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# Risk factors for bacteremia following endoscopic retrograde cholangiopancreatography

## Endoscopic retrograde cholangiopancreatography sonrası gelişen bakteriyemide eşlik eden risk faktörleri

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**Abstract**

Aim: Bacteremia after endoscopic retrograde cholangiopancreatography (ERCP) is a serious complication, but its risk factors have not yet been clearly defined. In this study, we aimed to determine the incidence of bacteremia and associated risk factors after ERCP.

Methods: This retrospective-cohort study was conducted between January 2017 and December 2018. Patients who had no signs of infection before the procedure and who developed bacteremia after the procedure were included in the study. For each patient who developed bacteremia, two randomized control patients who underwent ERCP and did not develop bacteremia were selected to compare risk factors, clinical and laboratory findings.

Results: A total of 91 bacteremia attacks were detected in 86 of the 4237 patients who underwent ERCP procedure. Bacteremia rate after ERCP was 2%. In multivariate analysis, the age of the patient, presence of biliary tract cancer, cholecystitis / cholangitis, pancreatitis and biopsy were determined as significant risk factors for post-ERCP bacteremia ($P$=0.009, $P$<0.001, $P$=0.008, $P$=0.002 and $P$=0.014 respectively).

Conclusion: The development of bacteremia after ERCP significantly increases the risk of mortality. The mean age of the patients who died was older. This result supports the use of prophylactic antibiotics especially in elderly patients. We think that knowledge of potential ERCP complications and risk factors may help reduce the incidence and severity of complications.

**Keywords:** Endoscopic retrograde cholangiopancreatography, Bacteremia, Risk factors

**Öz**

Amaç: Endoskopik retrograd kolanjiyopankreatografi (ERCP) sonrası bakteriyemi ciddi bir komplikasyondur, ancak bu komplikasyon için risk faktörleri henüz net olarak tanımlanmamıştır. Bu çalışmada ERCP sonrası bakteriyemi ve ilişkili risk faktörlerinin insidansını belirlemeyi amaçladık.

Yöntemler: Bu retrospektif-kohort çalışma Ocak 2017-Aralık 2018 tarihleri arasında yapıldı. İşlem öncesi enfeksiyon belirtisi olmayan ve işlem sonrası bakteriyemi gelişen hastalar çalışmaya alındı. Bakteriyemi gelişen her hasta için ERCP uygulanan ve bakteriyemi geliştirmeyen iki randomize kontrol hastası risk faktörlerini, klinik ve laboratuvar bulgularını karşılaştırmak için seçildi.

Bulgular: ERCP prosedürü uygulanan 4237 hastanın 86'sında toplam 91 bakteriyemi atağı tespit edildi. ERCP sonrası bakteriyemi oranı % 2 olarak bulundu. Çok değişkenli analizde, hastanın yaşı, safra yolları kanseri, kolesistit / kolanjit, pankreatit ve biyopsi bakteriyemi için anlamlı risk faktörleri olarak bulundu (sırasıyla $P$=0,009, $P$<0,001, $P$=0,008, $P$=0,002 ve $P$=0,014) .

Sonuç: ERCP sonrası bakteriyemi gelişimi mortalite riskini önemli ölçüde artırmaktadır. Çalışmamızda, kaybedilen hastaların yaş ortalaması daha büyüktü. Bu sonuç, özellikle yaşlı hastalarda profilaktik antibiyotik kullanımını destekler niteliktedir. Potansiyel ERCP komplikasyonları ve risk faktörleri hakkındaki bilgi sahibi olmanın, komplikasyon insidansını ve şiddetini azaltmaya yardımcı olabileceğini düşünüyoruz.

