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YÜKSEK CERRAHİ RİSKLİ AKUT KOLESİSTİT HASTALARINDA PERKÜTAN SAFRA KESESİ DRENAJI: TEK MERKEZ DENEYİMİ

PERCUTANEOUS GALLBLADDER DRAINAGE IN PATIENTS WITH HIGH SURGICAL RISK ACUTE CHOLECYSTITIS: A SINGLE-CENTER EXPERIENCE

İsmail DİLEK[1], Emre Utkan BÜYÜKCERAN[2], Görkem ATASOY[3], Erbil ARIK[4], Hüsnü ŞEVİK[5], Alaaddin NAYMAN[6]

[1]Selçuk Üniversitesi Tıp Fakültesi, Radyoloji Ana Bilim Dalı
[2]Ankara Güven Hastanesi, Radyoloji Kliniği
[3]Edirne Sultan 1. Murat Devlet Hastanesi, Radyoloji Kliniği
[4]Marmara Üniversitesi Pendik Eğitim ve Araştırma Hastanesi, Radyoloji Kliniği
[5]Başakşehir Çam & Sakura Şehir Hastanesi, Genel Cerrahi Kliniği
[6]Selçuk Üniversitesi Tıp Fakültesi, Radyoloji Ana Bilim Dalı

ÖZET

AMAÇ: Yüksek cerrahi riski bulunan akut kolesistit hastalarında perkütan safra kesesi drenajının etkinliği araştırılmıştır.

GEREÇ VE YÖNTEM: Ocak 2021 ile Eylül 2023 tarihleri arasında görüntüleme rehberliğinde perkütan safra kesesi drenajı yapılan toplam 51 hastanın elektronik kayıtları retrospektif olarak incelendi.

BULGULAR: Perkütan safra kesesi drenajı (PSD) işlemi, 51 hastanın tamamında başarılı bir şekilde gerçekleştirildi. İşlem sonrası, 43 hastada (%84,3) akut kolesistit semptomları geriledi. PSD prosedürü ile ilişkili mortalite veya majör komplikasyon bildirilmedi. PSD sonrası kateterizasyon süresi ortalama 23,6 gün (aralık 3-47 gün), hastanede kalış süresi ise ortalama 22 gün olarak tespit edildi. Çoğunluğu işlem öncesi sepsis nedeniyle takip edilen 7 hasta (%13,7), drenaj kateteri çekilmeden 30 gün içinde kaybedildi. PSD sonrası cerrahi risklerin en aza indirilmesini takiben 6-8 hafta içinde 27 hastaya (%52,9) kolesistektomi uygulandı.

SONUÇ: Görüntüleme rehberliğinde gerçekleştirilen perkütan safra kesesi drenajı, düşük komplikasyon oranlarına sahip güvenli bir prosedür olup, yüksek cerrahi riski bulunan hastalarda akut kolesistit ile ilişkili inflamatuar sürecin çözümünde etkili bir yöntemdir.

ANAHTAR KELİMELER: Akut kolesistit, Safra kesesi, Kolesistostomi, Kolesistektomi, Perkütan drenaj.

ABSTRACT

OBJECTIVE: We investigated the effectiveness of percutaneous gallbladder drainage (PGD) in a group of patients with acute cholecystitis (AC) who were at high surgical risk.

MATERIAL AND METHODS: The electronic records of a total of 51 patients who underwent percutaneous gallbladder drainage under imaging guidance between January 2021 and September 2023 were retrospectively reviewed.

RESULTS: The PGD procedure was successfully performed in all 51 patients. After the procedure, symptoms of AC regressed in 43 patients (84.3%). There were no reports of mortality or major complications associated with the PGD procedure. The average duration of catheterization post-PGD was 23.6 days (range 3-47 days), and the average hospital stay was 22 days. Seven patients (13.7%), mostly monitored due to pre-procedural sepsis, were lost within 30 days without catheter removal. Cholecystectomy was performed on 27 patients (52.9%) in the 6-8 weeks following PGD, after minimizing surgical risks.

