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Single-Stage Cholecystectomy at the Time of Pancreatic Necrosectomy Is Safe and Prevents Future Biliary Complications: a 20-Year Single Institutional Experience with 217 Consecutive Patients

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Abstract
Introduction Current guidelines recommend cholecystectomy (CCY) during the index admission for mild to moderate biliary pancreatitis as delayed CCY is associated with a substantial risk of recurrent biliary events. Delayed CCY is recommended in severe pancreatitis. The optimal timing of CCY in necrotizing pancreatitis, however, has not been well studied. We sought to determine the safety of single-stage CCY performed at the time of necrosectomy and its effectiveness in preventing subsequent biliary complications.
Methods We retrospectively queried our institutional database of patients who underwent pancreatic necrosectomy for necrotizing pancreatitis from 1992 to 2012.
Results We identified 217 consecutive patients who underwent pancreatic necrosectomy during the study period. The most common etiologies of pancreatitis were biliary (41 %) and alcoholic (24 %), with a median computed tomography (CT) severity index score of 6±1.6 and a 63.6 % incidence of infected necrosis. Ninety-eight patients had undergone CCY prior to necrosectomy. Seventy patients (59 % of those with gallbladders in situ) underwent CCY at the time of pancreatic necrosectomy. CCY was not performed in the remaining 49 due to a clear non-biliary etiology (35 %), technical difficulty (29 %), intraoperative hemodynamic instability (18 %), or surgeon preference (18 %). Postoperative morbidity and mortality was no different between the CCY and no CCY groups, with no bile duct injury or bile leaks in patients undergoing CCY at the time of necrosectomy. Of the patients undergoing CCY, 43 % of patients without cholelithiasis or biliary sludge on preoperative imaging had gallstones or sludge identified pathologically after single-stage CCY. Of those who did not receive a single-stage CCY, biliary complications developed in 17 (35 %) of patients (21 % cholecystitis, 14 % recurrent gallstone pancreatitis) at a median time to incidence of 10 months. Seventeen (35 %) patients eventually received a postnecrosectomy cholecystectomy, of which 75 % required an open procedure.
Conclusion Single-stage CCY at the time of pancreatic necrosectomy is safe in selected patients and should be performed if technically feasible to prevent future biliary complications and reduce the need for a subsequent separate, often open, CCY.

Keywords Pancreatic necrosectomy · Single-stage cholecystectomy · Cholecystitis · Gallstone pancreatitis

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Introduction

Acute pancreatitis is the single most frequent gastrointestinal cause of hospital admissions in the USA, affecting up to 45/100,000 persons and accounting for roughly $2.2 billion of inpatient cost annually.[1,2] The incidence of acute pancreatitis is rising and will likely only continue to do so as the population ages and the prevalence of obesity increases.[3–5] Approximately 44 to 54 % of these episodes of pancreatitis are caused by gallstones, and another 20 to 34 % are of unclear

etiology and may be related to occult biliary disease such as sludge or microlithiasis.[3] Without cholecystectomy (CCY), the risk of recurrent biliary pancreatitis and other biliary tract complications is as high as 18 % over a median period of 40 days.[6]

In order to mitigate these risks, current guidelines recommend CCY during the index admission for mild to moderate biliary pancreatitis.[7] Due to a higher rate of perioperative complications during CCY performed soon after severe pancreatitis with peripancreatic fluid collections, it is recommended to delay cholecystectomy in these cases until the collections are resolved or for at least 6 weeks.[8] The optimal timing of CCY in patients with necrotizing pancreatitis has not been well studied. We hypothesized that CCY performed at the time of pancreatic debridement would not add significant morbidity to the procedure but would decrease the risk of subsequent biliary tract complications.

Methods

This study was approved by Massachusetts General Hospital's (MGH) Institutional Review Board (study protocol no. 2011P002679) and was HIPAA compliant. We retrospectively queried our institutional database of patients who underwent pancreatic necrosectomy for necrotizing pancreatitis from 1992 to 2012. Relevant biliary-related variables (preoperative gallbladder imaging, single-stage CCY at time of necrosectomy, final pathology, postoperative biliary complications, need for eventual CCY postnecrosectomy) were supplemented to the database by means of an independent medical chart review.

