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ORIGINAL RESEARCH

From Screening to Strategy: Targeted Carbapenem-Resistant Enterobacteriaceae (CRE) Infection Prediction After Endoscopic Retrograde Cholangiopancreatography (ERCP)

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Background: Invariably, patients can be exposed to Carbapenem-resistant Enterobacteriaceae (CRE) through contaminated device during Endoscopic retrograde cholangiopancreatography (ERCP). We aimed to identify the risk factors and establish a model for predicting subsequent CRE infections in patients with CRE-positive bile screening after ERCP.

Methods: Patients underwent ERCP were performed with bile active screening of CRE. Medical records were reviewed to identify patient demographics, comorbidities, microbiology and antimicrobial treatments. The results were grouped according to the occurrence of subsequent CRE infection, and the patients were divided into two groups: a CRE infection group and a non-CRE infection group. The diagnosis for CRE infection was confirmed by more than 2 physicians. Logistic regression methods were used to determine the risk factors for CRE infections. The risk prediction model was constructed by integrating the clinical data and the result of logistic regression, by a nomogram and forest plot. Finally, goodness of fit of the final model was tested using the likelihood ratio test.

Results: Central venous catheterization (OR=11.32; 95% CI 1.15–40.62), cholecystitis (OR=3.82; 95% CI 1.12–13.01), malignancy (OR=4.33; 95% CI 1.41–13.35) and the antimicrobial drug use (OR=1.08; 95% CI 1.03–1.14) were considered as highly relevant risk factors for subsequent CRE infections in bile active screening positive patients. The goodness of fit test indicated that the model was well-calibrated for both groups.

Conclusion: A targeted active screening in bile samples can be beneficial for patients with high risk factors of CRE infections. The nomogram developed in this study can help clinicians accurately predict the possibility of patients with subsequent CRE infections after ERCP, so as to facilitate more precise individualized treatment.

Keywords: bile active screening, nomogram, ERCP, CRE

Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) has become a commonplace gastroenterological procedure.[1] Infections are recognized as major complications of Endoscopic retrograde cholangiopancreatography (ERCP). Microorganisms are becoming resistant to drugs, specifically Carbapenem-resistant Enterobacteriaceae (CRE), recently getting much attention among various researchers since resistance to antibiotics is a great threat in the ultra-modern therapeutic era.[2,3] One study showed that CRE infection is the leading cause of high mortality in clinical infections.[4] Studies have also reported that the in-hospital mortality rate caused by CRE can reach 68.33%.[5] Additionally, the options for treating CRE infections are quite restricted. The colonization of CRE in biliary tract is inevitable, owing to its associated technical difficulties.[6,7] The design of variations in the internal anatomy of the duodenoscopes makes adequate disinfection of the channels difficult.[8] In recent years, numerous reports of infection diffused by contaminated

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duodenoscopes following ERCP.[9] A meta-analysis including 13,112 samples calculated a 15.25% contamination rate of duodenoscopes.[10] Delaying adequate antibiotic therapy significantly increases the risk of mortality, early detection and treatment may lead to major health benefits.[11,12] Thus, screening the colonization of CRE in biliary tract among patients who performed with ERCP has become an important prevention measure for CRE infection in our hospital.

Even though the participation rates of bile active screening for CRE in our hospital were not high since 2020, there is a select group of patients that may still benefit from bile CRE screening. There are still many uncertainties concerning which patients benefit. Therefore, the purpose of our study was to determine the incidence and risk factors for infection of CRE colonization in biliary tract among patients after ERCP procedure. Early identification of important risk factors for CRE infections will enable clinicians to intervene earlier in high-risk patients, thereby prevent the formation of the amount of chain of vicious events. Developing a risk-prediction model might aid clinicians in devising effective strategies to reduce the infection rates.

