ORIGINAL ARTICLE

Risk Factors for ERCP-related Complications and what is the specific role of ASGE Grading System

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Background: Endoscopic retrograde cholangiopancreatography (ERCP) is one of the main therapeutic and sometimes diagnostic methods in biliary and pancreatic diseases. A grading system for the difficulty of ERCP (grade one to four, the higher grade represents the more complexity of the procedure) has been developed by the American Society for Gastrointestinal Endoscopy (ASGE). This study aimed to assess the prevalence of ERCP-related complications, their common risk factors, and specifically the role of difficulty of the procedure based on ASGE grading. **Material and Methods:** This cross-sectional study was performed on 620 ERCP-operated patients over 4 years in two tertiary referral centers affiliated with Isfahan University of Medical Sciences. Data about the difficulty of procedures based on the ASGE grading scale, complications including pancreatitis, bleeding, infection, perforation, arrhythmia, respiratory suppression, aspiration, and major common risk factors were collected. **Results:** The overall prevalence of complications was 11.6% including pancreatitis 8.2%, perforation 0.8%, gastrointestinal bleeding 1.3%, cholangitis 2.4%, and cardiopulmonary problems 0.5% (arrhythmia 0.3% and respiratory depression 0.2%). Patients with pancreatic contrast injection (66.7% vs. 11.3% $P = 0.04$) and sphincter of Oddi dysfunction (SOD) (44.4% vs. 11.1%; $P = 0.01$) showed a statistically significant higher overall complication rate. The association of these risk factors remained significant in multivariable logistic regression analysis. Patients with pancreatic contrast injection also showed a statistically significant higher prevalence of post-ERCP pancreatitis (66.7% vs. 11.3% $P = 0.04$). Furthermore, a significantly higher prevalence of arrhythmia (3.6% vs. 0; $P = 0.008$) was observed among patients with difficult cannulation. Based on the ASGE difficulty grading score, most of the patients were classified as grade 2 (74.2%) and 3 and 4 (23.4%). No statistically significant difference was noted between the difficulty-based groups in terms of complications. **Conclusion:** The current study showed that the most critical risk factors of ERCP-induced complications were pancreatic contrast injection and SOD. ASGE grading scale for ERCP complexity did not predict the occurrence of complications in our study population.

Key words: American Society for Gastrointestinal Endoscopy grading, cholangitis, pancreatitis, postendoscopic retrograde cholangiopancreatography complications, risk factor

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INTRODUCTION

When endoscopic retrograde cholangiopancreatography (ERCP) was first described by McCune, it was exclusively diagnostic, but over the past five decades, significant advances in endoscopic equipment made it possible to use it as a therapeutic technique.[1] ERCP is a high-risk procedure with 5%–10% of mild-to-severe complications, such as pancreatitis, bleeding, perforation, and infection.[2-6] Pancreatitis is the most common complication but various studies show different frequencies of sequels, which may be due to discrepancy in ERCP difficulty or target populations.[6,7] Numerous physicians, patients, and procedure-based risk factors are related to post-ERCP complications.[8-11] By precise identification of risk factors, ERCP can be avoided in high-risk

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groups, and to reduce cost in low-risk cases, it can be done in an outpatient setting.[12]

Many studies have been performed to evaluate post-ERCP complications and related risk factors.[8-11] It has, however, been difficult to compare various studies, due to the differences in the target populations, manner of data recording, and analysis.[3] Nonetheless, many scoring systems for grading ERCP difficulty have been published to compare different studies.[13,14] The American Society for Gastrointestinal Endoscopy (ASGE) released a new grading system for the complexity of ERCP procedures, which has been less studied.[15] According to the ASGE grading system, patients are divided into four groups based on the complexity of the procedure and a higher grade represented more complex difficulties.[15] This study aimed to assess the prevalence of ERCP-related complications, their common risk factors, and specifically the role of difficulty of the procedure based on the ASGE grading scale.