CONCLUSIONS: Under imaging guidance, PGD is a safe procedure with low complication rates in patients at high surgical risk and is an effective method for resolving the inflammatory process associated with AC.

KEYWORDS: Acute cholecystitis, Gallbladder, Cholecystostomy, Cholecystectomy, Percutaneous drainage.

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Yazışma Adresi / Correspondence: Dr. Öğr. Üyesi İsmail DİLEK
Selçuk Üniversitesi Tıp Fakültesi, Radyoloji Ana Bilim Dalı
E-mail: drismaildilek@gmail.com
Orcid No (Sırasıyla): 0000-0002-5398-7035, 0000-0001-6912-7737, 0000-0003-3776-6950, 0000-0002-5976-860X, 0000-0001-6381-6726, 0000-0003-3213-8576
Etik Kurul / Ethical Committee: Iğdır Üniversitesi Tıp Fakültesi Etik Kurulu (25.09.2024/11-13).

INTRODUCTION

Acute cholecystitis (AC) is a common condition encountered in surgical practice, characterized by gallbladder inflammation with significant morbidity and mortality risks. More than 90% of AC cases are associated with gallstones, and cholecystectomy is the standard treatment for eligible patients (1,2). Mortality rates for cholecystectomy are reported to be below 1%; however, for high-risk patients with comorbidities undergoing emergency cholecystectomy, mortality rates can reach up to 30% (3,4). Consequently, high-risk surgical patients are treated with broad-spectrum antibiotics and gallbladder decompression to prevent perioperative morbidity and mortality.

Percutaneous gallbladder drainage (PGD) under imaging guidance was first performed in 1980 using ultrasonography (USG) in a patient with gallbladder empyema. PGD is a minimally invasive procedure aiming to achieve decompression by placing a drainage catheter into the gallbladder under imaging guidance. PGD can be used as a bridging therapy for patients eligible for surgery and is also recommended as a definitive treatment for patients who are not surgical candidates or those with acute acalculous cholecystitis (AAC) (3,5,6).

This study aims to evaluate the effectiveness, clinical outcomes, and complications of PGD performed under imaging guidance.

MATERIALS AND METHODS

This retrospective study utilized data from patients who underwent percutaneous gallbladder drainage (PGD) under imaging guidance at Iğdır Dr. Nevruz Erez State Hospital between January 2021 and September 2023. Informed consent for the procedure was obtained from all patients or their families if the patients were unable to provide consent. The study included patients aged 18 and older diagnosed with acute cholecystitis (AC) based on clinical and radiological findings and treated with PGD under imaging guidance. Patients whose clinical information and procedure reports were unavailable in electronic records were excluded. The severity of AC was assessed using the 2018 Tokyo Guidelines (TG). The demographic and clinical data of the patients, the imaging modality and technique used for PGD, the macroscopic appearance of the initial aspiration sample during PGD, laboratory results of the aspiration samples, catheterization and hospital stay durations, minor and major complications related to the procedure, and the timing and number of patients who underwent cholecystectomy after PGD were recorded.

Procedure Technique: All procedures were performed under sterile conditions and local anesthesia with 5–10 mL of 2% lidocaine using ultrasonography (USG) or a combination of USG and fluoroscopy. Patients were initially evaluated for the suitability of a transparenchymal hepatic approach and the Seldinger technique. In one patient with coagulopathy, a transperitoneal approach was used to access the gallbladder directly through the peritoneum.

After identifying the appropriate entry site, an 18-gauge Chiba needle (Cook Medical) was inserted into the gallbladder, and approximately 10 mL of fluid was aspirated to confirm placement within the cavity. The aspirated sample was sent for microbiological analysis. A guidewire (Amplatz Super Stiff, Boston Scientific, USA) was advanced through the needle, which was then removed, and tract dilation was performed using 6–10 French (F) dilators. Subsequently, an 8–14 F, 25 cm pigtail catheter (GEOTEK Medical, Ankara, Turkey) was placed into the gallbladder lumen.

