Frequency of Bacteremia and the Preventive Effect of Prophylactic Antibiotics in Direct Peroral Cholangioscopy During Endoscopic Retrograde Cholangiopancreatography: A Real-life Retrospective Analysis

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ABSTRACT **Background:** Prophylactic intravenous antibiotics are not routinely administered prior to direct peroral cholangiopancreatoscopy. The frequency of post-procedure bacteremia has not been well studied.

Objectives: To evaluate the risk of bacteremia following endoscopic retrograde cholangiopancreatography (ERCP) with cholangiopancreatoscopy. To assess the prevalence of other infectious complications and the effect of real-life practices regarding prophylactic antibiotic administration.

Methods: We conducted a retrospective analysis on consecutive patients (2016–2022) who underwent cholangiopancreatoscopy using the single-operator SpyGlass System (Boston Scientific Corporation, USA). Prophylactic antibiotic treatment was administered based on clinical discretion. Demographic and clinical data, including procedure indication, procedure reports, blood culture results, pre- and post-procedure antibiotic treatment, hospital length, mortality, and infectious and non-infectious complications, were collected.

Results: Our single-center cohort included 75 patients who underwent ERCP with direct cholangiopancreatoscopy. We involved 63 patients in the analysis. In 17/63 patients (27%), post-procedural blood cultures were drawn based on clinical suspicion of infection. Positive cultures were found in 4/17 (23.5%) of all cultures and 4/63 (6.3%) of the entire cohort; 2/63 (3.2%) had clinically significant bacteremia. Antibiotic prophylaxis was administered to 35 patients (55.6%), with no evidence of significant reduction in bacteremia, cholangitis, hospitalization length, or mortality rates when compared to patients who did not receive prophylactic antibiotics ($P > 0.05$). Post-procedural cholangitis was observed in 5/63 patients (7.9%). There were no cases of acute cholecystitis or liver abscess.

Conclusions: The prevalence of bacteremia and cholangitis following ERCP with direct cholangiopancreatoscopy was 6.3% and 7.9%, respectively. Prophylactic antibiotics did not reduce post-procedural infectious adverse events.

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KEY WORDS: antibiotic prophylaxis, bacteremia, endoscopic retrograde cholangiopancreatography (ERCP), cholangiopancreatoscopy, SpyGlass

Endoscopic retrograde cholangiopancreatography (ERCP) is a method to evaluate and treat biliary and pancreatic diseases. In certain situations, cholangiopancreatoscopy during ERCP is used to directly visualize the bile ducts and is necessary to manage choledocholithiasis or to visualize and sample target lesions, such as suspected biliary strictures [1,2]. Recent reports have described successful treatment of intrahepatic cholangiolithiasis using a disposable ultrafine peroral cholangioscope [3]. This scope is effective for diagnostic and hemostatic applications of various forms of biliopathy [4,5]. In addition, endoscopic retrograde direct cholangioscopy has been proposed as a safe and effective cannulation technique in patients with diverticular papillae [6]. Thus, cholangiopancreatoscopy is a useful tool in navigating the intrahepatic bile ducts and extracting stones.

The cholangiopancreatoscopy SpyGlass direct visualization system (microvasive endoscopy; Boston Scientific Corporation, Natick, MA, USA) was the first direct peroral cholangiopancreatoscopy system. It was introduced in 2007 [1,7,8], and was used mainly in tertiary endoscopy centers. During the procedure, a normal saline solution is used to irrigate the bile ducts to obtain adequate visualization. Interventional instruments can be used, such as electrohydraulic lithotripsy (EHL), to treat difficult stones or biopsy forceps for histological evaluation. Serious post-procedural complications such as infectious adverse events, which can occur after ERCP, cholangiopancreatoscopy, and instrumentation, may further increase the risk of procedure-related cholangitis and bacteremia.

