Original Article

Success Rate and Adverse Events of Endoscopic Retrograde Cholangiopancreatography in North of Iran

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ABSTRACT

Background:
The efficacy of endoscopic retrograde cholangiopancreatography (ERCP) has increased significantly over time. However, there are few studies evaluating the success rate of ERCP in Iran.

Materials and Methods:
We aimed to evaluate the success rate, adverse events, and mortality of ERCP in an academic medical center. This cross-sectional study was conducted over 2 years between February 2018 and January 2020 and 347 patients were enrolled. The success rates and causes of procedure failure were recorded by the endoscopists. The patients were followed up for all adverse events until discharge.

Results:
Eventually, 302 patients ended the study. The most common indication for ERCP was CBD stone (73.2%). The ERCP procedure was successful in 240 (79.5%) patients. Unsuccessful outcomes were due to cardiovascular conditions (n=7) and endoscopic problems (n=34). Of 34 cases of impossible cannulation, in 32 (10.6%) cases, the papilla was found but cannulation was not possible and in 2 (0.7%) cases it was not possible to access the papilla. The mean (SD) age of the patients with unsuccessful ERCP was significantly higher than successful cases (P=0.001). The times of cannulation, cannulation attempts, and dye injection were significantly higher in unsuccessful procedures as compared with successful procedures (P=0.014, P=0.001, and P=0.001, respectively). The mean time of cannulation (minute) was 5.05 in successful ERCPs and 11.99 in unsuccessful cases (P=0.014). Failure of ERCP was significantly associated with adverse events during ERCP (P=0.001). The most common adverse event was post-ERCP pancreatitis (PEP) (14.6%) and severe cases were 3.6%. PEP was significantly associated with sex (P=0.034). There was no mortality during the study.

Conclusion:
We found that ERCP could be a safe and effective procedure, especially for patients under 65 years. The overall success rate and adverse events were compatible with the available data in the literature.

Keywords: Endoscopic retrograde cholangiopancreatography (ERCP), adverse events, common bile duct, post-ERCP pancreatitis (PEP), cannulation

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INTRODUCTION

The efficacy of endoscopic retrograde cholangiopancreatography (ERCP), as a standard procedure for the diagnosis and treatment of pancreaticobiliary disorders (1). has increased significantly over time. However, there are few studies evaluating the success rate of ERCP. In this regard, a multi-center study reported a success rate of 79.8% in hands-on training ERCPs and 85.5% in ERCPs performed by experienced endoscopists. Moreover, Lima and colleagues, in a recent study evaluating the risk factors for the success of ERCP, showed that patients with difficult cannulation, precutting, and endoscopic sphincterotomy-related complications had a significantly lower rate of success (2). Besides, hospitals with a lower ERCP volume reported higher rates of failure and longer hospitalization (3).

Among endoscopic procedures, ERCP is a complicated intervention with the highest rate of adverse events (4). The most common adverse event is post-ERCP pancreatitis (PEP). Other adverse events include perforations due to endoscope passage, hemorrhage (especially after sphincterotomy), cholangitis, hypoxia, and death (5,6). Previous studies have reported similar adverse events and mortality for ERCP (10-12% and 0.4-1.4% in two studies, respectively) (7,8). A meta-analysis reported that the overall incidence of PEP and the incidence of PEP in high-risk patients were 9.7% and 14.7%, respectively. Overall, the presence and duration of organ failure are more important in the pancreatitis severity rate than hospitalization (9).

In the literature, only a few studies have focused on the success rate of ERCP in Iran. Also, there are not enough studies evaluating the adverse events of ERCP in Iran. Therefore, in the present study, we aimed to evaluate the success rate, adverse events, and mortality of ERCP in a newly established ERCP unit in a tertiary care center in the northeast of Iran.

MATERIALS AND METHODS

Ethical considerations

This study was approved by the Ethics Committee of Golestan University of Medical Sciences (IR.GOUMS.REC.1396.63).

Study design

This cross-sectional study was conducted over 2 years between February 2018 and January 2020 at 5th Azar Academic Hospital in Golestan Province, northeast of Iran. All patients with indications for ERCP and complete medical records were enrolled in this study. Of 347 patients undergoing ERCP, 302 patients were recruited; the missing cases were due to missing data in the medical records (n=36) or the transfer of patients to another hospital (n=9).

