# Evaluating the Outcomes of Endoscopic Retrograde Cholangiopancreatography: Indications and Complications

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## Abstract

**Background and aim:** Endoscopic retrograde cholangiopancreatography (ERCP) is the gold standard for the treatment of the biliary and pancreatic diseases. Post-ERCP complications are inconsistent and sometimes have insufficient patients' follow-up. The aim of this study was to determine the outcomes of performing ERCP and compare these with published figures. **Methodology:** A prospective single-center study was conducted to evaluate the ERCP procedure on 155 consecutive patients during a period of 12 months. All ERCPs were therapeutic procedures or performed with therapeutic intent at Taleghani Hospital in Tehran, Iran. Data on the patients' characteristics, ERCP indications and findings during the procedure and after that as complications were collected. All results and complications were recorded simultaneously and entered into the database. **Results:** Total of 155 procedures was performed. Bile duct cannulation rate was 92.3% and therapeutic success rate was 88.5%. Complications occurred in 18.7% of patients and ERCP specific mortality was 1.3%. The most common complications were mild pancreatitis (7.7%), followed by cholangitis (7.1%), perforation (1.3%), and bleeding (1.3%). Choledocholithais was more common in patients with post-ERCP complications (P=0.01). Female gender, young age ($\leq$ 65 years), periampullary diverticulum, suspected sphincter of Oddi dysfunction (SOD), bile duct stent placement were not found to be risk factors for overall complications. Multivariate analysis showed a choledocholithais and PD guidewire entrance as independent risk factors for overall complications (P < 0.05). **Conclusion:** Despite its associated morbidity and risk of mortality, ERCP is an important method for managing the pancreatico-biliary diseases. Our indications, interventions, and complications rates as well as risk factors were comparable to those reported in other countries.

**Keywords:** Post-ERCP complications; Endoscopic sphincterotomy: Post-ERCP pancreatitis

## Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) was first introduced by the surgeon William S. McCune and his co-workers (1909-1998) in US as a diagnostic tool for evaluating diseases of the biliary tract and pancreas. [1] Eventually, it became a highly therapeutic procedure, which is mainly used to stent biliary strictures and remove common bile duct stone (CBD stone) or pancreatic duct after sphincterotomy. [2] It is less commonly used for diagnostic procedure because of the increased availability of the less invasive tools such as magnetic resonance cholagiopancreatography (MRCP) and endoscopic ultrasound (EUS). [3] ERCP was a revolutionary method and has provided new insights into imaging and therapeutic approaches, particularly in the field of pancreatico-biliary disorders. The general role of ERCP is controversial in the treatment of chronic pancreatitis where pain is a dominant symptom. ERCP can be used to perform trans papillary drainage of pseudocysts when there is a relationship with pancreatic duct; in addition, ERCP can be used to obtain samples from the duct when a mass is suspected to be precancerous or malignant. [4,5]

Although ERCP is a powerful therapeutic tool, there is a substantial risk for complication. [6] These complications are associated with significant morbidity and mortality and can often lead to hospitalization or prolongation of hospital stay. [7] Previous studies suggest that complications occur in about 10% of patients with an overall mortality of about 0.1-0.5%. [8,9] Complication includes post-ERCP pancreatitis (PEP), perforation of the esophagus, stomach, duodenum and jejunum, cholangitis, bleeding and anesthetic risks including cardiorespiratory complications. [10] Pancreatitis is the most common adverse event after ERCP. Its incidence varies between 1-7% and can reach values up to 25% in high-risk patient groups. The vast majority of post-ERCP pancreatitis are mild or moderate; however, 1-5% of patients are likely to develop sever pancreatitis, which can result in prolonged hospitalization and the need for endoscopic or surgical procedures. [11,12] Given the importance of ERCP therapeutic method in malignant

pancreatico-biliary diseases and the lack of knowledge in post-ERCP complications, the aim of this study was to determine the outcomes of performing ERCP at Taleghani Hospital as the main center of gastroenterology in Tehran and to identify whether ERCP is a safe and effective option in this center or not. In addition, the overall complication rate and risk factors for therapeutic ERCP complications were identified.