The rate of bacteremia following ERCP ranges from 6.4% to 26.5% [9-12]. However, cholangitis and sepsis related to the procedure can develop in 0.5% to 3% [12]. According to the American Society for Gastrointestinal

Endoscopy (ASGE) guidelines from 2015, antibiotic prophylaxis prior to endoscopic procedures during ERCP is recommended for patients with bile duct obstruction when incomplete drainage is anticipated; however, there are no specific recommendations for cholangioscopy [13]. The incidence of direct peroral cholangiopancreatoscopy related bacteremia and infectious clinical events has been evaluated in two prospective studies, reporting incidences of 8.8% and 13.9% for bacteremia, with 7% for cholangitis and 6.9% for fever and chills [14,15]. Later, the European Society of Gastrointestinal Endoscopy (ESGE) published guidelines on ERCP-related adverse events, which included a weak recommendation for antibiotic prophylaxis when performing cholangioscopy, based on moderate-quality evidence [16].

The primary objective of this study was to retrospectively assess the frequency of bacteremia following ERCP performed with direct peroral cholangiopancreatoscopy. Secondary objectives included evaluating additional infectious complications and determining the impact of real-life prophylactic antibiotic practices on these outcomes.

Table 1. Patients and procedure characteristics (N=63)

Variable	Value
Mean age, years ± SD	61.1 ± 16.3
Male, n (%)	25 (39.7)
Mean ASA score ± SD	2 ± 0.7
PSC, n (%)	5 (7.9)
OLT, n (%)	4 (6.3)
Indication, n (%)	
Pancreatic disease	9 (14.3)
Indeterminate biliary stricture	27 (42.9)
Difficult biliary stone	24 (38.1)
Stent removing	3 (4.8)
Guidewire placement	1 (1.6)
Mean number of stones ± SD	1.5 ± 0.8
Mean stones size, mm ± SD	14.1 ± 6.2
Previous ERCP, n (%) Mean number (±SD)	55 (87.3)
Previous papillotomy, n (%)	55 (87.3)
Prior stent, n (%)	22 (34.9)
The SpyGlass procedure, n (%)	22 (100)
Prior stent removing*	22 (100)
Papillotomy	8 (12.7)
EPBD	11 (17.5)
EHL**	10 (35.7)
Yag laser**	14 (50)
SpyBite biopsy***	22 (34.9)
Permanent stent insertion	40 (63.5)
Mean total procedure time, minutes ± SD	75 ± 35.6
Antibiotic prophylaxis, n (%)	35 (55.6)

EHL = electrohydraulic lithotripsy, EPBD = endoscopic papillary balloon dilation, ERCP endoscopic retrograde cholangiopancreatography, OLT = orthotopic liver transplantation, PSC primary sclerosing cholangitis, SD = standard deviation

*Patients with prior stent (n=22)
**Patients with stones (n=28)
***Patients with strictures (biliary and pancreatic, n=29)

PATIENTS AND METHODS

A total of 75 ERCPs with direct peroral cholangiopancreatoscopy were performed between August 2016 and April 2022 at our referral center. All procedures were conducted by members of our experienced advanced endoscopy team. Direct cholangioscopic examinations were performed using the SpyGlass system (Microvasive Endoscopy; Boston Scientific Corporation, Natick, MA, USA), which has a 10F outer diameter and contains four channels (two irrigation ports, one working channel, and one fiberoptic channel). The ultra-slim scope was inserted through a therapeutic duodenoscope during ERCP. Laser lithotripsy (2016–2018) or EHL (after 2018) was used to treat difficult stones. Biopsy samples of the common bile duct (CBD) were obtained using the SpyBite biopsy forceps (Boston Scientific). Prophylactic preprocedural or intraprocedural intravenous antibiotics were not routinely administered prior to ERCP with SpyGlass. The decision to administer prophylaxis was made based on clinical discretion by the ward physician or the endoscopist, for example, in cases of primary sclerosing cholangitis (PSC) or orthotopic liver transplantation (OLT). Blood cultures were drawn based on clinical indications (e.g., fever, chills, cholangitis). Post-procedural bacteremia was defined as a positive blood culture within one week from the ERCP procedure.