The following data were recorded in this study: demographic data (e.g., age, sex, body mass index [BMI], and ethnicity), history of opium addiction, indications for ERCP, laboratory tests, the volume of dye injection to the common bile duct (CBD), cannulation time, pancreatic duct cannulation, dye injection into the pancreatic duct, methods of conducting the procedure (simple sphincterotomy, balloon dilation, and biliary stent placement), adverse events of ERCP, and success rate of ERCP. We did not use pancreatic duct stent in this study. All patients were also monitored for cardiac and anesthesia conditions before ERCP. Medical approval and informed consent were obtained from all patients.

ERCP procedure

The ERCP-related laboratory tests were requested before the procedure, including white blood cell count, hemoglobin count, platelet count, aspartate aminotransferase, alanine aminotransferase, direct bilirubin, alkaline phosphatase, prothrombin time, partial thromboplastin time, and international normalized ratio. Also, the amylase level, white blood cell count, and hemoglobin level were requested at four hours and one day post-ERCP. The success rates and causes of procedure failure were recorded by the endoscopists. The patients were followed up regarding the adverse events, including pancreatitis, hemorrhage, perforations, cardiopulmonary complications, apnea, cholangitis, sepsis, or any other adverse events until discharge.

The first method for cannulation was sphincterotomy and standard guidewire assistant. If it was not successful we used fistulotomy or trans-pancreatic sphincterotomy. For PEP prophylaxis, an indomethacin suppository (100 mg) was administered to all patients before the procedure.

All ERCPs were performed under conscious sedation by an anesthesiologist and monitored by cardiopulmonary monitoring. Also, for fluid therapy, the patients received adequate normal saline. The patients' vital signs were monitored regularly until discharge.

Outcomes

The primary outcome of this study was the success of the ERCP procedure. The secondary outcome was the incidence of adverse events and mortality related to ERCP.

Definitions

The success rate was defined based on achieving the therapeutic/diagnostic goal of ERCP, such as complete stone extraction or adequate drainage in strictures and malignancies. Achievement of the ERCP goals was classified into successful and unsuccessful. The PEP was also defined as follows: presentation of signs and symptoms (i.e., development or worsening of abdominal pain, nausea, and vomiting); a three-fold increase in the amylase level above the normal limit within 24 hours after ERCP; and hospitalization for more than 2 days. Moreover, the severity of PEP was classified into three groups: mild, requiring hospitalization for 2-3 days; moderate, requiring hospitalization for 4-10 days; and severe, requiring hospitalization for > 10 days, development of phlegmon or pseudocyst, hemorrhagic pancreatitis, or need for intervention (percutaneous drainage or surgery) (10).

Computed tomography (CT) scan was performed for patients with severe PEP for further evaluation. Besides, post-ERCP cholangitis was defined based on a fever higher than 38°C, abdominal pain, and leukocytosis. Post-ERCP hemorrhage was also defined as clinically significant bleeding. Perforation was defined based on radiological data, tomographic data, and clinical manifestations (abdominal pain) (11). Besides, a decrease in oxygen saturation of less than 90% for two minutes was recorded as hypoxia (12). Finally, apnea was defined as an anesthesia-related adverse event if it lasted more than 30 seconds (13).

Statistical analysis

All statistical analyses were performed using SPSS software version 19. Data are presented as mean, standard deviation (SD), frequency, and percentage. The chi-square test was used to compare qualitative variables, and an independent t-test was used to compare the mean values between the two groups (successful and unsuccessful groups). P value < 0.05 was considered statistically significant.

RESULTS

A total of 302 patients (60.3% female), with a mean (SD) age of 61.97 (17.17) years, were enrolled in this study. The most common indication for ERCP was CBD stone (n = 216, 73.2%). Other indications included pancreatic cancer (n = 18, 6.1%), cholangiocarcinoma (n = 17, 5.8%), sphincter of Oddi dysfunction (SOD) (n = 17, 5.6%), ampullary cancer (n = 9, 3.1%), diagnostic ERCP (n = 7, 2.4%), complications of CBD-related surgeries (n = 6, 2.0%), and bile duct stricture (n = 5, 1.7%).