Method

Study Design

We extracted data on individuals admitted to the Hepatobiliary and Pancreatic Surgery Unit and the gastroenterology department from the hospital Patient Administration System database and the nosocomial infection surveillance system database. A list of patients with ERCP during a hospital admission was extracted from the hospital administrative database. Overall, 63298 patients were admitted to the Hepatobiliary and Pancreatic Surgery Unit or the gastroenterology department from 2020 to 2024. Patients underwent ERCP were requested to subject to routine bile or rectal CRE screening since 2020 in our hospital. Totally, a positive CRE was detected in 526 patients, including rectal samples and 365 bile samples. Only 160 patients who meet our requirements were included in this research, with 26 patients developing CRE infections in our hospital (see Figure 1).

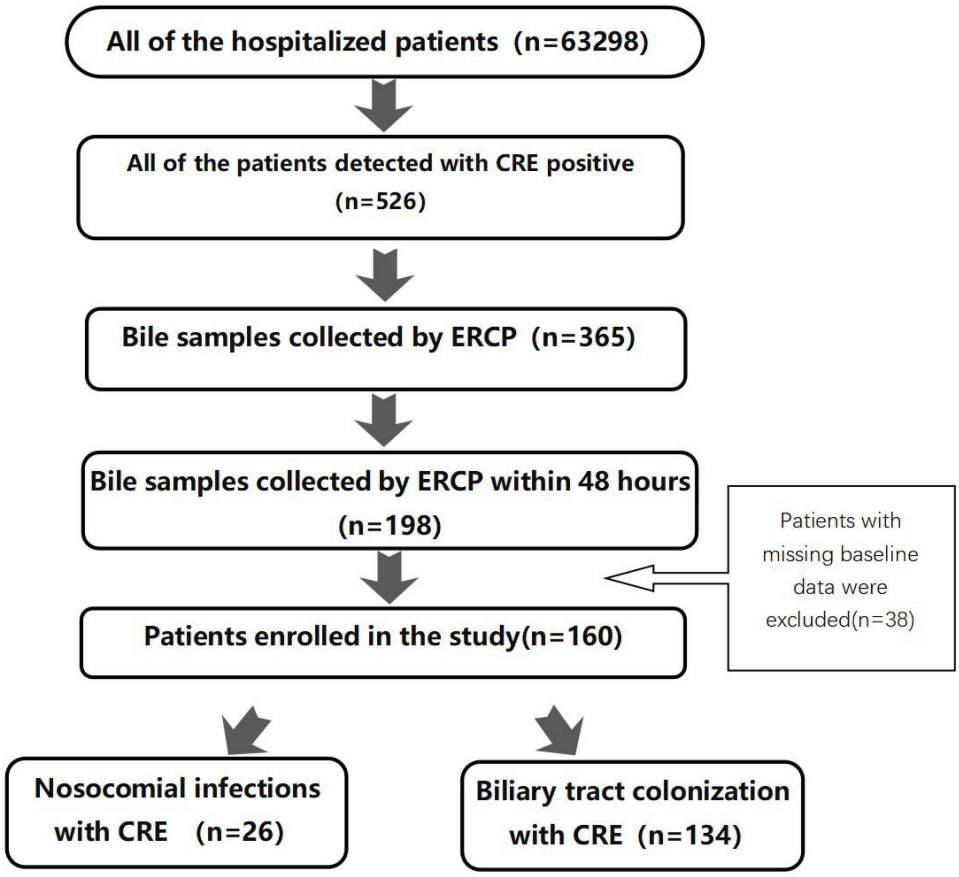

Figure 1 The study flowchart.

Ethics

The study was conducted according to the principles of the Declaration of Helsinki. The project was presented to the ethics and research committee of our hospital and was approved (approval number: 2025ZN062-1).

Bacterial Strains and Cultivation

During surgery of ERCP, bile samples were aspirated through a sterile catheter, collected into a sterile universal pot by clinicians and transported to the laboratory without delay. In the vast majority of instances, the samples of bile were transported to the microbiology laboratory by sample-transport workers within 2 hours from the time of procurement. After the samples were received in the Microbiology laboratory, they were positioned in the biosafety cabinet to begin culture inoculation. After the samples were received in the Microbiology laboratory, they were positioned in the biosafety cabinet to begin culture inoculation according to the relevant requirements of the National Operating Rules for Clinical Examination. Mostly, bile specimens were inoculated within three hours upon receipt. Cultivations were performed for no more than 7 days. Target samples were kept under normal culture conditions for no more than 3 days after the samples were observed.

