

CLINICAL STUDY

Risk factors for post-ERCP complications

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ABSTRACT

BACKGROUND: In the 21st century, endoscopic retrograde cholangiopancreatography (ERCP) has emerged as a diagnostic and therapeutic method for diseases of the pancreaticobiliary duct system. However, like any other diagnostic and therapeutic method, ERCP carries the risk of unwanted complications.

MATERIAL AND METHODS: We retrospectively followed patients who underwent ERCP examinations from January 2013 to April 2023. We focused on early post-ERCP complications and their risk factors, prevention, treatment, and mortality.

RESULTS: A total of 4,814 patients were recorded, of which 175 patients had early post-ERCP complications, including acute pancreatitis, acute cholangitis, perforation, and bleeding. We focused on the statistical significance of risk factors such as BMI, repeated ERCP, bleeding disorders, and repeated pancreatitis or cholangitis.

CONCLUSION: Ensuring proper preparation and appropriate indication for ERCP examination can significantly mitigate the risk of post-ERCP complications. Additionally, early diagnosis and prompt treatment of any post-ERCP complications are essential strategies for reducing mortality associated with these conditions (*Tab. 3, Fig. 3, Ref. 32*). Text in PDF www.elis.sk

KEY WORDS: post-ERCP complication, risk factor, BMI, prevention.

Introduction

Endoscopic retrograde cholangiopancreatography serves as a vital diagnostic and therapeutic tool for diseases of the pancreaticobiliary duct system. It is based on imaging the pancreaticobiliary system using a contrast agent with the potential for subsequent interventions across various diseases. Given that it is an invasive method, it carries the risk of undesirable consequences. Despite its utility, ERCP poses a notable risk of complications, earning it the distinction of the highest rate of complications among endoscopic methods. Post-ERCP complications are categorized into early and late occurrences. Early complications include acute pancreatitis, bleeding, cholangitis, infection, and intestinal perforation (1). Notably, ERCP's inception dates back to 1968 when McCune et al first employed it for bile duct cannulation (2). Since then, ERCP has become a mainstay procedure, with over 650,000 annual procedures performed in the USA alone (3) and 2,371 procedures conducted in the Slovak Republic in 2017 (4). Available studies indicate a mortality rate of approximately

10–15 % (1, 5, 6, 7). However, despite inherent complications and necessity of experienced endoscopists, ERCP remains widely regarded as a safe and effective diagnostic and therapeutic modality. Many studies have shown its safety, even in high-risk patients with comorbidities (8, 9).

Materials and methods*Study design and patients*

This retrospective study utilized existing data from a cohort of 4,814 patients who underwent ERCP and were hospitalized at our Department of Surgery, Medical Faculty of Safarik University and University Hospital, Kosice, Slovakia, spanning from January 2013 to April 2023.

All selected patients were older than 18 years. Data from patients were collected and recorded in a database.

Procedures and data collection

ERCPs were performed by experienced endoscopists. Patients were monitored before and after the procedure at our Department of Surgery, where they were hospitalized. Before the procedure, the patients underwent blood sample collection and an imaging examination (abdominal ultrasound or abdominal CT scan). All necessary pre-procedural protocols were adhered to. After the procedure, the patients were continuously monitored, and additional blood samples and biochemical parameters were obtained. All patients were instructed to promptly report any symptoms such

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as abdominal pain, icterus, fever, or gastrointestinal bleeding. If these symptoms arose or inflammatory parameters, serum amylases and lipase parameters were elevated, further examinations were performed (abdominal ultrasound, abdominal X-ray, abdominal CT scan, endoscopy of upper GIT). Patients with risk factors such as high BMI, history of previous occurrence of pancreatitis or cholangitis, thrombophilic conditions, or those undergoing repeated ERCP examinations were particularly closely monitored.

