to undergo surgical intervention with a reasonable chance to survive up to a reasonable recovery [11, 12].

Percutaneous drainage of the gallbladder

Question:
Which patients should be addressed for percutaneous drainage of the gallbladder?
Statements:

Table 1 Summary of statements

	Statements
Percutaneous gallbladder drainage	Percutaneous gallbladder drainage is recommended as the first option in high-risk or critically ill patients temporarily or definitively unsuitable for emergency cholecystectomy (GoR strong, LoE moderate)
	Percutaneous gallbladder drainage should be performed as soon as possible according to patients' conditions (GoR strong, LoE moderate)
Follow-up and tube removal	Trans-tube cholangiography is strongly suggested in patients with a suddenly reduced amount of bile drainage and/or recurrent biliary colic, before tube removal, and in the presence of tube dislodgement suspicion (GoR strong, LoE moderate)
Delayed cholecystectomy	Delayed laparoscopic cholecystectomy in patients with percutaneous gallbladder drainage is suggested in all those patients recovering from the conditions that previously discouraged surgical intervention (GoR moderate, LoE moderate)
	Cholecystectomy should be performed after at least 6 weeks from the gallbladder drainage (GoR moderate, LoE moderate)
Trans-duodenal/trans-gastric gallbladder drainage	Endoscopic ultrasound gallbladder drainage is suggested as a second-line option in high-risk or critically ill patients temporarily or definitively unsuitable for emergency cholecystectomy (GoR strong, LoE moderate)
	Endoscopic ultrasound gallbladder drainage, whenever feasible, is recommended as a definitive treatment in unfit-for-surgery patients (GoR moderate, LoE moderate)
Cholecystogastrostomy versus Cholecystoduodenostomy	Cholecystoduodenostomy is suggested in those patients scheduled for definitive treatment with EUS-GBD (GoR weak, LoE low)
	Cholecystogastrostomy is suggested in those patients scheduled for bridge to surgery treatment with EUS-GBD (GoR weak, LoE low)
Stent removal or substitution	Complete stone clearance and metal stent exchange with double-pigtail plastic stents is suggested when long-term drainage is required (GoR weak, LoE low)
	It is recommended to accurately evaluate life expectancy and stent removal-related risks before proceeding with its removal (GoR strong, LoE moderate)
Trans-cystic duct gallbladder drainage	Trans-papillary gallbladder drainage is suggested in high-risk, critically ill, and unfit-for-surgery patients as a third-line alternative to percutaneous or trans-gastric/duodenal gallbladder drainage, when common bile duct lithiasis is associated (GoR strong, LoE moderate)
	Trans-papillary gallbladder drainage may be performed together with endoscopic retrograde cholangiopancreatography and eventual stone removal (GoR Strong, LoE Moderate)
	Trans-papillary gallbladder drainage should be considered only in experienced centers and wherever the adequate endoscopic expertise exists (GoR strong, LoE moderate)
	Trans-papillary gallbladder drainage is not recommended as the first-choice definitive method in unfit-for-surgery patients; in these cases, percutaneous and then endoscopic gallbladder drainage feasibility should be first evaluated (GoR moderate, LoE moderate)

Percutaneous gallbladder drainage is recommended as the first option in high-risk or critically ill patients temporarily or definitively unsuitable for emergency cholecystectomy (GoR strong, LoE moderate).

Percutaneous gallbladder drainage should be performed as soon as possible according to patients' conditions (GoR strong, LoE moderate)

Frail, critically ill patients, those at high risk, or even those unfit for surgery may obtain benefit and risk reduction from PT-GBD. PT-GBD may be considered the procedure of choice to prevent or postpone cholecystectomy in AC whenever the surgical intervention may be contraindicated [16–21]. After an accurate patient selection [22], PT-GBD offers the most rapid and less risky approach to source control in AC in those patients where the risk–benefit ratio for surgical intervention is too high and where antibiotics and general supportive care fail to control inflammation [23–25].

It has been demonstrated to be feasible by surgeons as well and not only by radiologists, with the same rate of technical and clinical success of interventional radiologists [26].