MATERIALS AND METHODS

Study design and patients

This cross-sectional study was performed on existing data from 620 ERCP-operated patients for 4 years (March 2016–September 2019) in two tertiary referral centers who had our study inclusion criteria were recruited in our study. All selected patients were over 18 years old and those with incomplete documentation were excluded. Before the procedure, informed consent was taken from all patients or if not, their relatives. The difficulty of procedures based on the ASGE grading system was determined and complications and their risk factors were collected and compiled in a checklist. The local ethics committee has approved the study protocol by the approval code: IR.MUI.MED.REC.1399.271.

Procedures and data collection

ERCPs were performed by an endoscopist with more than 5 years of experience and about 120 procedures per year, using a standard duodenoscope (PENTAX EPK-1000 3.8 mm channel). Patients have been sedated by a combination of midazolam-propofol. Serum amylase level was checked 6 h after the procedure and repeated 12 h and 24 h later as required. All patients received nonsteroidal anti-inflammatory drugs before ERCP. Pancreatic stents were used in only a small number of patients. Patients were instructed to come back to the hospital in cases of symptoms such as fever, abdominal pain, vomiting, jaundice, bloody vomit, or black stools, and in such situations, necessary tests including complete blood count, serum amylase, abdominal X-ray, and computed tomography (CT) scan of the abdomen were requested.

Pancreatitis was defined as an increased level of serum amylase and lipase to more than three times the upper limit of normalcy, together with typical left upper quadrant abdominal pain.[16] Bleeding was determined by a drop in Hb of more than 2 g/dl with hematemesis or melena.[16] Infection (cholangitis) was illustrated by the rise in temperature to over 38°C for at least 1 day as well as jaundice, without evidence of other concomitant infections.[16] Perforation was depicted as abdominal pain and the presence of free air in the abdomen based on data from an abdominal CT scan. Difficult cannulation was construed as cannulation of the pancreatic duct more than two times and common bile duct cannulation using a needle knife. Sphincter of Oddi dysfunction (SOD) diagnosis was based on the revised Milwaukee SOD classification system,[17] independent of any manometric findings. Pancreatic contrast injection was characterized as the entrance of the contrast agent into the pancreatic duct. Arrhythmia was defined as nonsinus rhythm, sinus bradycardia, or tachycardia. Respiratory suppression was defined as a decrease in O_2 saturation or respiratory rate that requires injection of flumazenil. Aspiration was described as the presence of a productive cough and typical findings on imaging.

Considered risk factors included age, gender, previous history of pancreatitis, difficult cannulation, pancreatic contrast injection, SOD, and the difficulty of procedures based on the ASGE grading system.[9,10,18,19] Complications recorded included pancreatitis, bleeding, infection, perforation, arrhythmia, respiratory suppression, and aspiration.

Statistical analysis

Statistical analysis was performed using the SPSS version 24 (SPSS Inc., Chicago, IL, USA). Continuous variables were presented as mean ± standard deviation and categorical variables as numbers (percentage). The univariate association of each risk factor with overall complications or separately was evaluated using independent samples *t*-test, Chi-squared, or Fisher's exact tests. Those significant risk factors in univariate analyses were entered into univariate and multivariable logistic regression and their association with complications was quantified by odds ratio (OR) and 95% confidence interval (CI) for OR. Statistical significance was set at $P < 0.05$.

RESULTS

Finally, 620 patients from 738 studied patients' files enrolled in this study; 118 cases were excluded due to incomplete or lack of essential data. The mean age of patients was 60.5 ± 19.1 years, and the male-to-female ratio was 50%. Most of the patients were rated as grade 2 (74.2%) and 3 and 4 (23.4%) according to the ASGE grading system [Table 1].

Biliary type pain was the main reason for ERCP [Figure 1], and choledocholithiasis was the main finding after ERCP [Figure 2]. Pancreatic stents were used in only a small number of patients (32–5.2%); of these, five developed pancreatitis.

Overall complications were seen in 72 (11.6%) patients and the most common complication was pancreatitis 8.2%, perforation 0.8%, gastrointestinal (GI) bleeding 1.3%, cholangitis 2.4%, and cardiopulmonary problems 0.5% (arrhythmia 0.3% and respiratory depression 0.2%). Respiratory aspiration was not seen in any of the patients. On the other hand of 72 patients who had at least one of the complications, 63 (10.2%) had one, 8 (1.3%) had two and 1 (0.2%) had three complications. Among the studied patients, 2.3%, 24.7%, 44.7%, 24.4%, and 4% of patients had one, two, three, four, and five risk factors of gender, previous history of pancreatitis, difficult cannulation, pancreatic contrast injection, and SOD.