According to the ESGE guideline from 2020, post-ERCP pancreatitis must meet three criteria: new or worsening abdominal pain after ERCP, elevation of serum amylase and lipase levels above three times the upper limit of normal, and subsequent extension of hospitalization by at least two nights (10). Another early complication is bleeding, characterized by a drop in hemoglobin level of more than 2 g/dl along with signs of gastrointestinal bleeding, such as melena or hematemesis (11). While ERCP can be an effective method for treating acute cholangitis, it can also lead to its occurrence. Acute cholangitis, inflammation of the bile ducts, presents with mild icterus and elevation of inflammatory parameters and typically arises due to factors such as duodenal-biliary stent blockage, stricture formation induced by edema, or passage of stones through the bile ducts (12). Perforation represents the most severe complication, clinically manifesting as sudden abdominal pain with peritoneal irritation. The fastest and most cost-effective imaging method for detecting perforation is a standing abdomen X-ray, which can reveal the presence of pneumoperitoneum. Stapfer et al proposed the classification of ERCP-caused perforation, dividing them into four types based on their anatomical location: perforations produced by the metal guide occurring in intraperitoneal locations on the medial or lateral duodenal wall, resulting in contrast leaks into the retroperitoneum (Type I), perforations related to the periampullary site after biliary or pancreatic sphincterotomy (Type II), perforations occurring distant from the papilla and linked to instrumentation (Type III) and perforations associated with retro-pneumoperitoneum post-ERCP, which may not necessarily represent true perforations (Type IV) (13) (Fig. 1). Subsequently, our focus shifted to monitoring additional risk factors such as gender, age, and oncological diagnosis.

Statistical analysis

IBM SPSS Statistics 17.0 (SPSS Inc. Chicago, IL, USA) was used to conduct both bivariate and multivariate hypothesis testing. At the bivariate level of hypothesis testing, chi-square tests of independence or parametric Student's t-tests for two independent samples were employed. For multivariate hypothesis testing, we used binary logistic regression analysis. This analysis allowed us to assess the probability of patients experiencing specific health complications (such as acute pancreatitis, cholangitis, perforations, and bleeding) based on the presence or level of selected risk factors (including BMI, repeated ERCP, previous pancreatitis or cholangitis, and blood clotting disorders). The results were interpreted using the odds

ratio and presented as standardized numerical values alongside a percentage expression.

Results

In our retrospective study, we assessed a cohort of 4,814 patients, focusing on risk factors such as gender, age, and presence of an oncological diagnosis. The gender distribution in the cohort was 57 % male and 43 % female. The average patient age was 58 years. Among the cohort, 1,877 patients had an oncological diagnosis, accounting for approximately 39% of the total. Early complications were recorded in 175 cases (3.6 % of all patients). Of those with early complications, 86 patients had the history of oncological diagnoses (49 %). Six patients from our cohort died, resulting in a mortality rate of 0.1 %. The causes of death included heart disease (3 cases), septic shock after surgical revision (1 case), hemorrhagic shock (1 case) and oncological disease in the terminal stage (1 case).

Acute pancreatitis

Among, the most common post-ERCP complication in our cohort was acute pancreatitis, affecting 73 patients (1.5%). The management of post-ERCP acute pancreatitis primarily involved conservative therapy. Each patient underwent an Abdominal CT scan, adhering to recognized diagnostic standards. Among these patients, 72 were diagnosed with mild pancreatitis while 1 patient presented with a severe necrotic form. The latter received antibiotic treatment (meropenem) for seven days. We conducted a bivariate analysis to explore the relationship between the occurrence of acute pancreatitis and potential risk factors such as repeated ERCP and previous pancreatitis. The results of the chi-square test of independence revealed that acute pancreatitis occurred in 40.2% of patients without prior ERCP and in 45.2% of patients with repeated ERCP. However, this difference was found to be statistically insignificant ($\chi^2=0.438$, $p=0.508$) and clinically negligible ($\phi=0.050$).

The analysis reveals that post-ERCP acute pancreatitis occurred in 2% of patients with no history of previous pancreatitis,

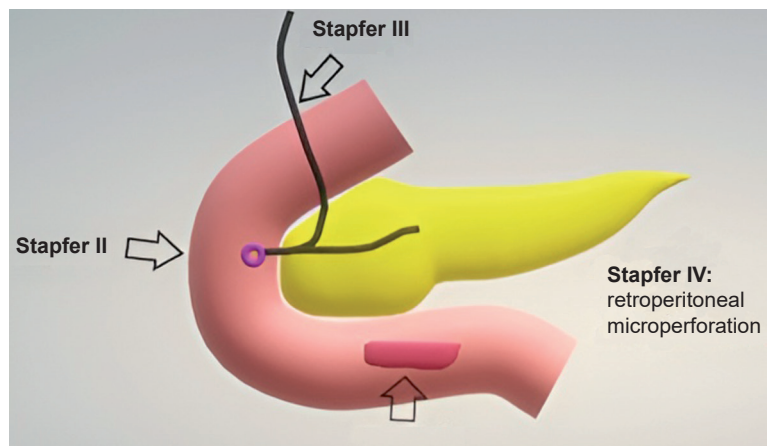


Fig. 1. Stapfer classification of ERCP perforation.

