ORIGINAL ARTICLE

Factors affecting interval cholecystectomy and mortality in percutaneous cholecystostomy patients

Ahmet Bülent Doğrul, M.D.,[1] Mustafa Oruç, M.D.,[1] Türkmen Turan Çiftçi, M.D.,[2] Kadir Mutlu Hayran, M.D.,[3] Osman Abbasoğlu, M.D.[1]

[1]Department of General Surgery, Hacettepe University Faculty of Medicine, Ankara-*Türkiye*
[2]Department of Radiology, Hacettepe University Faculty of Medicine, Ankara-*Türkiye*
[3]Department of Preventive Onchology, Hacettepe University Faculty of Medicine, Ankara-*Türkiye*

ABSTRACT

BACKGROUND: Percutaneous cholecystostomy is an alternative or bridge to cholecystectomy (CCY) in high-risk patients with acute calculous cholecystitis. Our primary aim was to determine the parameters that could be used in interval CCY decision-making and to predict mortality in high-risk patients.

METHODS: The medical records of 127 patients who underwent percutaneous cholecystostomy for acute calculous cholecystitis between 2010 and 2018 were retrospectively analyzed. The primary outcomes were the CCY rate and the factors affecting mortality in high-risk patients. Descriptive statistics and receiver operating characteristic analysis were performed using albumin and elective surgery.

RESULTS: Of the 127 patients undergoing percutaneous cholecystostomy, elective CCY was performed only in 43.1% of the high-risk patients. The 30-day and 1 year mortality rates were 11% and 17.3%, respectively. The American Society of Anesthesiologists' (ASA) score, Charlson comorbidity index (CCI), the negative predictive factors described in the Tokyo Guidelines 2018, the American College of Surgeons' (ACS) expected mortality rate, and albumin level were found to be significant factors affecting mortality and elective CCY probability. No mortality was observed, and an 82% elective CCY rate was achieved in patients whose albumin levels were higher than 3.16 mg/dL at initial presentation.

CONCLUSION: The plasma albumin level, ASA score, CCI, and ACS expected mortality rate can be used to predict mortality and decide on elective CCY. Percutaneous cholecystostomy is sufficient for resolving inflammation, but medical comorbidities determine the final condition of patients.

Keywords: Acute cholecystitis; albumin; cholecystectomy; mortality predictors; percutaneous cholecystostomy.

INTRODUCTION

Gallstone disease is a common disorder. In developed countries, 10%–15% of the adult population is affected by cholelithiasis. It may present as acute calculous cholecystitis (ACC) in about 20% of symptomatic patients.[1] Cholecystectomy (CCY) is generally regarded as the standard treatment for patients with ACC, but perioperative mortality may be as high as 19% in critical and elderly patients,[2] and it may not be possible to perform it in high-risk patients due to their significant comorbidities and possible consequent surgical morbidity and mortality. To eliminate these high mortality rates, percutaneous cholecystostomy (PC) has been used as an alternative or bridging method for these patients since 1980.[3]

Many studies have shown that PC successfully relieves the acute findings in ACC in up to 85% of patients,[4,5] but the rate of interval CCY after PC has been reported to be 23–57% in different studies.[4,5] PC is recommended as a treatment option for high-risk patients, who are defined as those with an American Society of Anesthesiologists' (ASA) score ≤3 and/or Carlson comorbidity index (CCI) score ≤5 in the Tokyo

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Address for correspondence: Ahmet Bulent Dogrul, M.D.
Hacettepe Üniversitesi Tıp Fakültesi, Genel Cerrahi Anabilim Dalı, Ankara, Türkiye
Tel: +90 312 - 305 16 77 E-mail: ahmetdogrul@yahoo.com

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Guidelines 2018, but it is not clear which patients can be eligible for elective CCY in the interval period.[6]

This study determined the predictors of interval CCY and mortality in high-risk patients, described the characteristics of patients who underwent PC, and compared the results of high-risk ACC patients depending on whether CCY was performed after PC placement in a tertiary care center.