## Patients and Methods

In this prospective single-center study, 155 consecutive patients who underwent ERCP in a tertiary care hospital during a one-year period (2016–2017) were analyzed. All ERCPs were therapeutic procedures and all were performed at Taleghani Hospital under supervision of a gastroenterology specialist. All patients submit their written informed consent for participating in this research before the ERCP procedure, and the study protocol was approved by the ethics committee of the Research Center for Gastroenterology and Liver Diseases at Shahid Beheshti University of Medical Sciences (IR.SBMU.RIGLD. REC.1395.110).

Data on the patients' clinical characteristics, ERCP indication and findings, cannulation technique, devices used during the procedure, performance of sphinctertomy and complication were collected during the procedure. All results and complications were recorded simultaneously and entered into the database. Exclusion criteria were to have a history of biliary sphincterotomy or pre-cut sphincterotomy, pre-procedure active pancreatitis, pregnancy, mental disability, or refusal to participate.

Post-ERCP complications were defined based on those described by Cotton et al. [10] The included pancreatitis were defined as abdominal pain persisting for at least 24h associated with a serum amylase greater than three times the upper limit of the normal. Mild pancreatitis was the case which required admission for three or fewer days, and was moderate for 4 to 10 days and severe for more than 10 days. Pancreatitis was also graded as severe if the patient had developed a phlegmon, pesudocyst or hemorrhage, or if he/she had required a further interventional procedure. Bleeding or hemorrhage was defined as clinical, rather than just endoscopic evidence of bleeding. Mild hemorrhage was defined as a hemoglobin drop of 30

g/L or less and not requiring transfusion, which is moderate by requiring a transfusion of four units or less and without needing for angiographic intervention or surgery, and is severe by requiring five or more units or intervention. Perforation was defined as air or contrast leak into the peritoneal or retroperitoneal cavity recognized either at the time of ERCP or on the subsequent imaging. A mild perforation refers to a possible or very small leak treated by fluids and nasogastric decompression for three or fewer days; a moderate perforation refers to any definite perforation treated medically within 4 to 10 days; and a severe perforation refers to medical treatment within more than 10 days or by any intervention (surgical or radiological). Cholangitis was characterized as a septic illness lasting more than 24h in an obstructed patient without any other clear source of infection. A mild cholangitis refers to a hospital treatment lasting less than 48 h; a moderate cholangitis refers to a hospital treatment lasting three or more days, or a treatment requiring endoscopic or percutaneous intervention; and a severe cholangitis refers to a septic shock or one that requires emergent surgery.

All complications were graded based on the time length of hospitalization and the need for surgery. A mild complication refers to a prolonged hospital stay of three days or less; a moderate complication refers to a prolonged hospital stay of 4 to 10 days; and a severe complication refers to a prolonged hospital stay lasting more than 10 days and/or one that requires intensive care or surgery [Table 1]. Mortality was defined as either ERCP-specific deaths or deaths resulted from all causes within 30 days. It was considered ERCP-specific if the death was secondary to a complication clearly related to the procedure, which occurs in organs traversed or treated by ERCP and has symptoms developing within 30 days.

### Follow up

After the ERCP procedure, all patients were admitted to the hospital for 24 hours and then were discharged with introductions to call or return back to the hospital in the case of occurring any problem. Those with suspected post-ERCP complications were admitted to the hospital for further management. All patients were controlled in the outpatient clinic or by telephone contact within 30 days after ERCP procedure to detect any delayed complications.

**Table 1: Classification of the severity of ERCP-related complications.**

| Complications | Mild | Moderate | Severe |
|---|---|---|---|
| Pancreatitis | Typical abdominal pain and amylase increase >3 times the upper normal value 24 hours after ERCP Requires hospital admission for less than three days | Pancreatitis that requires hospital admission for 4-10 days | Pancreatitis that requires hospital admission for >10 days, or presence of local complications or need for intervention |
| Bleeding | Hematemesis or melena Haemoglobin decrease of less than 2 g/dl No need for red blood cell transfusion | Red blood cell transfusion (four units or less) No need for angiographic or surgical treatment | Red blood cell transfusion (>5 units) Need for angiographic or surgical treatment |
| Perforation | Possible perforation or minor contrast leak (O minor collection) treatable with IV hydration, diet restriction and antibiotics for <3 days | Perforation confirmed by Rx, with medical treatment for 4-10 days | Medical treatment for >10 days or need for intervention (surgical or non-invasive drainage) |
| Cholangitis | >38°C, 24-48 hours | Febrile or septic illness required more than 3 days of hospital treatment or endoscopic or percutaneous intervention | Septic shock or surgery |