**Anahtar kelimeler:** Endoscopic retrograde cholangiopancreatography, Bakteriyemi, Risk faktörleri

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## Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) is a complex interventional procedure that is frequently used for diagnosis and treatment of pancreatic-biliary diseases [1-2]. Although the scope of its use increases daily due to advances in technology, ERCP remains an invasive procedure with potential complications including infection, bleeding, pancreatitis, and perforation [3]. Approximately 500,000 ERCP procedures are performed annually in the United States, with an ERCP-related complication rate of 4% to 10.3% and a mortality rate between 0.05% and 1% [4]. The most serious complication following ERCP is bloodstream infections (BSI). Although the actual incidence of BSI after ERCP is unknown, researchers have reported the incidence of bacteremia in different populations as ranging between 2.2% and 21% [4-6]. Enteric bacteria enter the biliary tree hematogenously or after endoscopic or radiological manipulation [7]. It has been reported that septic complications after ERCP are more common in patients with obstructed biliary ducts and inadequate drainage during the procedure [4,8]. ERCP bacteremia is reportedly more common during combined use of percutaneous and endoscopic procedures, placement of stent for malignant stenosis, presence of jaundice, in case of incomplete or unsuccessful biliary drainage or when the procedure is performed by less experienced doctors [7-9]. Sepsis is the most common cause of death associated with ERCP [8]. Risk factors need to be well known to improve the reliability of the ERCP procedure [10].

Few data are available on the rates of post-ERCP bacteremia. In this study, we aimed to determine the frequency of bacteremia after ERCP and associated risk factors in a tertiary branch hospital.

## Materials and methods

This study was conducted between January 2017 and December 2018 in a tertiary branch hospital where ERCP was performed intensively. A total of 4237 ERCP procedures performed during this period were evaluated. Patients who did not have any pre-procedural sepsis-related symptoms and signs or any microorganism reproduction in their blood culture were included in the study. Patients did not receive routine empirical antibiotic treatment before ERCP. 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 blood stream infection by the National Health Safety Network (CDC-NHSN) [11]. Patients with a fever of > 38.0 ºC, tremors in the first 30 days after ERCP procedure and positive blood cultures were included in the study. Patients with a proven infection at another site after ERCP were excluded. Age, ERCP indication, isolated microorganisms, and risk factors for bacteremia were recorded. For the identification of microorganisms, Phoenix 100 (Becton Dickinson, USA) automated system was used.

The distribution of microorganisms in patients who developed bacteremia after ERCP was evaluated. The characteristics of patients who developed and died of bacteremia after ERCP were compared with those of patients who lived.

For each patient who developed bacteremia, two randomized patients who underwent ERCP with no post-procedural bacteremia were selected as controls. A total of 172 patients were included in the control group. Patients with and without bacteremia after ERCP were compared in terms of risk factors, clinical and laboratory findings, and mortality rates.

**Statistical analysis**

Differences were assessed using a Pearson $\chi^2$ test or Fisher's exact test (when expected cell frequencies were <5) in categorical variables and independent t-test in non-categorical variables. SPSS version 20.0 was used for all statistical analyses. *P*-value of <0.05 was considered statistically significant.

## Results

A total of 4237 ERCP procedures were performed in our hospital between January 2017 and December 2018 under elective conditions, during which 91 bacteremia attacks in 86 patients were detected after the procedure. The rate of bacteremia after ERCP was 2%. Among 86 patients who developed post-ERCP bacteremia, 31 were female (36%) and 55 were male (64%). The patients' ages ranged from 20 to 95 years with a mean age of 65.36 (16.2) years. The median time for development of bacteremia after ERCP was 6 days. When bacteremia episodes were analyzed, it was found that 79% were gram-negative and 21% were gram-positive bacteremia. The most frequently isolated agent was Escherichia coli (32 isolates, 35%), followed by Klebsiella pneumonia (19%) with 18 isolates and Pseudomonas aeruginosa (18%) with 17 isolates (Table 1).

The most common risk factors in patients who developed bacteremia after ERCP were history of prior ERCP (52%), presence of a biliary stone (51%), stent (48%), cholecystitis / cholangitis (37%) and diabetes (31%). The distribution of microorganisms in patients with bacteremia after ERCP, according to the most common risk factors, is shown in Table 2.

