Acute Calculous Cholecystitis

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2.1 Introduction

Acute calculous cholecystitis is one of the most common conditions faced by a general surgeon. Cholecystectomy is the most common digestive operation and about 30 % of them are performed after an acute cholecystitis [1]. Still, many aspects about its treatment are controversial and common practice often differs from the indications provided by the literature.

The disease itself is very heterogeneous: the degree of inflammation may vary from a self-limiting to a life-threatening form; furthermore, associated conditions often impose a deviation from the most common course of action, and the general status of the patient has a relevant impact on both the severity of the illness and the treatment outcomes.

Such heterogeneity should correspond to a tailored approach, able to grant the more appropriate treatment to every single patient; however, the literature is devoid of clear indications about how to adapt the clinical pathway to the diverse scenarios, the parameters to stratify the risk of surgery in this population are not clear, the most commonly adopted risk scores are not validated for the acute cholecystitis, and no instrument is available to select the best course of action in different situations [2,3].

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The available guidelines provide a very valuable support for the daily surgical practice; however, their recommendations are affected by the lack of literature evidence about several crucial aspects.

We will try to examine the controversial clinical issues about acute calculous cholecystitis, analyzing the evidence supporting the guidelines and the most recent scientific literature data.

2.2 Diagnostic Issues in the Acute Calculous Cholecystitis

The diagnosis of acute calculous cholecystitis relies on a combination of local, systemic, and imaging signs. A systematic review by Trowbridge [4] suggested that no single clinical finding or laboratory test carries sufficient weight to establish or exclude acute cholecystitis. In 2006, based on these results, the European Association for Endoscopic Surgery (EAES) suggested that the presence of acute right upper quadrant pain for more than 6 h along with ultrasound evidence of acute cholecystitis (the presence of gallstones with a thickened and edematous gallbladder wall, positive ultrasound Murphy's sign, and pericholecystic fluid collections) could achieve a high diagnostic specificity. The demonstration of gallstones without clear imaging cholecystitis should be supported by one or more of the following: temperature above 38°, leukocytosis greater than 10,000/dL, and C-reactive protein higher than 10 mg/L [5]. The 2012 update of those guidelines maintained the validity of those criteria [6].

In 2007, the Tokyo Guidelines (TG07) proposed a similar set of criteria that quickly became widely adopted worldwide [7, 8]. The Tokyo Guidelines Revision Committee reported that 92.1 % sensitivity and 93.3 % specificity was achieved when those criteria were adopted in clinical practice. Their last revision (TG13) is reported in Table 2.1; the imaging findings necessary for the definite diagnosis are detailed in Table 2.2.

Table 2.1 TG13 diagnostic criteria for acute cholecystitis[a]

A. Local signs of inflammation, etc.
(1) Murphy's sign and (2) RUQ mass/pain/tenderness
B. Systemic signs of inflammation, etc.
(1) Fever, (2) elevated CRP, and (3) elevated WBC count
C. Imaging findings
Imaging findings characteristic of acute cholecystitis
Suspected diagnosis: One item in A + one item in B
Definite diagnosis: One item in A + one item in B + C

[a]RUQ, right upper abdominal quadrant, CRP, C-reactive protein, and WBC, white blood cell

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Table 2.2 TG07 Imaging findings of acute cholecystitis[a]

Ultrasonography findings
Sonographic Murphy sign (tenderness elicited by pressing the gallbladder with the ultrasound probe)
Thickened gallbladder wall (>4 mm; if the patient does not have chronic liver disease and/or ascites or right heart failure)
Enlarged gallbladder (long axis diameter >8 cm, short axis diameter >4 cm)
Incarcerated gallstone, debris echo, and pericholecystic fluid collection
Sonolucent layer in the gallbladder wall, striated intramural lucencies, and Doppler signals
Magnetic resonance imaging (MRI) findings
Pericholecystic high signal
Enlarged gallbladder
Thickened gallbladder wall
Computed tomography (CT) findings
Thickened gallbladder wall
Pericholecystic fluid collection
Enlarged gallbladder linear high-density areas in the pericholecystic fat tissue
Tc-HIDA scans
Non-visualized gallbladder with normal uptake and excretion of radioactivity
Rim sign (augmentation of radioactivity around the gallbladder fossa)

[a]With kind permission from Springer Science+Business Media: Hirota M et al. (2007) Diagnostic criteria and severity assessment of acute cholecystitis: Tokyo Guidelines. J Hepatobiliary Pancreat Sci 14:78–82. ©Springer-Verlag Tokyo 2007 [7] (modified)

2.3 Laparoscopic or Laparotomic Surgery for Acute Cholecystitis?

Early after the introduction of laparoscopic surgery, acute cholecystitis was considered a contraindication for mini-invasive surgery: laparoscopic cholecystectomy in the acute inflammatory phase of cholecystitis required uncommon dexterity and experience for those early times, and a higher complication rate was reported [9, 10].

