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Percutaneous Cholecystostomy as a Complementary or Alternative Method to Laparoscopic Cholecystectomy in Elderly and Comorbid Patients with Acute Calculous Cholecystitis

Akut Taşlı Kolesistitli Yaşlı ve Komorbid Hastalarda Laparoskopik Kolesistektomiye Tamamlayıcı veya Alternatif Bir Yöntem Olarak Perkütan Kolesistostomi

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ABSTRACT

Objectives: The technical and the clinical efficacy of percutaneous cholecystostomy (PC) in the management of acute calculous cholecystitis, factors affecting postprocedural morbidity and complications, and predictive factors that affect long-term results including recurrence of disease and eventual cholecystectomy were evaluated in a cohort of elderly with comorbid diseases.

Methods: The study group consisted of 80 PC patients, aged 50 or older. They were graded/classified according to Tokyo Guidelines 2018 for Acute Cholecystitis (TG18), Charlson Comorbidity Index (CCI), and the American Society of Anesthesiologists Physical Status Classification System.

Results: The technical success rate was 100%. The clinical efficacy was 65%, and the partial clinical efficacy was 93.33%. The 30-day mortality due to comorbid conditions was 11.25% and the mean time to death was 14.78±5.91 days. Patients who died and who survived were significantly different regarding mean ASA scores (p=0.003) and mean TG18 grades (p=0.032). Major complication was seen in only 2.5% and minor complication was seen in 3.75% patients. The median time from PC to discharge was 5 days. During a 12-month course, 18.75% of patients died. Of the remaining patients, 86.15% were able to be managed only with a temporary PC. The 1-year interval cholecystectomy rate was 13.85%. The median time to cholecystectomy was 72.50 days with a range between 7 and 340 days. There was no relationship between TG18/CCI and the subsequent need for cholecystectomy.

Conclusion: PC provides a significant clinical improvement in the early course and is life-saving in elderly and comorbid patients with acute calculous cholecystitis.

Keywords: Cholecystectomy; cholecystitis; cholecystostomy; gallbladder.

ÖZET

Amaç: Akut taşlı kolesistit tedavisinde perkütan kolesistostominin teknik ve klinik etkinliği, işlem sonrası morbidite ve komplikasyonları etkileyen faktörler, hastalığın nüksü ve nihai kolesistektomi gibi uzun dönem sonuçları etkileyen prediktif faktörler komorbid hastalıkları olan yaşlı bir kohortta değerlendirildi.

Yöntem: Çalışma grubu 50 yaş ve üstü 80 perkütan kolesistostomi hastasından oluşturuldu. Akut Kolesistit İçin Tokyo Kılavuzu 2018'e (TG18), Charlson Komorbidite İndeksi (CCI) ve Amerikan Anestezistler Derneği (ASA) Fiziksel Durum Sınıflandırma Sistemine göre derecelendirildi/sınıflandırıldı.

Bulgular: Teknik başarı oranı %100 idi. Klinik etkinlik %65 ve kısmi klinik etkinlik %93,33 idi. Komorbid durumlara bağlı 30 günlük mortalite %11,25 ve ortalama ölüm süresi 14,78±5,91 gün idi. Ölen ve hayatta kalan hastalarda, ortalama ASA skorları (p=0,003) ve ortalama TG18 dereceleri (p=0,032) önemli ölçüde farklıydı. Majör komplikasyon sadece %2,5 hastada, minör komplikasyon ise %3,75 hastada görüldü. Perkütan kolesistostomiden taburcu olmaya kadar geçen medyan süre beş gündü. On iki aylık bir takip sırasında hastaların %18,75'i eksitus oldu. Kalan hastaların %86,15'i sadece geçici perkütan kolesistostomi ile tedavi edildi. Bir yıllık interval kolesistektomi oranı %13,85 idi. Kolesistektomiye kadar geçen medyan süre 72,50 gündü ve 7 ile 340 gün arasında değişiyordu. TG18/CCI ile kolesistektomi ihtiyacı arasında bir ilişki yoktu.

Sonuç: Akut taşlı kolesistitli yaşlı ve komorbid hastalarda perkütan kolesistostomi erken dönemde önemli bir klinik iyileşme sağlamaktadır ve hayat kurtarıcıdır.

Anahtar sözcükler: Akut kolesistit; kolesistektomi; kolesistostomi; safra kesesi.