Antimicrobial Susceptibility Testing

Bacterial identification susceptibility tests were performed by VITEK2 compact system (BioMerieux, France).

Clinical Data Collection

Isolates from the same infection sites in the same patients were not included repeatedly. A review of medical records was performed to record pertinent background information including age, sex, comorbidities included the respiratory comorbidities, cardio-cerebrovascular comorbidities, diabetes mellitus, past medical history, past surgical history of the abdominal and so on.

Statistical Analysis

Logistic regression analysis, Chi-square, *T*-test were performed for risk factor selection. Differences with $P < 0.05$ were considered statistically significant. Data were analysed using version 22 of the SPSS software package. The forest plots and nomograms were drawn using RStudio software. The goodness-of-fit was tested using Hosmer–Lemeshow goodness-of-fit test.

Criterion to Determine the Infection or Colonization

In order to exclude the impact of antibiotic administration and other reasons on the result, we choose the patients who underwent ERCP examination within 2 days of admission. "Colonization" was defined in the following cases: There were no clinical signs of infection (or confirmed by more than 2 doctors), and no anti-CRE antibiotics were used. "Infection" was defined in the following cases: If two or more experts, including three or more departments (Department of Hospital Infection Management, Infectious disease department, The Department of Intensive Care Medicine, the Division of Hepatobiliary and Pancreatic Surgery, Department of Surgery and the Gastroenterology Department) confirmed infections, then the case is determined as a CRE infectious case, and antibiotics were used to treat the CRE infection.

Result

CRE Species Distribution of ERCP Patients

A total of 160 patients were screened positive for CRE in the bile samples, which were finally included in the analysis. The distribution of CRE among bile specimens is summarized in Table 1. The examined strains of CRE were including *Klebsiella pneumoniae, Escherichia coli, Enterobacter cloacae, Klebsiella aerogenes, Klebsiella acidogenes, Serratia marcescens* and *Proteus mirabilis*. Of these specimens, the most common species were *Klebsiella pneumoniae* (53.1%, [n=85]) and *Escherichia coli* (33.1%, [n = 53]). Among the 160 patients with CRE positive by bile active screening through ERCP, 26 patients developed CRE infections, with a CRE infection rate of 15.0%. Distribution of infection

Table 1 Classification of CRE Species in the Bile Samples

Classification of CRE Species	Quality (n, %)	Ceftazidime-Avibactam-Resistant (n, %)
Klebsiella pneumoniae	85 (53.1)	4 (4.7)
Escherichia coli	53 (33.1)	12 (22.6)
Enterobacter cloacae	10 (6.3)	2 (20.0)
Klebsiella aerogenes	4 (2.5)	0
Klebsiella acidogenes	3 (1.9)	0
Serratia marcescens	2 (1.3)	0
Proteus mirabilis	1 (0.6)	0
Combined with *E. coli* and *K. pneumoniae*	2 (1.3)	0

strains is represented in Figure 2. Of the 160 CRE isolates, 18 (11.3%) isolates were resistant to ceftazidime–avibactam (Figure 3 and Table 1). These include 12 strains of *Escherichia coli*, 4 strains of *Klebsiella* pneumoniae and 2 strains of *Enterobacter cloacae*, and 2 *Escherichia coli* isolates and 1 *Klebsiella pneumoniae* isolate were finally categorized as nosocomial infections (Figure 3 illustrates the distribution species of infections, the distribution frequency for various types of strains and the distribution of Ceftazidime-avibactam-resistant strains). *Escherichia coli* was the most common pathogen among the isolates resistant to ceftazidime–avibactam (12/53, 22.6%).