In later years, the increased experience and progressive acquisition of the required skills allowed us to safely complete a laparoscopic cholecystectomy even in the most severe acute conditions. All the recent guidelines consider laparoscopic cholecystectomy as the gold standard for the treatment of acute calculous cholecystitis [6, 11–13]. Nevertheless, practice pattern varies. Most patients, at least in the western world, receive laparoscopic cholecystectomy [14, 15]; however, many do not undergo surgery [16, 17] and almost 50 % of all complicated acute cholecystitis worldwide are still operated by laparotomy, as shown by the CIAO and CIAOW studies [18, 19].

Therefore, it is quite important to examine the clinical advantages reported in the literature in favor of the laparoscopic approach.

2.3.1 Laparoscopic Cholecystectomy for Acute Cholecystitis: The Evidence

The superiority of laparoscopic cholecystectomy in the treatment of acute calculous cholecystitis has been mainly demonstrated in four randomized controlled trials (RCTs) [20–23]. They show that laparoscopic cholecystectomy is associated with faster recovery and shorter hospital stay. They also indicated that the morbidity of the laparoscopic approach was not higher, as initially supposed, but actually lower. However, a full demonstration of a statistically significant reduction in the complication rate could only be obtained by the meta-analysis just recently published by Coccolini et al. [24]. This study took into consideration both randomized and non-randomized researches; however, some of the outcomes could be separately analyzed on the basis of RCTs data only. In this way, it was possible to demonstrate, with the highest level of evidence, that laparoscopic cholecystectomy in acute cholecystitis carries a lower risk of complications. Mortality also appeared lower in the laparoscopic group but the data were available only for non-randomized comparative studies. Among the complications, wound infection, pneumonia, and bile leakage deserved a separate inquiry: the wound infection and pneumonia rate favored laparoscopic surgery, while the bile leakage did not differ significantly between the two groups. These data represent a strong support for the role of laparoscopic cholecystectomy as the gold standard in the treatment of the acute calculous cholecystitis.

The interpretation of the results about faster recovery and postoperative length of stay deserves a word of caution. As a matter of fact, the evaluation of these parameters is partially subjective, and it cannot be excluded that the improved outcome of laparoscopic surgery be related to an expectation bias of the medical staff rather than to real clinical and physiopathologic changes. The trial by Johannson [21] was designed to avoid this bias and included a blind assessment of the outcomes: both patients and postoperative care staff were unaware of the surgical access received by the patient because the wounds were kept concealed at all times. Still a reduced hospital stay could be shown.

One of the RCTs [22] demonstrated a reduction in the surgical trauma and immunosuppression by measuring serum C-reactive protein and tumor necrosis factor-α (TNF-α) secretion of peripheral blood mononuclear cells.

If the data of the RCTs with their meta-analysis constitute the strongest evidence in support of the laparoscopic approach also in the acute setting, the findings reported by the large observational studies provide an insight into the reality of the everyday practice. In 2008, Csikesz conducted a population-based analysis on the USA National Hospital Discharge Surveys about more than one million cholecystectomies performed for acute cholecystitis from 2000 through 2005. The study confirmed that laparoscopic cholecystectomy is associated with lower morbidity, mortality, and shorter length stay. Open surgery was associated with a 1.3-fold increase in perioperative morbidity (95 % CI 1.1–1.4) after adjusting for patient and hospital factors [14].

2.4 When to Operate an Acute Cholecystitis? A Question of Timing

The optimal timing for surgical interventions in an acute cholecystitis is difficult to determine and controversial; most of the recent literature is devoted to this aspect.

In the pre-laparoscopic era, several randomized controlled trials had shown the superiority of early versus delayed open cholecystectomy: early surgery was associated with lower morbidity and shorter hospital stay [25–28].

