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Investigating mortality risk factors and blood/biliary drainage culture evaluation in percutaneous transhepatic biliary drainage procedures

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Abstract

Aim: Severe complications such as bacteremia and bile duct infection may arise following percutaneous transhepatic biliary drainage (PTBD). The objective of this study was to examine the factors that contribute to mortality and compare the differences between patients with positive blood and biliary drainage cultures following PTBD.

Materials and Methods: This retrospective study was conducted from January 2017 to February 2019. The study was carried out at a hospital where 547 percutaneous transhepatic biliary drainage (PTBD) procedures were performed during this period. The study evaluated patients who showed no signs of infection prior to the procedure. The patients were categorized into three groups based on culture results: the first group with only bacteremia, the second group with only positive bile drainage culture, and the third group with both bacteremia and positive bile drainage culture. This study compared the clinical and laboratory parameters among these groups and examined the culture results in a high-resistance environment.

Results: Ninety patients either developed bacteremia, bile duct infections, or both in this study. The laboratory results revealed that patients with bacteremia exhibited a notably higher serum level of alanine aminotransferase. (ALT) (p=0.001). Independent risk factors associated with 30-day mortality after PTBD included elevated neutrophil counts, lipase levels, and the presence of carbapenem-resistant isolates (p=0.01, p=0.01, and p=0.04, respectively). Gram-negative organisms were present in 71.2% of the cases; *Escherichia coli* was the most common species (28.1%) followed by *Enterococcus faecium* (18.1%), *Klebsiella pneumoniae* (15.8%) and *Pseudomonas aeruginosa* (9.9%). Of the cultured gram-negative bacteria, 41.8% (51 isolates) were found to be positive for extended spectrum beta-lactamases, while 15.8% (27 isolates) of the isolates showed carbapenem resistance.

Conclusion: The sole distinguishing factor observed among the three groups was the elevated level of alanine aminotransferase. Consequently, bacteremia and bile culture positive patients should be treated with the same care. Independent risk factors associated with mortality included elevated neutrophil counts, lipase levels, and the presence of carbapenem-resistant isolates. Finally, the choice of antibiotic prophylaxis should be reviewed according to the antimicrobial resistance profiles.

Introduction

Biliary Tract Patency and Bile Drainage are very important factors of physiological functioning of liver; biliary obstructions prevent the bile ducts from delivering bile to the duodenum, leading to jaundice, toxic accumulation of bile salts, and hyperbilirubinemia [1, 2]. Obstruction is a threat at any level of the biliary tract. While the leading cause of benign biliary obstruction is choledocholithiasis, obstructive jaundice is frequently observed in various cancers, particularly in the late stages of the disease [3]. Primary cancers (pancreatic cancer, cholangiocarcinoma, hepatocellular carcinoma, gallbladder cancer, etc...), lymph node compressions, or liver and hilar metastases of distant primary malignancy may cause malignant obstructive jaundice [4]. Due to the adverse consequences of progressive hyperbilirubinemia that cannot be avoided, biliary drainage is typically done to relieve symptoms, improve quality of life, and normalize serum biochemistry. Percutaneous transhepatic biliary drainage (PTBD), one of the biliary drainage methods,

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together with endoscopic retrograde cholangiopancreatography (ERCP) are well-known and effective methods for palliation in unresectable cases [5, 6]. Recently, thanks to increased technical success rate and expertise, there has been a significant increase in demand for such minimally invasive procedures compared to surgical bypass.

PTBD is an image-guided procedure that can be executed using fluoroscopy alone or with the assistance of both ultrasound and fluoroscopy. This procedure can be used for indications of access to the biliary system for advanced palliative interventions like palliation in obstructive jaundice (such as reducing pain and itching), lowering serum bilirubin levels before starting chemotherapy, stenting in cholangiocarcinoma, or transhepatic brachytherapy. Cholangitis and biliary sepsis are complications that can develop despite appropriate and adequate antibiotic therapy. Although the exact etiology is unknown, it may be due to many factors such as retrograde reflux of intestinal flora during the procedure, progression of ex-vitro infection through the drainage catheter, or it may be due to hematogenous spread [5, 7].