Demographic and clinical data, including indication, procedure details, blood culture results, pre- and post-procedure antibiotic treatments, hospital length of stay, mortality, and infectious and non-infectious complications, were collected and documented manually from patient records. Exclusion criteria were: patients with a fever > 38.0°C at admission, patients with cholangitis or cholecystitis at admission, positive bacterial blood culture prior to ERCP; and missing critical data.

Table 2. Primary and secondary outcomes

Variable	Value
Indication for post procedure blood cultures, n (%)	17 (27)
Bacteremia, all cohort, n (%)	4 (6.3)
Bacteremia, patients with blood cultures, n (%)	4 (23.5)
Escherichia coli	1
Enterococcus faecalis	1
Staphylococcus haemolyticus	1
Bacillus species	1
Clinically significant bacteremia, all cohort, n (%)	2 (3.2)
Infectious adverse events, n (%)	
Cholangitis	5 (7.9)
Cholecystitis	0
Liver abscess	0
Non-infectious adverse events, n (%)	
Pancreatitis	7 (11.1)
Abdominal pain	3 (4.8)
Perforation	1 (1.9)
Mean hospital length, all cohort, days ± SD	2.1 ± 2.6
Mean hospital length, days ± SD*	5.5 ± 6.3
Mortality, n (%)	1 (1.9)

*For patients with bacteremia/adverse events
SD = standard deviation

Table 3. Primary and secondary outcomes by antibiotics prophylaxis status

	Antibiotics prophylaxis		
	Yes (35)	No (28)	*P*-value
Bacteremia all cohort, n (%)	2 (5.7)	2 (7.1)	1.000
Bacteremia, patients with BC, n (%)	2 (25)	2 (22)	1.000
Cholangitis, n (%)	1 (2.9)	4 (14.3)	0.16
Mean hospital length, days ± SD*	5.1 ± 4.5	5.9 ± 2.9	0.71
Mortality, n (%)	1 (2.9)	0	1.000

BC =blood cultures, SD = standard deviation
*For patients with bacteremia/ adverse events

STATISTICAL ANALYSIS

Continuous parameters were described as mean ± standard deviation (SD) and categorical as number (percentage). To test differences in continuous variables between the two groups, independent samples Student's *t*-test (for normally distributed variables) or the Mann-Whitney U test (if non-parametric tests were required) were performed. To test the differences in categorical variables the Pearson chi-squared test was performed and Fischer's exact test when appropriate.

Statistical analyses were performed using IBM Statistical Package for the Social Sciences statistics software, version 20 (SPSS, IBM Corp, Armonk, NY, USA). A *P*-value < 0.05 was considered statistically significant for all analyses. This study was approved by the hospital's local ethics committee (local reference number TLV-0321-20).

RESULTS

Over a 6-year period (2016–2022), we identified 75 ERCP procedures indicated for direct peroral cholangiopancreatoscopy. After excluding 12 patients who were admitted with evidence of bacteremia and/or biliary infection prior to endoscopic intervention, a total of 63 patients were included in the analysis. In 17 of these 63 patients (27%), post-procedural blood cultures were drawn based on clinical suspicion of infection.

Demographic and procedure-related data are summarized in Table 1. The mean age at ERCP was 61.1 ± 16.3 years, with 39.7% male. The majority of the procedures (54, 85.7%) were cholangioscopies, while 9 (14.3%) were pancreatoscopies. The main clinical indications included indeterminate CBD strictures (27, 42.9%), complicated CBD stones (24, 38.1%), pancreatic disease (9, 14.3%), stent removal (3, 4.8%), and guidewire placement (1, 1.6%). Previous ERCP was performed in 55 patients (87.3%), and 22 patients (34.9%) had a prior stent, which was removed during the SpyGlass procedure. The mean total procedure time was 75 ± 35.6 minutes. Antibiotic prophylaxis was administered to 35 patients (55.6%).