Baseline Characteristics

The primary cohort consists of 160 patients from the Department of gastroenterology department in the final study population and 29 patients referred to the Department of Hepato-Biliary-Pancreatic Surgery who underwent surgery after ERCP procedure. Of the 160 patients, over half of the patients were male. Many patients had an underlying disease (see Table 2), including diabetes, cancer, pulmonary disease and so on; the most common underlying diseases were tumor (30.0%) and hypertension (44.3%). Among 100 patients who had a history of previous surgery, 88 patients underwent

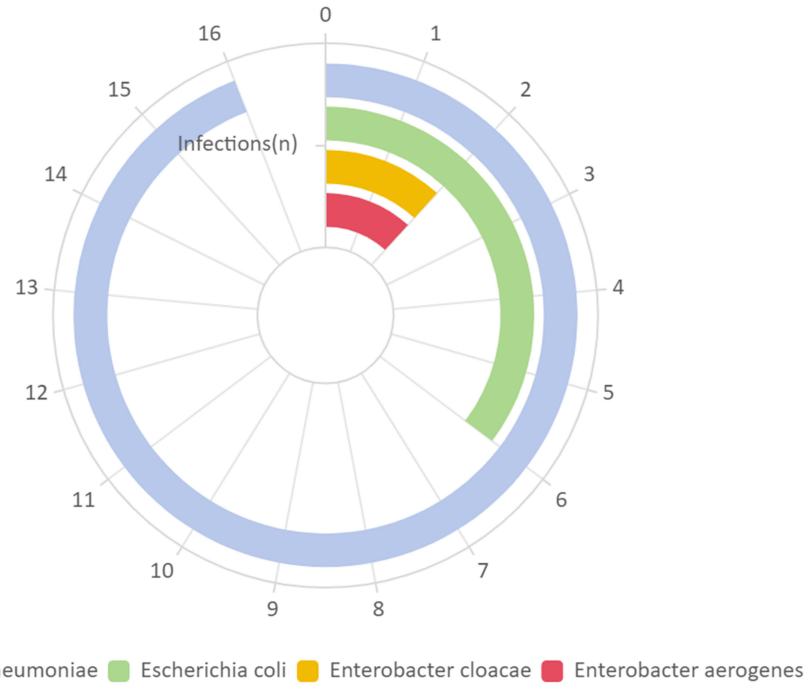

Figure 2 Distribution of isolates of the infected cases.

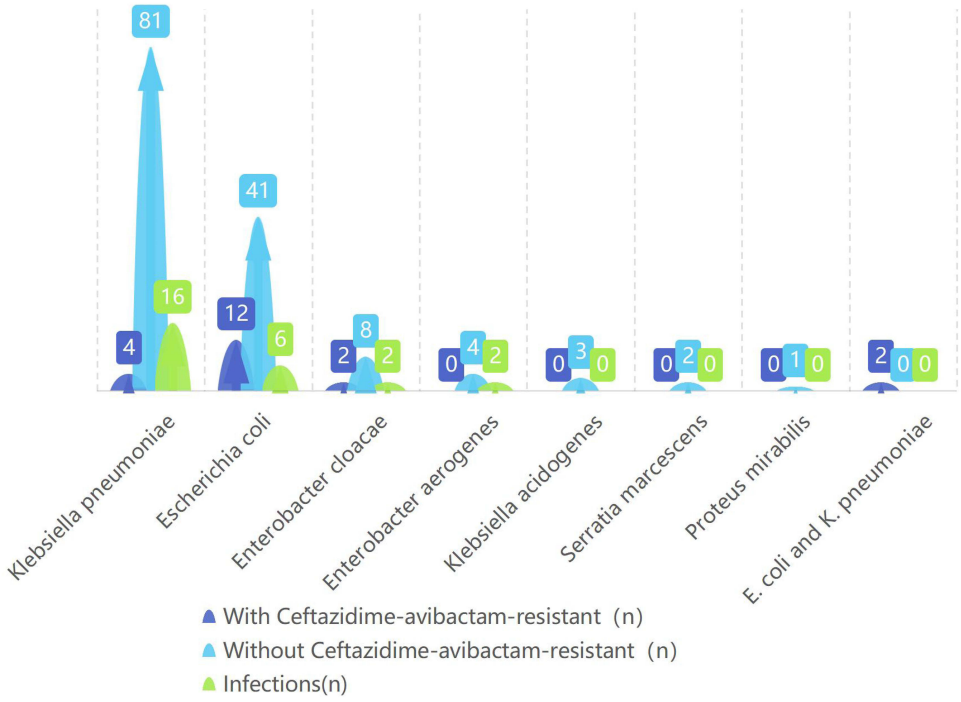

Figure 3 Distribution of types of CRE in the positive bile samples and number of strains with resistant to ceftazidime–avibactam.