As we underlined in section "Laparoscopic or Laparotomic Surgery for Acute Cholecystitis?," right after the introduction of laparoscopic surgery the skills to manage an acute cholecystitis by laparoscopy were uncommon, and the condition was considered to be a contraindication for mini-invasive cholecystectomy. The safety of laparoscopic surgery in the acute phase of the disease was questioned [9], and, again, practice evolved in favor of delayed laparoscopic cholecystectomy as an alternative to immediate open surgery: initial antibiotic treatment and resuscitation followed by elective laparoscopic surgery about 6 weeks after the acute attack.

Later, after having developed the necessary experience, the performance of mini-invasive cholecystectomies even in the acute phase of the disease became more and more common, and trials comparing early versus delayed laparoscopic cholecystectomy were possible.

2.4.1 The Evidence Supporting Early Laparoscopic Cholecystectomy

A systematic review of the literature found 15 randomized controlled trials comparing early versus delayed laparoscopic cholecystectomy [29–43], analyzed in several meta-analyses [1, 44–49].

The definitions of "early" and "delayed" differ among the trials; however, most of them take into consideration patients operated on less than 72 h or less than 7 days from the onset of symptoms as "early"; their treatment is planned at least 6 weeks after the initial diagnosis in the "delayed" groups. Here, we do not mean to analyze in detail this large amount of literature; however, all the studies agree that early laparoscopic cholecystectomy is superior because it reduces the total hospital stay (due to the two episodes of admission) without a significant difference in the complication or conversion rate. One of the meta-analyses shows that the rate of bile duct injury, the most feared complication, seems to be even higher in the delayed treated patients but the difference was not statistically significant [1]. The same review also revealed that 18.3 % of the patients included in the delayed groups, in five RCTs, had to undergo emergency surgery in the interval period for either non-resolution or recurrence of symptoms before their planned operation [1]. The conversion rate was 45 % in this subgroup.

A very large population-based study confirmed those findings on 10,304 acute cholecystitis patients who did not undergo cholecystectomy on the first admission. The probability of a gallstone-related event was 14 % at 6 weeks and 29 % at

12 weeks. At 1 year after discharge the likelihood of an acute gallstone-related episode raised to 29 %. Of these events, 30 % were for biliary tract obstruction or pancreatitis [50]. A Swedish study found that 6.1 % of patients discharged without cholecystectomy had emergency surgery in the 2-year study period [16].

Other recent and large population-based studies sustain early surgery and show that morbidity (included common bile duct injuries) is lower in the early treated patients [51–53].

These data further support the practice of early laparoscopic cholecystectomy.

Despite the growing evidence in favor of it, the optimal time to perform early laparoscopic cholecystectomy is still not clear. Is there any difference if the operation is performed at 24, 48, and 72 h after the onset of symptoms or even later? Can we establish a threshold of delay after which cholecystectomy can no longer considered "early" and surgery had better be deferred to a later date (delayed)?

The already mentioned Cochrane review [1] performed a subgroup analysis comparing the data obtained from the trials that included only patients treated less than 4 days from the onset of symptoms to those including also patients with a longer delay, and did not find any statistically significant difference between them.

Once again, population-based study helps to clarify the issue. In 2011, Banz et al. examined the outcome of 4113 patients divided into six different groups according to their preoperative length of stay (adopted as a surrogate measure of the onset of symptoms): operated on the day of admission, on the following day, 2, 3, 4 or 5, 6 days later, or afterwards. There was no significant difference between preoperative length of stay and postoperative morbidity or mortality. However, the longer was the preoperative stay and the higher were the operative times and the conversion rate [51]. Their work did not include any risk adjustment, but similar results were reported by Brooks et al. on the American College of Surgeons National Surgical Quality Improvement Program database [54]. Their risk-adjusted analysis showed an increasing morbidity for cholecystectomies performed from the day of the admission to 4 days later (from 6 to 19 %) even if they could not demonstrate a statistical significance. In their 2015 paper, Zafar et al. used propensity score matching techniques to account for severity differences in a very large (95,523 patients) population-based series from the Nationwide Inpatient Sample (NIS). They demonstrated that surgery performed within the first 48 h of presentation was associated with the lowest complication, length of stay, mortality, and hospital cost. In fact, patients who had surgery during days 2 through 5 and days 6 through 10 had increasingly worse outcomes than those undergoing surgery on days 0 through 1. They could show statistically significant differences for mortality (OR = 1.26; 95 % CI 1.00–1.58 and 1.93; 95 % CI 1.38–2.68) and postoperative infections (OR = 0.88; 95 % CI 0.69–1.12 and 1.53; 95 % CI, 1.05–2.23) for days 2 through 5 and days 6 through 10, respectively. Also significant were the differences for pneumonia, UTI, and postoperative length of stay. Their extensive analysis took also into consideration the adjusted mean hospital cost, and showed it to increase from $8974 (days 0–1) to $17,745 (days 6–10). The analysis by each incremental day demonstrated the optimal time of surgery to be within the first 48 h of presentation. As already mentioned, the relevant size of the series allowed to properly assess