The association of each risk factor with overall complications (experiencing at least one of the complications) has been evaluated. The results were reported in Table 2. As can be seen among studied risk factors, patients with pancreatic contrast injection (66.7% vs. 11.3% P = 0.04) and SOD (44.4% vs. 11.1%; P = 0.01) showed a statistically significant higher overall complications rate. The results of univariate logistic regression showed pancreatic contrast injection OR: 15.62 (95% CI: 1.4–174.60) and SOD OR: 6.40 (95% CI: 1.68–24.37) increase significantly the risk of experiencing at least one complication (overall complications). The association of these risk factors remained significant in multivariable logistic regression; OR: 10.51 (95% CI: 0.83–133.72; P = 0.07, marginally significant at $P < 0.1$) for pancreatic contrast injection and OR: 5.21 (95% CI: 1.27–21.292; P = 0.02) for SOD.

We performed the association analysis of all risk factors with pancreatitis, cholangitis, and bleeding, and other complications were not analyzed; because they occurred rarely among our study population.

The results of the association of all risk factors with pancreatitis, cholangitis, and bleeding separately have been presented in Table 3. Among studied risk factors, only pancreatic contrast injection showed a significant association with pancreatitis (66.7% vs. 7.9%, P = 0.02). Logistic regression analysis showed pancreatic contrast injection increase significantly the risk of pancreatitis OR: 23.18 (95% CI: 2.07–260.23; P = 0.01).

Marginally, a significant increasing trend was observed along with the increase in the ASGE grading system in terms of experiencing GI bleeding (P = 0.074). *Post hoc* proportion comparisons showed patients at grade 3 and 4 (2.8% vs. 0; P = 0.004) and patients at grade 2 (0.9% vs. 0; P = 0.01) of the ASGE grading system compared with patients at grade 1 had significant risk of experiencing GI bleeding.

DISCUSSION

Although ERCP is one of the main modalities of therapy for biliary and pancreatic diseases, it is not possible to definitively prevent post-ERCP complications, even when the procedure is performed by an experienced endoscopist.[2,7,20] Few studies evaluated post-ERCP complications and related risk factors with heterogeneous findings, which may be due to differences in the target population, study design, definition of complications, and endoscopists' experience.[4,5,18,19,21] Compared to other endoscopic procedures, ERCP carried the highest risk of complications; most of which are of mild-to-moderate severity.[4,6,22,23] Some prophylactic strategies were found to be relatively effective in reducing post-ERCP complications and especially pancreatitis.[24] The use of somatostatin or gabexate, prophylactic pancreatic stent placement, and patient stratification were applied but definite prophylaxis is still open to discussion.[24,25] By

Table 1: Frequency of complexity groups

ASGE grading	Grade subgroup	Number of patients, *n* (%)	Total, *n* (%)
Grade 1	Biliary stent removal/exchange	12 (80)	15 (2.42)
	Deep cannulation of the duct of interest, main papilla, sampling	3 (20)	
Grade 2	Biliary stone extraction <10 mm	277 (60.22)	460 (74.19)
	Treat extrahepatic benign and malignant strictures	175 (38.04)	
	Treat biliary leaks	7 (1.52)	
	Place prophylactic pancreatic stents	1 (0.22)	
Grade 3	Biliary stone extraction >10 mm	115 (80.42)	143 (23.07)
	Management of acute/recurrent pancreatitis	15 (10.49)	
	Manage suspected SOD (with or without manometry)	9 (6.29)	
	Treat benign biliary strictures, hilum, and above	4 (2.80)	
Grade 4	Pancreatic stones impacted and/or >5 mm intrahepatic stones	2 (100)	2 (0.32)
Total			620

ASGE=American Society for Gastrointestinal Endoscopy, SOD=Sphincter of Oddi dysfunction