Definitions and Grading Systems

Infected necrosis was confirmed if there was a positive microbiological culture from fine-needle aspiration or catheter drainage before necrosectomy or positive culture from index necrosectomy. Pancreatic fistula was defined as drainage of amylase-rich fluid (>450 U/ml) either through surgical drains or skin openings including through surgical site closures or cutaneous fistulas. Postoperative bleeding was defined as any decrease in hematocrit levels, with or without hemodynamic instability, that prompts angiographic, surgical, or endoscopic interventions or hemodynamic instability that requires two or more units of blood for treatment.

The computed tomography (CT) severity score index (Balthazar score) was used to characterize the extent of pancreatic parenchymal injury in patients with necrotizing pancreatitis. This scoring system combines a predefined acute pancreatitis grade[9] with the degree of pancreatic necrosis stratified according to the proportion of pancreatic parenchyma involved[10] and has been validated and shown to have prognostic correlation with disease morbidity and mortality. The Acute Physiology and Chronic Health Evaluation (APACHE) II score was used to stratify the patient's physiologic state 24 h prior to pancreatic necrosectomy.[11]

Surgical Technique

Open necrosectomies were performed by utilizing standard techniques. The majority were approached via a midline incision, with the lesser sac entered through the transverse mesocolon or the gastrocolic omentum. After entering the lesser sac, necrotic pancreatic tissues were bluntly dissected, leaving healthy parenchyma. If a single-stage cholecystectomy was to be performed, it was carried out in using the standard dome-down technique. At the conclusion of the procedure, closed suction drains were placed in all patients and, for a significant number of patients, ¾-in. Penrose drains stuffed with gauze were packed into each major extension of the cavity, brought out through separate stab wounds, and secured to the skin with sutures as previously described.[12]

Statistical Analyses

Statistical analyses were performed using Intercooled Stata software, version 12.0 (StataCorp, College Station, TX) and SAS version 9.2 (SAS Institute Inc., Cary, NC). Continuous variables were summarized as mean±standard deviation or median, as appropriate based on their distribution. Categorical variables were reported as frequencies and proportions. All reported p values are two sided and $p \leq 0.05$ was used to indicate statistical significance.

Results

Between January 1992 and January 2012, we identified 217 consecutive patients who underwent pancreatic necrosectomy for necrotizing pancreatitis with a median follow-up of 32 months. The most common etiologies of pancreatitis were biliary (41 %) and alcoholic (24 %), with a median CT severity index score of 6±1.6 and a 64 % incidence of infected necrosis. Twenty-eight percent of patients experienced organ failure within the 24 h prior to necrosectomy, with a similar proportion of patients requiring ICU admission prior to necrosectomy. The mean APACHE II score in the 24 h prior to necrosectomy was 7±5.7. Thirty-two percent of patients received percutaneous drainage prior to necrosectomy, with the mean time from the onset of pancreatitis to pancreatic necrosectomy being 37 days.

Of the 217 patients undergoing pancreatic necrosectomy, 70 (59 %) patients underwent concomitant CCY (Fig. 1). In the CCY group, an intraoperative cholangiogram (IOC) was performed in 6 (2.8 %) patients. Four IOCs were performed to evaluate for choledocholithiasis, which was not found, and