For patients guided by fluoroscopy, 5 mL of iodinated contrast material was injected, while for those guided by USG, 5–10 mL of fluid was aspirated through the catheter to confirm its placement within the gallbladder. The catheter was secured to the skin and left for free drainage. In non-operated patients, catheter removal was performed after assessing cystic duct patency with contrast injection through the catheter, following tract maturation, typically at 2–3 weeks.

Ethical Committee

This study was approved by the Institutional Non-Interventional Clinical Research Ethics Committee with protocol (25.09.2024/11-13). Due to the retrospective nature of the study, a waiver of informed consent was granted, and there were no conflicts of interest among the authors.

Statistical Analysis

Statistical evaluations were conducted using the SPSS 22 software package. Categorical data were presented as frequencies and percentages, while continuous numerical data were expressed as mean ± standard deviation and minimum-maximum values. Categorical variables were analyzed using Fisher's exact test or chi-square tests.

RESULTS

The study included 51 patients who underwent PGD. The demographic and clinical characteristics of the patients, as well as the procedural details, are described in **Table 1**. Among the patients, 28 (54.9%) were male, and 23 (45.1%) were female, with ages ranging from 44 to 96 years (mean: 69 years).

Table 1: Distribution of procedure-related characteristics and demographic data in patients undergoing percutaneous gallbladder drainage.

	Number (n)	Percentage (%)
GENDER		
Female	28	54.9
Male	23	45.1
GALLSTONE		
Present	48	94.2
Absent	3	5.8
TOKYO GUİDELİNE STAGE		
Stage 1	15	29.4
Stage 2	32	62.7
Stage 3	4	7.9
GUIDING METHOD		
Ultrasound	16	31.3
Ultrasound + Fluoroscopy	35	68.7
ACCESS ROUTE TO THE GALLBLADDER		
Transhepatic	50	98.1
Transperitoneal	1	1.9
CATHETERIZATION TECHNIQUE		
Seldinger technique	49	96.1
Trocar technique	2	3.9
FIRST ASPIRATION MACROSCOPIC APPEARANCE		
Normal	25	49
Purulent	15	29.4
Bile sludge	11	21.6

All patients underwent PGD due to acute cholecystitis (AC). Of the 51 patients, 49 (96.1%) were hospitalized from the emergency department with a diagnosis of AC, and 2 patients (3.9%) developed AC while hospitalized for malignancy. In 3 patients (5.8%) with acute acalculous cholecystitis, no gallstones were observed, whereas the remaining 48 patients (94.2%) were diagnosed with acute calculous cholecystitis. When the severity of AC was classified according to the Tokyo Guidelines, 15 patients (29.4%) were classified as Grade 1, 32 patients (62.7%) as Grade 2, and 4 patients (7.9%) as Grade 3. Among the Grade 1 patients, 12 (80%) were deemed ineligible for surgery due to being in ASA-3 (American Society of Anesthesiologists Classification), and the remaining 3 (20%) underwent PGD based on the surgical team's decision. In the Grade 2 group, 13 patients (40.6%) were classified due to WBC >18,000, and 19 (59.4%) met other criteria (Table 1).

The technical success rate of PGD was 100%. Transhepatic PGD was performed in 50 patients (98.1%), while a transperitoneal approach was used in 1 patient (1.9%) with no suitable entry site. PGD was performed under ultrasonography (USG) guidance alone in 16 patients (31.3%) and with combined USG and fluoroscopy guidance in 35 patients (68.7%). The Seldinger technique was used in 49 patients (96.1%), while the trocar method was employed in 2 patients (3.9%). The initial aspiration during PGD revealed normal bile in 25 patients (49%), purulent material in 15 patients (29.4%), and bile sludge in 11 patients (21.6%) (Table 1). Microbiological analysis results were available for only 4 patients, and Enterococcus species were cultured from these aspiration samples.