MATERIALS AND METHODS

The medical records of 127 patients who underwent PC for ACC between 2010 and 2018 were analyzed retrospectively. The patients' data were collected from the hospital database. This study was approved by the Local Ethics Committee (2019/06–23). All PC procedures were performed by our interventional radiologists with ultrasonography guidance through the transhepatic route after the evaluation of the patients by a surgeon.

The basic demographics; presenting vital signs; symptoms; laboratory tests; all comorbidities such as cancer, chronic obstructive lung disease, coronary artery disease, chronic kidney disease, atrial fibrillation, hypertension, hyperlipidemia, peripheral artery disease, diabetes, and neurological diseases; ACS expected mortality rate for PC; elective CCY;[7] and radiological signs related to acute cholecystitis were recorded. If elective CCY had been performed, the timing of the operation and length of hospital stay (LOS) was noted. The time between hospital admission and insertion and removal of the catheter and the complications of PC were also recorded.

The chronic operative risks for the patients were defined by the CCI and ASA scores. Low-risk patients were defined as those with ASA <3 and CCI <5 scores, and high-risk patients were defined as those with ASA ≤3 and CCI ≤5 scores. The severity of ACC was graded according to the Tokyo Guidelines 2018.[6] The primary outcomes were the predictors of interval CCY and mortality in high-risk patients, and the secondary outcomes were the characteristics of patients who underwent PC and the results of high-risk ACC patients, depending on whether CCY was performed after PC placement.

IBM Statistics SPSS version 20 was used for data analysis. Standard deviations and Student's t-test were used for the analysis of the parametric data mean, and interquartile range, Mann–Whitney U, and Kruskal–Wallis tests were used for the non-parametric data median. P<0.05 was considered statistically significant. The capacity of the serum albumin level measured during the first admission to hospital was analyzed using receiver operating characteristic curve analysis to predict mortality and decide on elective CCY. Sensitivity, specificity, and positive and negative predictive values were presented if a cutoff value was detected. A 5% type-I error level was used to accept a statistically significant predictive value of the test variables for the evaluation of the area under the curve.

RESULTS

During the study period, 180 patients underwent PC for AC. Patients with acalculous, gangrenous, or emphysematous cholecystitis, cholangitis, or choledocholithiasis were excluded from the study. Only 127 patients with confirmed ACC comprised the study group. The indication of percutaneous cholecystostomy for patients did not benefit from antibiotic treatment during hospitalization. The mean age of the patients was 69±13.5. The patients were evenly balanced by gender, with 67 (52.8%) of them being male. ASA III and II scores were seen in 65 (51.1%) and 37 (29.1%) cases, respectively. The mean CCI score was 5.61±2.89. Most of the patients were admitted for their first attack (71 patients, 55.9%), and the duration of their symptoms was more than 72 h (89 patients, 70%). The 30-day and 1 year mortality rates were 11% and 17.3%, respectively. The median LOS was 11 days (range 6–20 days) and was significantly longer for grade 3 patients (15 days, range 9–32, p=0.002). The overall complication rate of PC was 22%. Catheter dislodgement was the most common complication, but none of these complications were life threatening. Elective CCY could be performed in only 72 patients (56.6%). Laparoscopic CCY was performed in 54.1% of these patients.

Patients were grouped into low-risk and high-risk groups based on their ASA and CCI scores. High-risk patients were, further, categorized into operated and non-operated. Patient demographics, clinical data, and elective CCY rates according to patients' risk types are summarized in Table 1. Most of the low-risk patients had undergone surgery, while nearly half of the high-risk patients had elective surgery (97.1% vs. 43.1%, p=0.001). The ACS expected mortality rate for ELC was significantly higher in high-risk patients (0.002, range 0.001–0.005 vs. 0.031, range 0.014–0.127; p=0.001). All 30-day and 1 year mortality were observed only in high-risk patients. Grade 3 cholecystitis was significantly higher in high-risk patients.