while in patients with previous pancreatitis, the incidence was recorded higher, at 8.2%. Although the difference was statistically significant ($\chi^2=3.820$, $p=0.051$), it was considered weak in substantive significance ($\phi=0.148$).

Regarding the relationship between the occurrence of acute pancreatitis and BMI, the analysis using Student's t-test for two independent samples showed no significant statistical difference in the average BMI values between patients with acute pancreatitis (AM=26.80, SD=5.124) and those without the acute pancreatitis (AM=27.19, SD=5.527); $t(173)=0.470$, $p=0.639$. The detected difference in average BMI values was also negligible from a substantive point of view ($d=0.072$).

The results of the binary logistic regression analysis indicate that the variable of previous occurrence of pancreatitis is the only risk factor approaching the required level of statistical significance ($B=1.448$, $p=0.088$). Patients with no prior history of pancreatitis experienced acute pancreatitis in 1.5 % of cases, while those with a previous episode of pancreatitis developed acute pancreatitis in 8.2% of cases. Previous occurrence of pancreatitis increased the risk of acute pancreatitis by 4.255 times (OR=4.255). The BMI value was found to be inversely proportional to the risk of developing acute pancreatitis. Specifically, for each increase in BMI of 1 point, the risk of acute pancreatitis decreases by 1.003 times (OR=0.997), i.e., by 0.3%. However, this effect was statistically insignificant ($p=0.915$). Regarding the factor of repeated ERCP, the results of the analysis showed that in patients without repeated ERCP, acute pancreatitis occurred in 40.2% of cases, while in those with repeated ERCP, acute pancreatitis occurred in 45.2% of cases. Repeated ERCP increased the risk of acute pancreatitis by 1.085 times (OR=1.085), i.e., by 8.5%, but this effect was statistically insignificant ($p=0.803$).

Acute cholangitis

Acute cholangitis, documented in 50 patients from our cohort (1%) ranked as the second most common complication following ERCP. The management of acute cholangitis primarily involved intravenous hydration supplemented with ATB treatment, which resulted in favorable outcomes. We conducted a bivariate analysis to explore the relationships between the occurrence of cholangitis and its potential risk factors such as repeated ERCP and previous cholangitis. The analysis showed that patients without prior ERCP developed cholangitis in 36 % of cases. Conversely, the patients with repeated ERCP experienced cholangitis in 58 % of cases. This difference was found to be statistically significant, ($\chi^2=7.083$, $p=0.008$), although its significance was weak ($\phi=0.201$).

The analysis regarding the impact of previous cholangitis revealed that post-ERCP cholangitis occurred in 10.4% of patients without a history of cholangitis and in 44% of patients with a positive history for previous cholangitis. This difference is statistically significant, ($\chi^2=25.200$, $p<0.001$). The impact of the BMI factor was assessed using the Student's t-test for independent samples. The analysis showed a significant difference in BMI values between patients with a history of prior cholangitis (AM=26.14, SD=4.173) and those without such history (AM=27.38, SD=5.731)

($t(173)=1.391$, $p=0.166$). Furthermore, the observed difference in average BMI values was objectively weak ($d=0.233$).

The results of the binary logistic regression analysis indicate that the history of pre-ERCP cholangitis is a statistically significant predictor of post-ERCP cholangitis ($B=1.927$, $p<0.001$). The analysis revealed that post-ERCP cholangitis occurred in 10.4% of patients without a prior history of cholangitis and 44% of patients with a prior history of cholangitis. The presence of pre-ERCP cholangitis in case history increased the risk of cholangitis by 6.869 times (OR=6.869). The BMI values were found to be reversely related to the risk of developing cholangitis. Specifically, for each increase in BMI of 1 point, the risk of cholangitis decreases by 1.035 times (OR=0.966), i.e., by 3.5%, and this effect was statistically significant ($p=0.345$). In terms of repeated ERCP, the results of the analysis showed that patients without repeated ERCP developed cholangitis in 36% of cases, whereas those with repeated ERCP experienced cholangitis in 58% of cases. Repeated ERCP reduced the risk of cholangitis by 1.083 times (OR=0.923), i.e., by 8.3%, but this effect was statistically insignificant, $p=0.860$.