The ERCP procedure was successful in 240 (79.5%) patients. Unsuccessful outcomes were due to cardiovascular conditions (n = 7) and endoscopic problems (34 cases of impossible cannulation, seven cases of incomplete stone extraction because of the large stone size, three cases of distal duct stenosis, four cases of impossible enfacement, and lack of access to the ampulla of Vater, four cases of multiple stones in the CBD and intrahepatic ducts, two cases of impossible new stent placement, and one case of hemorrhage). Of 34 cases of impossible cannulation, in 32 (10.6%) cases, the papilla was found but cannulation was not possible and in two (0.7%) cases it was not possible to access the papilla. The mean (SD) age of the patients with unsuccessful ERCP was significantly higher than that of successful cases (P = 0.001). The success of the procedure was not significantly associated with sex, BMI, ethnicity, or opium addiction (P > 0.05) (Table 1). The times of cannulation, cannulation attempts, and dye injection were significantly higher in unsuccessful procedures as compared with successful procedures (P = 0.014, P = 0.001, and P = 0.001, respectively). The mean cannulation time (minute) was 5.05 in successful ERCPs and 11.99 in unsuccessful cases. Deep cannulation was more frequent in successful procedures (n = 227, 95.4% vs. n = 53, 86.9%; P = 0.015).

The most common therapeutic method used in ERCP

Table 1. Association of demographic data and definite diagnosis with the outcomes of ERCP.

Variables	Successful outcome (N=240)	Unsuccessful outcome (N=62)	Total (N=302)	P value
Age, years Mean (SD)	60.17 (17.17)	69.05 (15.35)	61.97±17.17	0.001
Age, years; N (%)				
Age<65	128 (53.3)	19 (31.7)	147 (49.0)	0.003
Age≥65	112 (46.7)	41 (68.3)	153 (51.0)	
Sex; N (%)				
Male	91 (37.9)	28 (45.2)	120 (39.7)	0.298
Female	149 (62.1)	33 (54.8)	182 (60.3)	
BMI (kg/m^2) Mean (SD)	26.51 (4.01)	26.41 (3.8)	26.49 (3.97)	0.861
Total opium addiction; N (%)	89 (37.1)	25 (40.3)	114 (37.7)	0.639
Inhalation	21 (8.8)	7 (11.3)	28 (9.3)	
Oral	63 (26.3)	14 (22.6)	77 (25.5)	0.279
Both	5 (2.1)	4 (6.5)	9 (3.0)	
Ethnicity; N (%)				
Fars	143 (59.6)	39 (62.9)	182 (60.3)	0.887
Turkmen	62 (25.8)	15 (24.2)	77 (25.5)	
Sistani	35 (14.6)	8 (12.9)	43 (14.2)	
Definite diagnosis; N (%)				
CBD stone	167 (71.1)	43 (74.1)	210 (71.7)	
SOD	25 (10.6)	4 (6.9)	29 (9.9)	
Pancreas cancer	14 (6.0)	5 (8.6)	19 (6.5)	
Cholangiocarcinoma	14 (6.0)	2 (3.4)	16 (5.5)	
Ampullary cancer	8 (3.4)	2 (3.4)	10 (3.4)	0.808
CBD stricture	2 (0.9)	2 (3.4)	4 (1.4)	
Diverticulitis	2 (0.9)	0	2 (0.7)	
Stent occlusion	1 (0.4)	0	1 (0.3)	
Bile leak	1 (0.4)	0	1 (0.3)	
Normal	1 (0.4)	0	1 (0.3)	

BMI: Body mass index; CBD: Common bile duct; SOD: Sphincter of Oddi dysfunction.

was simple sphincterotomy (n=212, 71.1%). Also, papillary balloon dilation was used more frequently than biliary stent placement. Failure of ERCP was significantly associated with adverse events during ERCP (P=0.001) (Table 2). There were three cases of apnea, which did not result in death. Hemorrhage during ERCP occurred in 13 patients, and no patient required blood transfusions. The most common adverse event was PEP (n=44, 14.6%), including mild (6%), moderate (5%), and severe (3.6%) cases. The total rate of PEP was higher in successful ERCPs, while severe PEP was more common in unsuccessful procedures; however, the difference was not significant (P=0.412, Table 3).

PEP was significantly associated with sex (males: n=11, 9.2%, and females: n=33, 18.0%; P=0.034), but not with ethnicity, BMI, or opium addiction (P=0.539, P=619, and P=0.192, respectively). Also, PEP had no significant association with the indications for diagnosis (P=0.624) or definite diagnosis (P=0.316). Non-fatal perforation occurred in a 70-year-old man during the procedure. He recovered after medical management and was discharged. There was no case of mortality during the study.

