Evaluating the Controversial Role of Cholecystostomy in Current Clinical Practice

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Percutaneous cholecystostomy (PC) for the treatment of acute cholecystitis is increasing in popularity, and has served as a definitive treatment, a bridge to surgery, or a means toward other minimally invasive therapies. The absence of quality literature supporting a clear definition of the role of PC and related adjunctive therapies in the treatment of acute cholecystitis often results in inconsistent application of this treatment option in clinical practice. Because excellent overviews of the technique of PC and associated clinical management have been published recently,¹ this article focuses on the controversial indications, complications, and evolving roles of percutaneous cholecystostomy and related therapies.

THE CONTROVERSIAL ROLE OF CHOLECYSTOSTOMY

PC is primarily indicated for accessing the gallbladder to manage cholecystitis or to serve as a portal to remove or dissolve gallstones.² In the current literature and in clinical practice, our colleagues in surgery and internal medicine continue to recommend PC as an alternative to surgical cholecystectomy in patients with acute cholecystitis deemed poor surgical candidates. This trend is based largely on low-grade, retrospective studies and anecdotal clinical experience, which result in an inconsistent and unsupported utilization of PC. The recommendation of PC over surgical alternatives will continue to be based largely on clinical intuition until randomized, controlled trials answer a series of questions regarding the treatment of acute cholecystitis. In summary, controlling for age, clinical parameters supporting the diagnosis, comorbidities, clinical signs of local or systemic infection, hemodynamic status, renal failure, and complications such as gallbladder rupture or abscess forma-

tion, randomized, controlled trials should attempt to address the following unanswered questions:

1. What is the procedural and 30-day morbidity and mortality of PC, open cholecystectomy, and laparoscopic cholecystectomy, and can untoward events resulting from comorbidities be distinguished from those resulting from these procedures?
2. What is the rate of recurrence of acute cholecystitis after removal of cholecystostomy drains placed for both acute calculous and acalculous cholecystitis?
3. For patients presenting with acute calculous cholecystitis, what is the morbidity and mortality after cholecystostomy coupled with adjunctive therapies such as percutaneous gallbladder ablation?
4. How do complication rates of those adjunctive procedures compare with complication rates of surgical cholecystectomy?
5. As technical improvements and clinical experience in laparoscopic cholecystectomy have improved, how does up-to-date laparoscopic cholecystectomy compare with PC with respect to procedural and 30-day morbidity and mortality?

The current literature fails to answer these questions and to establish precise guidelines for the application of PC in actual clinical practice because of the following limitations:

1. Randomized, controlled trials are limited and scant, leaving the basis for clinical decisions regarding the treatment of acute cholecystitis to anecdotal clinical experience, poorly defined clinical parameters for establishing the diagnosis of acute cholecystitis, and reluctance by surgeons to operate based on factors

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such as comfort level, operative experience, and the time of day.

2. Retrospective studies tend to bias PC toward more critically ill and unstable patients with a host of comorbidities deemed unsuitable by surgeons for both general anesthesia and cholecystectomy. Thus, the PC cohort is likely to suffer spuriously high rates of morbidity and mortality compared with the surgically treated cohort.
3. Retrospective studies tend to underestimate the clinical success of PC because clinical support for the diagnosis of acute cholecystitis is highly variable. PC is often prescribed for soft indicators such as “high clinical suspicion” despite little to no imaging evidence as compared with hard indicators such as indisputable findings on hepatobiliary iminodiacetic acid (HIDA) scan, ultrasound, or cross-sectional imaging studies. Because a cholecystostomy tube is unlikely to improve the clinical picture if acute cholecystitis is not present, the PC cohort is likely to suffer low rates of clinical success compared with the surgically treated cohort.
4. Review articles disguised as high-power studies amassing large patient populations produce deceptive results with little clinical applicability because they summarize a series of patient populations lacking precisely controlled and well-defined descriptors for clinical presentation and clinical response. The clinical benefit of a retrospective study of retrospective, uncontrolled studies does not change if the patient population numbers 1000 or 10,000.

To illustrate these problems, a review³ by surgeons of 53 studies comprising 1918 patients identified no randomized, controlled studies comparing the outcomes of PC and cholecystectomy in elderly or critically ill patients with acute cholecystitis. This painstaking review calculated a 30-day mortality of 15.4% in patients treated with PC and only 4.5% in those going directly to cholecystectomy, though such a comparison was emphasized in the final analysis as “not appropriate” based on the inadequate literature carefully outlined in the review. I would suggest the following interpretation: Of the PC patients that ultimately underwent cholecystectomy, 15.4% died, but because this patient cohort usually fell under the description of unacceptably high-risk for surgery in the acute setting, it should be assumed that the mortality rate of acute cholecystectomy would have been much higher. Interestingly, although the aforementioned review is authored by surgeons and falls short of finding a well-substantiated indication for PC over cholecystectomy in the acute setting, in actual clinical practice, the surgeons themselves are the driving force for the popularity of PC because they often control the decision to either perform cholecystectomy or defer patients to PC. They must perceive an advantage for

PC other than the after-hours avoidance of emergent cholecystectomy procedures on-call.

