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RESEARCH

Emergency cholecystectomy vs. percutaneous cholecystostomy for acute cholecystitis in high-risk patients: a comparison of mortality and clinical outcomes

Yüksek riskli akut kolesistit hastalarında acil kolesistektomi ile perkütan kolesistostominin mortalite ve klinik sonuçlar açısından karşılaştırılması

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Abstract

Purpose: The aim of this study was to compare emergency cholecystectomy (EC) and percutaneous cholecystectomy (PC) in high-risk acute cholecystitis patients in respect of mortality and other clinical characteristics.
Materials and Methods: A retrospective examination was made of patients graded as ASA/PS≥3 who underwent EC or PC because of acute cholecystitis. The two groups were compared in terms of demographic characteristics, mortality, complications, re-admission, and re-intervention rates.
Results: Patients in the PC group were older (78.11±9.76 vs 71.69±12.56 years) and had more frequent comorbidities (99.1% ve 89.7%). Both groups were similar in terms of gender distribution, complication rates and severity (Clavien-Dindo), re-admission rates, and length of stay in hospital. The need for re-intervention was greater in the PC group (30.2% vs.3.4%). Mortality rates were higher in the PC group (40.5% vs.6.9%. Independent predictive factors of mortality were determined to be the application of PC in treatment (odds ratio:8.756) and older age (odds ratio: 1.133).
Conclusion: In patients with high-risk acute cholecystitis, EC is superior to PC in terms of lower mortality and reducing the need for re-intervention. Research should be continued for subgroups of patients such as those with biliary sepsis, in intensive care, or with early cholecystectomy bridging.
Keywords: Acute cholecystitis, emergency cholecystectomy, percutaneus cholecystostomy, high risk, mortality.

Öz

Amaç: Bu çalışma ile yüksek riskli akut kolesistit hastalarında mortalite ve diğer klinik özellikleri açısından acil kolesistektomi(EC) ile perkütan kolesistostomiyi (PC) karşılaştırmayı amaçladık.
Gereç ve Yöntem: Akut kolesistit nedeniyle acil kolesistektomi(EC) veya perkütan kolesistostomi(PC) uygulanan ASA/PS≥3 hastalar retrospektif incelendi. Demografik özellikler, mortalite, komplikasyonlar, readmission, reintervention oranları karşılaştırıldı.
Bulgular: PC grubunda yaş daha yüksektir (78.11±9.76 ve 71.69±12.56 yıl), daha sık komorbid bir durum görülmektedir (99.1% ve 89.7%). Cinsiyet dağılımı, komplikasyon sıklığı, komplikasyonların ciddiyeti (Clavien-Dindo),tekrar yatış sıklığı ve yatış süresi gruplar arasında benzerdir. PC'de daha fazla yeniden müdahaleye ihtiyaç duyuldu(30.2% vs 3.4%). Mortalite, PC grubunda daha fazladır, 40.5% vs 6.9%, Tedavide PC uygulanması (odds ratio:8.756) ve yüksek yaş (odds ratio: 1.133) mortalitenin bağımsız yordayıcı faktörleridir.
Sonuç: Yüksek riskli akut kolesistit hastalarında EC mortalite ve reintervention'u azaltır, PC'ye göre üstündür. Bilier sepsis, yoğun bakım hastaları, erken dönem kolesistektomiye köprüleme gibi alt gruplar için araştırmalara devam edilmelidir.