This study aimed to detect and compare bacteremia and bile drainage culture growths post-PTBD and to investigate antibiotic susceptibility and accompanying risk factors for mortality.

Materials and Methods

Study patients

This study was conducted as a retrospective review of the medical records of PTBD procedures between January 2017 and February 2019 in a tertiary branch hospital where PTBD was performed intensively. In total, 547 PTBD procedures performed during this period were evaluated. Patients who did not have any pre-procedural sepsis-related symptoms or signs; had positive blood and/or bile cultures together with a fever of $>$ 38.0 ^{o}C and tremors in the first 30 days after PTBD procedure were contained in the research. The patients were divided into three groups based on their culture results: 1) first group was only bacteremic (Group 1), 2) second group was only bile drainage culture-positive (Group 2), and 3) third group was both bacteremia and bile drainage culture-positive (Group 3). Blood and bile drainage cultures were collected from patients simultaneously when bloodstream infections, sepsis, or biliary tract infection were suspected. Patients with a proven infection at other sites after PTBD were excluded. The categories of microorganisms that replicated in blood and/or bile cultures and antibiotic susceptibilities of microorganisms were evaluated in all included patients. The study was confirmed by the institutional ethics committee (University of Health Sciences Ankara High Specialization Training and Research Hospital, approval number: 25.10.2018-58/29620911-929).

Clinical data and laboratory tests

Age, PTBD indication, isolated microorganisms, and risk factors for bacteremia and/or bile culture positivity were recorded. These bile samples were collected via external catheters that adhered to sterility guidelines, and fresh samples were sent for culture testing. Bacteremia was defined as the presence of positive bacterial cultures (excluding contamination) in blood samples obtained from patients with postoperative fever, according to the definition of bloodstream infection by the National Health Safety Network (CDC-NHSN) [8]. Cholangitis was determined through clinical findings or, in asymptomatic patients, through laboratory parameters suggestive of infectious disease and/or through microbiological assessment of the bile culture [9]. %5 sheep blood agar and EMB agar were used for the isolation of aerobic bacteria, while Seboraud Dextrose Agar was used for fungal isolation. For the identification of microorganisms, Phoenix 100 (Becton Dickinson, USA) automated system was used. The study excluded susceptible and intermediate categories when a microorganism was categorized as resistant [10]. Antibiotic susceptibilities were determined according to the criteria of the Clinical and Laboratory Standards Institute. Colistin resistance was defined as MIC $>$4 µg/L [11]. Demographic and clinical data of culture-positive patients were extracted from the hospital information system. Considering the laboratory reference intervals used in our hospital, if alanine aminotransferase (ALT) was $>$41 U/L, aspartate aminotransferase (AST) $>$40 U/L, alkaline phosphatase (ALP) $>$130 U/L, gamma-glutamyl transferase (GGT) $>$61 U/L, total bilirubin $>$1.1 mg/dL, amylase $>$100 U/L, lipase $>$60 U/L, the international normalized ratio (INR) $>$1.2, creatinine $>$0.9 mg/dL, white blood cell count (WBC) $>$9.7 x10^3/uL, C-reactive protein (CRP) $>$5 mg/L, procalcitonin $>$ 0.1 ng/mL, and the neutrophil lymphocyte ratio (NLR) $\geq$3 levels were accepted as high.

Statistical analysis

Differences were assessed using a Pearson's χ^2 test or Fisher's exact test in categorical variables and the Kruskal-Wallis test in non-categorical variables. SPSS version 24.0 was used for all statistical analyses (v17.0 SPSS 24 Inc. Chicago, IL). Multivariable analyses were conducted to ascertain autonomous risk factors connected with mortality by using a stepwise logistic regression model. The p-value $<$0.05 was considered to be statistically significant.