Although some surgeons³ suggest that improvements in laparoscopic technique in recent years may obviate the need for PC in many cases, it should be noted that in the emergent setting, the reported conversion rates to open cholecystectomy have been historically high—often exceeding 15%.⁴ Given this information, when weighing the comparative risks of PC versus surgery in high-risk patients, perhaps open rather than laparoscopic surgery should be considered the comparative surgical option.

As the era of evidence-based medicine progresses, all physicians have had to accept the fact that many treatments are deemed indicated despite only anecdotal or theoretical evidence, expert clinical intuition, and the absence of prospective randomized studies. The bottom line remains: PC is performed when surgeons deem patients with acute cholecystitis to be unsuitable for surgery. That said, what evidence is available to assist in the decision to apply this treatment option?

CHOLECYSTOSTOMY AS A TEMPORIZING MEASURE

Most authors still describe PC as a temporizing measure prior to the definitive open or laparoscopic cholecystectomy. This application is most appropriate in patients with acute calculous cholecystitis. For calculous cholecystitis in otherwise healthy, stable patients, surgical resection of the gallbladder remains the first-line and definitive treatment option, and patients who happen to undergo cholecystostomy as a temporizing measure usually undergo interval cholecystectomy after resolution because of an unacceptable risk of recurrence. Even if resolution of cholecystitis can be achieved and patency of the cystic duct reestablished, recurrence rates after calculous cholecystitis range from 10 to 20%⁵ within the first few years. The utility of cholecystostomy with adjunctive treatments to reduce the risk of recurrence (addressed below) has yet to be fully established in quality, long-term studies. In low-risk patients, published periprocedural mortality rates of both open and laparoscopic cholecystectomy are typically below 1%,⁶ further establishing the one-step, definitive surgical option as a better option than prolonged catheterization after cholecystostomy.

For acute calculous cholecystitis in patients who are elderly, unstable, critically ill or suffering from severe comorbidities, the mortality rate of open cholecystectomy under general anesthesia approaches 20%.⁷ For this delicate patient population, PC with interval cholecystectomy or PC with adjunctive therapies such as stone removal and gallbladder ablation are likely to remain important options in the treatment algorithm.⁸

CHOLECYSTOSTOMY AS A DEFINITIVE TREATMENT

If surgical options under general anesthesia can be avoided by a fast, simple, low-risk procedure under conscious sedation in any patient, it stands to reason that that procedure should become the new primary treatment option. Controversy and confusion over the application of PC raises a key question: Does the existing, albeit insufficient, literature support the potential application of PC as a first-line and potentially definitive therapy for any cases of acute cholecystitis? With randomized, controlled trials, the treatment algorithm will likely evolve, but a review of the limited current literature suggests that there is the greatest support for PC as a first-line, definitive treatment in many patients with acalculous cholecystitis, less support in elderly patients, permanently comorbid patients or critically ill patients with acute calculous cholecystitis, and the least support in otherwise healthy, stable patients with acute calculous cholecystitis.

In the case of acalculous cholecystitis, if the cholecystitis as well as the acute, predisposing clinical conditions leading to its manifestation resolve, the cholecystostomy tube can be removed without the need for elective interval cholecystectomy in most cases. The question of whether or not to perform interval cholecystectomy depends on the risk of recurrence, which, though not adequately determined, is likely to be low based on the current literature. Chung et al retrospectively reviewed 57 patients undergoing PC for acute acalculous cholecystitis and found that of the 49% managed nonoperatively and followed over a median period of 32 months, only 7% of the nonoperative group recurred.⁹ This result raises the possibility that performance of elective cholecystectomy is often not worth the risk in a patient population that tends toward multiple, long-term systemic comorbidities.

In patients with calculous cholecystitis for whom cholecystectomy is likely to remain contraindicated indefinitely, authors have described permanent external drainage or the application of therapies described in the next section. Included in this category are many patients with nonoperable malignant obstruction of the cystic duct, high-risk elderly patients, and patients with critical illnesses and multiple comorbidities. In such patients, the choice of cholecystostomy versus cholecystectomy in the acute setting is made by estimating the risks of the two interventions on a case-by-case basis.

ADJUNCTIVE AND ASSOCIATED THERAPIES

Some authors have argued for the application of PC in patients who are likely to remain poor surgical candidates indefinitely. In such cases, cholecystostomy with or

without adjunctive therapies has been described as a first-line and definitive treatment. The availability of such therapies may sway the decision toward PC in select cases. They include percutaneous stone removal, gallbladder ablation, and gallbladder aspiration. Patients with gallbladder rupture and pericholecystic abscess are not considered candidates for these therapies.