## Statistical analysis

Categorical variables were analyzed using the chi-squared and Fisher's exact tests and were considered as appropriate, while continuous variables were expressed by means and standard deviations (SDs) and analyzed using the Student t-test. Factors associated with increased risk for complication development were examined by univariate and multivariate analysis. Logistic regression was performed using Statistical Package for Social Science program (SPSS 21.0, SPSS Inc., Chicago, IL). Factors with $P < 0.15$ in univariable analysis were entered into a stepwise logistic regression model in order to estimate the adjusted odds ratios (ORs) with a confidence interval (CI) of 95%. In the multivariable analysis, the statistical significance was set at $P < 0.05$.

**Table 2: Characteristics of the patients and indications of ECP (N=155).**

| Characteristics | | Number (%) |
|---|---|---|
| Sex | Male | 87 (56.1) |
| | Female | 67 (43.9) |
| Age (Mean ± SD) years | | 58.4 ± 16.0 |
| Age range (years) | | 9-88 |
| Age | ≤65 | 105 (67.7) |
| | >65 | 50 (32.3) |
| BMI (Mean ±SD) Kg/m² | | 25.0 ± 4.0 |
| BMI | ≤25 | 94 (60.6) |
| | ≤25.1-29.9 | 39 (25.2) |
| | ≥30 | 22 (14.2) |
| History of ERCP | Yes | 30 (19.4) |
| | No | 125 (80.6) |
| Previous Sphincterotomy | Yes | 18 (11.6) |
| | No | 137 (88.4) |
| **Indications** | | **Number (%)** |
| Choledocholithiasis | | 76 (49.0) |
| Biliary or pancreatic cancer | | 32 (20.6) |
| Bile duct stricture | | 16 (10.3) |
| Bile duct sludge | | 8 (5.2) |
| PSC * | | 8 (5.2) |
| History of pancreatitis | | 7 (4.5) |
| Klatskin tumor | | 6 (3.9) |
| Hydatid cyst | | 2 (1.3) |

* PSC: Post-Cholecystetomy Complication

**Table 3: Characteristics of ERCP procedure (N=155).**

| Characteristics of ERCP procedure | | Number (%) |
|---|---|---|
| Manipulation time around papillary orifice | <5 min | 90 (58.1) |
| | 5-10 min | 42 (27.1) |
| | >10 min | 23 (14.8) |
| Number of cannulation attempts | <5 | 105 (67.7) |
| | 5-10 | 33 (21.3) |
| | >10 | 17 (11.0) |
| Duration of ERCP | <20 min | 52 (33.5) |
| | 20-60 min | 95 (61.3) |
| | >60 min | 8 (5.2) |
| ERCP difficulty grading | Grade 1 | 104 (67.1) |
| | Grade 2 | 33 (21.3) |
| | Grade 3 | 18 (11.6) |
| Minor papilla morphology | Normal | 154 (99.4) |
| | Edematous | 1 (0.6) |
| Major papilla morphology | Normal | 126 (81.3) |
| | Small | 6 (3.9) |
| | Edematous | 17 (11.0) |
| | Tumoral | 6 (3.9) |
| Periampullary diverticulum | Yes | 13 (8.4) |
| | No | 142 (91.6) |

## Results

### Procedures, indications and findings

During the study period (2016-2017), 155 consecutive patients underwent therapeutic ERCP at Taleghani Hospital. The sample consists of 87 (56.1%) male and 68 (43.9%) female. The mean age was 57.9 ± 15.6 years (range: 9-88 years). The most common indications for ERCP were choledocholithiasis 76 (49.0%), Bile duct cancer 19 (12.3%), and bile duct stricture 16 (10.3%), followed by pancreatic cancer (8.4%), bile duct sludge (5.2%), PSC (5.2%), and history of pancreatitis (4.5%) [Table 2].