Results

Among 547 patients who underwent PTBD during the study period, we selected 90 patients with bacteremia and/or positive bile drainage culture after the procedure. A total of 171 culture results of these 90 patients were evaluated. Forty-nine patients (54.4%) were male and the median age was 65 years (range, 24 to 90 years). The rate of bacteremia and mortality were 61.1% and 27.8% post-PTBD, respectively. There were no differences in comorbidities, primary diagnosis for PTBD, and outcomes between the three groups. In the laboratory findings, group 1 showed significantly higher serum levels of ALT (p=0.001) and CRP, procalcitonin and GGT levels were found high in all patients.

The baseline characteristics of patients were shown in Table 1.

Forty-one patients (45.5%) had multiple organisms among 90 patients with post-PTBD cultures. Twenty-two patients (24.4%) had both bacteremia and bile tract infection while 16 (72.7%) patients out of 22 had the same

Table 1. Baseline characteristics of patients.

Characteristics	Group 1 (n=31)	Group 2 (n=37)	Group 3 (n=22)	Total (n=90)	p
Age, median (min-max), year	65 (26-90)	64 (24-87)	68 (37-81)	65 (24-90)	0.87*
Gender (female), (n, %)	15 (48.4)	13 (35.1)	13 (59.1)	41 (45.6)	0.70Ý
Comorbid diseases, (n, %)					
Diabetes	10 (32.3)	7 (18.9)	6 (27.3)	23 (25.6)	0.44Ý
Kidney disease	9 (29.0)	7 (18.9)	2 (9.1)	18 (20.0)	0.20Ý
Primary indication for PTBD					
Tumorous conditions (n, %)					
Biliary tract cancer	18 (58.1)	26 (70.3)	14 (63.6)	58 (64.4)	0.58Ý
Gallbladder cancer	8 (44.4)	9 (34.6)	7 (50.0)	24 (41.4)	0.53Ý
Gastric cancer	5 (27.8)	2 (7.7)	1 (7.1)	8 (13.8)	0.16ý
Pancreas cancer	2 (11.1)	2 (7.7)	2 (14.3)	6 (10.3)	0.86ý
Hepatocellular carcinoma	1 (5.6)	4 (15.4)	2 (14.3)	7 (12.1)	0.67ý
Other metastatic cancers	2 (11.1)	3 (11.5)	2 (14.3)	7 (12.1)	1.0ý
Nontumorous conditions (n, %)	-	6 (23.1)	-	6 (10.3)	0.02ý
Choledocholithiasis	13 (41.9)	11 (29.7)	8 (36.7)	32 (35.6)	
Cholecystitis					
Benign stricture	-	1 (9.1)	2 (25.0)	3 (9.4)	0.17ý
Pancreatitis	1 (7.7)	-		1 (3.1)	-
Cholangitis	5 (38.5)	6 (54.5)	5 (62.5)	16 (50.0)	0.67c
	1 (7.7)	-		1 (3.1)	-
	6 (46.2)	4 (36.4)	1 (12.5)	11 (34.2)	0.29c
Laboratory findings					
WBC >9.7 x10^3/uL	16 (51.6)	15 (40.5)	11 (50.0)	42 (46.7)	0.62Ý
Neutrophils >7.9 x10^3/uL	15 (48.4)	13 (35.1)	10 (45.5)	38 (42.2)	0.51Ý
ALT >41 U/L	23 (74.2)	14 (37.8)	6 (27.3)	43 (47.8)	**0.001**Ý
AST >40 U/L	20 (64.5)	20 (54.1)	11 (50.0)	51 (56.7)	0.53Ý
Total bilirubin >1.1 mg/dL	26 (83.9)	31 (83.8)	18 (81.8)	75 (83.3)	0.98Ý
ALP >130 U/L	27 (87.1)	31 (83.8)	19 (86.4)	77 (85.6)	0.93ý
Amylase >100 U/L	20 (64.5)	27 (73.0)	12 (54.5)	59 (65.6)	0.35Ý
Lipase >60 U/L	5 (16.1)	5 (13.5)	3 (13.6)	13 (14.4)	1.0ý
NLR ≥3	29 (93.5)	29 (78.4)	20 (90.9)	78 (86.7)	0.20ý
GGT>61 U/L	30 (96.8)	35 (94.6)	22 (100.0)	87 (96.7)	0.79ý
CRP >5 mg/L	31 (100.0)	37 (100.0)	22 (100.0)	90 (100.0)	1.0ý
Procalcitonine >0.1 ng/mL	31 (100.0)	37 (100.0)	22 (100.0)	90 (100.0)	1.0ý
Dead (n, %)	10 (32.3)	9 (24.3)	6 (27.3)	25 (27.8)	0.77Ý