Acute cholecystitis is a common disease with significant risk of morbidity and mortality, especially in cases with poor general condition.[1] Standard and definitive treatment of this disease is laparoscopic cholecystectomy.[2] Open surgery is only reserved for cases with severe inflammation and fibrosis.[3] Surgery, whether open or laparoscopic, has significant risk in patients with advanced age and/or comorbid conditions.[4] Both of these factors are present in the majority of patients with acute cholecystitis. For such cases, percutaneous cholecystostomy (PC) is the only method that can be used to prevent major complications of acute cholecystitis and it may serve a bridge to surgery.[5-7] Recently, it has also been speculated that PC could even provide definitive treatment in certain cases.[8-10]

In this study, the technical and the clinical efficacy of PC in the management of acute calculous cholecystitis, factors affecting postprocedural morbidity and complications, and predictive factors that affect long-term results including recurrence of disease and eventual cholecystectomy were evaluated in a cohort of elderly with comorbid diseases.

Methods

Ethical Approval

The study was approved by the Institutional Review Board (Approval no: 17073117-050.60 on 21.05.2021, 2021/5) and was conducted according to the Declaration of Helsinki. All participants gave their informed consent for the study.

Patients

The study group consisted 80 patients, aged 50 or older, referred to non-vascular interventional radiology between June 2013 and 2020. During that period, 104 new cases were admitted, roughly 4% of total admissions for acute cholecystitis and almost 10% of all invasively managed cases. The age cut-off of the study was determined according to Charlson Comorbidity Index (CCI).[11] The primary indication for PC was the presence of acute cholecystitis in a patient with medical problems that may interfere with surgery. In that context, a radiological verification of acute cholecystitis – including hydropic gallbladder, was required.[5] The procedure had no absolute contraindication as its primary indication was the presence of a surgical contraindication. The only exception would be an intestinal interposition that may obstruct the needle trajectory.[12] Patients with acalculous/emphysematous cholecystitis with high morbidity and mortality and patients with missing data were excluded from the analysis (Fig. 1).

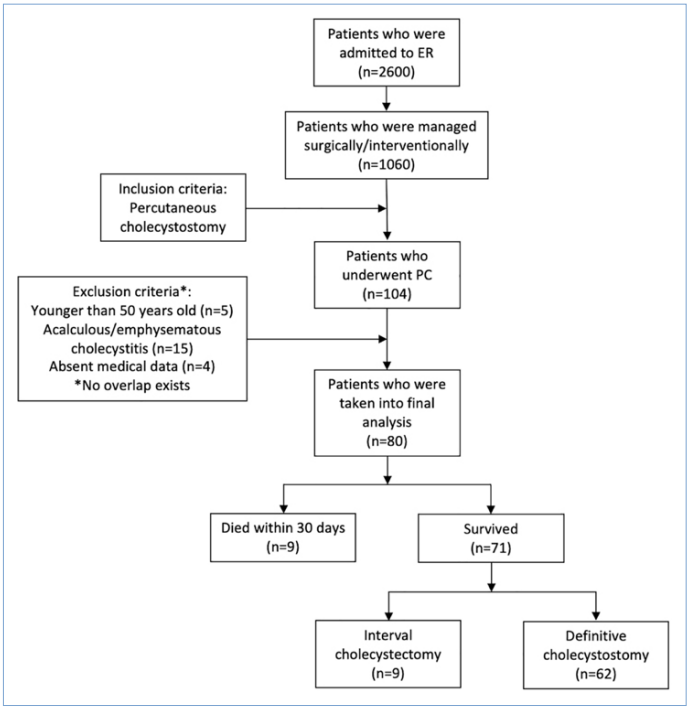

Figure 1. Flowchart for patient selection and grouping.

Preprocedural Classifications

All patients had prior physical and radiological examinations, including ultrasonography (US) and, in certain cases, computed tomography (CT). They were scored and classified according to Tokyo Guidelines 2018 for Acute Cholecystitis (TG18), CCI, and the American Society of Anesthesiologists Physical Status (ASA) Classification System.[3,11,13] TG18 provided a severity grading for acute cholecystitis.[3] Patients who were admitted earlier than the publication of TG18 were retrospectively assessed according to that guideline using the data retrieved from EMRs. This guideline recommended the use of CCI and ASA scores to further stratify patients into low-risk and high-risk surgical candidates.[3] Among them, CCI was originally developed to predict long-term survival in patients with multiple comorbidities in outcomes research from administrative databases, but it was also shown to provide a simple indicator in certain disease with short life expectancy.[14] In the context of CCI, comorbid factors that could influence the course and the outcome of the PC were recorded. These factors were myocardial infarction, congestive heart failure, peripheral vascular disease, cerebrovascular accident/transient ischemic attack, dementia, chronic obstructive pulmonary disease, connective tissue disease, peptic ulcer disease, liver disease, diabetes mellitus, hemiplegia, chronic kidney disease, sold tumor, leukemia, lymphoma, and AIDS (Table 1).[11]