the differences in the rare event of perioperative death: the lowest risk-adjusted mortality was found for surgery performed within 1 day or 2 days of presentation (0.36 % and 0.37 %, respectively), and sudden increase in mortality appeared from day 3 and later (0.45 %, $P = 0.01$). It is interesting to point out that mortality for surgery performed on day 0 was higher (0.42 %) than later. The authors explain the finding with the higher probability of under-resuscitated patients among those operated on the day of the admission [55].

Then, laparoscopic cholecystectomy should be performed as early as possible after the onset of symptoms, and preceded by an adequate resuscitation.

A recent large randomized controlled trial compared laparoscopic cholecystectomy performed within 24 h of admission versus surgery between 7 and 45 days after initial diagnosis [40]. This trial demonstrated that the morbidity rates were lower in the delayed than early laparoscopic cholecystectomy group and the length of hospital stay was 5 days shorter.

In conclusion, several RCTs and their meta-analyses show that laparoscopic cholecystectomy in the first 7 days after the diagnosis is preferable for its reduced length of stay, while morbidity is similar if the operation is performed after 6 weeks; on the other side, one trial reports that cholecystectomy between 7 and 45 days carries a higher morbidity rate. Therefore, we can affirm that laparoscopic cholecystectomy is safe within 7 days from the diagnosis but, outside that window, is probably better to wait until the 6th week. Large and sophisticated retrospective studies demonstrate that, within the 7 days of diagnosis, the earlier the operation the better the outcome and, ideally, laparoscopic cholecystectomy should be performed within the first 48 h of presentation.

Of course, it is just the case to underline that some of the above examined data use the time of diagnosis or day of admission as surrogate indicators of the onset of symptoms because the knowledge of the real beginning of the latter was not easy to determine; it can be assumed that the symptoms occur just before the hospital admission but this is not always the case. The everyday clinical practice has to keep into consideration this variability.

2.5 Laparoscopic Cholecystectomy in Particular Conditions

If the gold standard role of laparoscopic cholecystectomy for acute cholecystitis in the general population is well clarified by the above reported evidence, still a few particular conditions deserve a separate review. Are the above described principles applicable in every case irrespective of the severity of the inflammation and the local conditions? Are there groups in which a different conduct may be more appropriate?

2.5.1 Severe Cholecystitis

Is laparoscopic surgery indicated for empyema, perforated or gangrenous cholecystitis (severe cholecystitis)? Local inflammatory changes can be a real challenge for

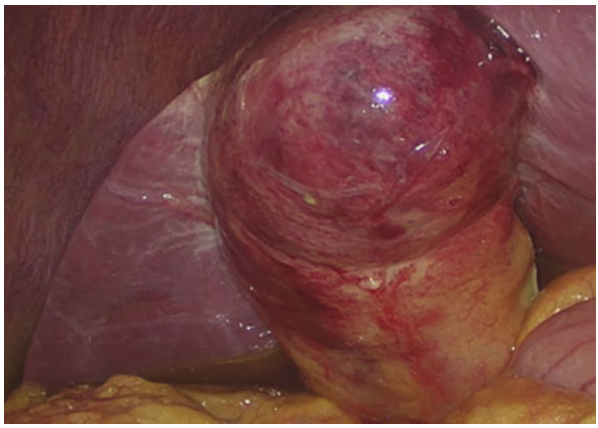

Fig. 2.1 A case of severe cholecystitis: gallbladder empyema

any surgeon, and the question of safety of laparoscopy in these extreme conditions needs to be addressed.

The EAES guidelines published in 2012 stated that empyema, perforated or gangrenous cholecystitis do not preclude the indication for laparoscopic cholecystectomy [6]. However, the Tokyo guidelines incorporate severe cholecystitis in Grade II of their classification (moderate cholecystitis), likely to be associated with increased operative difficulty (Fig. 2.1). Therefore, they advocate more cautious indications with a major propensity for gallbladder drainage and delayed surgery [8].