abdominal surgery and 12 patients underwent surgery in other sites. The vast majority of CRE-positive patients underwent ERCP more than once during the inpatient period. In total, 28 variables were selected in the univariable analysis.

Table 2 Conditions and Complications of the Patients Screened Positive for Bile CRE

Condition or Characteristic	No. of Patients (%, If Applicable)
Male	100 (62.5)
Female	60 (37.5)
Age (years)	69.7±14.4
Inpatient Days	13.7±15.1
CRE infections	26 (16.3)
Surgical procedure during hospitalization	29 (18.1)
History of abdominal surgery	88 (55.0)
History of other sites surgery	12 (7.5)
Malignancy	48 (30.0)
Hypertension	71 (44.3)
Coronary heart disease	28 (17.5)
Diabetes mellitus	33 (20.6)

(*Continued*)

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Table 2 (Continued).

Condition or Characteristic	No. of Patients (%, If Applicable)
Hypoproteinemia	41 (25.6)
Chronic respiratory disease	16 (10.0)
Pneumonia	24 (15.0)
Cerebral infarction	2 (1.3)
Sepsis	27 (16.9)
Choledocholithiasis	121 (75.6)
Cholangitis	145 (90.6)
Biliary obstruction	34 (21.3)
Bile Duct stricture	33 (20.6)
Pancreas-related diseases	127 (79.4)
Cholecystitis	57 (35.6)
Hepatic cysts	30 (18.8)
Contact isolation	105 (65.6)
Duration of hospital stay ≤ 1 week	69 (43.1)
1 week <Duration of hospital stay ≤ 2 weeks	51 (31.9)
2 week <Duration of hospital stay ≤ 30 days	26 (16.3)
Duration of hospital stay >30 days	14 (8.8)
Number of ERCP procedures≤1	48 (30.0)
1<Number of ERCP procedures≤2	67 (41.9)
Number of ERCP procedures>2	45 (28.1)
Tracheal intubations	6 (3.8)
Central venous catheterization.	45 (28.1)
Indwelling urinary catheter	26 (16.3)

Risk Factor Analysis

A total of 160 patients could be included in risk factor analysis. CRE infection occurred in 26 of the 160 patients with CRE colonization (detection), with a CRE infection rate of 16.3%. From the results of the primary analyses, fever was only identified as a risk factor (P=0.069) in the comparison CRE colonized group versus CRE infections group, which means it should be considered as a spurious finding. Unexpectedly, in multivariate analysis (Table 3), patients with cholecystitis were associated factors for subsequent CRE clinical infection among patients with CRE bile colonization (OR 3.82; 95% CI 1.12–13.01, P=0.032). The risk for subsequent infections with CRE increased significantly if patients diagnosed with cancer during hospitalization (OR 4.33, 95% CI 1.41–13.35, p=0.011). In addition, logistics analyses revealed that central venous catheterization was significant risk factor for conversion to CRE infections in CRE bile carriers (OR 11.32; 95% CI 3.15–40.62, p<0.001). It is important to emphasize that prior antimicrobial may increase risk

Table 3 Result of Multivariate Analysis of Risk Factors for CRE Infections

Variables	Incidence Rate Ratio (95% CI)	P Value
Cholecystitis	3.82 (1.12–13.01)	0.032
Malignancy	4.33 (1.41–13.35)	0.011
Central venous catheterization	11.32 (3.15–40.62)	<0.001
Days of antimicrobial (days)	1.08 (1.03–1.14)	0.002

of subsequent CRE infection (OR 1.08, 95% CI 1.03–1.14, p=0.002). Days of antibiotic treatment after ERCP, for each usage increase in days, the odds of subsequent CRE infections increase by 8%.