Table 1: Distribution of the microorganisms in patients who developed bacteremia after ERCP

| Microorganisms | No (%) of microorganisms |
|---|---|
| Gram positive microorganisms | |
| Enterococcus spp | 8/91 (8.79%) |
| Staphylococcus spp | 8/91 (8.79%) |
| Streptococcus spp | 3/91 (3.30%) |
| Gram negative microorganisms | |
| Escherichia coli | 32/91 (35.16%) |
| Klebsiella pneumonia | 18/91 (19.78%) |
| Pseudomonas aeruginosa | 17/91 (18.68%) |
| Acinetobacter baumannii | 2/91 (2.20%) |
| Stenotrophomonas maltophilia | 2/91 (2.20%) |
| Proteus spp | 1/91 (1.10%) |

Table 2: The most common microorganisms according to risk factors in patients with bacteremia after ERCP

| Microorganism | Risk Factors | | | | | | Exitus (n:20) |
|---|---|---|---|---|---|---|---|
| | Malign biliary stricture (n:33) | DM (n:27) | Stent (n:42) | Prior ERCP (n:45) | Biliary stone (n:44) | Cholecystitis / cholangitis (n:32 ) | |
| E. coli | 10 (30%) | 14 (52%) | 15 (36%) | 18 (40%) | 15 (34%) | 12 (37.5%) | 2 (10%) |
| Klebsiella spp. | 8 (24%) | 4 (15%) | 11 (26%) | 11 (24%) | 8 (18%) | 7 (21.9%) | 4 (20%) |
| Pseudomonas spp. | 9 (27%) | 2 (7%) | 12 (29%) | 12 (27%) | 8 (18%) | 6 (18.8%) | 4 (20%) |
| Enterococcus spp. | 6 (18%) | - | 2 (5%) | 2 (4%) | 3 (7%) | 2 (6.2%) | 2 (10%) |
| Staphylococcus spp. | 1 (3%) | | 2 (5%) | 2 (4%) | 6 (14%) | 4 (12.5%) | 2 (10%) |

The mean age of patients with post-procedural bacteremia was higher than those without (*P*=0.007). There was no difference in terms of gender between those with and without bacteremia. The risk of bacteremia was 5.7 fold higher in the presence of biliary tract cancer (*P*<0.001), (OR: 5.7, 95% CI: 2.925-11.017), 2.1 fold higher in the presence of cholecystitis / cholangitis (*P*=0.01) (OR: 2.09, 95% CI: 1.186 -3.682) and 3.5 fold higher in patients with cirrhosis, which was not statistically

significant ($P$=0.122) (OR: 3.5, 95% CI: 0.811-14.908). Bacteremia risk significantly increased in patients with pancreatitis ($P$=0.003). The risk of bacteremia was 2.9 times higher in patients who underwent diagnostic biopsy of intrahepatic or extrahepatic biliary tracts during ERCP, which was significant ($P$=0.03). In those with bacteremia, mortality risk was 25.8 times higher ($P$<0.001) (OR: 25.8, 95% CI: 5.857-113.274), CRP elevation was 49 fold (OR: 49.1, 95% CI: 6.677-361.460), WBC elevation (leukocytosis), 8.7 fold (OR: 8.7, 95% CI: 4.207-18.067), bilirubin elevation, 8.7 fold (OR: 8.7, 95% CI: 4.723-16.093) and ALP elevation, 4.2 fold (OR: 4.2, 95% CI: 2.277-7.763) ($P$<0.001 for all) (Table 3).

Multivariate analysis showed that the age of patients, presence of biliary tract cancer, cholecystitis / cholangitis, pancreatitis and biopsy were significant risk factors for the development of bacteremia ($P$=0.009, $P$<0.001, $P$=0.008, $P$=0.002 and $P$=0.014, respectively).