As a matter of fact, some of the RCTs mentioned in section "Laparoscopic Cholecystectomy for Acute Cholecystitis: The Evidence" specifically included patients with severe cholecystitis [20, 23], and a systematic review of observational series of severe cholecystitis did not show an increase in local postoperative complications despite a threefold conversion rate [56]. In their case-series, Nikfarjam et al. did not find any difference in the complication rate between the gangrenous and non-gangrenous cholecystitis [57].

In addition, some observational reports examined the treatment of severe cholecystitis with the aim to compare open versus laparoscopic surgery. A recent very large retrospective population-based series about gangrenous cholecystitis studied a total of 141,970 cholecystectomies from the 2005–2011 National Surgical Quality Improvement Project Participant User File. The authors extracted 7017 gangrenous cholecystitis. Although they were associated with increased morbidity and mortality compared with the general series of acute cholecystitis, the multivariate logistic regression model demonstrated a significant decrease in overall complication rate (odds ratio = 0.46; $P < 0.001$) for laparoscopic versus laparotomic cholecystectomy, with a lower, although not significant, perioperative mortality (OR = 0.59; $P = 0.12$) [58].

The retrospective investigation by Lo et al. [59] included 74 patients with cholecystitis and gallbladder perforation divided into 3 groups: early open cholecystectomy, early laparoscopic cholecystectomy, and percutaneous gallbladder

drainage followed by delayed elective surgery. There were no differences in operative time, blood loss, conversion rate, and morbidity between the groups, but the length of hospital stay was significantly shorter for laparoscopic cholecystectomy. The authors concluded that early LC should be considered the optimal treatment for gallbladder perforation.

If in Lo's study early laparoscopic cholecystectomy compared favorably with both early open and delayed laparoscopic surgery for perforated cholecystitis, other observational reports examined the treatment of different forms of severe cholecystitis, with the aim to compare early laparoscopic surgery versus some kind of delayed treatment. Recently Choi et al., in a retrospective study about gangrenous cholecystitis, compared patients who had early versus delayed laparoscopic surgery, the latter often preceded by percutaneous cholecystostomy. They failed to find a significant difference in the morbidity rate, and the total hospital stay was longer in the delayed group [60]. Similar results were reported by Kwon et al. about gallbladder empyema [61].

Therefore, laparoscopic surgery is not precluded by severe cholecystitis and actually seems to be beneficial in terms of morbidity and hospital stay. Early surgery appears to be advantageous and there is little support for the assumption that deferring the definitive treatment of these conditions may improve the outcome and reduce complications.

Nonetheless, the operation may be extremely demanding in those cases in which the intense inflammation around the Calot's triangle increases the risk of serious complications. When a positive identification of the vascular and biliary structures cannot be achieved with the "critical view of safety" (Fig. 2.2) [62] a laparotomy is advocated. However, conversion not always grants an improved

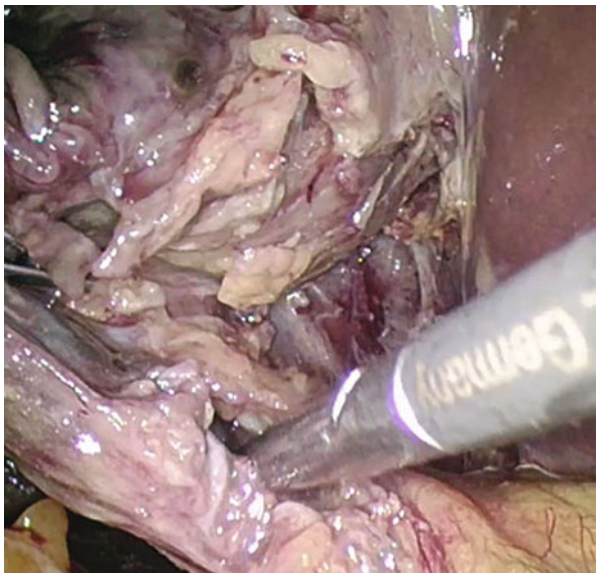

Fig. 2.2 Identification of the "critical view of safety" window in a gangrenous cholecystitis