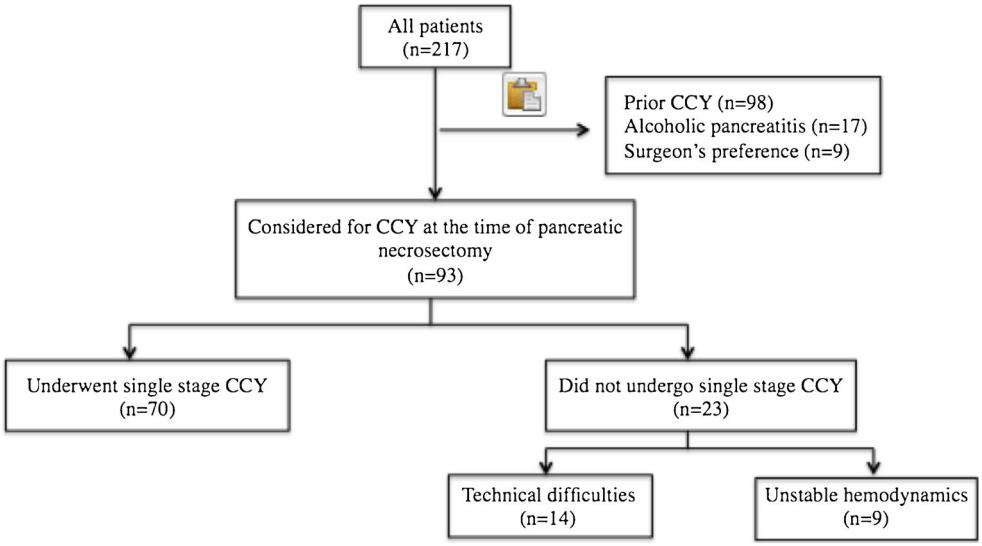

Fig. 1 Denominator diagram of patients who underwent single-stage cholecystectomy at the time of pancreatic necrosectomy and those that did not. *CCY* cholecystectomy

two were performed to confirm biliary anatomy prior to cystic duct transection. The CCY cohort was analyzed against the no CCY group. There was a statistically significant difference in the etiology of pancreatitis between both groups; 83 % of patients in the CCY group had biliary pancreatitis, versus 50 % in the no CCY group ($p<0.001$). There were no differences in patient demography, CT severity index score, incidence of infected necrosis, severity of disease, need for percutaneous intervention prior to necrosectomy, and time from admission to necrosectomy (Table 1).

The duration of surgery was longer for patients who underwent simultaneous CCY when compared to the group that did not (128 vs 100 min, $p=0.003$). The estimated operative blood loss (425 vs 375 cc, $p=0.459$) and requirement for intraoperative blood transfusion (40 vs 40 %, $p=1.000$), however, did not differ. The postoperative outcome did not differ between groups (Table 2). Postoperative bleeding occurred in 2.9 and 6.1 % of patients in the CCY and no CCY groups, respectively ($p=0.305$). Similarly, there was no difference in the incidence of pancreatic fistula between the groups (40 % in the CCY group vs 36 % in the no CCY group, $p=0.574$). In the CCY group, there were no incidences of bile duct injury or biliary leaks.

Based on final histopathological analysis, 79 % of patients with gallstones or biliary sludge on preoperative imaging had gallstones or sludge identified on final pathological analysis. Forty-three percent of patients who had no cholelithiasis or biliary sludge on preoperative imaging had gallstones or sludge identified pathologically in the gallbladder specimen after single-stage CCY (Table 3).

In the no CCY group ($n=147$), 98 patients had undergone CCY prior to the time of necrosectomy. In the remaining 49 patients, CCY was not performed due to a clear non-biliary etiology (35 %), technical difficulty (29 %), intraoperative hemodynamic instability (18 %), or surgeon preference (18 %) (Table 4). Of those who did not receive a single-stage CCY, biliary complications developed in 17 (35 %) patients (21 % cholecystitis, 14 % recurrent gallstone pancreatitis) at a median time to incidence of 10 months (range 0.5 to 112 months). This is in contrast to the simultaneous CCY group where only 3 (4.3 %, $p<0.001$) patients developed biliary complications (all were biliary pancreatitis). Of the patients in the no CCY group who eventually developed biliary complications, 37 % had no gallstones or sludge on preoperative imaging. In the no CCY cohort, 17 (35 %) patients eventually received a postnecrosectomy cholecystectomy, of which 75 % required an open procedure.

Discussion

The International Association of Pancreatology/American Pancreatic Association (IAP/APA) evidence-based guidelines for the management of acute pancreatitis recommend that CCY should be performed during index admission for mild biliary pancreatitis, but should be delayed in patients with severe biliary pancreatitis with peripancreatic collections until the collections either resolve or 6 weeks has passed.[13] After discussion at the consensus conference, the committee declined to make a recommendation on the advisability of performing simultaneous cholecystectomy at the time of pancreatic necrosectomy, citing a lack of evidence. That discussion provided the impetus for us to perform this study.