The correct PT-GBD timing is debated. However, an early placement (< 24 h after symptoms onset) is related with a lower procedure-related complication rate and with a shorter hospital stay [27].

The timing of PT-GBD must be related to the patient's clinical conditions as well. After an adequate resuscitation,

whenever needed, and an early empiric antibiotic therapy start, the more severe the patient's conditions are, the earlier gallbladder must be drained [27–29].

Tube insertion within 3–6 days from symptom onset seems to reduce the delayed cholecystectomy conversion rate [30]. PT-GBD may be performed also in awake patients without the necessity of general anesthesia.

Upfront cholecystectomy in patients at high surgical risk resulted in higher conversion to open surgery and complication rate than those undergone to PT-GBD and subsequent cholecystectomy [20, 25, 31].

Moreover, PT-GBD showed a reduction in 30-day mortality when compared to surgery [32]. As a counterpart, data from the only randomized controlled trial ever published about the topic showed no difference in death rate between laparoscopic cholecystectomy and PT-GBD. Major complications rate was significantly higher in PT-GBD patients. Lastly, PT-GBD experienced a longer hospital stay [4].

Contraindications

In general, two main factors are considered as contraindications to PT-GBD: presence of gastrointestinal interposition preventing direct gallbladder visualization and severe alteration of the coagulation not amenable to correction.

Follow-up and tube removal

Question:
Which is the follow-up strategy in patients undergone to percutaneous gallbladder drainage?
Statement:
Trans–tube cholangiography is strongly suggested in patients with a suddenly reduced amount of bile drainage and/or recurrent biliary colic, before tube removal, and in the presence of tube dislodgement suspicion (GoR strong, LoE moderate).

Routine cholangiography is not indicated after successful tube placement during the first phases of AC management. Prior to tube removal, cholangiography via the tube may be done [33]. It allows to visualize the biliary tree and its eventual obstruction. In some patients, cholangiography is strongly suggested (i.e., those with a suddenly reduced amount of bile drainage, recurrent biliary colic, and suspicion of tube dislodgement). Asymptomatic patients do not need routine cholangiography before tube removal [34].

No data exist focusing on quality of life and PT-GBD.

Complication management

The reported incidence of PT-GBD-related complications varies from 2.5 to 69% [4, 20, 33, 35]. Patients generally undergone to PT-GBD are the most compromised ones. For this reason, complications management must be accurately tailored according to each patient.

Tube dislodgement is the most common complication and bile leakage is common as well. Bleeding, tube obstruction, infection, organ perforation, and death have also been reported, but are rare. Complications management should be tailored according to each patient. Complete tube dislodgement should be evaluated in terms of general conditions and for the necessity of tube repositioning and/or intraabdominal fluid collection. No differences in terms of 90-day reoperation, 30-day readmission, 30-day ED visit, LOS, or discharge destination seem to exist between those who repositioned a dislodged tube and those who did not in the absence of biliary peritonitis [36]. For patients with suspected partial tube dislodgement, cholangiography may be performed to confirm the tube position and to plan subsequent procedures. Bile leakages are usually symptomatic, and in the event of bile leak, antibiotics and image-guided drainage should be considered. Minor bleeding can be managed conservatively in most patients. However, in patients with major bleeding, embolization or emergency laparotomy should be evaluated. In suspected tube obstruction, bedside irrigation and cholangiography may be sufficient [35].

Delayed cholecystectomy after PT-GBD

Question:
Which is the best strategy for delayed cholecystectomy after the resolution of critical conditions?
Statements:
Delayed laparoscopic cholecystectomy in patients with percutaneous gallbladder drainage is suggested in all those patients recovering from the conditions that previously discouraged surgical intervention (GoR moderate, LoE moderate).

Cholecystectomy should be performed after at least 6 weeks from the gallbladder drainage (GoR moderate, LoE moderate)

Several data suggest PT-GBD as a definitive treatment option due to low rates of AC recurrence. The described rate of patients who did not undergo cholecystectomy after PT-GBD ranged from 43 to 94% [30]. Twenty-five percent of the recurrent AC events happen within 3 months after PT-GBD [37]. Readmission rates and need for cholecystectomy have been demonstrated to be significantly higher in the conservative medical treatment of AC than those in PT-GBD patients [38]. However, PT-GBD followed by delayed laparoscopic cholecystectomy seems better in terms of surgical safety, patients' post-operative recovery, and rate of conversion to open surgery and post-operative morbidity [30, 39, 40].