Develop the Predictive Models for Prediction of CRE Infections

But how would a clinician use this data, that is, how can physicians specific risk values to a CRE colonized patient in an appropriate manner? To do so, we designed a forest plot (see Figure 4), the forest plot illustrated the associated risk factors about CRE infections. But, as a physician specialized in hospital infection management, I did not think it was enough. Subsequently, a nomogram was constructed (see Figure 5), which can be used more intuitively and easily to guide clinical decision-making.

For example, a case of choledocholithiasis with cholecystitis quo ERCP with DBE to remove common bile duct stones. He was detected with CRE positive in bile sample. Meanwhile, the patient had undergone right hemicolectomy 2 years previously because of tumor. For post-procedural complications, the patient developed with postoperative acute pancreatitis. So the patient empirically started on piperacillin-tazobactam and central venous (CV) catheterization was used. After 20 days of antibiotics, what is the probability of suffering subsequent CRE infection in this patient? Let us go ahead and fix the problem with our nomogram. We can see in Figure 6, the actual total score is calculated after the score of each item is obtained. This calculation produced the final site scores (score≈130), which corresponds to that probability is approximately 0.8 (80%). That is to say, the probability of CRE infection in this patient would be almost 80%.

Validating the Reliability of the Evaluation Model

We further verified the predictive efficacy of this model using calibrate function. As shown in Figure 7, the calibration curves were plotted for internal and external validation, the x axis represents the predicted CRE infections risk after ERCP, and the y axis represents the actual diagnosed CRE infections, the diagonal dotted line symbolizes an ideal model's perfect, the solid line represents the performance of the nomogram, of which a closer fit to the diagonal dotted line represents a better prediction. The Hosmer–Lemeshow test results showed acceptable goodness of fit.

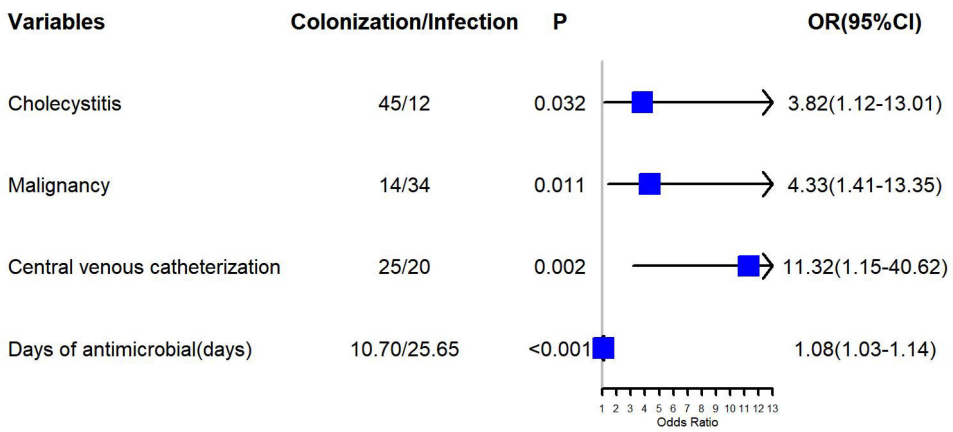

Figure 4 Forest plots of study (Forest plot of risk factors of CRE infections predicted).

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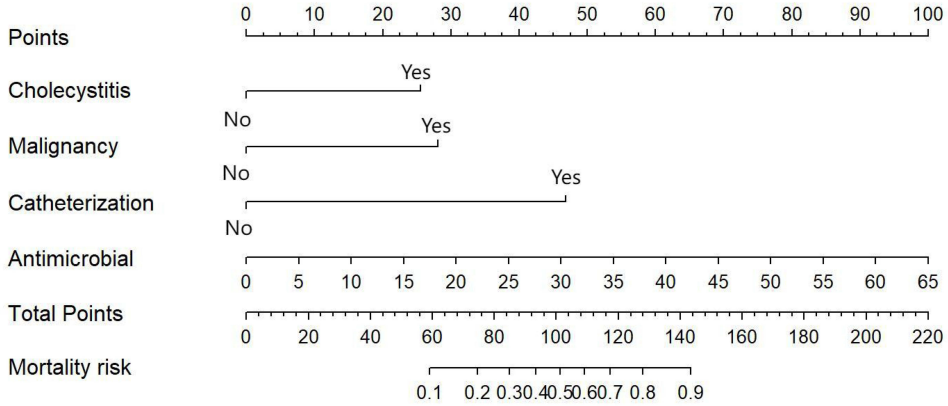