Positive blood cultures were identified in 4 of 17 cultures (23.5%) and in 4 of 63 patients (6.3%) during the 7 days following the direct peroral cholangiopancreatoscopy procedure. Of these, two patients (3.2%) had clinically significant bacteremia [Table 2]. Two blood cultures grew *Staphylococcus haemolyticus* and *Bacillus* species, which were considered contaminants. The remaining two patients (3.2%) had positive cultures with *Escherichia coli* and *Enterococcus faecalis*, requiring intravenous antibiotic treatment.

The incidence of cholangitis was 7.9%. Five patients developed cholangitis during hospitalization; two (40%) had concurrent bacteremia. There were no cases of post-procedure cholecystitis or liver abscess.

Seven patients (11%) developed post-procedure pancreatitis. One patient (1.9%) experienced a contained duodenal perforation during pancreatic duct stone treat-

Table 4. Summary of cofactors by cholangitis.

	Post SpyGlass cholangitis		
	No (58)	Yes (5)	*P*-value
Mean age, years ± SD	60.8 ± 16.4	63.4 ± 16.5	0.63
Male, n (%)	23 (39.7)	2 (40)	1.000
Mean ASA score ± SD	2 ± 0.6	2 ± 0.7	0.93
PSC, n (%)	5 (8.6)	0	1.000
OLT, n (%)	4 (6.9)	0	1.000
Stricture, n (%)	24 (49)	3 (60)	1.000
Mean number of stones ±SD	1.5 ± 0.8	1 ± 0	0.51
Mean stones size, mm ± SD	13.8 ± 6.3	16.5 ± 4.9	0.57
Prior stent removing, n (%)	21 (36.2)	1 (20)	0.65
EPBD, n (%)	10 (17.2)	1 (20)	1.000
EPBD+ stone removal+ stent insertion, n (%)*	10 (37)	1 (50)	1.000
Stricture biopsy+ dilatation, n (%)**	3 (12.5)	0	1.000
Devices used during SpyGlass, n (%)			
EHL*	9 (34.6)	1 (50)	1.000
Yag laser*	13 (50)	1 (50)	1.000
SpyBite biopsy**	19 (73.1)	3 (100)	0.30
Permanent stent insertion, n (%)	36 (62.1)	4 (80)	0.42
Mean total procedure time, minutes ± SD	74.3 ± 36	82.4 ± 34.2	0.58
Antibiotics prophylaxis, n (%)	34 (58.6)	1 (20)	0.16
Bacteremia, n (%)	2 (3.4)	2 (40)	0.53
Mean hospital length, days	1.9 ± 2.4	5.2 ± 3.2	**0.002**
Mortality, n (%)	1 (1.7)	0	1.000

EHL = electrohydraulic lithotripsy, EPBD = endoscopic papillary balloon dilation, OLT = orthotopic liver transplantation, PSC = primary sclerosing cholangitis, SD = standard deviation

*For patients with stones only
**For patients with strictures only
Bold signifies statistical significance

ment, which was managed conservatively with a successful outcome. There was one case of mortality (1.9%), which involved a patient who developed severe complicated post-ERCP pancreatitis.

Antibiotic prophylaxis with a single dose of ceftriaxone was administered based on physician or endoscopist discretion in 35 patients (55.6%), while 28 patients (44.4%) received no antibiotics. When comparing these groups, there was no significant difference in bacteremia rates, cholangitis, mortality, or length of hospitalization [Table 3]. Patients with cholangitis had significantly longer hospital stays (5.2 ± 3.2 days vs. 1.9 ± 2.4 days; $P = 0.002$). Other cofactors were not associated with an increased risk of cholangitis [Table 4]. Notably, all patients with PSC or OLT received prophylactic antibiotics, and none developed cholangitis.