In the comparison between high-risk patients who could and could not undergo surgery, there were significantly more ASA IV patients in the non-operated high-risk group as expected. For the non-operated and operated high-risk patients, the mean CCI was 7.15±2.9 and 6.35±1.92 (p=0.048), respectively. Among the non-operated high-risk patients, the ratio of grade 3 ACC was higher than in the operated group (34.2% vs. 60%, p=0.026). The non-operated high-risk patients stayed significantly longer in the hospital. The non-operated high-risk patients had a significantly lower albumin level than the operated group (3.54±0.6 vs. 3.11±0.65, p=0.01). Moreover, the non-operated high-risk patients had a 6 times higher than expected risk of mortality for ELC than the operated group according to the ACS risk calculator.

The factors affecting 30-day and 1 year overall mortality are summarized in Table 2. Age, ASA score, and CCI score were

Table 1. Demographics, results, and comparison according to patients' risk type

Variable	Low risk (n=39)	High risk (n=88)	p-value	High-risk operated (n=38)	High-risk non-operated (n=50)	p-value
Age*	61.85±16.2	71.75±10.8	0.001	71.54±8.5	73.35±12.1	0.489
Male†	18 (46.2)	51 (557)	0.341	20 (53.1)	29 (59.1)	0.281
ASA*	1.87±0.33	3.29±0.47	0.001	2.97±0.36	3.36±0.48	0.001
CCI*	2.95±1.52	6.78±2.56	0.001	6.35±1.92	7.15±2.9	0.048
30-day mortality†	0 (0)	14 (15.4)	0.001	0	14 (28)	0,000
1-year mortality†	0 (0)	22 (25)	0.001	2 (5.1)	20 (40)	0.000
Grade 3 percentage†	9 (23,1)	43 (48.9)	0.02	13 (34.2)	30 (60)	0.026
Length of stay in hospital‡	8 (6–15)	12 (6–22)	0.183	9 (6–17)	15 (6–26)	0.01
Albumin*	3.50±0.62	3.29±0.66	0.053	3.54±0.6	3.11±0.65	0.01
ACS expected mortality rate for LC‡	0.002 (0.001–0.005)	0.031 (0.014–0.127)	0.001	0.025 (0.009–0.048)	0.124 (0.02–0.323)	0.001
Elective cholecystectomy†	34 (97.1)	38 (43.1)	0.001			
LC percentage†	22 (64.7)	17 (44.7)	0.355			
Cholecystectomy time‡	44 (44–80)	37 (37–87)	0.925			
Discharge after cholecystectomy‡	3 (2–4)	3 (2–5)	0.145			
cholecystectomy‡						

*Values presented as the mean±standard deviation. †Values presented as the number of patients (percentage). ‡Values presented as the median days (25th–75th percentile). ASA: American Society of Anesthesiologists; CCI: Carlson comorbidity index; ACS: American College of Surgeons; LC: Laparoscopic cholecystectomy.

Table 2. Demographics and results affecting 30-day and 1-year mortality

Variable	30-day mortality (-) (n=113)	30-day mortality (+) (n=14)	p-value	1-year mortality (-) (n=105)	1-year mortality (+) (n=22)	p-value
Age*	68.33±13.6	77.86±9.36	0.010	68.27±13.6	74.82±12	0.050
ASA*	2.6±0.7	3.71±0.46	0.001	2.6±0.6	3.67±0.48	0.001
CCI*	5.21±2.6	8.79±3.2	0.001	5.1±2.5	8±3.1	0.001
Grade 3 count†	40 (35.4)	12 (85.7)	0.003	32 (30.4)	20 (90.9)	0.001
INR‡	1.17 (1.07–1.32)	1.48 (1.2–1.66)	0.001	1.15 (1.07–1.32)	1.4 (1.25–1.65)	0.001
Albumin*	3.46±0.6	2.5±0.39	0.001	3.4±0.59	2.8±0.67	0.001
Negative predictive factor†§	45 (39.8)	12 (85.7)	0.001	38 (36.1)	19 (86.3)	0.001
ACS expected mortality rate for LC‡	0.01 (0.004–0.03)	0.19 (0.04–0.47)	0.001	0.01 (0.003–0/03)	0.16 (0.03–0.40)	0.001
ACS expected mortality rate for PC‡	0.03 (0.007–0.07)	0.24 (0.06–0.56)	0.001	0.02 (0.006–0.06)	0.18 (0.06–0.49)	0.001