According to Schultz's grading system, [13] 67.1% of the procedures were graded as with difficulty level 1, 21.3% were graded as with difficulty level 2, and the remaining, i.e., 11.6%, were graded as with difficulty level 3. More than half of the ERCP process (61.3%) was performed between 20 and 60 minutes, 33.5% of ERCP was done within less than 20 minutes, and only 5.2% lasted more than one hour. From 13 patients were diagnosed to have periampullary diverticulum, and 8 (61.5%) and 5 (38.5%) patients had type 1 and 2, respectively [Table 3].

The most common finding was choledocholithiasis 55 (35.5%), bile duct sludge 52 (33.5%), bile duct stricture 36 (23.2%), and intrahepatic dilation 16 (10.3%), followed by pancreatic duct stone, PSC and bile duct leaks by 6 (3.9%), 2 (1.3%) and 1 (0.6%) respectively. A total of 15 (9.7%) resulted was normal findings [Table 4].

**Table 4: Findings and therapeutic endoscopic interventions during ERCP (N=155).**

| Findings and Interventions | | Number (%) |
|---|---|---|
| Findings | Choledocholithiasis | 55 (35.5) |
| | Bile duct sludge | 52 (33.5) |
| | Bile duct stricture | 36 (23.2) |
| | Intrahepatic dilation | 16 (10.3) |
| | Pancreatic duct stone | 6 (3.9) |
| | PSC* | 2 (1.3) |
| | Bile duct leaks | 1 (0.6) |
| | Normal ERCP | 15 (9.7) |
| Interventions | Endoscopic sphicterotomy | 61 (39.4) |
| | Bile duct stent | 55 (35.5) |
| | Bile duct stone extraction | 50 (32.3) |
| | Electrocauthery current | 43 (27.7) |
| | Balloon sphincter dilation | 40 (25.8) |
| | Balloon dilation of SOD | 38 (24.5) |
| | PD guidewire enterance | 22 (14.2) |
| | Brush cytology | 18 (11.6) |
| | Pancreatic duct stent | 12 (7.7) |
| | Pre-cut fistulotomy | 11 (7.1) |

* PSC: Post-Cholecystetomy Complication

**Table 5: Complications and mortality rate of ERCP (N=155).**

| Complications and mortality rate | Number (%) |
|---|---|
| Post-ERCP pancreatitis | 12 (7.7) |
| Post-ERCP cholangitis | 11 (7.1) |
| Post-ERCP bleeding | 2 (1.3) |
| Post-ERCP perforation | 2 (1.3) |
| Post-ERCP cardiac vascular | 2 (1.3) |
| ERCP-specific mortality | 2 (1.3) |
| Non-ERCP mortality | 6 (3.9) |
| Total of mortality whiten 30 days | 8 (5.2) |