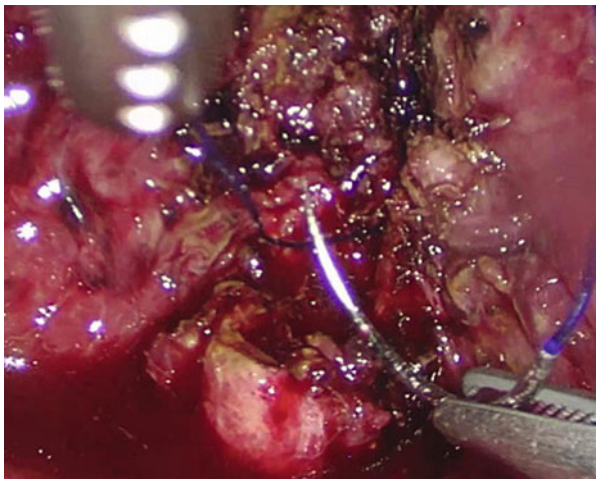

Fig. 2.3 Subtotal laparoscopic cholecystectomy in a patient with "frozen" Calot's triangle: suture of the infundibulum

understanding of the biliary anatomy, and experienced laparoscopic surgeons may proceed laparoscopically with a subtotal (or "partial") cholecystectomy that appears to be a reasonable alternative (Fig. 2.3).

The two most recent systematic reviews about partial cholecystectomy report relatively low morbidity rates, comparable to those of total cholecystectomy in simple cases. Nowadays, most of them are carried out laparoscopically with reduced risk of subhepatic collection (odds ratio OR = 0.4; 95 % CI = 0.2–0.9), retained stones (OR = 0.5; 95 % CI = 0.3–0.9), wound infection (OR = 0.07; 95 % CI = 0.04–0.2), reoperation (OR = 0.5; 95 % CI = 0.3–0.9), and mortality (OR = 0.2; 95 % CI = 0.05–0.9) but more bile leaks (OR = 5.3; 95 % CI = 3.9–7.2) compared with the open approach [63, 64].

2.5.2 Acute Cholecystitis in the Elderly

In a later chapter, we will treat the issue of laparoscopic emergency surgery in the elderly. Here, we will examine some specific aspects concerning acute cholecystitis.

The prevalence of gallstones increases with age and the life expectancy rises worldwide. Therefore, the analysis of the more appropriate treatment modalities in this age group is becoming more and more relevant. In addition, the co-morbidities in the elderly are obviously more frequent and the acute biliary disease itself appears to be more severe in this age group. It does not surprise, then, that age is often considered a risk factor for laparoscopic biliary surgery, particularly in the acute setting, both for morbidity [65, 66] and conversion, [67, 68], but it is very difficult to reach solid conclusions comparing younger versus older patients, because the two age groups are generally not comparable in terms of co-morbidities and functional status.

In the case-series published in 2001 by Decker, cholecystectomy lethality in acute calculous cholecystitis was much higher in the laparoscopic group in patients older than 80 [69]. Lupinacci et al., in their retrospective study, pointed out that the increase in mortality was relevant for cholecystectomy performed in emergency but not for the elective cases [70]. They suggested that, in the aged, laparoscopic cholecystectomy should be performed early after they are found to have symptomatic gallstones, preventing the occurrence of the inflammation, its increased morbidity and mortality risk. Of course, their series had more high risk patients (ASA III and IV) and less laparoscopic cholecystectomies in the urgent (acute cholecystitis) than in the elective groups; these factors can be responsible for part of the worse outcome of the emergency treatment.

Nielsen et al., on the other hand, could demonstrate a significantly worse mortality in the patients older than 80 even if they had a low anesthetic risk (ASA I and II). Their retrospective study showed that the odds for mortality are much higher in the aged (>80) than in the younger groups (65–79 vs. 50–64), with Odds Ratio of 30.86 vs. 5.51 vs. 1 [71].

However, the few observational studies able to compare directly open versus laparoscopic cholecystectomy for acute cholecystitis in the elderly, demonstrated a reduction in hospital stay [72, 73], and morbidity either unchanged [72] or even improved [73] in the patients who had laparoscopic surgery.

Having clarified that mini-invasive cholecystectomy is beneficial even in the aged, one question arises from the above reported data: if it is true that mortality is higher for laparoscopic surgery performed in the acute but not in the elective setting in the elderly group, could delayed cholecystectomy be beneficial at this age?