Bleeding

Bleeding, another early post-ERCP complication, emerged in 46 patients from our cohort (1%).

All patients with post-ERCP bleeding complications underwent an upper GIT endoscopic examination. Forty patients who did not exhibit signs of active bleeding were treated conservatively. The management of conservative therapy included hemostyptics and volume therapy. Active bleeding was confirmed in 6 patients, one from esophageal varices, two from gastric ulcer, two from bleeding esophagitis, and one from the papilla of Vater. Endoscopic treatment was successful in 5 patients, while the patient with bleeding from the papilla of Vater underwent surgical intervention.

The relationship between the presence of blood clotting disorder as a risk factor for post-ERCP bleeding was analyzed using the chi-square test of independence. The analysis showed that patients without blood clotting disorders developed post-ERCP bleeding in 3.1% of cases, whereas those with blood clotting disorders exhibited post-ERCP bleeding in 43.5% of cases. The difference was statistically significant ($\chi^2=46.717$; $p<0.001$).

The relationship between the occurrence of post-ERCP bleeding and BMI as a potential risk factor was analyzed using the Student's t-test for independent samples. The analysis showed that the difference in mean BMI between patients with the occurrence of post-ERCP bleeding (AM=28.51, SD=6.607) and those without bleeding (AM=26.50, SD=4.744) was statistically significant ($t(173)=-2.209$, $p=0.029$). Specifically, we found that patients without bleeding had a significantly lower BMI than those with bleeding. However, the significance of the latter difference was weak from a substantive point of view ($d=0.379$). The results of binary logistic regression analysis indicate that blood clotting disorders are a statistically significant predictor of post-ERCP bleeding ($B=3.170$, $p<0.001$). Post-ERCP bleeding was recorded in 3.1% of patients without blood clotting disorders, whereas in

those with blood clotting disorders, the incidence of bleeding was recorded at 43.5% of cases. Thus, blood coagulation disorders increased the risk of bleeding by 23.813 times (OR=23.813). The patients' BMI values were directly proportional to the risk of bleeding. Specifically, for each increase in BMI of 1 point, the risk of bleeding rose by 1.065 times (OR=1.065), i.e., by 6.5%, but this effect was statistically insignificant, $p=0.111$.

Perforation

In our group, we had three patients with type I perforation by Stapfer (Fig. 2). Two of these patients required surgical revision and duodenal suture, while one patient was managed endoscopically with a clip. Type II perforations by Stapfer typically result from sphincterotomy or cutting with a needle knife around the periampullary region of the duodenum. Although these perforations require surgical revision, there have been documented cases of successful endoscopic closure using self-expanding metal stents. In our group of patients, we did not observe perforations of this type. Type III perforations by Stapfer occur during bile duct and pancreatic duct cannulation and often involve guidewire perforation through a side branch of the pancreatic duct or liver capsule (14). They are usually small and associated with wire or basket devices near obstacles. In our group, we had one patient in whom we addressed this type of perforation by performing a suture of the distal common bile duct. Finally, type IV perforations by Stapfer are retroperitoneal micro-perforations that are not considered as true perforations. They are characterized by retroperitoneal air alone and are likely associated with the use of compressed air to maintain lumen patency. In our group of patients, this type of perforation was recorded in only one patient (Fig. 3). Consequently, urgent revision and drainage of the bile ducts were necessary. In our group of patients, one patient died due to septic shock after surgical revision.