Data were presented as median (min-max) or n (%). *Kruskal-Wallis test, bPearson's χ^2 test, cFisher's exact test. PTBD:percutaneous transhepatic biliary drainage; WBC: white blood cell; ALT: alanine aminotransferase: AST, aspartate aminotransferase, ALP: alkaline phosphatase; GGT: gamma-glutamyl transferase; NLR: neutrophil lymphocyte ratio.

microorganism in blood and bile cultures. When bacteremia and/or biliary drainage culture-positive episodes were analyzed, it was found that 71.3% were gram-negative and 28.7% were gram-positive. Escherichia coli was the most common species (n=48; 28.1%) followed by *Enterococcus faecium* (n=31; 18.1%), *Klebsiella pneumoniae* (n=27; 15.8%), *Pseudomonas aeruginosa* (n=17; 9.9%), *Acinetobacter baumannii* (n=10; 5.8%) and *Enterococcus feacalis* (n=8; 4.7%). 51 (41.8%) of the cultured gram-negative bacteria (included *E.coli* and *K. pneumoniae*) were extended spectrum beta-lactamases (ESBLs) positive and carbapenem resistance (excluded intrinsic resistant bacteria) was found in 27 (15.8%) isolates. There was no colistin-resistant non-fermenting bacteria (*Pseudomonas spp* and *Acinetobacter baumannii)*. 28 (70%) Enterococcus spp isolates out of 40 were ampicillin-resistant and only three isolates (7.5%) were vancomycin-resistant. Gram-positive bacteria were 100% susceptible to linezolid and daptomycin. In our study, no fungal growth or anaerobic culture growth was detected in any of the cultures. The microorganisms that were isolated from blood and/or biliary drainage cultures of the post-PTBD patients are shown in Table 2. A multivariate analysis was performed to evaluate the risk factors which were significantly as-

Table 2. Distribution and resistance profiles of microorganisms.

	Blood Cultures (n, %)	Bile Cultures (n, %)	Total (n=171) (n, %)
Escherichia coli	26 (54.2)	22 (45.8)	48 (28.1)
ESBLs (+)	16 (61.5)	14 (63.6)	
Carbapenem-resistant	4 (15.4)	2 (9.1)	
Klebsiella spp	11 (37.0)	19 (63.0)	30 (17.5)
ESBLs (+)	9 (32.1)	12 (70.6)	
Carbapenem-resistant	5 (45.5)	10 (58.8)	
Colistin-resistant	1 (9.1)	2 (11.8)	
Pseudomonas spp	5 (27.8)	13 (72.2)	18 (10.5)
Colistin-resistant	-	-	
Cephalosporin-resistant	4 (80.0)	7 (53.8)	
Acinetobacter baumannii	4 (40.0)	6 (60.0)	10 (5.8)
Carbapenem-resistant	4 (100.0)	4 (66.6)	
Colistin-resistant	-	-	
Stenotrophomonas maltophilia	1 (16.6)	5 (83.3)	6 (3.5)
Other gram-negative bacteria	2 (22.2)	7 (77.8)	9 (5.3)
Enterococcus spp	7 (17.5)	33 (82.5)	40 (23.4)
Ampicillin-resistant	7 (100.0)	21 (63.6)	
Vancomycin-resistant	1 (14.8)	2 (9.6)	
Staphylococcus spp	3 (42.8)	4 (57.1)	7 (4.1)
Methicillin-resistant	3 (100.0)	3 (75.0)	
Other gram-positive bacteria	1 (33.3)	2 (66.6)	3 (1.75)

ESBLs: extended spectrum beta-lactamases.