There is no definitive evidence on this particular aspect. Only a few retrospective cohort studies compare the outcome of early versus delayed cholecystectomy in elderly acute calculous cholecystitis patients. Mortality and morbidity do not appear to be significantly different [74–76]. Furthermore, a recent cohort study showed that recurrent episodes of pancreatitis, cholecystitis, and cholangitis were four times more likely after delayed cholecystectomy, and the conversion rate did not change [77]. These findings are confirmed by a recent population-based study on a sample of the US Medicare Claims Data System. In this analysis, a lack of a definitive surgical treatment at the index admission in the elderly is associated with 38 % gallstone-related readmission rate in 2 years versus 4.4 % in similar patients who had early cholecystectomy and a worse 2-year survival (hazard ratio 1.56, 95 % CI 1.47–1.65) even taking into account patient demographics and co-morbidities [78]. The very large series reported in the study (29,818 Medicare beneficiaries urgently or emergently admitted for acute cholecystitis from 1996 to 2005) showed that most US surgeons are confident in operating elderly cholecystitis patients in emergency: 75 % of the patients aged 66 years and older had an early cholecystectomy (laparoscopic in 71 % of them). The authors conclude in favor of early cholecystectomy for elderly patients to prevent recurrent episodes of cholecystitis, multiple readmissions, and increased costs.

2.6 The High Risk Patient

Acute calculous cholecystitis is a very heterogeneous condition. The severity and complexity of the clinical picture is determined not only by the degree of inflammation and the local conditions but also by the general status of the patient. In the previous chapters we examined the data about laparoscopic cholecystectomy as the definitive therapy of the disease. As a matter of fact, surgery is the gold standard treatment. Nevertheless, quite often, local or general circumstances suggest or even impose a different course of action. The optimal surgical treatment should be examined according to the severity of the disease. In fact, it could be argued that alternative treatment could better fit the needs of patients with reduced functional reserve [2, 3]. Should surgery be avoided in some very high risk patients? Could a delayed treatment be beneficial in some of them? Are there any alternatives to surgery?

The identification of the parameters and instruments to stratify the risk of surgery in this population would be of paramount importance to evaluate the role for alternative therapeutic pathways.

2.6.1 How to Stratify the Risk?

Let's examine the literature to verify if there is any available instrument to select the best course of action in particular high risk groups.

Recently, the Tokyo guidelines attempted to address the acute cholecystitis heterogeneity with a therapeutic algorithm that includes some elements of risk evaluation. Their staging system is based upon severity assessment criteria such as degree of local inflammation and associated co-morbidities, without including any of the most commonly adopted risk stratification scores [11]. However, a retrospective series failed to find any significant benefit following the introduction of their guidelines [79].

Advanced age is often identified as a risk factor for the surgical treatment of acute cholecystitis. We have examined in section "Acute Cholecystitis in the Elderly" the literature about laparoscopic cholecystectomy in the elderly and in particular about the timing for surgery; however, the possibility to compare directly surgical treatment versus an alternative strategy is not available.

In 2006 Yi stratifies the risk in relation to the ASA score, showing a significant difference in morbidity (20 % vs 9.1 %) in patients in ASA III vs ASA I, with no significant differences on the conversion rate, recovery time, and hospital postoperative stay [80].

The only other available comparison of risk assessment scores (ASA, APACHE II, and POSSUM) is limited to the perforated acute cholecystitis. It highlights a significant association of the three scores with morbidity and mortality. Both POSSUM and APACHE II were superior to ASA in risk prediction [81]. However APACHE II is built as an evaluation score in patient admitted to intensive care units,

and its use as preoperative risk prediction instrument may be suboptimal. As a matter of fact, a validated score to choose the best treatment in relation to the patient's surgical risk is currently not available.