Table 1. Baseline demographics, comorbidities, scores, and grades

Variables	Frequency (n)	Relative frequency (%)
Gender		
Male	39	48.8
Female	41	51.2
Age		
50–59	7	8.8
60–69	11	13.75
70–79	19	23.75
80 and over	42	
TG18 grades		
I (Mild)	21	26.3
II (Moderate)	34	42.5
III (Severe)	25	31.3
Comorbidities*		
Myocardial infarction	21	26.3
Congestive heart failure	20	25.0
Peripheral vascular disease	3	3.8
Cerebrovascular accident	16	20.0
Dementia	14	17.5
COPD	10	12.5
Peptic ulcer disease	4	5.0
Diabetes mellitus	28	35.0
Hemiplegia	9	11.3
Chronic kidney disease	8	10.0
Solid tumor	9	11.3
ASA scores		
1	2	2.5
2	23	28.7
3	33	41.3
4	21	26.3
5	1	1.3

TG18: Tokyo Guidelines 2018 for Acute Cholecystitis; ASA: The American Society of Anesthesiologists Physical Status Classification System; *Charlson Comorbidity Index.

Invasive Procedure

PC was performed within a few hours after diagnosis; thus, time between the admission to emergency department and the intervention was <12 h in all patients. Almost all cases were treated at interventional radiology department except for a very few cases that necessitated bedside intervention in intensive care unit. US guidance was used in all cases. Fluoroscopy, as an adjunct, was used as appropriate. Transhepatic approach was preferred in all but two cases. An 8 F pigtail drainage catheter (Flexima, Boston Scientific, USA) was inserted into the gallbladder lumen using Seldinger technique. The gallbladder was not aspirated to prevent intraluminal hemorrhage, but left to free drainage, except in few cases with severe biliary colic and intense sludge formation.

Follow-up

Patients were assessed at 3rd day, and at the end of the 1st, 4th, and 6th week and at 12th month. At the 3rd day, the clinical efficacy of the procedure was determined with clinical and laboratory findings (i.e., white blood cell level, WBC).[15] Position of the catheter and its mechanical efficacy in decompression were verified at 1st and 4th weeks by US. Catheters were irrigated at regular intervals until 4th week, clamped at the end of this period, and were withdrawn at 6th week under fluoroscopy after evaluating cystic duct patency and tract maturity. The last control examination was conducted at 12th month. Procedure-related complications, postprocedural 30-days mortality, and long-term results including recurrence of disease and need for subsequent cholecystectomy were assessed.

Statistical Methods

Statistical analysis was performed using IBM SPSS Statistics (version 25, IBM, USA). Data were described using descriptive statistical methods. Continuous variables were reported as the mean±standard deviation with range except for time from PC to discharge. Ordinal variables were reported as the median with interquartile range (IQR). The similarity between two groups was tested using paired-samples t-test for continuous and using Mann–Whitney U-test for ordinal variables. The technical success was defined as placement of the drain into the gallbladder and external free flow of contents.[16] The short-term clinical efficacy was determined as percentage of the normalized WBC count.[15] All p-values were reported in an opened form and $p<0.05$ was accepted as the level of significance.

Results

The study group was comprised 39 (48.8%) males and of 41 (51.2%) females. They were between 50 and 104 (78.10±11.32) years of age. The relative frequencies for each age category, as defined in CCI, are presented in Table 1.

The technical success rate, as defined in methods, was 100%. The preprocedural WBC count was between 5.9–39.6×10^9/L (17.90±6.94×10^9/L), and 75.0% (n=60) of patients had elevated WBC count (>11.0×10^9/L) at initial admission. At 3rd day, WBC count was decreased to 3.8–18.9×10^9/L (9.57±3.51×10^9/L) and leukocytosis was persisted in only 35.0% (n=21) of these 60 patients. In four of them, postprocedural WBC counts were higher than initial values with an average increase of 2.1×10^9/L. In the remaining 17 patients, WBC counts were decreased by 15.8×10^9/L with regard to initial values during admission. On that basis, the clinical success (i.e., normalized WBC count) was 65.0% and the partial clinical success (i.e., decreased WBC count) was 93.33%. The difference between preprocedural and postprocedural mean WBC count was highly significant ($p<0.0001$) (Fig. 2).