Early PT-GBD was associated with a decreased rate of conversion to later laparotomy, among patients who had used PT-GBD as a bridging therapy for AC. Patients with tube insertion 3–6 days from the onset of symptoms had a conversion rate of 33.3% [30]. At present, however, there does not exist a definitive cutoff defining early PT-GBD [30]. Few data suggest to postpone cholecystectomy after at least 14 days from tube positioning [36]. After PT-GBD, a period of at least 6 weeks is suggested before proceeding to laparoscopic cholecystectomy; this seems to reduce the complication and conversion rate [34, 41–45].

Trans-duodenal/trans-gastric drainage of the gallbladder

Question:
Which patients should be addressed for endoscopic ultrasound gallbladder drainage?
Statements:
Endoscopic ultrasound gallbladder drainage is suggested as a second-line option in high-risk or critically ill patients temporarily or definitively unsuitable to emergency cholecystectomy (GoR strong, LoE moderate).

Endoscopic ultrasound gallbladder drainage, whenever feasible, is recommended as a definitive treatment option in unfit-for-surgery patients (GoR moderate, LoE moderate)

In the management of patients with AC in the condition not to be temporarily or definitively undergone to surgical intervention, EUS-GBD may represent one viable alternative [46]. In high-volume medical centers, with availability of an appropriate endoscopic expertise, it seems to bring good results [6, 12, 16, 47].

In fact, patients beneficiating from EUS-GBD may be divided into three main categories: (1) patients unfit for surgery, (2) high-risk patients that may beneficiate to a bridge treatment to cholecystectomy, (3) patients that need a conversion from PT-GBD to EUS-GBD due to a failure of the first one or to the ineffectiveness of the PT-GBD as a bridge to surgical procedures [48].

Moreover, EUS-GBD may be indicated in very selected cases in the presence of altered anatomy, cystic duct obstruction (i.e., metal stent deployed, distal bile duct obstruction not traditionally manageable) in the impossibility to proceed to surgical intervention [5, 49].

Reported technical success deployment rate of 95.3% associated with a clinical success rate of 90.8%, with a 30-day adverse event rate of 15.3% and 30-day mortality rate of 9.2%, has been reported for EUS-GBD [12].

In general, fully or partially covered self-expanding metal stents (SEMSs) or plastic stents have been utilized, with high clinical success rates [3]. However, plastic stents may fail to adequately seal bilio-digestive anastomosis, increasing the risk of bile leak [50].

The lumen-apposing fully covered metal stents (LAMS) brought a cumulative technical and clinical success rate of 94.9% and 94.6%, respectively. Moreover, early and delayed adverse event rates were, respectively, 6.5% and 8.3% [51].

Long-term outcomes of EUS-GBD have been shown with no AC recurrence in 96.4% of patients and a reintervention rate of 3.6% with 275-day median follow-up [52].

Selection of LAMS diameter usually depends on the size of the largest stone to allow for subsequent stone self-clearance or lithotripsy [12, 47, 53–55]. A high successful deployment rate with both the 10- and 15-mm diameter LAMS has been demonstrated with no differences in clinical success or adverse event rates [56].

Some data suggest that EUS-GBD should be favored over PT-GBD and TPA-GBD gallbladder drainage (whenever both techniques are available) as a definitive treatment for AC in patients with high risk and/or unfit for surgery. In fact, EUS-GBD seems to bring lower rates of 30-day and 1-year adverse events, unplanned readmission, recurrent AC, and need for reintervention. Moreover, post-procedural pain scores and analgesic requirement were lower [2, 46, 47, 53, 57–59].

EUS-GBD may be performed without general anesthesia, with a consequent potential reduction/no need for ICU admissions [60].

In patients with anti-thrombotic therapy (ATT), EUS-GBD should be performed after its discontinuation. In the case of a high risk of thromboembolism, aspirin monotherapy may be maintained, accepting a higher bleeding risk [61–63].