The recommendation for index CCY in mild biliary pancreatitis is based on a systematic review of nine studies describing 988 patients with almost equal distribution of patients undergoing CCY at index admission (48 %) versus interval CCY after a median of 40 days. In that study, the interval CCY group experienced increased readmission for biliary events when compared to the CCY at index admission group (18 vs

Table 1 Patient demographics and disease-related variables of patients with necrotizing pancreatitis undergoing necrosectomy, dichotomized to those that received simultaneous CCY and those that did not

	All patients, % (n=217)	Simultaneous CCY with pancreatic necrosectomy, % (n=70)	No CCY at time of pancreatic necrosectomy, % (n=147)	p value
Male	66.8	75.7	62.6	0.055
Age (years)	57±15.4	55.5±13.9	59±16	0.854
Etiology of pancreatitis				
Biliary	41.0	64.3	29.9	
Alcoholic	24.4	12.9	29.9	
Other	34.6	22.8	40.2	<0.001
CT severity index score	6±1.6	6±1.8	5±1.6	0.340
Necrosis (%)				
0–30	72.4	65.5	75.7	
31–50	12.9	18.1	10.4	
>50	14.7	16.4	13.9	0.164
Infected necrosis				
Suspected	6.9	4.3	8.2	
Confirmed	63.6	67.1	61.9	0.837
Organ failure 24 h before necrosectomy	28.1	24.3	29.9	
Cardiovascular	8.8	4.3	10.9	
Pulmonary	23.0	17.1	25.9	
Renal	11.1	11.4	10.9	0.387
ICU admission 24 h before necrosectomy	28.1	20.0	31.9	0.067
APACHE II score 24 h before necrosectomy	7±5.7	6±5.2	7±5.9	0.111
Perc drainage before necrosectomy	32.3	28.6	34.0	0.423
Day from admission to first necrosectomy	37±171.8	36±120.9	37±191.6	0.730
Median no. of necrosectomies	1±0.4	1±0.3	1±0.4	0.538

CCY cholecystectomy, *CT* computed tomography, *ICU* intensive care unit, *APACHE* Acute Physiology and Chronic Health Evaluation, *Perc* percutaneous

0 %, p<0.0001). A similar study from the Dutch Pancreatitis Study Group corroborated these findings (13.7 % readmission for biliary events)[14] and, together with the systematic review, led to a strong recommendation (grade 1C) supporting index CCY for mild biliary pancreatitis.[6] The recommendation for delayed CCY in severe biliary pancreatitis, however, is solely based on two retrospective studies and is weak (grade 2C). In a study of 151 patients, Nealon et al. found an increased incidence of infected collections in patients undergoing early CCY after severe biliary pancreatitis.[8] Patients undergoing pancreatic necrosectomy for biliary pancreatitis routinely underwent cholecystectomy at the author's institution, but were excluded from the study. In the other study of just 30 patients, Heider et al. reported no recurrent biliary events

Table 2 Intraoperative and postoperative outcomes of patients with necrotizing pancreatitis undergoing necrosectomy, dichotomized to those receiving simultaneous CCY and those that did not

	All patients, % (n=217)	Simultaneous CCY with pancreatic necrosectomy, % (n=70)	No CCY at time of pancreatic necrosectomy, % (n=147)	p value
Duration of surgery	115±55	128±52	100±53	0.003
EBL	375±787	425±770	375±727	0.459
PRBC transfusion	40	40	40	1.000
Postoperative bleeding	5.1	2.9	6.1	0.305
Pancreatic fistula	37.3	40.0	36.1	0.574
LOS after necrosectomy	17±32	16±29	18±33	0.575
Reoperation	11.1	8.6	12.2	0.420
Mortality	8.3	5.7	9.5	0.342

EBL estimated blood loss, *CCY* cholecystectomy, *LOS* length of stay

Table 3 Correlation between the presenting preoperative imaging of biliary disease with the final postoperative histopathological analysis

	Positive pathology, % (n=42)	Negative pathology, % (n=24)
Positive imaging	79.0	21.0
Negative imaging	42.9	57.1

during the waiting interval prior to CCY if endoscopic sphincterotomy was performed,[15] leading to the aforementioned recommendation. Overall, we believe the evidence for the effectiveness of early cholecystectomy for preventing recurrent biliary complications is much stronger than the evidence that early cholecystectomy is harmful in severe pancreatitis. Furthermore, the complication most strongly associated with early cholecystectomy in severe pancreatitis—infection of peripancreatic collections—may not be relevant to the population of patients undergoing pancreatic necrosectomy in which peripancreatic collections are either already infected or will be evacuated at the time of surgery. No prior studies have investigated the safety and feasibility of simultaneous CCY at the time of open necrosectomy.