Various classifications, such as those provided by ASGE or AGREE, address challenging aspects of procedures, complications, and risk factors (15, 16). In Table 1, we present the AGREE classification alongside our patient results. Our focus was aimed at grades II, III, and IV because our cohort was comprised exclusively of hospitalized patients who were followed up at our clinic after the procedure. The relationship between the occurrence of perforations and repeated ERCP was analyzed using chi-square test of independence. The analysis indicated that patients without repeated ERCs experienced perforations in 42.9% of cases. Conversely, patients with repeated ERCs suffered perforations in 20% of cases. This difference was statistically insignificant, ($\chi^2=1.047$, $p=0.306$) and negligible from the point of view of substantive significance ($\phi=0.077$). The relationship between BMI as a potential risk factor and the occurrence of perforations was analyzed using the Student's t-test for independent samples. The analysis showed no statistically significant difference in mean BMI values between patients who experienced perforations (AM=28.97, SD=2.255) and those without perforations (AM=26.97, SD=5.408); $t(173)=0.830$, $p=0.408$. The latter difference was also weak from a material point of view, $d=0.377$.

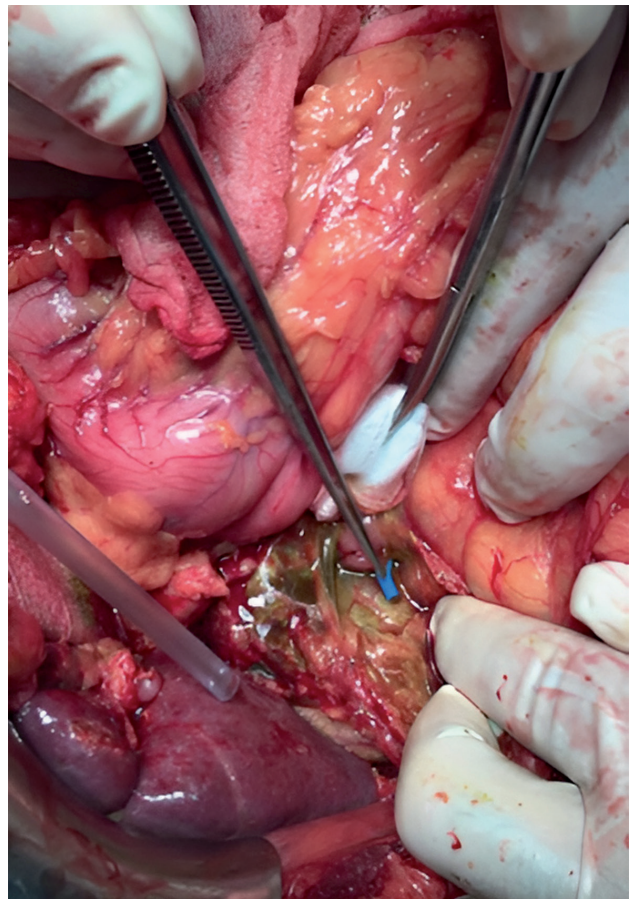


Fig. 2. Duodenum-biliary drainage in the retroperitoneum through a perforation hole in the duodenal wall (Stapfer I).

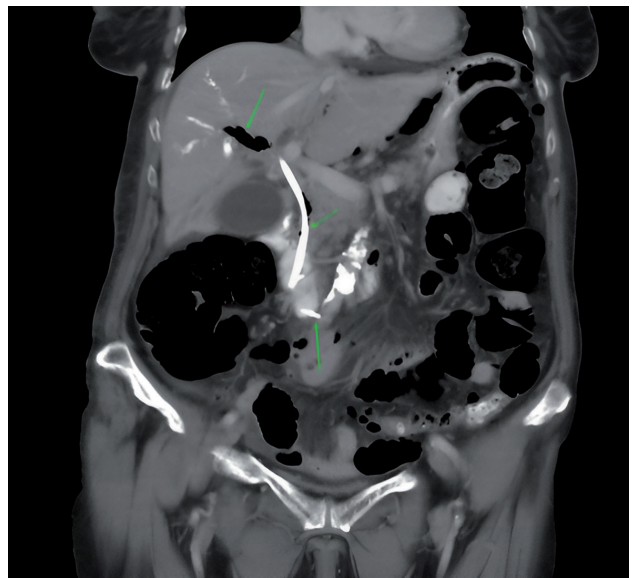


Fig. 3. Coronal CT section of the abdomen with intravenous contrast showing the pneumoperitoneum after ERCP with the introduction of DBD (Stapfer IV).