DISCUSSION

This study was designed to determine the success rate of

Table 2. Procedure characteristics and details of ERCP

Variables	Successful outcome (N=240)	Unsuccessful outcome (N=62)	Total (N=302)	P value
Cannulation time (min); mean	5.05	11.99	5.97	0.014
Cannulation attempts; mean	2.73	6.69	3.53	0.001
Dye injection; N (%)	42 (20.5)	23 (43.4)	65 (25.2)	0.001
Dye volume; mean (SD)	11.45 (7.10)	13.81 (9.55)	11.71 (7.39)	0.319
Cannulation method; N (%)				
Standard guidewire assistant; N (%)	146 (61.3)	30 (50.0)	176 (59.1)	0.110
Fistulotomy; N (%)	13 (5.5)	4 (6.7)	17 (5.7)	0.719
Precut sphincterotomy; N (%)	20 (8.4)	6 (10.0)	26 (8.7)	0.695
Pancreatic duct cannulation; N (%)	40 (22.2)	9 (19.6)	49 (21.7)	0.696
Pancreatic duct dye injection; N (%)	9 (10.7)	4 (20.0)	13 (12.5)	0.259
Biliary stent placement; N (%)	42 (17.6)	10 (16.7)	52 (17.4)	0.858
Papillary balloon dilation; N (%)	69 (29.0)	6 (10.0)	75 (25.2)	0.002
Sphincterotomy; N (%)	184 (77.3)	28 (46.7)	212 (71.1)	0.001

Table 3. Association of ERCP outcomes with adverse events.

Adverse events	Successful outcome (N=240)	Unsuccessful outcome (N=62)	Total (N=302)	P value
PEP; N (%)				0.412
Mild	16 (6.7)	2 (3.2)	18 (6.0)	
Moderate	14 (5.8)	1 (1.6)	15 (5.0)	
Severe	7 (2.9)	4 (6.5)	11 (3.6)	
Total	37 (15.4)	7 (11.3)	44 (14.6)	
Post-ERCP hemorrhage; N (%)	0	2 (3.2)	2 (0.7)	
Adverse events during ERCP; N (%)				0.004
Hemorrhage	8 (3.6)	5 (9.1)	13 (4.7)	
Apnea	1 (0.5)	2 (3.6)	3 (1.1)	
Hypoxia	0	2 (3.6)	2 (0.7)	
Perforation	0	1 (1.8)	1 (0.4)	

ERCP: Endoscopic retrograde cholangiopancreatography; PEP: Post-ERCP pancreatitis.

the ERCP procedure, the incidence of various adverse events, and the mortality rate of ERCP in our academic hospital. Although ERCP is an invasive method associated with adverse events, it is still one of the most important diagnostic and therapeutic techniques for biliary and pancreatic diseases. Therefore, it is important to study the post-ERCP adverse events to increase the efficacy and safety of this technique.

In the present study, the CBD stone was the most common indication for ERCP with a frequency of 73.2%, which is consistent with the rates reported by other researchers (14,15). Also, the incidence of tumor stenosis was 15%, and the incidence of postoperative biliary complication was 2%. The results of a study by Vitte and Morfoisse, which showed incidence rates of 22.5% and 3.3% for tumor stenosis and postoperative biliary complication, respectively, are in line with our findings. Moreover, in this study, the incidence of biliary cancer was 5.8%, and the incidence of SOD was 5.6%. Similar results were obtained by Katsinelos and colleagues, who reported frequencies of 2.9% and 9.3%, respectively.

In a study by Finkelmeier and co-workers, the overall success rate was estimated at 84.4%. This study also found that the success rate was higher in old (61-80 years) and

very old (>80 years) patients as compared with younger patients (≤60 years). In the present study, the procedure was successful in 79.5% of patients. Also, our results showed that patients<65 years had a higher chance of successful ERCP (P=0.003) (16). Moreover, the success rate reported in a study by Kapral and colleagues on 3102 ERCP cases was estimated at 84.8%. They demonstrated higher success rates and fewer adverse events in procedures done by endoscopists with more than 50 ERCPs annually (17). It should be noted that our ERCP unit admits about 170 patients annually and has four endoscopists; therefore, the number of patients for each endoscopist is less than 50 annually. However, our ERCP unit is newly established, and the volume of ERCPs is increasing every year. In another study on patients with only CBD stones, the rate of achieving CBD clearance in the first or second attempt was 94.9%. Nonetheless, the success of stone removal in patients with a small papilla or a thinner distal duct was 81.9% (2).