*Values presented as the mean±standard deviation. †Values presented as the number of patients (percentage). ‡Values presented as the median days (25th–75th percentile). §Neurological dysfunction, respiratory dysfunction, coexistence of total bilirubin ≥2 mg/dl. PC: Percutaneous cholecystostomy; LC: Laparoscopic cholecystectomy; ASA: American Society of Anesthesiologists; CCI: Carlson comorbidity index; ACS: American College of Surgeons.

the factors that significantly affected the 30-day mortality. INR and albumin levels were the only significant laboratory parameters affecting the 30-day mortality. The negative predictive factors (i.e., neurological dysfunction, respiratory dysfunction, and coexistence of total bilirubin ≥2 mg/dl), which are described in the Tokyo Guidelines 2018 and used for PC decision making in grade 3 cholecystitis) were present in 12 (85.7%) patients in the 30-day mortality group and in 45 patients (39.8%) in the non-mortality group (p=0.001). The ACS expected mortality rate of PC was eight times higher in the mortality-positive groups (0.03 vs. 0.24 p=0.001), and the expected mortality rate of ELC was 19 times higher (0.01 vs. 0.19 p=0.001). When the causes of death of the 30-day mortality patients (14 patients) were examined, six were septic

for other reasons before cholecystitis, and four had extensive metastatic cancer. Only four patients had cholecystitis-related mortality.

The cutoff value for albumin was 3.16 mg/dl (AUC: 0.768, 95% confidence interval: 0.67–0.86, p=0.000) in predicting elective CCY probability. The elective cholecystostomy rate was 82% in patients with albumin levels higher than 3.16 mg/dl. There was a medium-high correlation between albumin and elective CCY rate (sensitivity 81.9%, specificity 56.6%, positive predictive value 81.9%, and negative predictive value 62.8%).

The cutoff value for albumin was 3.16 mg/dl (AUC: 0.905, 95% confidence interval: 0.84–0.96, p=0.001) in predicting mortality. Among the patients whose albumin levels were higher than 3.16, there was no 30-day mortality (sensitivity 100%, specificity 72.4%, positive predictive value 30.4%, and negative predictive value 100%).

DISCUSSION

In this study, we demonstrated that almost all low-risk patients underwent surgery (97.1%). On the contrary, only 43.1% of the high-risk patients underwent elective surgery. Our high-risk patients were compared among themselves according to their operation status, and the non-operated patients had significantly higher ASA and CCI scores, grade 3%, and lower albumin levels. The non-operated high-risk patients had 6 times higher ACS expected mortality rates for PC than the operated high-risk group. A similar study concluded that higher Tokyo grades and CCI scores were independently associated with a lower likelihood of interval CCY and that a higher albumin level was independently associated with having interval CCY.[8]

The factors predicting mortality were also examined in the present study. Thirty-day mortality was observed in 11% of patients, in accordance with the literature (4–17% in-hospital mortality).[9,10] Among the significant laboratory parameters predicting mortality, there was a strong correlation only for albumin. No mortality was observed in patients whose albumin levels were higher than 3.16 mg/dl. Moreover, age, ASA and CCI scores, and the presence of negative predictive factors (i.e., neurological dysfunction, respiratory dysfunction, and coexistence of total bilirubin ≥2 mg/dl) were the clinically significant factors affecting mortality. Yeo et al.[11] found that patients with higher APACHE II scores, higher CCI, delay in diagnosis, and PC placement had a higher in-hospital mortality rate. Note that our mortality patients already had some systemic burdens, such as sepsis, other related infections, or metastatic malignancies, and only four patients had cholecystitis-related mortality. Therefore, PC cannot be expected to benefit these patients.

Both the literature and our study point out unchangeable factors, such as ASA, CCI, and albumin, to predict mortality and elective CCY. It can be concluded that those who are eligible for elective CCY among high-risk patients can safely undergo surgery by eliminating the additional risks posed by acute surgery with PC. However, patients who are not eligible for elective CCY under any circumstances do not see the expected benefit from PC. The absence of mortality and morbidity after elective CCY in our operated high-risk patients and the six-fold higher risk of elective CCY with 28% 30-day mortality in the non-operated high-risk patients also support this finding. The absence of mortality and reaching an elective CCY rate of 82% with albumin levels above 3.16 indicates that albumin is the most important laboratory parameter in terms of patients' general health status and treatment expectations during and after hospitalization.