Tab. 1. AGREE classification of our patients.

Grading	Definition	Number of patients
No adverse event	<ul style="list-style-type: none"> A telephone contact with a general practitioner, outpatient clinic, or endoscopy service without any intervention, Extended observation of the patient after procedure in less than 3 hours, without any intervention 	–
Grade I	<ul style="list-style-type: none"> Adverse events with any deviation from the standard post-procedural course, without the need for pharmacologic treatment or endoscopic, radiologic, or surgical interventions 	–
Grade II	<ul style="list-style-type: none"> Adverse events requiring pharmacologic treatment with drugs other than those allowed for grade I adverse events (ATB, antithrombotics) Blood or blood product transfusion Hospital admission for more than 24 hours 	137 (78.3 %)
Grade III	<ul style="list-style-type: none"> Adverse events requiring endoscopic, radiologic, or surgical intervention 	Endoscopic intervention 27 (15.4 %)
		Surgical intervention 5 (2.8 %)
Grade IV	<ul style="list-style-type: none"> Adverse events requiring care in intensive care unit/critical care unit admission 	–
Grade V	<ul style="list-style-type: none"> Death of the patient 	6 (3 %)

Discussion

Consistent indication, preparation of the patient, appropriate technique selection, and subsequent care of the patient after the procedure can significantly contribute to reducing post-ERCP complications. Given that ERCP is an invasive method, it carries the risk of undesirable consequences. In the 21st century, ERCP can also be performed on an outpatient basis. The patient must, however, be educated about possible complications and the necessity of adherence to a strict regimen. In hospitalized

patients, blood samples should be assessed 24 hours after the ERCP procedure, alongside continuous monitoring for potential complications and prompt intervention if necessary. Our study, which focused on patients hospitalized at our clinic, provides insights into improving the prevention of early complications in future ERCP procedures. Freeman et al highlighted risk factors such as gender, associated comorbidities, and history of pancreatitis (17). Katsinelos et al conversely found no association of age and gender with post-ERCP complications. In our cohort, with average age of 58 years and higher proportion of women undergoing ERCP (18), our focus remains on identifying comorbidities and patients with a history of pancreatitis. For these patients, alternative methods such as magnetic resonance cholangiopancreatography (MRCP), endoscopic ultrasound, and percutaneous transhepatic biliary drainage could be considered (19).

We should prioritize prophylactic measures, especially for PEP, given its status as the most common complication, with an incidence in approximate range of 2–10 %. In our patient cohort, it occurred in 1.5% of patients (20–23). The use of non-steroidal anti-inflammatory drugs (NSAIDs) to prevent post-ERCP acute pancreatitis has long been debated. The recent ESGE guidelines reference 27 meta-analyses demonstrating the efficacy of NSAID prophylaxis in reducing PEP incidence (20). In these studies, the authors focused on various administration methods and differences between individual NSAIDs. According to Cheon et al, diclofenac has emerged as the most effective option (24). Geraci et al investigated different routes of administra-

Tab. 2. Comparison of average BMI value in patients with complications.

		BMI			Student t-test			
		No	AM	SD	t	df	P	d
Acute pancreatitis	–	102	27.19	5.527	0.470	173	0.639	0.072
	+	73	26.80	5.124				
Acute cholangitis	–	125	27.38	5.731	1.391	173	0.166	0.233
	+	50	26.14	4.173				
Perforations	–	170	26.97	5.408	–0.830	173	0.408	0.377
	+	5	28.97	2.55				
Bleeding	–	129	26.50	4.744	–2.209	173	0.029	0.379
	+	46	28.51	6.607				

AM – arithmetic mean, Mdn – median, SD – standard deviation, t – Student’s t-test for two independent samples, df – degrees of freedom, p – two-way level of statistical significance, d – Cohen’s d as an indicator of effect size

Tab. 3. Independent risk factors for complications after ERCP.