Figure 5 Nomogram on the basis of four risk factors was constructed for clinical utilize.

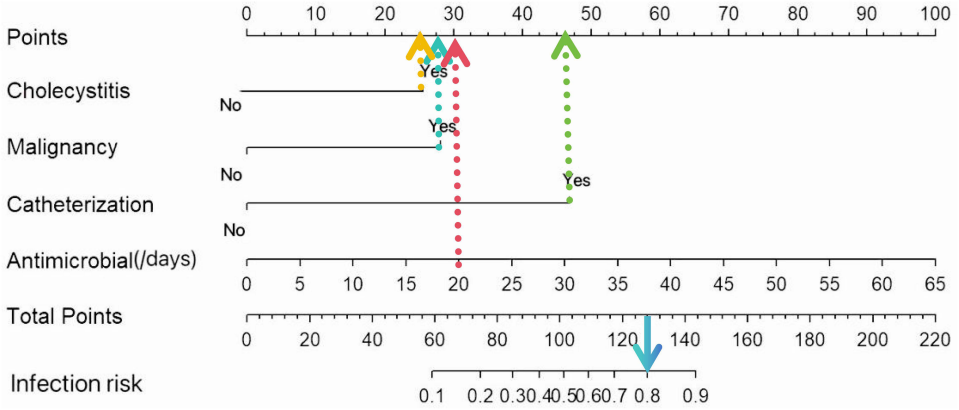

Figure 6 One patient from our study is shown as an example using the nomogram (Total points 25+27.5+30+47≈130, the predictive probability of developing CRE infection became 0.8).

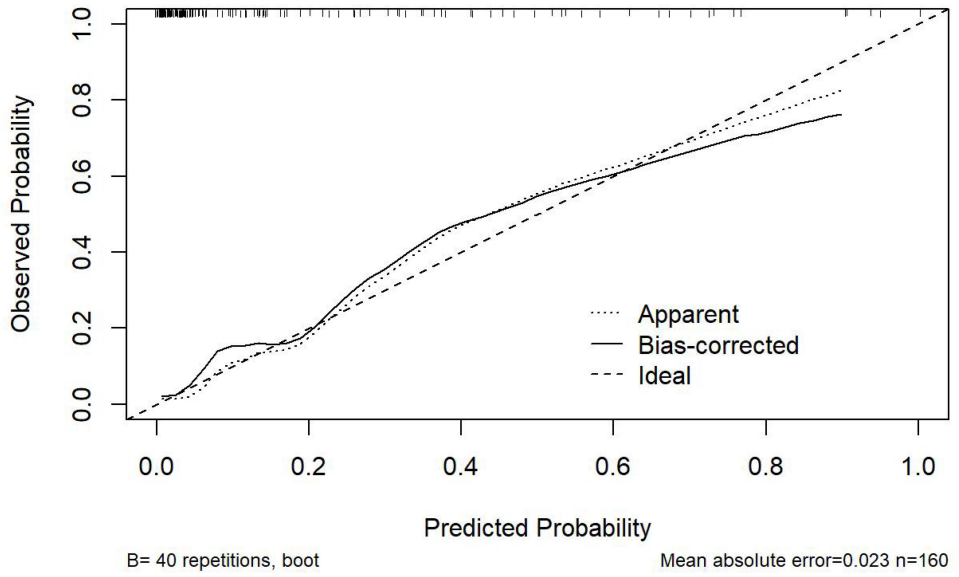

Figure 7 Validation of the reliability of the risk score model.