We have not observed intraprocedural mortality. The 30-day mortality was 11.25% (n=9) and the mean time to death was 14.78±5.91 (6–26) days. The most frequent cause was cardiac arrest (n=5), followed by sepsis (n=3) and pneumonia (n=1) in decreasing order of frequency. Distributions of TG18, CCI, and ASA grades/scores for the cohort are presented in Table 1. The median TG18, CCI, and ASA grades/scores of patients who died in the first 30 days were 3, 5, and 4, respectively. In survived cases, these scores were 2, 5, and 3, respectively. There was a statistically significant difference between patients who died and survived regarding ASA scores ($p=0.003$) and TG18 grades ($p=0.032$), but not regarding CCI scores ($p=0.764$) (Table 2).

Complications were grouped as major and minor according to the CIRSE complication classification.[16] Major complication was seen in only 2.5% (n=2) of patients. Both had been treated at the bedside under suboptimal conditions. One of

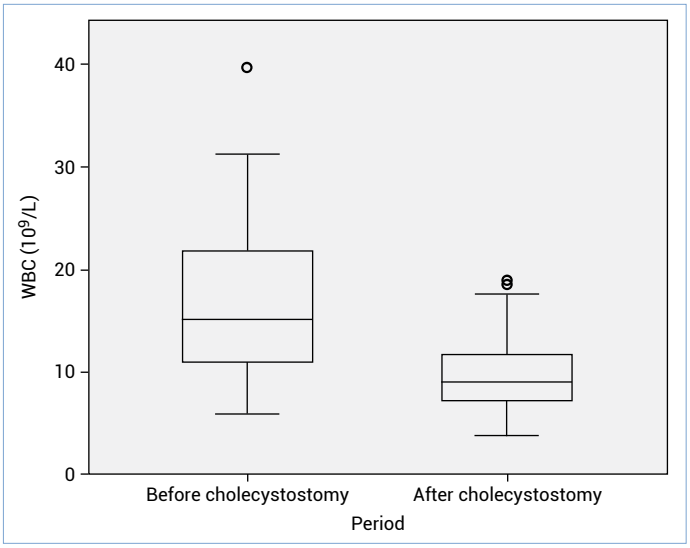

Figure 2. Comparison of median white blood cell levels and their statistical deviations before and after cholecystostomy.

Table 2. The comparison of TG18 grades, CCI, and ASA scores in deceased and survived patients

Grade	Deceased patients			Survived patients			p*
	Min	Max	Median	Min	Max	Median	
TG18	1	3	3	1	3	2	0.032
CCI	4	10	5	1	15	5	0.764
ASA	1	4	4	1	4	3	0.003

TG18: Tokyo Guidelines 2018 for Acute Cholecystitis, CCI: Charlson Comorbidity Index, ASA: American Society of Anesthesiologists Physical Status Classification System; Min: Minimum, Max: Maximum; *>0.05.

them had intestinal perforation, and the other had capsular bleeding due to hepatic injury. Minor complication was seen in 3.75% (n=3) of patients. That was hemorrhage that resolved spontaneously within a week after the procedure.

The median time from PC to discharge was 5 (2–61, IQR: 5) days. Patients who had not died within the first 30 days (n=71) were followed up to 73 months with a mean follow-up of 17.36 months. At the end of the 1st month, 4.23% (n=3) of these patients had perforation, 14.09% (n=10) had acute cholecystitis, 1.41% (n=1) had developed pancreatitis, and 1.41% (n=1) had cholecystectomy. Except being catheterized, 70% (n=56) of patients who did not die during 1st month were normal.

First year's mortality was 18.75% (n=15). Nine patients, including the one who had cholecystectomy within the first 30-days, required cholecystectomy. Of remaining patients, two had pancreatitis that three had chronic cholecystitis. Regarding all patients who were alive at the end of the 1st year, 78.47% (n=51) of them were found to be normal (i.e., normal clinical and radiological evaluation) and were able to be managed only with temporary PC. One-year interval, cholecystectomy rate was 13.85%, excluding patients who died during that period. Median time to cholecystectomy was 72.50 days with a range between 7 and 340 days. The need for interval cholecystectomy in patients who survived beyond 30 days had no significant relationship with TG18 grades (p=0.238) or CCI scores (p=0.122) scores (Table 3).