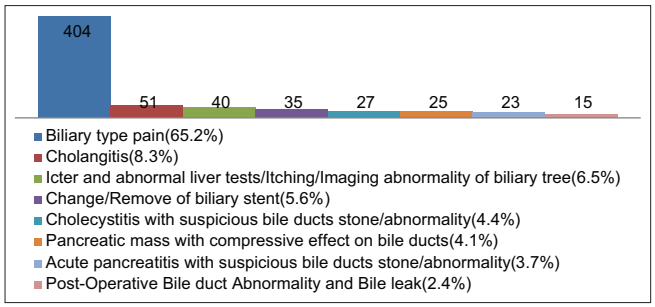


Figure 1: Reason for ERCP. ERCP = Endoscopic retrograde cholangiopancreatography

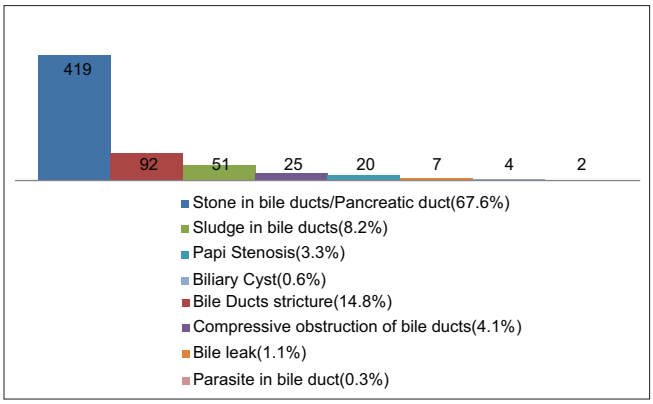


Figure 2: ERCP findings. ERCP = Endoscopic retrograde cholangiopancreatography

precise identification of risk factors, ERCP can be avoided in high-risk groups and alternative methods such as magnetic resonance cholangiopancreatography (MRCP), endoscopic ultrasound, and percutaneous transhepatic biliary drainage can be used.[12,20]

As reported by Katsinelos, *et al.*, we found that age and gender were not related to the post-ERCP complications.[12] In this study, a history of pancreatitis was not found to be a risk factor for complications. Other studies revealed a significant relationship between patient-related risk factors and post-ERCP complications, especially pancreatitis.[2,26,27] The lower number of studied patients and the deficiencies in recorded data used to determine the history of the previous pancreatitis can explain such discrepancy.

Patients with pancreatic contrast injection showed a statistically significant higher overall complication rate; and more than 66% of them developed pancreatitis after ERCP, so pancreatic contrast injection, as reported by other studies, seems to be a risk factor for overall post-ERCP complications and specifically pancreatitis.[21,26,28]

Patients with SOD showed a statistically significant higher overall complication rate; therefore, SOD was a risk factor for overall post-ERCP complications, and this finding is consistent with previous studies.[18,28]

Difficult cannulation was not found to be a risk factor for post-ERCP complications, but other studies depicted it as a significant risk factor.[18,19,21,28] The definition of difficult cannulation varies between different studies[10,12,19] and this can explain the discrepancy between the findings of this study and the others.

The frequency of different levels of ERCP complexity varies widely compared to other studies[29,30] which is a rational finding and can be due to the differences in patients' characteristics. In this study, like the others, the complexity of ERCP according to the ASGE grading system was not found to be a risk factor for post-ERCP complications.[29,30] This can be explained by the three following reasons: (1) the ASGE grading system is eminence rather than evidence based as mentioned by its providers, (2) the size of removed biliary stones, which can differentiate grade 2 from 3, was determined approximately, not accurately, and (3) the synergistic effect of multiple parameters determining the grade of complexity was not considered in the grading system, for example, a stone measuring <10 mm in diameter removed from a strictured common bile duct is the same as a similar stone removed from a normal common bile duct (both regarded as grade 2) and this may not be rationally true.