Discussion

Summary of Main Findings

The outstanding point of this research is collecting the bile specimens from patients for CRE screening during the ERCP, rather than rectal CRE screening. The finding suggests a potential need for proactive bile CRE screenings among cholecystitis and malignancy patients. CRE prevention and control measures based on bile active screening combined with early removal of indwelling catheter might be beneficial for patients with CRE-positive bile screening. The model could also predict time for antimicrobial therapeutic intervention needs to determined.

Basis of Previous Studies

Currently available CRE surveillance and screening measures primarily based on rectal swab cultures,[13,14] which may be an effective measure to reduce CRE infection and transmission.[15] However, the screening programs in rectal swab cultures may not reflect the situation of microorganisms in the bile. ERCP is an invasive procedure requiring transient deep analgesia and conscious sedation, which may elevate the risk of nosocomial CRE transmission. Complex internal channels in endoscope causes a major challenge for interrupting CRE nosocomial transmission.[16] There have been reports of nosocomial infections post endoscopy.[17] Since the invasive maneuvers and pathogen invasion are unavoidable, some infection-control measures become of paramount importance. At present, there are still not many hospitals that can carry out bile CRE screening. There has been reported previously focusing on analyzing the risk factors of CRE transmission in duodenal endoscopy.[18] However, there are few reports of bile CRE screening and analyzing the risk factors of subsequent CRE infection in CRE bile colonized patients. This study is valuable for it detects the factors associated with subsequent infection in CRE bile colonized patients with ERCP procedure. This type of study has not been reported so far.

Main Prospect and Meaning

Patients at high risk of CRE infections could be screened out in advance according to our study. We could use the model to successfully predict patients at high risk of CRE infection and the proposed model can also effectively forecast occurrence time of subsequent CRE infections. This enables a straight forward and continuous monitoring of these patients with CRE infection risk factors. This finding suggests clinician should pay close attention to bile CRE colonized patients with those risk of factors to prevent subsequent infection. We hope that our efforts will motivate the pursuit of CRE bile active screening after ERCP. Moreover, we develop a new nomogram model for predicting the probability of further CRE infection in patients with CRE-positive bile screening after ERCP, which we hope can advance domestic efforts in our country as well as similar efforts internationally. As we have entered an exciting age of AI and robotics, our study provides an excellent start to decision making model for intelligent agent.

Limitations

Limitations still exist concerning our study. Despite the loose inclusion criteria, of 63298 patients, there were only 160 patients included in the final analysis. Due to the small sample, no valid statements can be made on immune deficiency. Our institution does not have high in vigilance in routinely active screening for CRE in bile samples. Here is a call for the engagement of public health practitioners and clinicians in addressing issues for in this study.

Conclusion

More attention should be paid to the prevention and control of the subsequent CRE infection in Cholecystitis and malignancy patients with screen-detected CRE in bile compared to other patients. Catheter indwelling time and the duration of antimicrobial therapy should be shortened as much as possible according to the actual situation of the patient. Our model will predict the probability of subsequent infection by CRE, and doctors can make clinical decisions based on probability. All patients with CRE-positive bile screening could be considered to use this model. By inputting specific risk factors into the model, a corresponding risk score can be generated which corresponds to the probability of subsequent infections in the nomogram. The final model showed a good fit (Hosmer–Lemeshow Goodness-of-Fit test; $p > 0.05$). Targeted surveillance of high-score patients is essential to prevent subsequent nosocomial infections by CRE.

Ethics Statement

This study was performed in accordance with the Declaration of Helsinki and public health. Ethical approval was obtained from the institutional review board of Hangzhou First People's Hospital Affiliated of Westlake University School of Medicine (approval number: 2025ZN062-1). The ethics committee exempted the study from the informed consent requirement during the ethics review. Patient consent to review their medical records was not required by institutional review board of Hangzhou First People's Hospital Affiliated of Westlake University School of Medicine, since this was a retrospective database analysis.

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Disclosure

The authors report no conflicts of interest in relation to this work.

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