Cholecystogastrostomy versus cholecystoduodenostomy

How to choose between cholecystogastrostomy and cholecystoduodenostomy?

Cholecystoduodenostomy is suggested in those patients scheduled for definitive treatment with EUS-GBD (GoR weak, LoE low).

Cholecystogastrostomy is suggested in those patients scheduled for bridge to surgery treatment with EUS-GBD (GoR weak, LoE low)

When performing EUS-GBD, the puncture location depends on few main factors: the absence of interposed blood vessels or other anatomical structure and intestinal lumen-gallbladder distance.

No evidence exists about the superiority of a specific puncture site [5].

In general, puncture site may influence the subsequent procedures. Puncture from gastric antrum access the gallbladder in the body or fundus and puncture from duodenum at the neck. Gastric punctures are easier to convert in subsequent cholecystectomy whenever EUS-GBD is utilized as a bridge to surgery [64, 65]. As a counterpart, gastric puncture may be more at risk for stent dislocation, bile leakage, and food impaction, but the correction of an eventual stent migration may result technically easier in cholecystogastrostomy [3, 66–74]. Reported technical and clinical success rates are, respectively, 94.4% and 91.2%, for patients punctured in the antrum, and 100% and 95.7%, respectively, for patients punctured in the duodenum. The overall adverse events, however, were significantly different (antrum vs. duodenum; 11.1% vs. 4.3%) [67].

In the case where stent deployment fails after the gallbladder has already been punctured, an immediate percutaneous gallbladder drainage or cholecystectomy becomes necessary as the consequent bile leakage may result in severe peritonitis.

Lastly, it is possible to place a double pigtail in those patients at high risk of SEMS and LAMS deployment [71].

Contraindications

Suspected or established perforation of the gallbladder represents the main contraindication to EUS-GBD. In conditions of severe emphysematous or gangrenous AC, EUS-GBD is contraindicated as they are at higher risk of perforation during stent deployment. The impossibility to clearly delineate the anatomy and a gallbladder distance > 10 mm from the gastric-duodenal lumen. Relative contraindications are active antiplatelet or anticoagulation therapy or uncorrected coagulopathy [5, 49, 64].

Other potential technical contraindication may be represented by patient's intolerance to general anesthesia, gastric, duodenal or pancreatic cancer, ascites, suboptimal anatomy secondary to a contracted gallbladder, and lumen filled with stones [5, 75–78].

In patients previously undergone to percutaneous cholecystostomy, the gallbladder may be contracted and fibrotic; therefore, it may be more difficult to puncture and drain via endoscopic procedure [12].

Follow-up

No univocal and definitive indication to follow-up after EUS-GBD exist. In the case of outpatients, they do not require hospitalization in uncomplicated stent deployment.

In general, inpatients remain admitted in the hospital until the signs and symptoms of the disease are resolved. No definitive indication can be given about the more appropriate diet regulation.

At present, the best re-alimentation strategy seems to be a liquid diet in the first 24–48 h and then progressively reintroducing a soft solid diet with a low content of residue.

Thirty-day peroral cholecystoscopy may be performed to check the stent viability and the eventual stone clearance [54, 79]. Reported recurrence rate of AC ranges between 0 and 8.3% [70].

No data exist focusing on quality of life and EUS-GBD.

Stent removal or substitution

Which is the best strategy for stent removal or substitution?

Complete stone clearance and metal stent exchange with double-pigtail plastic stents is suggested when long-term drainage is required (GoR weak, LoE low).

It is recommended to accurately evaluate life expectancy and stent removal-related risks before proceeding with its removal (GoR strong, LoE moderate)

No indication can be given about the timing of stent removal, even if concerns exist about the potential degradation of stent covering. In any case, its removal should be postponed after the maturation of the tract, and it may be replaced with a double pigtail to allow bile drainage preventing recurrent cholecystitis after an accurate evaluation of the clearance of gallbladder calculi [71, 72, 80].

