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Comparison of the Effectiveness and Safety of ERCP in Patients with Choledocholithiasis at Different Ages

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ABSTRACT

Background and Objective: Endoscopic retrograde cholangiopancreatography (ERCP) is an important tool for the diagnosis and treatment of pancreaticobiliary diseases. Complications associated with ERCP in the elderly due to comorbidities may be more than in non-elderly individuals. Given the lack of studies and diversity of results in studies, the aim of this study was to compare the results of ERCP in elderly and non-elderly individuals.

Methods: In this cross-sectional study, the findings related to 774 patients with common bile duct stones (choledocholithiasis) who underwent ERCP at Rouhani Hospital in Babol from 2011 to 2021 were collected. Demographic information and outcomes were examined and compared in three age groups in terms of treatment success, complications, and risk factors: over 80 years, under 65 years, and 66-79 years.

Findings: The mean age of the patients was 62.02±13.46 years. In this study, 51.6% of the patients were under 65 years of age and 17.4% were over 80 years of age. 5.9% of the procedures were unsuccessful. Older age was associated with an increased chance of failure in the ERCP procedure for the removal of common bile duct stones. Furthermore, the presence of periampullary diverticulum as an independent variable could predict failure in the ERCP procedure. In patients of the same age and over 80 years of age, acute cholangitis ($p=0.004$) and periampullary diverticulum ($p<0.001$) were significantly more common than in other age groups.

Conclusion: The results of the study showed that diverticula and older age, especially age over 80 years, are effective factors in ERCP failure. The results of this study showed that periampullary diverticula and older age, especially age over 80 years, should be considered as risk factors for ERCP failure.

Keywords: *Elderly, Old Age, ERCP, Common Bile Duct.*

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Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) is a combined endoscopic and fluoroscopic procedure in which an upper endoscope is advanced into the second part of the duodenum, allowing passage of other instruments through the major duodenal papilla into the bile ducts and pancreas (1, 2). The risk of complications associated with ERCP has been reported to be up to 6.8%. The mortality rate is approximately 0.3%. Pancreatitis is the most common complication after ERCP, occurring in 3.5% of cases (3). ERCP has diagnostic applications, such as cholangiopancreatoscopy, biopsy or cytology with special instruments, as well as therapeutic applications, such as sphincterotomy, stent placement, and stone removal (4, 5). Over time, this diagnostic and therapeutic method has been replaced by other procedures, including MRCP and EUS, due to the nature of the procedure and the need for bile duct cannulation and its greater risks (6).

According to the World Health Organization, people aged 65 years or older are considered elderly, and people aged 80 years or older are considered very elderly (7). In the 21st century, with the development of the economy and the increase in medical knowledge, population aging has become a global trend (8-10). The total elderly population is growing faster than other age groups worldwide (11). Studies have shown that despite efforts, the services available in the international community are inadequate (12-14). Studies have also shown that without support, intervention, and planning and policy-making by governments, the quality of life of the elderly will be severely impaired (15). The increase in the elderly population is associated with the increase in the demand for ERCP treatment in elderly patients with pancreatic and biliary diseases (7).

Common bile duct stones (choledocholithiasis) and cancer account for more than 70% of all cases of jaundice in patients older than 75 years (16, 17). This is related to the increasing prevalence of nephrolithiasis, choledocholithiasis, and malignancy with age (18). Complications and mortality after surgery for common bile duct stones and cancers are significantly more common with age (2). Compared with surgery, complications associated with ERCP are less common in the elderly (3). However, complications such as bleeding, perforation, cholangitis, and acute pancreatitis associated with ERCP have been observed in this age group (19). Potentially, these complications are more frequent in the elderly than in non-elderly patients, as people older than 80 years often have cardiovascular, pulmonary, and neurologic comorbidities (3).

ERCP has been shown to be a safe and cost-effective procedure in the elderly and very elderly (>85) in both inpatient and outpatient settings (20-22). In the very elderly, there is decreased tolerance to longer procedures and changes in physiologic reserve and drug metabolism. Other complications, including acute pancreatitis, intraprocedural bleeding, fever, and abdominal pain, were not statistically different between the very elderly and their younger counterparts (23). In a study by Mohammad Alizadeh et al., the incidence of post-ERCP pancreatitis was significantly lower in patients older than 70 years compared with their younger counterparts. There was no significant difference in other complications, including perforation, hemorrhage, and cholangitis (24). Increasing age may be protective against postoperative pancreatitis because pancreatic exocrine function declines with age (25).

Although ERCP has been shown to be effective and safe in the elderly, there is a lack of studies comparing the results of ERCP in elderly and non-elderly patients. Given the above information and the high risk of patients over 80 years of age for procedure-related complications, as well as being the first study of the Babol population in this regard, this study aims to investigate the effectiveness and safety of ERCP in patients with choledocholithiasis over 80 years of age compared to patients under 65 years of age during the ten-year from 2011 to 2021.