Anahtar kelimeler: Akut kolesistit, acil kolesistektomi, perkütan kolesistostomi, yüksek risk, mortalite

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INTRODUCTION

Biliary tract infections are among the leading causes of emergency department admissions and sepsis in elderly patients with comorbid conditions[1]. Acute cholecystitis is one of the most important surgical reasons for presentations at the Emergency Department. Approximately 1 in 10 cases of abdominal pain originate from acute cholecystitis[2,3]. Emergency laparoscopic cholecystectomy is accepted as the first treatment option for young patients with no comorbid disease and sufficient physiological reserve[4,5]. However, surgeons are unwilling to perform cholecystectomy on patients with limited cardiac or respiratory reserves who are at high risk of perioperative mortality[6]. Percutaneous cholecystostomy is a procedure performed under ultrasound guidance, involving transhepatic access to the gallbladder and drainage of its contents via catheter placement[7]. As percutaneous cholecystectomy (PC) can be performed bedside for elderly patients with low physiological reserve, it provides a solution for patients to avoid the stress of surgery[8,9]. It decreases inflammation of the gallbladder and surroundings[10], and is recommended for patients with high risk and severe inflammation (grade 3) according to Tokyo criteria[5,11]. However, the gallbladder remains in place with PC, and definitive treatment is not performed for the patient. Therefore, severe complications and mortality can develop secondary to recurrent biliary colic attacks, cholecystitis, choledocolithiasis or cholangitis[12]. Due to the advanced age, comorbidities, and physiological performance status of high-risk acute cholecystitis patients, the debate continues on the subject of whether emergency cholecystectomy (EC) or PC is more advantageous[13-16].

In patients with acute cholecystitis who are considered high-risk due to advanced age and comorbidities, there are unresolved issues in the literature regarding optimal treatment strategies. Firstly, there is no consensus on the definition of "high risk." Secondly, most studies conducted to date have been retrospective in nature and subject to selection bias[13,17]. The only randomized controlled trial included in the scientific literature has a very limited sample size[15]. The aim of this study was to provide concrete evidence on the optimal treatment strategy for high-risk patients with acute cholecystitis by comparing percutaneous cholecystostomy and emergency cholecystectomy in terms of mortality, complications, length of hospital stay, and cost.

MATERIALS AND METHODS

Sample

A power analysis for Pearson's chi-square test was performed using proportions of 0.65 and 0.12 derived from a previously published study with a similar topic and methodology[15]. Considering the higher number of patients undergoing percutaneous cholecystostomy (PC) in the current cohort, a group size ratio (N2/N1) of 4 was assumed. With a significance level (α) of 0.05 and a power ($1-\beta$) of 0.99, the minimum required sample size was calculated as 15 patients for the emergency cholecystectomy (EC) group and 59 for the PC group, yielding a total minimum sample size of n = 74. Given that the reference study was terminated early, additional patient data were included in the current study to enhance statistical robustness. The sample size was calculated using G*Power version 3.1.9.7 (Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany).

The data of patients who underwent EC or PC because of acute cholecystitis in Dışkapı Research and Education Hospital, General Surgery Department between January 2017 and December 2020 were collected retrospectively by scanning the hospial database and patient files. The study exclusion criteria were defined as pregnancy, the presence of chronic liver disease, gallbladder or cholangiocellular cancer, a history of major abdominal surgery, an American Society of Anesthesiology physical status (ASA/PS) score of <3, or age <18 years[18].

During the defined study period, data from 308 patients were reviewed. Of these, 136 were excluded due to an ASA physical status classification of I or II. A total of 27 patients were excluded; 3 due to pregnancy, 8 due to chronic liver disease, 12 due to a history of major abdominal surgery, and 4 due to gallbladder or cholangiocellular malignancy. Scientific and ethical approval for the study was granted by the Clinical Research Ethics Committee of Dışkapı Yıldırım Beyazıt Training and Research Hospital with decision number 135/11, dated 18.04.2022.

Procedure

The EC or PC procedure was performed within 48 hours of the emergency presentation. PC was performed by experienced interventional radiologists in the Interventional Radiology Department of Dışkapı Yıldırım Beyazıt Training and Research Hospital. Under local anaesthesia, a 6-10 French pigtail catheter was placed within the gallbladder using the Seldinger or trocar technique via the transhepatic route[19]. The EC procedure with the laparoscopic method was started by general surgery department specialists using four trocars. Following identification of the cystic artery and cystic canal and obtaining a critical view of safety, the cholecystectomy was completed. In cases of conversion to the open technique, the gallbladder was approached with a right subcostal incision. The follow-up data of the patients for 1 year after the intervention were examined.