Figure 1 (A) Axial, contrast-enhanced computed tomography image shows a cholecystostomy drain coiled within the gallbladder (large arrow). The radiopaque marker indicating the position of the most peripheral sidehole (small arrow) has been inadvertently retracted to the peritoneum, and a large bile leak has developed in the right perihepatic space (arrowhead). Note that this catheter was placed via a transperitoneal window, which may reduce catheter stability. (B) Coronal reconstruction shows bile extending from the subdiaphragmatic space to the pelvis (arrowhead). Gas in the subdiaphragmatic space (arrow) indicated superinfection in this patient who presented with sepsis and peritonitis.

Stone Removal

Authors have employed the cholecystostomy tract to facilitate removal of gallstones by basket extraction,^{10,11} dissolution with bile acids, and/or destruction and retrieval with shock-wave lithotripsy.^{12,13} Retrospective studies have demonstrated a gallstone recurrence rate of ~10 to 30% per year and a symptomatic recurrence rate requiring repeat treatment of ~6 to 18% per year. Stone removal can be repeated as needed, but the high rate of symptomatic recurrence and the risks and consequences of recurrent acute cholecystitis

may limit the future of this option as a definitive treatment.

Gallbladder Ablation

A combination of thermal ablation of the cystic duct and chemical ablation of the gallbladder lumen have been described to treat patients at high risk for complications of surgery. Xu et al described small-bore cholecystostomy followed by microwave ablation of the cystic duct and chemical ablation of the gallbladder lumen by infusion of

Figure 2 (A) This fluoroscopic image was obtained immediately after percutaneous cholecystostomy for acute acalculous cholecystitis. The catheter is positioned correctly (arrow). (B) The patient was referred back to interventional radiology for worsening fevers and abdominal pain. The catheter is kinked (arrow). (C) Axial, noncontrast computed tomography image shows that the tube does not pass through liver parenchyma, which may reduce its stability.

Figure 3 (A) Prior to catheter removal, one should obtain a fluoroscopic image showing contrast opacification of the cystic duct (arrow) and common bile duct (arrowhead) and free spillage of contrast into the small bowel. (B) An over-the-wire tractogram is usually obtained to verify the presence of an intact tract (arrow) to prevent bile leakage and peritonitis.

95% ethanol¹⁴ in 34 patients. Ethanol infusion for 30-minute intervals was repeated every 4 hours eight times. In this retrospective study, mean follow-up was 9 years and the long-term clinical success without recurrence was 85.3%. Future corroboration of these results in randomized, controlled trials would suggest a place for ablation as a primary, definitive treatment in high-risk patients with calculous cholecystitis.

Gallbladder Aspiration

Some interventional radiologists have advocated gallbladder aspiration over PC for the treatment of acute cholecystitis. Theoretically, the success of aspiration is dependent on two assumptions: the gallbladder cannot refill after drainage (a ball-valve obstruction is not present) and adequate drainage is achievable. Ito et al prospectively randomized patients with severe acute cholecystitis to either PC ($n = 30$) or gallbladder aspiration with a 21-gauge needle ($n = 27$) and obtained good clinical response in 90% of PC patients versus 61% of aspiration patients, with no difference in procedural complication rates.¹⁵ Despite its lower clinical response rate, aspiration alone removes the risk of delayed complications of prolonged catheterization such as dislodgment and obstruction.

Chopra et al suggest a place for gallbladder aspiration as a primary treatment for high-risk patients with acute cholecystitis who are not critically ill,¹⁶ and reserving PC as a salvage procedure if aspiration is technically or clinically unsuccessful. They retrospectively compared 31 patients who underwent aspiration with 22 who underwent PC and found no difference in

clinical outcomes of the acute cholecystitis but a higher complication rate for PC. However, unlike gallbladder ablation or gallstone removal, gallbladder aspiration still fails to offer a protracted solution to address the high recurrence rates of acute calculous cholecystitis, a life-threatening condition.

COMPLICATIONS OF CHOLECYSTOSTOMY

Major periprocedural complications include sepsis, hemorrhage, abscess, peritonitis, transgression of intervening structures such as the colon, and death.² Studies of patients with the poorest clinical status demonstrate an incidence of up to 2 to 3% for each of these complications, but other studies report lower rates that compare favorably with surgical alternatives in the setting of acute cholecystitis in critically ill patients with multiple comorbidities. Major postprocedural complications include inadvertent catheter dislodgment or removal resulting in repeat PC, surgery, or death (<1%). Although there is likely no difference in the incidence of peritonitis after transperitoneal versus transhepatic placement, transhepatic placement may improve stability during and after placement (Figs. 1, 2). Safe removal of the catheter is usually performed after complete demonstration of cystic and common bile duct patency and an intact tract (Fig. 3).

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