		p	CI (95%)		OR
Acute pancreatitis	BMI	0.915	0.940	1.057	0.997
	Repeated ERCP	0.803	0.487	1.747	1.085
	Previous acute pancreatitis	0.088	0.044	1.242	4.255
Acute cholangitis	BMI	0.345	0.898	1.038	0.966
	Repeated ERCP	0.860	0.444	2.645	1.084
	Previous acute cholangitis	0.001	2.566	18.391	6.869
Perforations	BMI	0.544	0.902	1.216	1.047
	Repeated ERCP	0.393	0.281	25.332	2.668
Bleeding	BMI	0.111	0.986	1.150	1.065
	Blood clotting disorders	0.001	7.354	77.101	23.813

p – two-way level of statistical significance, OR – odds ratio, CI – confidence interval

tion. They administered diclofenac orally, intramuscularly, intravenously, or rectally. Patients with rectal diclofenac had the lowest prevalence of post-ERCP pancreatitis (25). Another option to be considered is the fluid prophylaxis for PEP. However, given that many patients have associated comorbidities such as heart failure or chronic kidney disease, the administration of fluid prophylaxis should be carefully evaluated on an individual patient basis. ESGE recommends applying 3 ml/kg/h during ERCP and 20 ml/kg after ERCP to optimize patient hydration (10). Using sublingual nitrates PEP holds promise in preventing PEP, as highlighted in a meta-analysis carried out by Ding et al (26). These nitrates are particularly recommended for patients at high risk, as these drugs relax smooth muscles in the sphincter of Oddi and enhance blood flow to the pancreatic tissue (27). ESGE suggests administering 5 mg sublingual GNT before ERCP in patients with contraindications to NSAIDs or when aggressive hydration is not feasible in PEP prevention (10). While somatostatin and protease inhibitors on pancreatic tissue have long been recognized for their effects on pancreatic tissue, their use in reducing PEP incidence remains controversial. Although some studies have reported a reduction in the overall incidence of PEP after administration of somatostatin 30–60 minutes before ERCP (28, 29), its cost-effectiveness has been questioned. Moreover, in a recent meta-analysis, the risk reduction was marginal compared to placebo (30).

ERCP serves as both a diagnostic and therapeutic tool for acute cholangitis, but it can also inadvertently induce this condition. Cholangitis may occur following ERCP due to contamination of the sterile field by instruments or injection of contrast material. The estimated incidence of cholangitis ranges from 0.5% to 3% (10, 31), with a recorded incidence of 1% in our patient cohort. Preventing acute cholangitis involves the prophylactic administration of antibiotics (5). However, blanket antibiotic prophylaxis is not recommended due to potential adverse effects of antibiotics. Kager et al conducted a retrospective study confirming the efficacy of antibiotic prophylaxis for acute cholangitis in specific high-risk patient groups with proximal biliary obstruction, such as those with hilar tumors sclerosing cholangitis, pseudocyst pancreatitis, or incomplete biliary drainage. Additionally, antibiotic prophylaxis may be warranted for patients with prosthetic heart valves undergoing ERCP for unrelated reasons (5).

Prior to undergoing the ERCP procedure, it is essential for every patient to have their coagulation status assessed. The American Society classifies endoscopic biliary and pancreatic sphincterotomy for gastrointestinal endoscopy as procedures carrying a higher risk of bleeding (32). Therefore, patients with bleeding disorders should undergo proper preparation and evaluation before such intervention. Subsequently, these patients should be intensively monitored due to their susceptibility to bleeding or thrombosis.

Perforation represents the most severe complication of ECRP. It poses a life-threatening risk, necessitating rapid diagnosis and subsequent surgical or endoscopic revision. To-date, guidelines for preventing complications have not been established. The successful execution of endoscopic techniques largely relies on the expertise of experienced endoscopists. Nonetheless, vigilant patient monitoring and early symptom recognition play an

important role. Therefore, educating the patient about potential complications, dietary guidelines before and after the procedure and ensuring patient compliance are pivotal in mitigating the risk of complications.

Conclusion

In our retrospective study we focused on risk factors of early post-ERCP complications, particularly acute pancreatitis, acute cholangitis, bleeding, and perforation. We briefly noted the treatment of these patients and mortality. Successful mitigation of adverse effects of ERCP lies in correct indication of the patient, identification of risk factors, consistent preparation, and prevention. Educating the patients and monitoring their condition after the procedure are essential aspects. The emergence of complications requires prompt initiation of treatment. Manifestations of peritoneal irritation demand a prompt surgical intervention to eliminate fatal consequences. Every invasive method carries the risk of adverse effects.

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