We audited our institutional experience with single-stage CCY at the time of pancreatic necrosectomy in severe pancreatitis of all etiologies. General concerns about single-stage CCY include the advisability of performing an additional procedure in patients who may be hemodynamically unstable from necrotizing pancreatitis and the safety of CCY in an inflamed abdominal environment which in theory could increase the rates of bleeding, biliary tract injury, or infection. Our data indicate that simultaneous CCY at the time of necrosectomy was safe and usually feasible. We found slightly higher operative times in the CCY group, but no evidence of increased morbidity or mortality. The duration of surgery was longer in the CCY group, but the estimated blood loss and requirement for intraoperative blood transfusion were no different between both groups.

In patients with a gallbladder who did not receive a single-stage CCY, biliary complications developed in 35 % of patients (21 % cholecystitis, 14 % recurrent gallstone pancreatitis) at a median time to incidence of 10 months, versus 4 % in the single-stage CCY group. It is important to note that while endoscopic sphincterotomy reduces subsequent biliary complications (from 24 to 10 % at a median follow-up of 40 days in one study), CCY confers superior protection against biliary events (0 to 4 % in the literature at 31 weeks, 4.3 % in our series).[6,14] Additionally, within the no CCY cohort, 17 (12 %) patients eventually received a postnecrosectomy cholecystectomy, of which 75 % required an open procedure, well known to carry a higher perioperative morbidity, mortality, and prolonged length of hospital stay.[16] It is also worth noting that all the aforementioned studies and recommendations from guidelines specifically referred to gallstone-induced pancreatitis. Within our study, 43 % of patients who had no radiographic evidence of cholelithiasis preoperatively were found to have gallstones or sludge identified within the gallbladder specimen on final histopathological analysis. In fact, 37 % of patients who did not receive single-stage CCY and developed biliary complications did not have evidence of gallstones or biliary sludge prior to their pancreatic necrosectomy. This suggests that CCY should possibly be considered even in pancreatitis of unclear etiology.

Table 4 Reasons for why simultaneous CCY was not performed with pancreatic necrosectomy in the no CCY group

Reasons simultaneous CCY was not performed with pancreatic necrosectomy, % (n=147)	
Did not have gallbladder at time of necrosectomy	45.1
Alcoholic pancreatitis etiology	11.5
Technical difficulties	9.5
Unstable hemodynamics	6.1

CCY cholecystectomy

The utility of intraoperative cholangiography (IOC) at the time of CCY for gallstone pancreatitis is not well defined. Small retrospective studies have reported no difference in the rate of recurrent pancreatitis or biliary complications when IOC was utilized at the time of CCY.[17,18] One even suggested that IOC resulted in a longer operative time and a prolonged postoperative course with no effect on the incidence of retained common bile duct stones.[19] One quarter of patients with gallstone pancreatitis may have stones in the common bile duct at the time of IOC, a proportion of which would pass spontaneously.[18–21] At our institution, we do not routinely perform IOC at the time of cholecystectomy unless technical difficulty is encountered at the time of CCY or if there is concern for persistent choledocholithiasis. As reported above, IOC was performed in only six (2.8 %) patients. No choledocholithiasis was found at the time of pancreatic necrosectomy, though a number of patients had undergone preoperative endoscopic retrograde cholangiopancreatography (ERCP) and sphincterotomy. If choledocholithiasis were found at the time of debridement, the choice of whether to perform surgical common bile duct exploration or postoperative ERCP and sphincterotomy would need to be made on a case-by-case basis.