Discussion

Early laparoscopic cholecystectomy within a week is recommended for low-risk candidates in acute cholecystitis. For high-risk candidates, on the other hand, PC should be considered. PC is performed with a relatively standard technique and the technical success is between 98.9 and 100%.[17] In our study, the technical success rate was 100%. According to our guidelines, radiological confirmation of hydropic gallbladder was required to proceed to PC, accounting for the high technical success. The clinical success rate, reported to date, is much more variable. This variability is most probably due to the differences in study cohorts and the use of different sets of criteria for clinical success.[12] Most agreed criteria are resolution of pain, fever, and inflammatory markers.[17,18] Among them, pain is a subjective and ordinal variable, and fever is an objective but interval variable. WBC, on the other hand, is preferred by being more objective and ratio variable that have a true zero point. These properties make it more robust for statistical analysis and preferred bay many.[15] Although C-reactive protein also has same characteristics, we have not used it as several of our patients did not have it. Based on WBC count, the clinical success rate reported to date was around 60-90% with an average rate of 85.6%.[19-21] According to Devane et al.,[17] the suggested threshold should be 74.2%. In our study, the clinical success rate was 65%. Our relatively lower success rate was most probably due to the advanced age of the cohort and the presence of multiple comorbidities.

The general status of PC candidates is generally very poor and they succumb to comorbid diseases despite the technical success of that procedure.[1] Therefore, the 30-days mortality rate largely depends on patient selection/referral patterns and has known to have a very wide range (8–36%) depending on the population presented.[17] One of the lowest numbers for this rate was reported by Dvorak et al.[22] and was 10.7%. However, those researchers had included patients as young as 33 years of age. In our study, the 30-days mortality rate (11.25%) was almost as low as that rate, although we had only included elder patients. Only three (3.75%) of these deaths were due to sepsis. According to most recent reviews, the value range for relative frequency of sepsis was between 3.5 and 5.6%, with an acceptable threshold of 3.9%.[17] Our value was under that threshold.

Table 3. The comparison of TG18 grades and <CCI scores in patients with and without interval cholecystectomy

Grade	Patients with cholecystectomy			Patients without cholecystectomy			p*
	Min	Max	Median	Min	Max	Median	
TG18	1	3	2	1	3	2	0.238
CCI	1	7	4	2	15	5	0.122

TG18: Tokyo Guidelines 2018 for Acute Cholecystitis, CCI: Charlson Comorbidity Index, Min: Minimum, Max: Maximum; *>0.05.

ASA score was highly (p=0.003) and TG18 grade was moderately (p=0.032) associated with mortality. However, we could not find any significant relationship between survival and CCI scores, hence comorbid conditions.

PC may serve as a bridge to surgery if such treatment cannot temporarily be provided.[7] The rate of interval cholecystectomy that was indicated in the literature was around 40%.[5,6] In our study, this rate was only 13.85% within the first 12 months. Such a low rate may point to the possibility of the use of PC as the final step in many patients. This conclusion is supported by a relatively recent study that found PC as definitive treatment in 86% of patients.[10] In our study, we have reached the same conclusion as we were able to manage 86.15% of the patients who survived up to a year using cholecystectomy as the final step. We were not able to show a relationship between the need for cholecystectomy and TG18 grades or CCI scores, making any prediction impossible.

PC is usually a low-risk procedure and the mean complication rate is 11.4% according to most recent reports.[17] However, this rate my reach up to 39.1% and any value under 38.5% is acceptable.[17] In our study, the overall rate of minor and major complications was 6.25% and was within the lower-end of the above stated value range. The most common complication reported in the previous studies was the biliary leakage during catheter insertion and removal.[23,24] This complication is usually due to the fragility of the inflamed gall bladder wall, to manipulations during the initial entry or directly or to the mechanical pressure of the catheter on the gallbladder wall. Bile leakage can also occur during catheter removal and has been reported as 3% in the literature.[24] In our study, we have not encountered these complications. However, it should be kept in mind that, even in such cases, the bile leakage is usually self-limited and does not require further treatment. Larger leaks, however, may cause bilioma, where additional drainage is appropriate. Hemorrhage into the gallbladder is another minor complication and is usually due to rapid decompression of the fragile gallbladder. It is usually self-limited and its treatment is attempted by the temporary clamping of the catheter to provide a tamponade. In our study, we have encountered it in 3.75% of cases. This relative frequency was slightly higher than the recommended threshold of 1.5%.[17] It was most possibly due to forceful aspiration of the gallbladder content in two cases. In the remaining case, hemorrhage was occurred spontaneously within hours following a successful procedure, possibly due to erosion that had been caused by the catheter's pressure on the wall.