Table 3. Factors associated with mortality after percutaneous transhepatic biliary drainage*

	OR	95% CI	p-value
Carbapenem resistance	3.74	1.03-13.53	0.04
Elevated lipase level	8.49	1.48-48.62	0.02
Elevated neutrophil count	5.54	1.55-19.77	0.01

*Regression model: age, gender, kidney disease, Escherichia coli infection, Klebsiella pneumoniae infection, Pseudomonas aeruginosa infection, Acinetobacter baumannii infection, Enterococcus spp infection, bacteremia, neutrophil count, total bilirubin, lipase, carbapenem resistance, extended spectrum beta-lactamases positivity and amikacin resistance. OR, Odds ratio; CL, confidence interval.

sociated with after PTBD 30-day mortality in univariate analysis (Table 3). These factors were as follows; laboratory findings (neutrophil counts, lipase) and carbapenem resistance. Elevated neutrophil counts (odds ratio [OR], 5.54; 95% confidence interval [CI], 1.55 to 19.77), elevated lipase levels (OR, 8.49; 95% CI, 1.48 to 48.62), and carbapenem-resistant isolates (OR, 3.74; 95% CI, 1.03 to 13.53) were the independent risk factors for 30-day mortality after PTBD.

Discussion

The visualization and drainage of the biliary tract have been increasing and improving since the first practice in 1921 [11]. Although endoscopic intervention, which is the most common choice of treatment whenever biliary drainage is needed, have increased in recent years, PTBD is still frequently used in cases where endoscopic palliation cannot be achieved. The purpose of this study is to detect and compare bacteremia and/or bile drainage culture growths related to post-PTBD and to investigate antibiotic susceptibility and accompanying risk factors for mortality. We found that elevated ALT level was the only difference between our three groups; elevated neutrophil counts and lipase levels and carbapenem-resistant isolates were the independent risk factors for 30-day mortality after PTBD.

In previous studies, complication rates related to PTBD were reported to be between 3% and 42%, and procedural mortality rates were reported to be between 0% and 8% [12-16]. Because PTBD is an invasive technique, potential complications such as pain, bleeding (2%-3%), bile leakage, obstruction of the catheter, cholangitis, acute pancreatitis (2%-4%) and duodenal perforation may occur [17]. Cholangitis and PTBD-related bacteremia were observed between 1.2%-14.5% [15, 18-21] and 1.8%-6.3% [14, 22]

in studies, respectively. Since our study only included patients with bile culture-positive and/or bacteremia, it does not represent the rates among all complications. Elevated ALT level was the only difference between our three groups. Sub-group analysis showed that bacteremia patients had higher ALT serum levels. While patients with cholangitis are expected to have higher ALT levels by definition of the disease [9], it is surprising to see higher ALT levels in only bacteremia patients. It might be because relatively higher rates of bacteremia occurred after post-PTBD in patients with cholangitis [23]. Previous reports on post-PTBD Complications focused on general types of complications and mortality rates [17, 19, 20] so it is difficult to make direct comparisons with our study results.

The incidence of positive bacterial cultures after PTBD is similar to other studies reporting biliary tract infections and bacteremia; *Escherichia coli*, *Enterococcus spp*, and *Klebsiella spp* were the most common microorganisms isolated [13, 24-26]. The rate of ESBL positivity was over %60 in *E.coli* isolates in all cultures. Carbapenem resistance and ESBL positivity rates for *Klebsiella spp* reached 32.1% and 45.5%; 70.6% and 58.8% in blood and bile cultures, respectively. In previous studies, it was reported that the antibiotic resistance rates of gram-negative bacteria after PTBD procedure were lower than in our study [24, 25, 27]. The reason for not finding anaerobic microorganisms as the causative agent in our study is thought to be due to the retrospective design of our study, which may have resulted in the lack of necessary transport media and culture conditions for anaerobic culture production.