Among 86 patients who developed bacteremia after ERCP, all-cause 30-day mortality rate was 23% (n: 20). Of the 20 patients who died within 30 days, 11 had malignant biliary stenosis (55%). Klebsiella, Pseudomonas (each in 4 patients, 20%) and E. coli (in 2 patients, 10%) were the most common causative agents.

In terms of gender, no difference was found between patients who lived and those who died within 30 days (p> 0.05). The mean age of non-survivors (71.9 (12.2) years) was higher than survivors (63.3 (16.8) years) ($P$=0.039). In patients who died, the incidences of biliary tract cancer was 2.4 times higher, diabetes mellitus, 1.6 times higher, and biopsy, 1.8 times higher than those who lived; however, no statistically significant difference was found between non-survivors and survivors in terms of risk factors or laboratory findings (Table 4).

Table 3: Comparison of baseline characteristics, laboratory findings, risk factors and mortality

| Characteristic | Patients with bacteremia (n:172) % | Patients without bacteremia (n:86) % | *P*-value |
|---|---|---|---|
| Age, mean | 59.05 | 65.36 | 0.007 |
| Male sex | 55.2 | 64 | 0.181 |
| Biliary tract cancer | 9.9 | 38.4 | <0.001 |
| Diabetes mellitus | 24.4 | 31.4 | 0.233 |
| Common bile duct stone | 56.4 | 51.2 | 0.426 |
| Cholecystitis/cholangitis | 22.1 | 37.2 | 0.010 |
| Pancreatitis | 8.1 | 24.4 | 0.003 |
| Liver cirrhosis | 1.7 | 5.8 | 0.122 |
| Presence of stent | 52.3 | 48.8 | 0.597 |
| ERCP before processing | 55.2 | 52.3 | 0.659 |
| Biopsy | 5.2 | 14 | 0.030 |
| Exitus | 1.2 | 23.3 | <0.001 |
| Laboratory findings | | | |
| Increased white blood cell (N: 3.9-11.7 x103/µL) | 7.0 | 39.5 | <0.001 |
| Increased C-reactive protein (N: <5 mg/L) | 63.4 | 98.8 | <0.001 |
| Increased total bilirubin (N: 0.3-1.2 mg/dl) | 30.2 | 79.1 | <0.001 |
| Increased alkaline phosphatase (N: 30-120 U/L) | 51.2 | 81.4 | <0.001 |
| Increased amylase (N: 28-100 U/L) | 28.5 | 10.5 | 0.002 |
| Mean white blood cell | 7.3 | 10.8 | <0.001 |
| Mean C-reactive protein | 24 | 141 | <0.001 |
| Mean total bilirubin | 2.03 | 6.02 | <0.001 |
| Mean alkaline phosphatase | 194 | 306 | 0.006 |
| Mean amylase | 103 | 70 | 0.074 |

Table 4: Comparison of the baseline characteristics, laboratory findings, risk factors for bacteremia between living and deceased patients