There was no case of mortality in our study. Other similar studies have reported very low rates of mortality or no mortality at all. In research on mortality, usually, the cause of death is not directly related to ERCP, and the patients experience comorbidities, such as liver failure (16,18,19). In a recent systematic review, the incidence of PEP varied from less than 1% to 40% because of its dependence on patient-related factors, procedures, study definitions, and methodology (4). Another study demonstrated that the incidence of PEP was 13% in North American clinical trials. (9) In the present study, the overall incidence of PEP, as the most common adverse event, was 14.6%; mild PEP (6%) was more frequent than moderate PEP (5%) and severe PEP (3.6%). This systematic review of controlled trials revealed that the incidence of mild, moderate, and severe PEP was 5.7%, 2.6%, and 0.5%, respectively; also, in high-risk patients, the corresponding rates increased to 8.6%, 3.9%, and 0.8%, respectively (9).

Our results showed a significant association between PEP and sex; in other words, the incidence of PEP was higher in women than men (25.0% in men vs. 75.0% in women; P=0.034). The findings of studies by Freeman and colleagues and Vandervoort and co-workers are consistent with our results, as they found female sex as a risk factor for PEP (12,20). On the other hand, in line with a study by Abdelfatah and others, our results did not show a significant relationship between obesity and the probability of PEP (21). Moreover, Nakeeb and colleagues demonstrated that the risk of PEP increased with the number of cannulation attempts (22). Similarly, in our study, the number of cannulation attempts was higher in patients with PEP (4.7%) as compared with non-PEP patients (3.3%); however, this association was not statistically significant (P=0.07).

Another adverse event of ERCP is hemorrhage. Hemorrhage commonly occurs after endoscopic biliary or pancreatic sphincterotomy. The rate of post-ERCP hemorrhage has been estimated at 0.3% to 2% (20,23,24). In our study, hemorrhage was more frequent during the procedure than after the procedure (4.7% vs. 0.7%), while in a cohort study (7), the prevalence of hemorrhage was similar during and after ERCP (1.2% vs. 1.2%; total=2.4%). It should be noted that most of the previous studies only measured post-ERCP hemorrhage. In a previous study (25), the prevalence of hemorrhage after ERCP was 0.6%. Also, the incidence of hemorrhage from the sphincterotomy site was 3.23% in a study on 1023 ERCP patients in Iran (26).

The ERCP-induced perforations are severe adverse events that can be related to the guidewire, sphincterotomy, or endoscope passage.[1] However, the incidence rate of perforations is almost less than 1% (27).In this regard, Langerth and others (28) reported the incidence of perforations to be 0.7%, while another study (7) reported an incidence rate of 0.9%. In another meta-analysis, the frequency of duodenal and biliary perforations during ERCP was 0.60% (95% CI: 0.48, 0.72) (29), which is compatible with our study. Apnea is an anesthesia-related adverse event of ERCP, with a prevalence of 0.98% (0.49% in each group of men and women) (26), the reported incidence rate was close to the rate measured in our study (1.1%).

In conclusion, the achieved success rate in this study was acceptable since our ERCP unit is newly established, and the load of patients is moderate. The mean cannulation time and cannulation attempts were significantly lower in successful ERCPs. Overall, age≥65 years can be considered a risk factor for failure in ERCP. PEP was the

most frequent adverse event, occurring more commonly in women. Also, the rate of severe PEP was 3.6%; all of the patients received appropriate care and were discharged from the hospital.

CONCLUSION

We found that ERCP could a safe and effective procedure, especially for patients under 65 years. The overall success rate and adverse events were compatible with the available data in the literature.

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CONFLICT OF INTEREST

The authors have declared no conflicts of interest including financial, consultant, institutional and other relationships that might lead to bias.

ETHICAL APPROVAL

This study was approved by the Ethics Committee of Golestan University of Medical Sciences (IR.GOUMS.REC.1396.63).

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