Major complications of the procedure are pleural or intestinal perforation, peritonitis due to bile leakage and sepsis. The first two of these complications may be prevented in many if not all cases by adopting a transhepatic approach to avoid these structures. We, therefore, have performed all procedures using that approach, except two cases. One of them was an obese intubated patient at intensive care unit, and the other was a patient with severe cachexia and irregular respiration (Fig. 3). Transhepatic approach has many additional advantages such as (i) providing a lengthy route to support drainage catheter, (ii) preventing bile leakage due to the collapsed gall bladder toward its bed, (iii) provision of a straight-forward and non-motile approach to the relatively small gallbladders, and (iv) rapid tract maturation that may allow shorter catheterization. However, due to the very low number of patients with, we were not able to observe any of such effects.

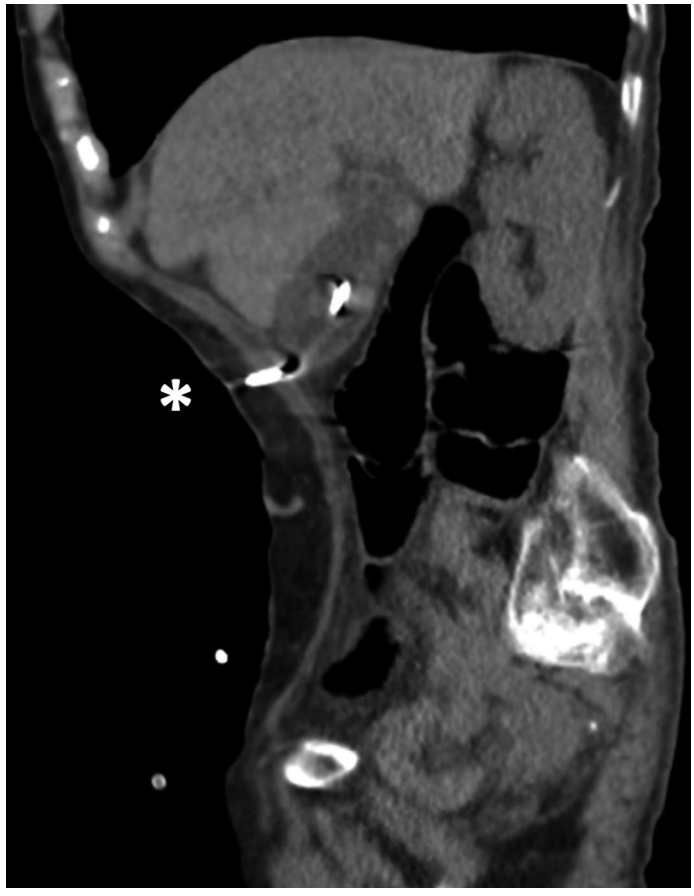

Figure 3. Transperitoneal (*) cholecystostomy for percutaneous biliary drainage. Heavy cachexia and irregular respiration prevented the acquisition of optimal US images for guidance.

Even in transhepatic approach, adjacent structures may be perforated if the anatomic structures are not fully evaluated before or during the PC or if the patient cannot be optimally positioned during the procedure (Fig. 4). This may result in inadvertently traversed pleural space or large bowel lumen.[12] This is a rare complication and seen in only 0.35–1.4% of cases.[17] In our series, colon perforation developed in only one (0.8%) patient. She was intubated, and the intervention was conducted at bedside in intensive care unit. In this patient, the subcostal transhepatic approach was used. In a subsequent surgical exploration, large bowel loops were shown to adhere to the diaphragm as a result of a previous abdominal trauma. She was successfully managed with the primary repair.

This study has some limitations. It was retrospective in nature and there was no control group in terms of the surgical option.