DISCUSSION

Endoscopic procedures such as ERCP and direct peroral cholangiopancreatoscopy pose a potential risk for bacteremia and biliary infections due to their invasive nature. The current direct peroral cholangiopancreatoscopy systems contain four ports and use water irrigation to distend the CBD and improve visualization [1]. Forceful irrigation during these procedures may inadvertently facilitate bacterial translocation from the CBD into the bloodstream, increasing the risk of infection.

Prophylactic antibiotics are often considered to mitigate this risk. However, the widespread use of antibiotics raises concerns about antibiotic resistance, a growing global health threat. A study conducted by Du et al. [17] found that the majority of bacteria isolated from blood cultures after ERCP were resistant to ciprofloxacin and ceftriaxone.

Previous prospective studies have reported on bacteremia and cholangitis rates after ERCP with direct cholangioscopy: In a study by Chen et al. [18], 297 patients underwent single-operator cholangioscopy across 15 referral centers in the United States and Europe, resulting in nine cases of cholangitis. The decision to administer antibiotics prior to the procedures was based on each institution's standard practice and was not specifically detailed in the study. Othman and colleagues [14] included 57 patients undergoing ERCP with direct cholangioscopic examination of the CBD. The bacteremia rate was 8.8%, significantly higher in patients with CBD strictures who underwent biopsy sampling. Cholangitis occurred in 7%, with no antibiotics administered before or after the procedure, which may bias the observed bacteremia rate. Thosani and co-authors [15] studied 72 patients undergoing ERCP with cholangioscopy, with blood cultures obtained at three time points: before, immediately after, and 15 minutes post-cholangioscopy. All patients received a single intravenous dose of antibiotics after the third sample. The authors found a 27.8% rate of true positive blood cultures, with 8.3% experiencing transient bacteremia, and 13.9% having sustained bacteremia related to direct cholangioscopy. Notably, older age, and use of electrohydraulic or laser lithotripsy increased the risk of sustained bacteremia. The authors concluded that pre-procedure antibiotics should be considered for high-risk patients.

In our study, the overall bacteremia rate after ERCP with direct cholangioscopy was 6.3%, with only 3.2% having clinically significant bacteremia. The cholangitis rate was 7.9%, slightly higher than in the study by Chen et al. [18], but similar to the prospective study conducted by Thosani and colleagues [15]. Importantly, our data indicate that prophylactic antibiotics did not significantly reduce the incidence of bacteremia or cholangitis. Despite multiple interventions during procedures, such as stent removal or insertion, stone fragmentation with EHL or laser, and biopsy sampling, we found no significant factors that increased the risk of cholangitis.

Guidelines on antibiotic prophylaxis for ERCP-related infections have evolved. The latest ASGE guidelines recommend antibiotic prophylaxis prior to ERCP in patients with bile duct obstruction when incomplete drainage is anticipated, but do not provide specific recommendations for cholangioscopy [13]. Conversely, the ESGE guidelines recommend antibiotic prophylaxis before cholangioscopy; however, this recommendation is considered weak based on moderate-quality evidence [16]. In our cohort, the decision to administer antibiotics was based on the discretion of the performing physician, reflecting real-life clinical practice. Since the release of updated guidelines, the approach has shifted toward routine prophylactic treatment for all patients. However, our findings suggest that cholangitis cannot be wholly prevented by this practice.

To the best of our knowledge, this study is the first to evaluate, in a real-world setting, the impact of prophylactic antibiotics on bacteremia and cholangitis following ERCP with cholangioscopy, including clinical follow-up during hospitalization. Although prophylactic antibiotics did not significantly reduce infectious complications in our cohort, it remains essential to identify patient groups (e.g., older adults, immunocompromised individuals) who might benefit from preventive treatment.