The clinical and follow-up outcomes of patients who underwent PGD are described in table 2. Post-procedure, AC symptoms resolved in 43 patients (84.3%). A comparison of pre-procedure and 72-hour post-procedure white blood cell (WBC) counts showed that WBC levels returned to normal in 42 patients (82.3%) post-procedure. In 3 patients with persistently elevated WBC counts, pericholecystic abscess formation not amenable to percutaneous drainage was identified, prompting changes in medical management. The mean duration of catheterization was 23.6 days (range: 3–47 days), and the mean length of hospital stay was 22 days. Post-procedure, 27 patients (52.9%) were monitored in the intensive care unit. 7 patients (13.7%), the majority of whom had been monitored for sepsis prior to the procedure, succumbed within 30 days before the drainage catheter was removed. Six patients (11.7%) were discharged with catheters in place but were lost to follow-up. Catheters became dislodged in 4 patients (7.8%), and 2 of these cases required no re-catheterization during follow-up. Cholecystectomy was performed in 27 patients (52.9%) 6–8 weeks after PGD when surgical risks were minimized.

No procedure-related mortality or major complications were observed. The most common minor complication was catheter malposition (n=4, 7.8%). Catheter revision was required in 2 patients (3.9%) due to catheter obstruction **(Table 2)**.

Table 2: Post-procedural outcomes of patients who underwent percutaneous gallbladder drainage.

	Number (n)	Percentage (%)
POST-PROCEDURAL SYMPTOMATIC IMPROVEMENT	43	84.3
RESOLUTION OF POST-PROCEDURAL LEUKOCYTOSIS	42	82.3
COMPLICATIONS		
Catheter Misplacement	4	7.8
Catheter Occlusion	2	3.9
Pericholecystic Abscess	3	5.8
MONITORED IN INTENSIVE CARE	27	52.9
UNDERWENT CHOLECYSTECTOMY	27	52.9
DECEASED WITH CATHETER IN PLACE	7	13.7
CATHETER REMOVED	4	7.8
NO FOLLOW-UP AFTER DISCHARGE	6	11.7

DISCUSSION

Acute cholecystitis (AC), an acute inflammation of the gallbladder, is a primary complication of gallstones and a common emergency encountered in surgical practice (7). The standard first-line treatment for AC is laparoscopic cholecystectomy following fluid-electrolyte balance restoration and gastric decompression. In high-risk patients, acute infection can be treated with percutaneous gallbladder drainage (PGD), which does not require general anesthesia, instead of laparoscopic cholecystectomy (8).

According to the 2018 Tokyo Guidelines (TG), PGD is indicated in Grade 2 and Grade 3 patients. For Grade 1 patients, PGD is not indicated unless they are considered high surgical risks (3). In our study, 32 patients (62.7%) were classified as Grade 2, and 4 patients (7.9%) as Grade 3. The remaining 15 patients (29.4%) in the Grade 1 group included 12 patients (80%) who were classified as ASA-3 (American Society of Anesthesiologists Classification) and therefore ineligible for surgery, and 3 patients (20%) who underwent PGD based on the surgical clinic's decision.

For patients diagnosed with AC, PGD is a definitive treatment in cases with high surgical risk, while it serves as a bridge to surgery in patients scheduled for delayed surgical intervention (9,10). In our study, the rate of patients undergoing cholecystectomy after PGD for AC was 52.9% (27/51). In the literature, the rate of patients undergoing cholecystectomy after PGD varies widely, ranging from 16.4% to 94% (11-14). Studies investigating predictors for subsequent surgery following PGD have shown that advanced age, prolonged hospital stays, and the presence of respiratory comorbidities reduce the likelihood of surgery (12,15,16). In our study, the mean age of the patients was found to be 69 years, and the average length of hospital stay was 22 days. After PGD, it was observed that patients who did not undergo surgery had a higher age and more comorbidities, in accordance with the literature.