In conclusion, PC provides significant clinical improvement in the early course and is life-saving in elderly and comorbid patients with acute calculous cholecystitis. It has been shown to have low mortality and low complication rates in that patient group with high surgical risk. The low recurrence rate after the procedure makes it a definitive treatment option for acute cholecystitis in many patients. For others, it may still serve as a bridge to surgery.

Anknowledgment

We would like to thank Dr. Findik for her contribution to the collection of data.

Main Points

- Cholecystectomy, whether open or laparoscopic, has significant risk in patients with advanced age and/or comorbid diseases. Both of these factors are present in the majority of patients with acute cholecystitis
- For such cases, PC is the only method that can be used to prevent major complications of acute cholecystitis and is life-saving
- PC does not have an absolute contraindication due to the life-threatening nature of the disease where other treatment options cannot be offered due to their risks
- The low recurrence rate after the procedure makes PC the final and definitive treatment for acute cholecystitis in selected cases. For many others, it may serve a bridge to surgery.

Disclosures

Ethics Committee Approval: The study was approved by the Institutional Review Board (Approval no: 17073117-050.60 on 21.05.2021, 2021/5) and was conducted according to the Declaration of Helsinki. All participants gave their informed consent for the study.

Peer-review: Externally peer-reviewed.

Conflict of Interest: None declared.

Authorship Contributions: Concept – H.M.K., G.Y.; Design – H.M.K., G.Y.; Supervision – H.M.K.; Materials – G.Y., O.F.; Data collection &/or processing – G.Y., H.M.K., O.F.; Analysis and/or interpretation – G.Y.; Literature search – G.Y.; Writing – G.Y., Critical review – H.M.K.

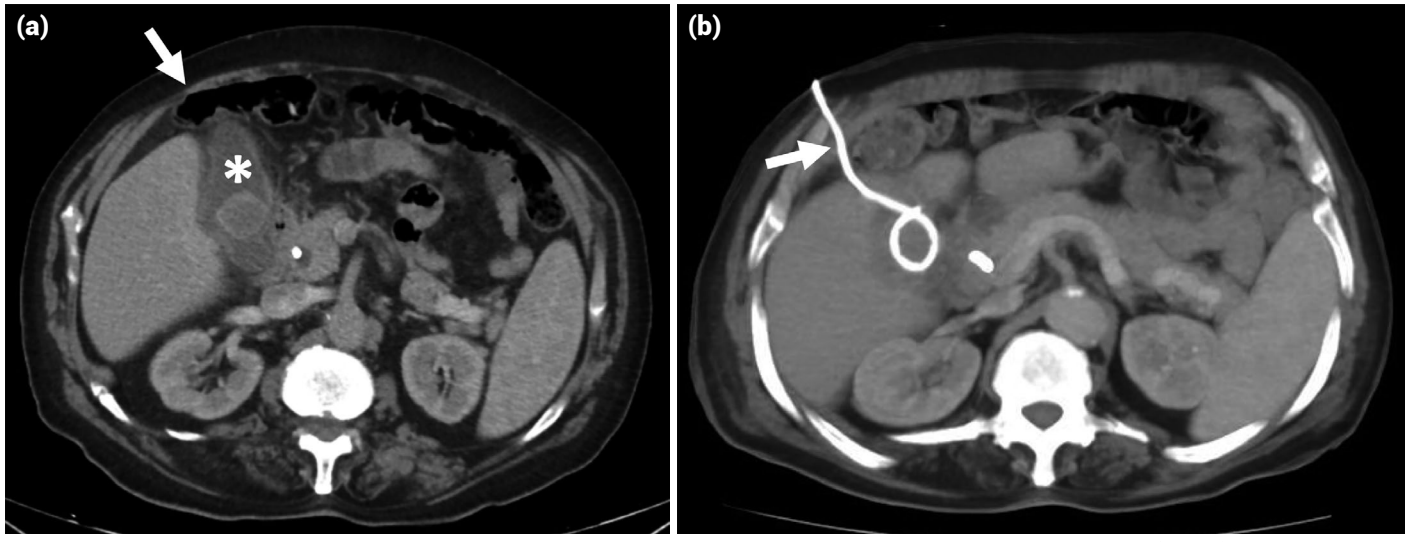

Figure 4. Transhepatic cholecystostomy for percutaneous biliary drainage. Interposition of large bowel loops (arrow) may complicate the procedure during bedside interventions if computed tomography images **(a)** are not available on site. Follow-up computed tomography **(b)** confidently rule out bowel transgression (arrow).

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