We acknowledge the study limitations, including the retrospective design and relatively small sample size, which may impact on the generalizability of our findings. Nonetheless, the real-life context provides valuable insights into routine clinical practice. Furthermore, the retrospective study design may introduce selection bias, including confounding by indication, whereby patients perceived to be at higher risk or with greater illness severity were more likely to receive prophylactic antibiotics. Consequently, the absence of a difference in infection rates between groups should not be interpreted as evidence of lack of efficacy and should be evaluated in prospective, controlled studies.

CONCLUSIONS

The prevalence of bacteremia and cholangitis following ERCP with direct cholangiopancreatoscopy was 6.3% and 7.9%, respectively. Prophylactic antibiotics did not significantly reduce post-procedural infectious adverse events. Further prospective studies are needed to clarify the role of antibiotics in this setting, with the goal of minimizing the development of resistance and adverse effects.

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Capsule

Discovery and development of a new oxazolidinone with reduced toxicity for the treatment of tuberculosis

Crowley and colleagues showed the development of a new oxazolidinone, MK-7762, with antitubercular activity that is better than linezolid and limited mitochondrial protein synthesis inhibition. The cryogenic electron microscopy structure of the stalled mycobacterial ribosome with MK-7762 revealed the basis for this selectivity. BALB/c mouse models of disease showed MK-7762 reduced lung bacterial burden by a 3-log-fold decrease in an acute model (n=18) and a 2-log-fold decrease in chronically infected animals (n=18). MK-7762 showed lesion penetration similar to linezolid in C3HeB/FeJ mice. MK-7762 had pharmacokinetic properties predicting low once-daily doses in humans and a favorable 14-day preclinical safety profile in Wistar Han rats (n=30) and Beagle dogs (n=6). Four-month safety studies in both rats (n=20) and dogs (n=24) showed no changes in hematology parameters at exposures well above the 100-mg predicted human dose. These data will enable MK-7762 to be explored as a component of new tuberculosis treatment combinations for all forms of the disease.

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Capsule

Microfluidic automation improves oocyte recovery from follicular fluid of patients undergoing in vitro fertilization

Infertility is a global health challenge affecting millions worldwide, and in vitro fertilization (IVF) remains the main treatment option. The increasing demand for IVF necessitates innovations that improve access, efficiency and outcomes. To address this need, **Mutlu** et al. developed a microfluidic device (FIND-Chip) that automates the isolation and denudation of oocytes from follicular fluid (FF), a critical step in IVF workflow. In a clinical study involving 582 patients from four IVF centers, FIND-Chip was utilized to perform automated oocyte recovery from FF and revealed that in more than 50% of the cases functional and mature oocytes are inadvertently discarded under current clinical practice. These undetected oocytes successfully developed into high-quality blastocysts, thereby substantially expanding the embryo pool available for patient treatment. Notably, an oocyte that was retrieved by FIND-Chip from a clinically screened and discarded FF sample led to a live birth, highlighting the potential of microfluidic automation to enhance IVF success rates.

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Capsule

Tobacco cessation among nondaily and low-intensity smokers

Llambi et al. addressed the growing and often underrecognized population of nondaily and low-intensity smokers in Latin America and the unique challenges they pose for tobacco control. In many Latin American countries, tobacco-control policies have reduced overall smoking prevalence, but patterns of use are shifting. Social smoking, intermittent use, and dual use with other nicotine products are becoming more common, particularly among younger adults and urban populations. Traditional cessation programs, which are often designed for daily dependent smokers, may be less effective for these groups. The authors highlighted several opportunities including tailoring public health messaging to emphasize that there is no safe level of smoking, integrating brief cessation counseling into primary care, expanding access to pharmacotherapy when appropriate, and leveraging digital and community-based interventions. They also underscored the importance of surveillance systems that accurately capture nondaily smoking patterns to guide policy and resource allocation.

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