| Characteristic | Living patients (n:66) % | Deceased patients (n:20) % | *P*-value |
|---|---|---|---|
| Age, mean | 63.38 | 71.90 | 0.039 |
| Male sex | 68.2 | 50.0 | 0.223 |
| Biliary tract cancer | 33.3 | 55.0 | 0.138 |
| Diabetes mellitus | 28.8 | 40.0 | 0.502 |
| Common bile duct stone | 54.5 | 40.0 | 0.376 |
| Cholecystitis/cholangitis | 36.4 | 40.0 | 0.976 |
| Pancreatitis | 10.6 | 0 | 0.193 |
| Liver cirrhosis | 6.1 | 5.0 | 1.000 |
| Presence of stent | 51.5 | 40.0 | 0.518 |
| ERCP before processing | 57.6 | 35.0 | 0.130 |
| Biopsy | 12.1 | 20.0 | 0.462 |
| Laboratory findings | | | |
| Increased white blood cell (N: 3.9-11.7 x103/µL) | 39.4 | 40.0 | 1.000 |
| Increased C-reactive protein (N: <5 mg/L) | 98.5 | 100 | 1.000 |
| Increased total bilirubin (N: 0.3-1.2 mg/dl) | 80.3 | 75.0 | 0.844 |
| Increased alkaline phosphatase (N: 30-120 U/L) | 81.8 | 80.0 | 1.000 |
| Increased amylase (N: 28-100 U/L) | 10.6 | 10.0 | 1.000 |
| Mean white blood cell | 10.6 | 11.2 | 0.609 |
| C-reactive protein mean | 137.9 | 150.6 | 0.586 |
| Mean total bilirubin | 6.2 | 5.4 | 0.647 |
| Mean alkaline phosphatase | 280.8 | 389.3 | 0.370 |
| Mean amylase | 2.1 | 61.4 | 0.742 |

## Discussion

Although ERCP is a semi-critical procedure, various instruments such as wire, stent, and balloon are pushed along a long duodenoscope through an elevator mechanism to enter a sterile ductal environment [12]. The colonization and incomplete sterilization of the complex mechanism at the end of this duodenoscope used in the procedure has been held responsible for the transmission of infections [12]. In recent years, multidrug resistant microorganisms and carbapenem-resistant Enterobacteriaceae (CRE) have been reported to cause duodenoscope-related infections [12]. In our study, we found carbapenem resistance in 61.1% (11/18) of Klebsiella spp. isolates. Four of these 11 patients died. Three of the 32 E. coli isolates were also resistant to carbapenem (9.4%).

Our incidence of bacteremia after ERCP was 2%, which was similarly reported as 3.1% in the study of Kwak et al. [3], 2.24% in that of Anderson et al. [5] and 3.56% in that of Du et al. [6]. Worldwide, ERCP mortality ranges from 0 to 1.5% and can be caused by any complication. Mortality rate is generally high in therapeutic procedures [13]. In the study performed by Borges et al. [13], infection rate after ERCP was reported as 3%, bacteremia rate as 0.5% and mortality rate as 1.5%. In a 10-year retrospective study by Coelho-Prabhu et al. [4], post-ERCP infection and 30-day mortality rates were 1.5% and 2.4%, respectively. Although the reported frequency of clinically significant iatrogenic infections after ERCP is limited (1-3%), sepsis represents a common cause of death [14]. In our study, 30-day mortality rate was 23% in patients who developed bacteremia after ERCP. In a study by Novello et al. [15] including 2010 patients who underwent ERCP, septic complications were reported in 51 patients (2.5%), and 16 patients (31%) with tumor obstruction died within 30 days after ERCP.

The microorganisms responsible for infection after ERCP are Enterobacteriaceae (especially Escherichia coli and Klebsiella spp), alpha hemolytic streptococci, Pseudomonas aeruginosa, Enterococcus spp and Staphylococcus epidermidis