Data collection and outcomes

The data collected and examined included age, gender, comorbidities, 1-year mortality, cholecystitis-related mortality, complications (according to the Clavien-Dindo classification), re-intervention (within 1 year), length of hospital stay, and costs. The patients who underwent PC and EC were compared in respect of these parameters. The main aim of the study was to investigate the effect of form of treatment for acute cholecystitis on complications and mortality. The risk factors affecting mortality were also investigated.

Statistical analysis

Data obtained in the study were analyzed statistically using SPSS v. 26.0 software (SPSS Inc., Chicago, IL, USA). The distribution of numerical variables was examined using visual (histogram and probability graphs) and analytical methods (Kolmogorov-Smirnov/Shapiro-Wilk tests). Descriptive statistics were stated as mean ± standard deviation (SD) values for continuous variables with normal distribution and as median, minimum and maximum values for continuous variables not showing normal distribution.

Categorical variables were stated as number (n) and percentage (%). For age, which followed a normal distribution, the Student's t-test was used. For variables that did not conform to a normal distribution, such as length of hospital stay and cost, the Mann–Whitney U test was applied. Categorical variables including gender, comorbidities, mortality, complications, readmission, and re-intervention rates were compared using Pearson's chi-square test. Logistic regression analysis was used in the evaluation of the risk factors of mortality. A value of $p<0.05$ was accepted as statistically significant.

RESULTS

Evaluation was made of a total of 145 patients with acute cholecystitis, as 116 (80%) applied with PC and 29 (20%) applied with EC. The patient characteristics, comorbidities, and complications of both groups are presented in Table 1. The mean age of the PC group patients (78.11±9.76 years) was significantly higher than that of the EC group patients (71.69±12.56 years) ($p=0.003$). The gender distribution was similar in both groups. Comorbidities were determined at a statistically significantly higher rate in the PC group than in the EC group (n:115, 99.1% vs. n:26, 89.7%) ($p=0.025$). When the comorbid diseases were compared separately between the groups, there was seen to be similarity, with only a greater number of cardiovascular diseases in the PC group, but not at a statistically significant level ($p=0.077$).

The frequency of complications was determined to be similar between the groups. The severity of complications was examined according to the Clavien-Dindo classification, and the frequency of complications of Calvien-Dindo grade 3-4 was similar in both groups. Subgroups of complications were investigated, and no significant difference was determined between EC and PC in respect of surgical and medical complications. Of the surgical complications, biloma, and of medical complications, pneumonia, were seen more in the EC group patients ($p=0.039$, $p=0.037$) (Table 1). There was a greater tendency for the surgical complications of wound site infection in the EC group (10.3% vs. 1.7%) and for obstruction icteria in the PC group (11.2% vs. 0%) but the differences were not statistically significant ($p=0.055$, $p=0.071$, respectively).

Table 1. Comparison of patient characteristics, comorbidities and complications.