**Table 6: Risk factors for overall complications after therapeutic ERCP in univariate and multivariate analysis.**

| Risk factors | All procedure (N=155) | Overall Complications (N=29) | Univariate analysis | | | Multivariate analysis | | |
|---|---|---|---|---|---|---|---|---|
| | | | P-value | OR | 95% CI | P-value | OR | 95% CI |
| Female gender | 67 (43.9) | 13 (44.8) | 0.752 | 0.837 | 0.27-2.51 | | | |
| Age ≤ 65 | 105 (67.7) | 17 (58.6) | 0.110 | 0.414 | 0.14-1.22 | 0.183 | 1.64 | 0.64-4.19 |
| BMI ≥30 | 22 (14.2) | 5 (17.2) | 0.874 | 0.889 | 0.21-3.77 | | | |
| History of ERCP | 30 (19.4) | 6 (20.7) | 0.792 | 1.18 | 0.33-4.28 | | | |
| Previous sphincterotomy | 18 (11.6) | 6 (20.7) | 0.099 | 0.40 | 0.13-1.18 | 0.163 | 0.33 | 0.95-1.16 |
| Periampullary diverticulum | 13 (8.4) | 1 (3.4) | 0.648 | 1.71 | 0.17-17.33 | | | |
| PSC | 8 (5.2) | 1 (3.4) | 0.023 | 0.221 | 0.14-3.69 | 0.177 | 0.22 | 0.14-3.69 |
| Difficult cannulation | 23 (14.8) | 3 (10.3) | 0.094 | 12.78 | 0.64-25.0 | 0.331 | 1.56 | 0.37-6.60 |
| ERCP grade 3 | 18 (11.6) | 4 (13.8) | 0.115 | 0.117 | 0.08-1.68 | 0.804 | 0.35 | 0.08-1.74 |
| Choledocholithasis | 55 (35.5) | 4 (13.8) | 0.021 | 8.92 | 1.38-57.51 | 0.011 | 4.25 | 1.39-12.94 |
| Bile duct stent | 55 (35.5) | 15 (51.7) | 0.207 | 0.428 | 0.11-1.59 | | | |
| stone extraction | 50 (32.3) | 5 (17.2) | 0.815 | 0.824 | 0.16-4.16 | | | |
| Balloon dilation SOD | 38 (24.5) | 9 (31.0) | 0.045 | 0.270 | 0.07-0.97 | 0.110 | 0.66 | 0.27-1.61 |
| BSD | 40 (25.8) | 6 (20.7) | 0.131 | 3.04 | 0.71-12.9 | 0.417 | 1.41 | 0.53-3.77 |
| Blended current | 43 (27.7) | 9 (31.0) | 0.118 | 0.341 | 0.08-1.31 | 0.330 | 0.82 | 0.34-1.97 |
| Brush cytology | 18 (11.6) | 7 (24.1) | 0.099 | 5.6 | 0.72-43.4 | 0.230 | 0.472 | 0.13-1.60 |
| PD guidewire | 22 (14.2) | 1 (3.4) | 0.025 | 0.301 | 0.10-0.86 | 0.050 | 3.26 | 0.93-6.32 |
| sphincterotomy | 61 (39.4) | 9 (31.0) | 0.056 | 5.48 | 0.95-31.5 | 0.311 | 1.56 | 0.65-3.70 |
| Pre-cut sphincterotomy | 19 (12.3) | 4 (13.8) | 0.097 | 0.143 | 0.01-1.43 | 0.568 | 0.84 | 0.25-2.76 |

PSC: Post-Cholecystetomy Complication, BSD: Balloon Sphincter Dilatation

The therapeutic endoscopic interventions were applied during ERCP on 92.3% of patients, and successful cannulations, endoscopic sphincterotomy was performed on 61 (39.4% of) patients, of whom 19 (31.1%) had pre-cut sphincterotomy. Biliary and pancreatic duct stent were attributed to 67 (43.2% of) patients, of whom 55 (35.5%) had bile duct stent and 12 (7.7%) had pancreatic duct stent. Among 55 patients with bile duct stent, 47 (85.5%) had plastic and the remaining 8 (14.5%) had metal stent. Among 12 (7.7%) patients with pancreatic duct stent, 9 (75%) had prophylactic PD stent. Electrocautery current was implanted in 43 (27.7% of) patients and all of them had blended current. Balloon sphincter dilation (BSD) was performed on 40 (25.8% of) patients, among whom for 31 (77.5% of) patients, BSD was performed by the through the scope (TTS) balloon, and for the remaining 9 (22.5%) patients, BSD was performed by savary dilator. Balloon dilation of SOD was performed on 38 (24.5%) patients. PD guidewire, brush cytology, and pre-cut fistulotomy were performed on 22 (14.2%), 18 (11.6%), and 11 (7.1%) patients, respectively. When a therapeutic procedure was performed, it was successful in 124 (88.5% of) cases among 140 patients [Table 4].

## Complications and mortality

The total rate of complications in this study was 18.7%, occurring in 29 patients. The most common complications were pancreatitis 12 (7.7%), all of which were mild, followed by cholangitis 11 (7.1%). Table 5 provides the further details.