In alternative, whenever the stent placement is planned to be long standing, a plastic stent may be preferred to a metal one [5, 75, 81]. In general, stents are left in situ for periods lasting from 1 to 3 months [67, 82]. Leaving metal stents in situ may be associated with stent migration or stent-induced gallbladder wall erosive injuries and bleedings or LAMS syndrome caused by a buried stent [5, 67].

Some data about the long-term duration (3 years) of stent placement have been reported without stent-related adverse events. Late adverse event rate was 7.1%, and the 3-year stent patency was 86% [52, 83–85].

The long-standing presence of EUS-GBD placed stent has a very low AC recurrence rate; different and worse outcomes have been reported for PT-GBD [66, 84].

Moreover, some data exist about the potential protective role of EUS-GBD for common bile duct calculi migration in those patients treated with cholecystoduodenostomy [84].

In patients with a minimal residual life expectancy or whenever the risk–benefit ratio to attempt stent removal presents a too high-risk balance, stents should be left in situ [52, 72, 85–87].

Cholecystoscopy

No definitive role to peroral cholecystoscopy has been assigned. Currently, no data suggest that cholecystoscopy and calculi extraction may change the clinical courses and outcomes. Some studies described a complete calculi clearance of 88% after a mean number of 1.25 procedures and the reported time lapse between EUS-GBD and cholecystoscopy ranges between 1 week and 4 months [5, 12, 54, 54, 54, 88–90].

Delayed cholecystectomy after EUS-GBD

Cholecystectomy after EUS-GBD is feasible. Endoscopic drainage does not preclude subsequent cholecystectomy, either laparoscopic or laparotomic [5, 53]. In fact, inflammation and/or adhesions following EUS-GBD with plastic stents did not prevent safe laparoscopic cholecystectomy [91]. The reported success rates of cholecystectomy range between 79.3 and 100%. The reported conversion rate is 11.5% [91, 92].

Trans-cystic duct drainage of the gallbladder

Despite the common notion that TPA-GBD for AC is a novel approach, already in 1984, Kozarek described that the cystic duct could be selectively cannulated in about 74% of patients undergoing an endoscopic retrograde cholangiopancreatography (ERCP) [93].

Whenever surgery is contraindicated, endoscopic transpapillary gallbladder drainage (TPA-GBD) is considered to be the third-line drainage procedure [6, 16, 94].

Due to the reported rate of 7–20% CBD stones in patients with AC, pre-operative ERCP may be necessary. Single-step drainage of CBD and gallbladder through ERCP and TPA-GBD is reported in high-risk or unfit-for-surgery patients [95–98].

Indications

Question:
Which patients should be addressed for trans-papillary gallbladder drainage?
Statements:
Trans-papillary gallbladder drainage is suggested in high-risk, critically ill, and unfit-for-surgery patients as a third-line alternative to percutaneous or trans-gastric/duodenal gallbladder drainage, when common bile duct lithiasis is associated (GoR strong, LoE moderate)
Trans-papillary gallbladder drainage may be performed together with endoscopic retrograde cholangiopancreatography and eventual stone removal (GoR strong, LoE moderate).
Trans-papillary gallbladder drainage should be considered only in experienced centers and wherever the adequate endoscopic expertise exists (GoR strong, LoE moderate).
Trans-papillary gallbladder drainage is not recommended as the first-choice definitive method in unfit-for-surgery patients; in these cases, percutaneous and then endoscopic gallbladder drainage feasibility should be first evaluated (GoR moderate, LoE moderate).

Whenever the aforementioned gallbladder drainage techniques, especially PT-GBD, are unapplicable or failed, TPA-GBD may be considered as the third-line drainage procedure [6, 16].

Some contraindications to PT-GBD and EUS-GBD exist and have been previously described; whenever they coexist, TPA-GBD may result as the only viable alternative to surgical intervention especially in the event of CBD lithiasis [92, 99–102].

Although not always technically feasible, TPA-GBD has a success rate ranging from 50 to 97% [100, 103–109]. However, TPA-GBD is the procedure with higher failure rate among all the possible gallbladder draining techniques [58, 59, 98]. It necessitates advanced endoscopic expertise and dedicated resources and should be attempted only in experienced centers.