	Percutaneous Cholecystotomy (n = 116) (80%)	Emergency Cholecystectomy (n = 29) (8020%)	p value	95% Confidence interval of difference
Age[a] (years)	78.11±9.76	71.69 ±12.56	0.003	2.165 - 10.680
Gender(male)	51 (44.0%)	13 (44.8%)	0.933	
Comorbidity*	115 (99.1%)	26 (89.7%)	0.025	
DM*	52 (44.8%)	17 (58.6%)	0.183	
HT*	67 (57.8%)	14 (48.3%)	0.358	
Cardiovascular Diseases*	53 (45.7%)	8 (27.6%)	0.077	
Respiratory Diseases*	32 (27.6%)	8 (27.6%)	1.000	
Renal Diseases*	13 (11.2%)	1 (3.4%)	0.302	
Neurological Diseases	9 (7.8%)	0 (0%)	0.205	
Mortality(1 year)	47 (40.5%)	2 (6.9%)	0.001	
Cause of Mortality			1.000	
Associated with cholecystitis	3 (6.4%)	0 (0%)		
Other reasons	44 (93.6%)	2 (100%)		
Complications*	32 (26.6%)	10 (34.5%)	0.464	
Clavien-Dindo(3-4)*	12 (37.5%)	2 (20.0%)	0.451	
Surgical Complication*	18 (15.5%)	5 (17.2%)	0.782	
Wound infection*	2 (1.7%)	3 (10.3%)	0.055	
Bilioma*	0 (0%)	2 (6.9%)	0.039	
Intra-abdominal abscess*	2 (1.7%)	0 (0%)	1.000	
Biliary Obstruction*	13 (11.2%)	0 (0%)	0.071	
Medical Complication*	17 (14.7%)	8 (27.6%)	0.099	
Pneumonia*	13 (11.2%)	8 (27.6%)	0.037	
Myocardial Infarction*	3 (2.6%)	0 (0%)	1.000	
Urinary Infection*	1 (0.9%)	0 (0%)	1.000	
Pulmonary Thromboembolism*	2 (1.7%)	0 (0%)	1.000	

* present, DM: diabetes mellitus, HT: hypertansion [a]mean ± standard deviation

Data about the post-treatment period are presented in Table 2. The 1-year follow-up data, excluding routine check-ups, were compared and the groups were seen to be similar in respect of numbers of re-admission and total re-admission. There was determined to be a greater need for re-intervention in the PC group than in the EC group (n:35, 30.2% vs. n:1, 3.4%) (p=0.003). Of the 35 patients in the PC group who required re-intervention, elective cholecystectomy was performed in 27 (77.14%), ERCP in 7 (20.0%), and percutaneous drainage because of intra-abdominal fluid collection in 1 (2.85%). The re-intervention to the 1 patient in the EC group was percutaneous drainage of intra-abdominal fluid. The length of stay in hospital was seen to be similar in both groups. The costs were examined with the total cost of the hospital stay during treatment and did not include expenses after discharge. The median cost of EC was 4550 TL (range, 1040-17273 TL), which was determined to be statistically significantly higher than the median cost of PC of 1974 TL (range, 862-31475 TL) (p=0.003) (Average conversion rate for January 2017-December 2020: 1 USD=5.58 TL) (Table 2).

The 1-year mortality rate after treatment was statistically significantly higher in the PC group (40.5%) than in the EC group (6.9%) (p=0.001). Mortality for reasons other than acute cholecystitis developed in both of the 2 cases in the EC group (100%) and in 47 (93.6%) cases in the PC group (Table 1). A multivariate logistic regression model was formed to investigate the risk factors of mortality (Table 3). Taking into account both previous studies and the results of pairwise comparisons in the current study, a logistic regression model was developed to identify potential risk factors for mortality in high-risk patients with acute cholecystitis, incorporating variables such as age, comorbidities, complications, and treatment modalities. As comorbid diseases were determined in all but 4 patients, a significant odds ratio value could not be obtained in the logistic

regression model, so comorbid diseases were removed from the model. The development of complications was not evaluated as an independent risk factor in the multivariate analysis in terms of 1-year mortality following treatment for acute cholecystitis. The application of PC increased the risk of mortality 8.756-fold (odds ratio) and age increased the risk 1.133-fold. PC and older age were determined to be independent predictive factors for mortality in acute cholecystitis (p=0.009, p<0.001, respectively).