The technical success rate of imaging-guided PGD procedures is reported to be above 90% in the literature (17). In our hospital, routine imaging guidance for PGD procedures includes either ultrasonography (USG) alone or a combination of USG and fluoroscopy. Following catheter placement, the position of the catheter within the gallbladder lumen was verified using USG and aspiration for bedside procedures relying solely on USG. For cases using both USG and fluoroscopy, the catheter placement was confirmed by injecting contrast material. In our study, the technical success rate of PGD was 100%.

Positive culture results are essential for identifying the source of sepsis, while negative results direct attention to non-biliary sources of sepsis. In our study, microbiological evaluation of the initial aspiration samples from 4 patients yielded Enterococcus in culture, and medical treatments were adjusted accordingly.

In comparison to the transperitoneal approach, the transhepatic approach in PGD procedures has been reported to carry higher risks of bleeding and hemobilia fistula formation (18).

In our study, 50 patients (98.1%) underwent transhepatic PGD, while 1 patient (1.9%) with no suitable entry point underwent transperitoneal PGD. None of the patients experienced bleeding or hemobilia fistula complications. We believe that the dynamic imaging capability of ultrasonography (USG), which allows clear visualization of the needle's relation to major vascular structures and bile ducts as it advances through the liver parenchyma, plays a crucial role in preventing bleeding complications. Additionally, abnormalities in the patient's bleeding parameters are critical etiological factors contributing to such complications.

The Society of Interventional Radiology (SIR) quality improvement guidelines define the clinical success of PGD as pain relief, normalization of fever, white blood cell count (WBC), and C-reactive protein (CRP) levels (17). Studies have reported the clinical success of PGD to range between 80.6% and 87.9% (18-21). In our study, similar to the literature, symptoms of AC resolved in 43 patients (84.3%), and WBC levels returned to normal ranges in 42 patients (82.3%) within 72 hours post-procedure. Among the patients whose WBC levels did not normalize, three were found to have developed pericholecystic abscesses. After their medical treatments were adjusted, these patients met the clinical improvement criteria, and their catheters were removed. Similarly, studies in the literature have reported pericholecystic abscess formation in most patients whose WBC levels remained elevated post-procedure (20).

Early complications of PGD include vagal reactions, bleeding, sepsis, bile peritonitis, pneumothorax, bowel perforation, and catheter migration, while late complications include catheter migration and recurrent cholecystitis. Studies in the literature report catheter migration as the most common complication, with an incidence of 4-8% (14, 21). In our study, no major complications were observed related to PGD. Similar to the literature, the most common complication was catheter migration, which occurred in 4 patients (7.8%). Among these patients, 2 who showed clinical improvement did not require repeat PGD and were monitored clinically.

In patients with AC, especially those with high comorbidities, in addition to the technical difficulty of surgery, the potential morbidity, prolonged hospitalization/intensive care unit admission, and long-term medical treatment risks are also present, leading to high costs associated with surgical treatment. PGD performed under imaging guidance and local anesthesia using relatively small-caliber catheters (8-14 F) has the advantage of lower potential risks compared to surgery, requiring a shorter hospital stay. Additionally, it allows for earlier mobilization and, being a minimally invasive technique, offers significant benefits in terms of patient comfort, along with achieving a lower cost treatment.

Our study has several limitations. First, due to its retrospective nature, some patients' medical and clinical follow-up records were not accessible. As a result, clinical improvement criteria were based on pain and WBC counts, as data on fever and CRP levels were unavailable for some patients. Second, no comparative analysis was conducted with patients who underwent emergency cholecystectomy. Third, the study's limited sample size and lack of long-term outcome data or information on additional interventions needed by the patients pose further limitations. Studies with larger participant groups and long-term follow-up are necessary to provide valuable insights into the sustainability of this treatment.

Imaging-guided PGD is an effective and reliable treatment method for patients with AC, offering high success rates, low morbidity and mortality, and applicability as a bridging or definitive therapy in high-risk surgical patient groups.

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