There were 8 (5.2%) patients who died within 30 days of having their ERCP. Two cases were ERCP-specific, having a cholangitis and perforation post-procedure as outlined above. The remaining 6 (3.9%) patients were reviewed, and their deaths deemed not to be as a result of ERCP. This non-ERCP mortality was related to progressive metastatic disease except one case. A 85-year-old male patient, who died due to comorbidity of cardiac vascular diseases, had cardiac arrested. Other causes for non-ERCP related mortality were biliary and pancreatic cancers. Comparison was made between patients who died within 30 days because of all causes and those who did not. Patients who died were significantly older than those who did not (mean = 70.3 vs. 58.4 years old; P < 0.001). There was no significant difference in terms of sex (P < 0.05) [Table 5].

## Risk factors for overall complications after therapeutic ERCP

A total of six variables including patients-related factors and 14 procedure-related factors were investigated as risk factors for overall complications after therapeutic ERCP by univariate and multivariate analysis. In the univariate analysis (Logistic regression), statistical significance was set at P < 0.15. Therefore, the univariate analysis showed that age is ≤ 65 years (P = 0.11 OR 0.414, 95% CI = 0.14-1.22) and previous sphincterotomy (P = 0.09 OR 0.40, 95% CI = 0.13-1.18) was a significant patient-related factor for complications. Significant procedure-related factors were found to be: PSC (P = 0.02 OR 0.221, 95% CI = 0.14-3.69), difficult cannulation (P = 0.09 OR12.78, 95% CI = 0.64-25.0), ERCP of grade 3 (P = 0.11 OR 0.117, 95% CI = 0.08-1.68), choledocholithasis (P = 0.02 OR 8.92, 95% CI = 1.38-12.9), balloon dilation SOD (P = 0.13 OR 3.04, 95% CI = 0.71-12.9), balloon sphincter dilation (P = 0.13 OR 3.04, 95% CI = 0.71-12.9), blended current (P = 0.11 OR 0.341, 95% CI = 0.08-1.31), brush cytology (P = 0.09 OR 5.6, 95% CI = 0.72-43.4), PD guidewire entrance (P = 0.02 OR 0.30, 95% CI = 0.10-0.86), shpincterotomy (P = 0.05, OR 5.48, 95% CI = 0.95-31.25), and Pre-cut sphincterotomy (P = 0.09, OR 0.143, 95% CI = 0.01-1.43).

Multivariate analysis after forward stepwise binary logistic regression on the pool of 20 potential risk factors for overall complications identified the following procedure-related

independent risk factors for post-ERCP complications (the statistical significance was set at P < 0.05 in the multivariate analysis) [Table 6]: choledocholithiasis (P < 0.05 OR 4.2, 95% CI = 1.39-16.41) and PD guidewire entrance (P<0.05, OR 3.26 95% CI 0.93-6.4).

## Discussion

ERCP is a valuable procedure in the treatment of a variety of pancreaticobiliary diseases. Despite the development of the technology and equipment of ERCP in recent years, the incidence of adverse events after ERCP has not decreased significantly and the complications after ERCP have been reported between 5% and 10%. [14,15] The identified risk factors for post-ERCP complications have a significant impact on the practice, helping in the implementation of appropriate pharmacological[16,17] and technical measures. [18,19] Therefore, in this study, we sought to evaluate the outcomes of performing ERCP and post-ERCP complications and identified the risk factors for overall complications at Taleghani Hospital as the main center of gastroenterology in Tehran.

The most common indications for ERCP in our study were choledocholithiasis (49%), pancreatico-biliary tumors (20.6%), and bile duct stricture (10.6). These are comparable to the indications reported by other studies. [20-22] The most common finding on ERCP was bile duct stone (35.5%). In most cases, this was associated with filling defects, strictures, or leaks. ERCP is the most likely primary treatment for choledocholithiasis. [23] It has been shown to be highly effective in detecting and removing bile duct stones before laparoscopic cholecystectomy. [24,25] When combined with endoscopic sphincterotomy and/ or biliary stenting, it also helps to diagnose and manage post-cholecystectomy residual bile duct stones and postoperative biliary complications such as bile duct injuries with bile leakage or stricture. [26,27]