Table 2. Data about the post-treatment period

	Percutaneous Cholecystotomy (n = 116)	Emergency Cholecystectomy (n = 29)	p value
Re-admission*	62 (53.4%)	11 (37.9%)	0.135
Number of Re-admissions[b]	2.00 (1 - 6)	2.00 (1 – 6)	0.385
Re-intervention*	35 (30.2%)	1 (3.4%)	0.003
Elective Cholecystectomy*	27 (23.27%)		
ERCP*	7 (6.0%)	0 (0%)	0.345
Percutaneous Drainage*	1 (0.9%)	1 (3.4%)	0.361
Length of Stay[b]	4.00 (2 – 33)	5.00 (2 – 20)	0.466
Cost[bc]	1974.00 (862.0 – 31475.00)	4550.00 (1040.00 – 17273.00)	0.003

* present, [b] median (minimum –maximum), [c] Turkish Lira (January 2017 – December 2020 average 1 USD = 5.58 Turkish Liras); ERCP: Endoscopic Retrograde Cholangiopancreatography

Table 3. Risk factors of mortality, logistic regression analysis

	p value	Odds Ratio	95% Confidence Interval of Odds Ratio
Age	<0.001	1.133	1.076 to 1.193
Treatment (Percutaneous Cholecystostomy)	0.009	8.756	1.739 to 44.076
Complication (present)	0.500	1.363	0.554 to 3.352

DISCUSSION

Previous studies on the subject of the optimal treatment option for patients with acute cholecystitis at high risk have raised more than one unresolved question. First, there is no consensus on the definition of high risk, as studies have generally been retrospective with a selection bias. In the only randomised controlled trial, the sample number was extremely low[13,15,17,20]. Therefore, there is a need for new, extensive studies.

In the research first added to the literature together with the emergence of PC, it was seen that PC was preferred more for elderly, high-risk patients with comorbidities[21,22]. To be able to avoid this bias, it is necessary to first identify and compare high-risk patients. The first stage is a reasonable risk evaluation. Several scoring systems have been used in literature on the subject of surgical risk in acute cholecystitis, including the Severity of Illness (SOI), Simplified Acute Physiology Score II (SAPS II), Acute Physiology Assessment and Chronic Health Evaluation II (APACHE II), and ASA/PS scores[15-17,23-25]. Of these, the ASA/PS is often used and is used in daily practice in our centre, but to avoid the selection bias formed due to the retrospective nature of the current study, patients with an ASA/PS score of ≥3 were accepted as high-risk and were included in the study.

The mean age of the PC group in the current study was higher than the age of the EC group patients, and in previous studies the age of the PC group has generally been higher[16,23]. This difference was thought to be due to the prejudice adopted by clinicians of avoiding acute cholecystitis surgery at an advanced age. To be able to overcome this there is a need for the literature to be supported with randomised controlled trials with greater patient numbers. The gender distribution of the current study groups was similar, in parallel with previous papers. Comorbid conditions are chronic diseases that affect the physiological reserve of the patient. In the current study, comorbidities were determined in almost all (99.1%) of the PC group and in most (89.7%) of the EC group. It has been seen in previous

studies that when high-risk patients are selected, the groups have similar rates in respect of comorbid diseases[16].

Previous retrospective studies have yielded conflicting results for EC and PC in respect of complications. The only randomised, controlled study in literature on this subject, by Loozen et al. in 2018, was terminated early because of a greater number of complications in the PC group[15,16,23,25,26]. In the current study, the complication rates after treatment were similar in both groups, and even complications of grade ≥ 3 severity according to the Clavien-Dindo scoring were similar in both groups. Of the surgical complications, biloma, and of medical complications, pneumonia, were seen more in the EC group patients. There is still no consensus on complications, and the current study supports the view that there is no significant difference between EC and PC when performed by experienced radiologists.