Approximately 95% of patients who did not have any microorganism reproduction in their blood culture prior to the procedure were administered ceftriaxone and metronidazole prophylactic antibiotic treatment in our center. However, the drug susceptibility results showed that only 31.8% of *E.coli* isolates and 16.7% of *Klebsiella spp* isolates were susceptible to ceftriaxone. It should be noted that traditional prophylactic antibiotics may not be sufficient to control infections due to high resistance rates, and the antibiotic prophylaxis used may need to be reviewed. Previous studies reported that gram-positive microorganisms had lower antibiotic resistance rates in contrast to gram-negative microorganisms [24, 25, 27]. Similarly, in our study all gram-positive isolates were susceptible to linezolid and daptomycin, and only 6.1% of gram-positive microorganisms were resistant to vancomycin.

In this study, Carbapenem-resistant isolates were found to be an independent risk factor for mortality after PTBD. Our finding is supported by previous studies evaluating carbapenem- resistance as a risk factor for mortality that found patients with CRE had significantly higher mortality rates [28, 29]. CRE isolates being resistant to nearly all antibiotics hence leaving more toxic or less effective treatment options available may explain the positive correlation between higher mortality rates and CRE isolates [30]. Our study found higher rates of 30-day mortality compared to other published studies [16, 31-34]. The 30-day all-cause mortality was 25 (27.8%). Higher mortality rates may be a reflection of our data being collected in a tertiary branch hospital where patients with severe underlying conditions are being transferred.

Elevated lipase levels were also an independent risk factor for post-PTBD mortality in our study. High lipase levels observed in our patients may be associated with acute pancreatitis. Acute pancreatitis is a life-threatening and uncommon complication post-PTBD and has a reported prevalence of 4%-6% [17]. In patients with organ failure or infected necrosis, the mortality rate of acute pancreatitis can reach up to 30% [35]. However, the fact that the findings of abdominal pain are not specific to this patient group and imaging methods, one of the diagnostic criteria of acute pancreatitis [36], were not examined in this study, make it difficult for us to use precise statements. In clinical practice, WBC count is widely used as an indicator of non-specific systemic inflammation and numerous studies have shown a positive correlation between higher WBC count and deaths from all-cause [37-39]. Similarly, in the multivariate analysis we conducted, increased WBC count was found to be associated with mortality. In conclusion, it should be kept in mind that patients with high WBC count should be evaluated more carefully, even if WBC count elevation is a non-specific inflammation response.

This study was conducted at a tertiary referral center and a training and research hospital, therefore, the results might not be generalized. Our study has several drawbacks. We might start by considering our study's retrospective design. Secondly, this study includes a relatively small number of cases. Last limitation is the usage of a single center's patient data, which increases the possibility of selection bias. Main advantages of this study include selecting definite groups to evaluate the differences and risk factors for affecting mortality as well as showing blood and bile culture results together with antibiotic susceptibility.

Conclusion

As a result, we compared three patient groups after PTBD, and we could not find any difference other than higher ALT levels in bacteremic patients.The independent risk factors for 30-day mortality following PTBD were elevated neutrophil counts, lipase levels, and carbapenem-resistant isolates. In addition, culture results showed higher rates of antibiotic resistance in gram-negative bacteria and higher rates of Enterococcus spp infections. Keeping in mind the high mortality rate of the infections that are caused by these microorganisms, it is a good idea to use caution when selecting empirical antibiotics.

Ethical approval

This study was conducted with the approval of the Ethics Committee (University of Health Sciences Ankara High Specialization Training and Research Hospital, approval number: 25.10.2018-58/29620911-929).

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