In the case of concomitant CBD stones in high-risk and critically ill patients with AC, PTA-GBD may be performed together with ERCP with stone removal. This approach provides significantly higher clinical successful rate and better outcomes for those who are candidates to a future cholecystectomy when compared to EUS-GBD [97, 100].

No difference between TPA-GBD and PT-GBD exists in terms of operative time, tight adhesions, surgery-related adverse events, gallbladder integrity, length of hospitalization, and conversion rate during subsequent laparoscopic cholecystectomy [110].

The main technical challenge of a trans-papillary endoscopic drainage of the gallbladder is represented by the selective cannulation into the cystic duct [106]. Furthermore, TPA-GBD is associated with a complication rate of 10%, with complications such as post-sphincterotomy bleeding, perforation, biliary injuries, post-ERCP pancreatitis, and stent migration [111, 112].

TPA-GBD in unfit-for-surgery patients is to be considered as a definitive approach [56, 83, 100, 104, 105].

The reported success rate is of 75%, with a complication rate of at least 5%. Clinical resolution was reported in 97% of patients and subsequent cholecystectomy was performed in 93%. The discharge happened after a median delay after drainage of 42 days [108, 109].

In unfit-for-surgery patients with AC, TPA-GBD is not the preferable method. The other drainage systems should be the first choice, even in concomitant CBD lithiasis. Technical

success rate in percutaneous and trans-duodenal approach was higher than TPA-GBD, regardless of the presence of concomitant CBD stones. Similarly, the clinical success rate was significantly higher in PT-GBD group for patients without concomitant CBD stones, although they presented the highest risk of recurrence [100]. Technical success (99.3% vs. 86.6%) and clinical success (99.3% vs. 86%) rates were significantly higher in the EUS-GBD than in the TPA-GBD, respectively. At the same time, the complication rate (7.1% vs. 19.3%) and the cholecystitis or cholangitis recurrence rate (3.2% vs. 12.4%) were significantly higher in the TPA-GBD group [83, 113].

Contraindications

The only absolute contraindication to TPA-GBD is the absence of high-level endoscopic training and experience in performing this specific procedure [92].

Relative contraindications are represented by altered anatomy for the high failure risk [114].

Coagulopathy is not a contraindication to TPA-GBD; it may, as a counterpart, represent a relative indication [115].

Ultrasonography is the best method for predicting potential technical difficulties. TPA-GBD's success is most likely in patients who present a short gallbladder minor axis or thin gallbladder wall [116].

Pre-procedural imaging or combined intraductal ultrasonography increases the success rate of drainage deployment [98, 99, 117].

Whenever the cystic duct orifice could not be identified on cholangiography, a digital single-operator cholangioscope (SpyGlass®) may be inserted into the common bile duct (CBD). This may facilitate a guide-wire insertion under direct visualization [86]. It remains unclear to what extent the success rate of ET-GBD could be improved by cholangioscopic assistance, but it is known that SpyGlass® has a fairly high cost and it cannot be applied to all cases of AC.

Follow-up

Endoscopic naso-gallbladder drainage is suggested when the waiting time for cholecystectomy is estimated to be short and during the same hospitalization. This is especially an effective management strategy for those patients listed for an endoscopic CBD stone removal [108, 109].

No data exist focusing on quality of life and TPA-GBD.

Conclusion

Acute cholecystitis management in high-risk, critically ill, and unfit-for-surgery patients should be multidisciplinary. The different gallbladder drainage methods must be tailored according to each patient and based on the expertise of the hospital. Percutaneous gallbladder drainage is recommended as the first choice as a bridge to surgery or in severely physiologically deranged patients. Endoscopic gallbladder drainage (cholecystoduodenostomy and cholecystogastrostomy) is suggested as a second-line alternative especially as a definitive procedure for those patients not amenable to surgical management. Transpapillary gallbladder drainage is the last option to be reserved only to those unfit for other techniques. Delayed laparoscopic cholecystectomy in patients with percutaneous gallbladder drainage is suggested in all those patients recovering from the conditions that previously discouraged surgical intervention after at least 6 weeks from the gallbladder drainage.

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