With PC, gallbladder flow is re-started and inflammation is resolved but the gallbladder and stones within it remain in place. This can cause recurrent biliary attacks, acute cholecystitis, or choledocolithiasis[27]. The re-admission rate in the current study was seen to be higher in the PC group (53.4% vs.37.9%). Re-intervention was required in 30.2% of the PC group compared to 3.4% in the EC group. Meta-analyses published by Huang et al. in 2021, Crocchi et al. in 2023, and Terrone et al. in 2024 demonstrated that EC is associated with lower rates of re-admission[20,26,28]. Previous studies have also reported higher rates of re-admission and re-intervention contrary to PC[15,16,20,21,29]. The current study results showed lower costs with PC but the costs in question were calculated as the costs of first presentation and treatment. When re-admission and re-intervention costs are added to these, it is thought that a cost rate in favour of EC will emerge in parallel with the literature[23,30]. With PC, permanent treatment of acute cholecystitis does not occur, recurrent biliary symptoms emerge and this has negative effects on both costs and the healthcare workforce.

Following the introduction of PC, the relevant literature included studies showing low mortality rates[14,31]. Subsequently, studies comparing EC and PC were published. However these generally did not have homogenous patient groups, the definition of high-risk patients was not consistent with other studies, and the follow-up periods were different. The studies mostly showed high mortality rates of PC, but in some the difference was not statistically significant[17,23-25,32,33]. In a study by Garces-Albir et al., it was reported that the mortality rate of PC increased significantly in all patients, and in elderly and high-risk patients of ASA/PS ≥3, the mortality rate also increased but the difference was not significant[16]. A recent meta-analysis evaluating only patients aged <65 years did not demonstrate a significant difference in mortality[28]. In a randomised, controlled study by Loozen et al., the mortality rates were determined to be 9% with PC and 3% with EC, with no statistically significant difference determined. That study is the only RCT on this subject, but was terminated early as the complications of PC were seen to have increased in the intermediate evaluation, so a statistically significant difference could have emerged if the study had continued to recruit patients[15].

In three comprehensive meta-analyses that included all of the above-mentioned studies, PC was reported to be associated with higher mortality compared to EC[20,21,26]. Studies have also shown that mortality was reduced in some subgroups of PC such as intensive care patients or those who underwent planned EC after PC[25,34]. In the current study, mortality was determined to be 6.9% in the EC group and 40.5% in the PC group in the 1-year follow-up of the acute cholecystitis patients. The risk factors of mortality were investigated in the multivariate analysis, and complications were not seen to have an effect on mortality but age and the form of treatment (PC) were seen to be risk factors for mortality. Therefore, compared to EC, PC was considered to increase mortality in high-risk acute cholecystitis patients.

This study had some limitations, primarily that the retrospective design could have caused selection bias. As it has been seen in previous studies that high-risk patients are directed more to PC by clinicians, only ASA/PS ≥3 patients were included in this study to prevent this bias. Multivariate logistic regression analysis was added to the statistical examination. A second important limitation was the relatively low number of patients in the EC group, which was due to the exclusion of ASA/PS 1-2 patients. A further limitation was that when calculating the costs, a more accurate result could have been obtained by including the re-admission and re-intervention costs. However, the patients presented at several centres and difficulties were experienced in accessing the financial records of all these centres, so re-admission

and re-intervention costs could not be added to the cost calculation.

In high-risk patients with acute cholecystitis, EC is superior to PC in terms of reducing mortality and the need for re-intervention. The selection of treatment for high-risk patients with acute cholecystitis is often dependent on the surgeon's clinical judgment, which may introduce selection bias in retrospective studies. Therefore, there is a critical need for prospective, randomized controlled trials involving well-defined and homogeneous patient populations[26,35]. Percutaneous cholecystostomy should be considered as a temporary solution only in cases where surgery is absolutely contraindicated or when the patient declines surgical intervention[36]. In certain subgroups such as those with biliary sepsis, critically ill patients in intensive care units, or as a bridge to early cholecystectomy percutaneous cholecystostomy remains an important therapeutic option[37]. Further dedicated studies are warranted to investigate the potential benefits of percutaneous cholecystostomy in these specific subgroups[38].

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