This study has a number of limitations. Only patients in whom CCY was judged intraoperatively to be reasonable and feasible based on the physiologic status of the patient and the perceived technical difficulty underwent single-stage CCY. This study should not be interpreted as an endorsement of single-stage CCY at the time of pancreatic necrosectomy in all cases of biliary pancreatitis. It is entirely possible that if this

were undertaken, significant complications related to CCY would arise. Rather, our data show that with appropriate intraoperative decision-making, single-stage CCY can be safely performed in selected patients and that this effectively reduced subsequent morbidity related to the biliary tract. This study analyzed patients undergoing open necrosectomies and simultaneous cholecystectomies by experienced pancreatic surgeons in a high-volume referral center. Whether these results are generalizable to laparoscopic approaches during minimally invasive necrosectomy or in the general community is unknown. This study also has important implications regarding the timing of CCY for biliary pancreatitis patients debrided by endoscopic and retroperitoneal routes. As video-assisted retroperitoneal[22] and endoscopic debridement[23] gain popularity, it is likely that more patients will retain their gallbladders after necrosectomy. Our data strongly suggests that cholecystectomy should be performed in these patients to reduce their subsequent risk of biliary complications. We also report a relatively high rate of open CCY in patients undergoing CCY after pancreatic necrosectomy. Our data encompass two decades of clinical practice, and it is likely that as experience with laparoscopic CCY has grown, our data may overestimate the current need for open CCY after necrosectomy. Finally, due to our retrospective cohort design, we may fail to capture late complications that were not managed at our institution.

In summary, this is the first study investigating outcomes after single-stage CCY at the time of pancreatic necrosectomy and showing that it is safe in selected patients. Single-stage CCY should be performed if technically feasible to prevent future biliary complications and reduce the need for a subsequent separate, often open, abdominal operation. We propose that future consensus statements and evidence-based guidelines consider revising their recommendations to support performing CCY at the time of necrosectomy for biliary pancreatitis if feasible.

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Discussant

Dr. Nicholas J Zyromski (Indianapolis, IN):

The authors demonstrate that cholecystectomy can safely be included at the same time as pancreatic necrosectomy in select patients. This highlights the excellent clinical judgement from this experienced group.

Two points are important. First, 35 % of patients who did not have cholecystectomy developed recurrent biliary symptoms (cholecystitis and pancreatitis) within the next 10 months. Secondly, 43 % of patients with no preoperative imaging evidence of biliary pathology (stones or sludge) ultimately were found to have either gallstones or sludge at final pathologic analysis.

I have two questions:

1.Regarding safety of cholecystectomy, can you tell us more information about intraoperative variables in these two groups—i.e., EBL, OR time, etc.

2.Tell us about your strategy regarding cholangiography—is this routine practice at MGH?

Closing Discussant

Dr. Zhi Ven Fong (Boston, MA)

Thank you, Dr. Zyromski, for your insightful comments. Your group has contributed to a great deal of our understanding of the disease process, and we are privileged to have a pancreatitis expert such as yourself to discuss our paper.

We decided to exclude the intraoperative variables in these two groups because metrics such as EBL, OR time, and need for blood transfusion are not likely to be representative of the feasibility of the cholecystectomy. Rather, it would be more of a reflection of the degree of necrosis and friability of the pancreatic parenchyma involved in the necrotizing process, which was very heterogeneous in both groups. Instead, we utilized end points like common bile duct injury and biliary leaks as end points that would be more reflective of the safety of single-stage CCY at the time of necrosectomy. That said, when the initial analysis was performed, there were no differences in EBL and OR time between both CCY and no CCY groups.

In addressing your second question, it depends on what we are performing the cholangiography for—to interrogate the biliary tract for gallstones or to delineate intraoperative biliary anatomy (cystic and common bile duct location) in technically difficult situations. There were very few cholangiograms performed in these patients. At MGH, we perform cholangiography for most patients needing a CCY after biliary pancreatitis, but not for run-of-the-mill cholecystitis or during CCY after non-biliary pancreatitis unless clinically indicated. In this series of CCYs done at the time of pancreatic debridement, if there was any belief that we needed a cholangiogram to ascertain intraoperative biliary anatomy, we would forego the CCY altogether (and the case would be categorized as no CCY because of technical difficulty as described in this manuscript).

That said, if a cholangiogram was done and common bile duct gallstones were found in the setting of a feasible CCY, we would hesitate to recommend a common bile duct exploration at the time of pancreatic debridement, but would favor a postoperative endoscopic sphincterotomy for most cases.

We would like to emphasize again that we are not advocating for single-stage CCY in all patients undergoing necrosectomy. Rather, our data suggest that if it is deemed technically feasible, and the patient is hemodynamically optimized to tolerate the additional procedure, a single-stage CCY should be performed to reduce the significant risk of subsequent biliary complication, which oftentimes necessitates a separate, open abdominal procedure.