This study has some limitations. First, it is a retrospective study. Second, only patients who underwent PC were included in the study. Third, after excluding mortality and lost to follow-up patients, there were no patients who were followed up only with PC. Therefore, the high-risk patients who were followed up only with PC and those who underwent CCY could not be compared. Although we found clues to expect strong mortality and underlined the variables for deciding on elective CCY in high-risk PC patients, larger multi-center studies that include only CCY patient groups are needed to better define this cohort of patients.

Conclusion

PC may have proven effects to resolve inflammation, according to the literature. However, this benefit is particularly important in high-risk patients who are eligible for elective CCY. Albumin is highly predictive of treatment expectations in cholecystitis patients.

Ethics Committee Approval: This study was approved by the Hacettepe University Non-interventional Clinical Research Ethics Committee (Date: 19.03.2019, Decision No: 2019/08-26).

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ORİJİNAL ÇALIŞMA - *ÖZ*

Perkütan kolesistostomi hastalarında mortaliteyi ve elektif kolesistektomi kararını etkileyen faktörler

Dr. Ahmet Bülent Doğrul,[1] Dr. Mustafa Oruç,[1] Dr. Türkmen Turan Çiftçi,[2] Dr. Kadir Mutlu Hayran,[3] Dr. Osman Abbasoğlu[1]

[1]Hacettepe Üniversitesi Tıp Fakültesi, Genel Cerrahi Anabilim Dalı, Ankara
[2]Hacettepe Üniversitesi Tıp Fakültesi, Radyoloji Anabilim Dalı, Ankara
[3]Hacettepe Üniversitesi Tıp Fakültesi, Prevantif Onkoloji Anabilim Dalı, Ankara

AMAÇ: Perkütan kolesistostomi akut kolesisti olan yüksek riskli hastalar için bir alternatif veya köprü tedavisi görevi görmektedir. Amacımız perkütan kolesistostomili yüksek riskli hastalarda mortaliteyi tahmin etmek ve elektif kolesistektomi kararını belirleten parametreleri tespit etmektir.
GEREÇ VE YÖNTEM: Akut kolesistit nedeniyle, 2010–2018 yılları arasında perkutan kolesistostomi işlemi yapılmış olan 127 hastanın medical bilgileri geriye dönük olarak toplandı. Kolesistektomi oranları ve yüksek riskli hastalarda mortaliteyi belirleyen faktörler analiz edildi. Tanımlayıcı istatistikler yapıldı. Ayrıca mortalite, elektif kolesistektomi ve albumin için ROC analizi kullanıldı.
BULGULAR: Perkütan kolesistostomi yapılan 127 hastadan yüksek riskli olanlarının sadece %43.1'ine elektif kolesistektomi yapıldı. Otuz günlük mortalite %11 ve bir yıllık mortalite %17.3 idi. The American Society of Anesthesiologists (ASA) skoru, Charlson comorbidity index (CCI) skoru, 2018 Tokyo Klavuzu'nda belirlenmiş olan negatif prediktif faktörlerin varlığı, American College of Surgeons (ACS) beklenen mortalite yüzdesi ve albümin değeri; mortaliteyi ve elektif kolesistektomiyi belirlyen anlamlı faktörler olarak bulundu. Albümin değeri 3.16 mg/dL'den büyük olan hiçbir hastada mortalite izlenmedi ve %82 elektif kolesistektomi oranı elde edildi.
TARTIŞMA: Plazma albümin değeri, ASA skoru, CCI ve ACS beklenen mortalite yüzdesi mortaliteyi ve elektif kolesistektomiyi kararını belirlemek için kullanılabilir. Perkütan kolesistostomi enflamasyonu azaltmak için faydalıdır ancak hastaların medikal komorbiditeleri, nihai durumlarını belirlemektedir.
Anahtar sözcükler: Akut kolesistit; albümin; kolesistektomi; mortalite belirleyiciler; perkütan kolesistostomi.

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