[8]. In our study, analysis of the bacteremia episodes after ERCP revealed that 79% were gram negative and 21% were gram positive bacteremia. The most isolated microorganisms were E. coli (35.16%), Klebsiella pneumonia (19.78%) and Pseudomonas aeruginosa (18.68%). In the study of Kwak et al. [3], the most common microorganisms in bacteremia episodes after ERCP were listed as E. coli, Klebsiella and Pseudomonas, akin to our study. Novello et al. [15] reported that P. aeruginosa was the most common causative agent, with a rate of 30%. Blockage of the bile duct system due to strictures, stones and tumors has been shown to be associated with bacteriobilia. Increasing the intrabiliary pressure (>25 mmHg) results in biliovenous reflux and bacteremia in patients with infected bile [16]. Specific risk factors for post-procedural infection include stenting in malignancy, presence of obstructed ducts and jaundice, combined percutaneous endoscopic procedures, primary sclerosing cholangitis, and incomplete or unsuccessful biliary drainage [14]. In our study, malignant biliary stenosis, pre-existing stents, recurrent ERCP procedures, and presence of stones in the biliary system were the most common risk factors in patients with post-ERCP bacteremia. Contaminated duodenoscopes, biliary stent placement, diagnosis of cholangiocarcinoma and active inpatient status were reported as risk factors for transmission of CRE infection in a single-center case series of 115 patients with ERCP-associated CRE bacteremia [12]. In patients with cholangiocarcinoma, there is a risk of sepsis, especially when intrahepatic biliary tract cannot be drained, in which case administration of intrahepatic contrast agent should be avoided [8-9]. It has been reported that the best predictor for development of infectious complications after ERCP is the confirmation that biliary tract obstruction is not fully resolved, and prophylactic antibiotic treatment reduces the risk of bacteremia after ERCP but does not affect overall mortality [17]. Dutta et al. [18] reported that sepsis may develop in the presence of abnormal biliary and pancreatic ducts after ERCP and appropriate antibiotic treatment should be initiated after the procedure.

Routine prophylactic antibiotics were not administered before ERCP in our center. In meta-analyses, the benefit of routine prophylactic antibiotic use before ERCP was not shown [9]. A retrospective review of 11,484 ERCPs over a 11-year period in a single institution assessed the role of antibiotics in cholangitis prevention, and showed that although the rate of routine prophylactic antibiotic use decreased from 95% to 25% over the years, the reduction of infection rate was limited (0.48% to 0.25%). In the multivariate analysis of the study, the risk of infection was found to be high only in transplant recipients who underwent biliary intervention [9]. The American Society for Gastrointestinal Endoscopy (ASGE) also does not recommend antibiotic prophylaxis in patients with biliary obstruction in which complete biliary drainage was provided by ERCP [8]. However, Thosani et al. [19] recommend the use of prophylactic antibiotics before the procedure, especially in elderly patients, patients who had been previously stented and those who underwent intraductal stone lithotripsy.

In our study, the presence of presence of biliary tract cancer, cholecystitis / cholangitis and pancreatitis, as well as biliary biopsy obtained during the procedure were found to be associated with the development of post-ERCP bacteremia. In a prospective study, Mollison et al. [20] reported that patients with biliary obstruction and those who underwent therapeutic endoscopic procedures were at the highest risk for bacteremia. In their study including 55 patients who developed sepsis after ERCP, Deviere et al. [21] reported that the incidence of septicemia was more prominent in malignant obstruction than in benign obstruction (% 21 versus % 3; $P<0.01$) mainly due to drainage problems associated with tumor infiltration. They also stated that the previous diagnostic ERCP procedure without drainage was associated with the development of septicemia after therapeutic ERCP. In our study, WBC, CRP, bilirubin, and alkaline phosphatase levels were significantly higher in patients who developed post-ERCP bacteremia. In their study, Kwak et al. [3] reported that alkaline phosphatase level was high in post-ERCP bacteremia. Motte et al. [22] did not detect any statistically significant difference between WBC, bilirubin, and alkaline phosphatase levels in patients with sepsis after endoscopic biliary stent implantation. In a study in which Rupp et al. [23] investigated risk factors associated with biliary infection, they found that serum CRP levels were increased in patients with bactobilia.

**Limitations**

The principal limitation of our study is its retrospective nature. In addition, the synergistic effects of multiple risk factors which may have led to post-ERCP complications were not analyzed. The third limitation was the usage of a single center's patient data, which increased the possibility of selection bias.

**Conclusions**

The development of bacteremia after ERCP significantly increases the risk of mortality. The mean age of the patients who died was older. This result supports the use of prophylactic antibiotics, especially in elderly patients. We think that knowledge of potential ERCP complications and risk factors may help reduce the incidence and severity of complications.

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