Table 2: Association of each risk factor with experiencing at least one of post endoscopic retrograde cholangiopancreatography complications

Variable	Complications		*P**
	Yes (*n*=72), *n* (%)	No (*n*=548), *n* (%)	
Age (mean±SD)	61.74±19.32	60.32±19.12	0.825
Gender			
Male	34 (11.0)	276 (89.0)	0.616
Female	38 (12.3)	272 (87.7)	
History of pancreatitis			
Yes	2 (5.3)	36 (94.7)	0.296
No	70 (12.0)	512 (88.0)	
Difficult cannulation			
Yes	7 (12.7)	48 (87.3)	0.787
No	65 (11.5)	500 (88.5)	
Pancreatic contrast injection			
Yes	2 (66.7)	1 (33.3)	0.037
No	70 (11.3)	547 (88.7)	
ASGE grade			
1	2 (13.3)	13 (86.7)	0.11
2	47 (10.2)	413 (89.8)	
3 and 4	23 (15.9)	122 (84.1)	
SOD			
With	4 (44.4)	5 (55.6)	0.013
Without	68 (11.1)	543 (88.9)	

*Resulted from independent samples *t*-test for continuous and Chi-squared or Fisher's exact test for categorical data. SOD=Sphincter of Oddi dysfunction, ASGE=American Society for Gastrointestinal Endoscopy, SD=Standard deviation

Table 3: Association of all risk factors with more prevalent post endoscopic retrograde cholangiopancreatography complications separately

Variable	Pancreatitis		*P**	Cholangitis		*P*	Gastrointestinal bleeding		*P*
	Positive, *n* (%)	Negative, *n* (%)		Positive, *n* (%)	Negative, *n* (%)		Positive, *n* (%)	Negative, *n* (%)	
Age	58.00±20.67	60.71±18.99	0.334	69.27±10.05	60.27±19.26	0.072	63.88±19.33	60.44±19.14	0.614
Gender									
Male	20 (6.5)	290 (93.5)	0.14	10 (3.2)	300 (96.8)	0.296	5 (1.6)	305 (98.4)	0.725
Female	31 (10.0)	279 (90.0)		5 (1.6)	305 (98.4)		3 (1.0)	307 (99.0)	
History of pancreatitis									
Yes	2 (5.3)	36 (94.7)	0.76	0	38 (100.0)	0.616	0	38 (100.0)	>0.99
No	49 (8.4)	533 (91.6)		15 (2.6)	567 (97.4)		8 (1.4)	574 (98.6)	
Difficult cannulation									
Yes	4 (7.3)	51 (92.7)	>0.99	0	55 (100.0)	0.384	2 (3.6)	53 (96.4)	0.153
No	47 (8.3)	518 (91.7)		15 (2.7)	550 (97.3)		6 (1.1)	559 (98.9)	
Pancreatic contrast injection									
Yes	2 (66.7)	1 (33.3)	0.019	0	3 (100.0)	>0.99	0	3 (100.0)	>0.99
No	49 (7.9)	568 (92.1)		15 (2.4)	602 (97.6)		8 (1.3)	609 (98.7)	
ASGE grade									
1	2 (13.3)	13 (86.7)	0.467	1 (6.7)	14 (93.3)	0.295	0 (0.0)	15 (100.0)	0.074
2	34 (7.4)	426 (92.6)		8 (1.7)	452 (98.3)		4 (0.9)	456 (99.1)	
3 and 4	15 (10.3)	130 (89.7)		6 (4.1)	139 (95.9)		4 (2.8)	141 (97.2)	
SOD									
With	4 (44.4)	5 (55.6)	0.004	0	9 (100.0)	>0.99	0	9 (100.0)	>0.99
Without	47 (7.7)	564 (92.3)		15 (2.5)	596 (97.5)		8 (1.3)	603 (98.7)	

**P*-values resulted from independent samples *t*-test for continuous and Chi-squared or Fisher's exact test for categorical data. SOD=Sphincter of Oddi dysfunction, ASGE=American Society for Gastrointestinal Endoscopy

Because this study was performed on existing patient data, one of the limitations is the possibility of incorrect or incomplete recording of information.

CONCLUSION

This study provides an estimate of the ERCP-related complications and their common risk factors. The most critical risk factors of ERCP-induced complications were pancreatic contrast injection and SOD. Some of the considered risk factors, including age, previous history of pancreatitis, etc., were not related to complications; this can be due to study limitations. The ASGE grading scale for ERCP complexity did not predict the occurrence of complications in our study population.

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Conflicts of interest
There are no conflicts of interest.

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