2.6.2 The Percutaneous Cholecystostomy

A large amount of literature addresses the role of gallbladder drainage (tube cholecystostomy), generally percutaneous, as an alternative to early surgery in septic high risk patients. More than 100 papers have been published in the last few years about this topic. They are generally small case-series of poor quality. Their inclusion criteria, results, and conclusions are largely not homogeneous. The only randomized controlled trial of cholecystostomy versus surgery is under way and not even preliminary results are available [82]. The purpose of gallbladder drainage is decompression of the infected bile, removal of the purulent collection, and solution of the sepsis with an improvement of the clinical conditions. Surgery may be planned at a later date. In particular, the panel of the Tokyo guidelines states that it is known to be a safe option in critically ill patients, and their guidelines consider the percutaneous (or surgical) drainage as mandatory in the severe grade of acute cholecystitis. Its use is also suggested in the moderate grade. However, cholecystostomy has never been proven to be an effective alternative to early surgery, and the evidence on its role is still poor. With all the methodological limits mentioned above, a survey of the literature shows that in-hospital mortality for cholecystostomy varies between 4 and 50 % and its morbidity between 8.2 and 62 %. A recent systematic review performed a particularly detailed examination of 53 papers about gallbladder drainage as an option in acute cholecystitis. It found no evidence to support the recommendation of tube cholecystostomy rather than straight early emergency cholecystectomy even in critically ill patients. Actually, it suggested that cholecystectomy seems to be a better option for treating acute cholecystitis in the elderly and/or critically ill population. The authors include 53 studies with 1918 patients; once again, they warn that the results obtained from the studies reviewed are very heterogeneous. They outline a high success rate of the procedure (85.6 %) with a low mortality directly related to the procedure (0.36 %) but a 30-day mortality of 15.4 %, significantly higher ($P < 0.001$) than after early cholecystectomy (4.5 %), as reported in published series of similar patients [83]. A recent prospective study in high risk patients examined the outcomes of 29 patients treated by percutaneous cholecystostomy and 32 by emergency cholecystectomy. The groups were homogeneous by age and surgical risk, estimated by physiological POSSUM, Charlson, APACHE II, and ASA scores. Eight patients (29.6 %) in the cholecystostomy group required emergency cholecystectomy anyway. The mortality rate was significantly higher in the cholecystostomy group (17.2 % vs nil). The authors concluded that percutaneous drainage appears of little benefit and should be reserved for the patients with surgical contraindication [84]. A large retrospective cohort study, based on administrative databases capturing all emergency department (ED) visits and hospital admissions in a populous area, examined 27,718 acute

cholecystitis patients. Of them, 890 (3.3 %) underwent tube cholecystostomy. In-hospital mortality was 5 %, but an additional 18 % had died without surgery. Only 40 % had cholecystectomy within 1 year (due to intercurrent mortality or ongoing contraindications) and 49 % was evaluated in the emergency department or admitted to the hospital for a gallstone-related complication [50].

Therefore, at the moment, tube cholecystostomy, as a bridge to surgery or definitive management of acute cholecystitis, cannot be considered as an established and safe option. More studies are needed.

2.6.3 Endoscopic Gallbladder Drainage

In the attempt to find less invasive solutions in the old-frail patients and those with increased surgical risk, endoscopic gallbladder drainage methods have been proposed. Two techniques have been described: the endoscopic transpapillary (ETGD) and endoscopic ultrasound-guided transmural gallbladder drainage (EUS-GBD).

In the former, endoscopic naso-gallbladder drainage and gallbladder stenting via a transpapillary endoscopic approach are included.

In retrospective studies, endoscopic naso-gallbladder drainage and gallbladder stenting have a technical success rate of 81 % and 96 %, but a clinical success rate of 75 % and 88 %, respectively [85]. However, this technique is not feasible if obstruction or tortuosity of the cystic duct does not allow a guidewire to be advanced into the gallbladder.

As an alternative, a drain or a stent can be placed in the gallbladder by the transgastric or transduodenal route under the guide of endoscopic ultrasound (EUS-GBD). A recent systematic review of the English language literature about this technique collected 155 reported patients with acute cholecystitis treated with EUS-GBD in eight studies and 12 case reports. Their technical and clinical success rates were very high and adverse events were reported only in 8 % of the cases [86]. Of course non-comparative observational studies and case reports carry a very high risk of selection bias and further studies are needed to ascertain the potential role of the endoscopic techniques. Besides, the scarce availability of the technical expertise to complete these procedures is an additional limitation factor.

2.7 Conclusions

Laparoscopic cholecystectomy is the gold standard for the definitive management of acute calculous cholecystitis. It should be performed as soon as possible after the symptoms occurrence. The disease, however, is very heterogeneous as far as degree of inflammation and local conditions are concerned; besides, the general characteristics of the patient (age, associated co-morbidities, and functional status) have a very relevant impact on the disease itself, and surgical intervention may result in increased morbidity and mortality in the elderly, patients with multiple co-

morbidities, or those with advanced cholecystitis. The management of the disease should be established according to its severity; but reliable and validated instruments to assess the surgical risk and choose the more appropriate therapeutic pathway for each situation are not available. The search for safer and less invasive interventions takes into consideration surgical, percutaneous, and endoscopic methods (single or combined) to achieve the best possible success. However, the evidences about the outcomes of each therapeutic procedure are difficult to evaluate in this heterogeneous context. The quest for the optimal treatment of acute cholecystitis is still ongoing.

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