The major endoscopic intervention applied during ERCP in our study was endoscopic sphincterotomy, which is one of the most important interventions that aids in the management of choledocholithiasis, papillary stenosis, sphincter of Oddi dysfunction, ampullary carcinoma in poor surgical candidates, and bile duct injuries. Also it facilitates biliary stent placement and access to pancreatic duct. [28] The other intervention applied during ERCP after endoscopic sphincterotomy in our study was biliary or pancreatic duct stent, and the most used bile duct stent in this study was plastic. Biliary stenting was successfully used in preoperative drainage or palliative treatment of pancreatico-biliary malignancies; especially when complete the bile duct clearance was not ensured. It was also used in patients with large bile duct stones that could not be removed in a single session. [29] In this study, the plastic stent was used more than the metal stent (85.5% vs. 14.5%), but we could not find any significant differences between the two type of stent and complications. The choice of stent depends on patient prognosis and the relative costs of metal stents and the number of repeating endoscopic ERCP. In general, plastic stents are reasonable for patients surviving less than three months and metal stents are more cost-effective for patients who are expected to live longer. [30-33]

In previous studies, complication and mortality rates of ERCP have been reported to range from 4.0% to 15.9%[33,34] and from 0.06% to 2.4%, [8,11] respectively. The total rate of complication (18.7%) in the current study was higher than that in the other studies. Post-ERCP pancreatitis (PEP) is one of the most serious complications, and in several studies, its incidence was reported to be between 1.3% to 15.1%. [35-39] A meta-analysis study conducted by Kochar et al. [40] on 108 randomized controlled trials (RCT) involving 13296 patients reported an overall incidence of 9.7% for PEP (95% CI = 8.6–10.7%), with an increased incidence of 14.7% (95% CI = 11.8–17.7%) in the high-risk patients. In our study, the rate of post-ERCP pancreatitis (PEP) was 7.7%, which is completely consistent with previous studies. In the present study, different from previous studies, no cases of moderate or severe PEP or long admission were reported. All cases were mild pancreatitis. This may be due to the use of anti-inflammatory drugs (NASIDS) that were given to the patients in a routine manner at this center. According to the previous studies, [41-44] the predictor factors for PEP include: younger age, female sex, normal serum bilirubin levels, a history of acute recurrent pancreatitis, and some procedure-related factors such as frequent pancreatic duct visualization, cannulation time > 10 min, needle-knife precut, pancreatic sphincterotomy, pancreatic duct stent implantation, pancreatic deep wire pass, and development of pain during the procedure. The placement of pancreatic stent can be used to reduce the risk of PEP. By conducting a meta-analysis, Mazaki et al. [45] showed the efficacy of pancreatic duct stent (PDS) placement for the prevention of PEP; they found a pooled relative risk (RR) of 0.39 (95% CI = 0.29-0.53) for the effective PDS as a preventive measure against PEP. In addition, Cennamo et al. [46] showed that the early precut strategy when facing a possible difficult biliary cannulation could reduce PEP incidence.

Perforation of the duodenum is one of the post-ERCP complications that may lead to great mortality if left untreated. As a serious complication after ERCP, perforations have been reported in some cases to occur in 0.35% to 2.1% of patients [10,47] and it occurred in 1.3% of patients in our study. According to previous studies, the risk of post-ERCP bleeding is (0.14-1.5%). [48-51] In our study, bleeding was reported in 1.3% of patients but it was minor bleeding that responded to local measures in the form of balloon compression, adrenaline spray, and thermal therapy. No cases of severe bleeding necessitating blood transfusion or long hospital admission were reported.

The present study has some limitations. The sample size was drawn from a single center-study. Many patients had ERCPs performed by their referring gastroenterologist. These patients typically have complex pancreatic or biliary diseases that might bias the findings of the study. Future studies with larger samples drawn from diverse communities are needed to support the findings.

## Conclusion

In the current study, Choledocholithais was more common in patients with post-ERCP complications (P = 0.01). Female gender, younger age (≤ 65 years), periampullary diverticulum, suspected sphincter of Oddi dysfunction, bile duct stent placement, and sphincterotomy were not found to be risk factors for overall post-ERCP complications. Multivariate

analysis showed choledocholithais and PD guidewire entrance as independent risk factors for overall complications (P < 0.05). Analysis of the risk factors was performed only for overall post-ERCP complications, and the number of other complications were too small for further analysis in our study.

## Acknowledgment

## Conflict of Interest

The authors disclose that they have no conflicts of interest.

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