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Methods

After approval by the Ethics Committee of Babol University of Medical Sciences with the code IR.MUBABOL.HRI.REC.1402.200, this cross-sectional study was conducted on all patients with common bile duct stone (choledocholithiasis) who underwent ERCP and referred to Ayatollah Rouhani Hospital in Babol between 2011 and 2021. Patients older than 18 years of age and confirmed stone diagnosis by a gastroenterologist who underwent ERCP were included in the study. Patients with concomitant malignancy in the biliary and pancreatic areas, patients with biliary stents, history of sphincterotomy, concomitant pancreatitis, structural abnormalities of the esophagus, stomach, or small intestine, and incomplete file information were excluded from the study. Finally, 774 patients were included in the study and divided into three equal age groups: over 80 years, between 66-79 years, and under 65 years.

All patients underwent ERCP using standard duodenoscopy (Olympus TGF 260 V, Tokyo, JAPAN) following an eight-hour fast. Conscious endoscopic sedation was performed by trained nurses using a combination of intravenous midazolam, fentanyl, or propofol in doses calculated for each patient. All ERCP procedures were performed by a gastroenterologist with further confirmation by at least one gastroenterologist colleague who was a member of the hospital faculty. The success of the procedure in removing the stone in the same session, the success of the procedure performed during ERCP for ampullary cannulation, and the failure of ERCP were considered as the presence of ERCP complications, including bleeding, perforation, pancreatitis, and cholangitis.

Data were analyzed using SPSS version 22 and the chi-square test, logistic and linear regression tests, Mann-Whitney test, and T-Test, and $p<0.05$ was considered significant.

Results

In this study, 774 patients with common bile duct stones who underwent ERCP from 2011 to 2021 were studied in three age groups. 399 (51.6%) were less than or equal to 65 years, 240 (31%) were 66 to 79 years, and 135 (17.4%) were greater than or equal to 80 years of age. Among the 774 patients with a mean age of 62.02±13.46 years (range 18-97 years), more than half of them, 467 (60.3%) were women, and 121 (23.9%) had diverticula. 5.9% of the procedures were unsuccessful. Also, the most common underlying disease was hypertension (12%), and 45 patients also reported a history of smoking (Table 1).

A significant difference was reported between genders in different age groups. In all ages, women underwent ERCP with common bile duct stones more often than men. In addition, it was observed that people over 80 years of age had more periampullary diverticula than other age groups ($p<0.05$). Similarly, the presence of acute cholangitis (as a reason for ERCP) was more common in people over 80 years of age than other age groups ($p<0.05$) (Table 2).

Univariate and multivariate logistic regression tests were used to examine the predictive effect of variables on the studied age groups. In each model, the variables of age, female gender, history of hypertension, heart disease, and diabetes, periampullary diverticula, acute cholangitis, smoking history, and number of ERCP sessions were entered into the model. In this model, the dependent variable for both types of analysis was the procedure success and failure variable (the failure variable was used as a reference and the table is interpreted based on it).

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The age variable showed that, alone and without simultaneous examination with other variables, it can be a predictor of failure in patients who have undergone ERCP with common bile duct stones. Thus, with each year of age, the chance of failure in performing this procedure in these patients increases by 2% (p=0.026). In a multivariate analysis that simultaneously examined all variables (except the number of ERCP sessions) to better eliminate confounding factors, it was observed that the only variable was periampullary diverticula, which still increased the odds of failure in performing this procedure by nearly 4 times (p=0.006) (Table 3).

Table 1. Frequency of study variables

Variable	Frequency(%) n=774
Age (Mean±SD)	62.13+02.46
Gender	
Woman	467(60.3)
Man	307(39.7)
Age	
≤65	399(51.6)
66-79	240(31.0)
≥80	135(17.4)
Acute cholangitis	
Yes	45(5.8)
No	728(94.2)
Diverticulum	
Yes	121(23.9)
No	385(76.1)
Procedure success	
Yes	633(94.1)
No	40(5.9)
History of blood pressure	
Yes	55(12.0)
No	402(88.0)
History of diabetes	
Yes	34(7.6)
No	415(92.4)
History of ischemic disease	
Yes	34(7.6)
No	415(92.4)
Complication following ERCP	
Bleeding	9(81.8)
Organ failure	1(9.1)
Infection	1(9.1)
Smoking history	
Yes	45(9.9)
No	409(90.1)

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Table 2. Comparison of the results of the primary study variables by age groups

Variable	Age ≤65 (n=399)	66-79 (n=240)	≥80 (n=135)	p-value
Gender				
Woman	260(65.2)	130(54.2)	77 (57.0)	0.016
Man	139(34.8)	110(45.8)	58 (43.0)	
Acute cholangitis				
Yes	14(3.5)	16(6.7)	15(11.1)	0.004
No	384(96.5)	224(93.3)	120(88.9)	
Diverticulum				
Yes	29(12.3)	50(29.8)	42(41.2)	<0.001
No	207(87.7)	118(70.2)	60(58.8)	
Procedure success				
Yes	326(95.9)	197(91.2)	110(95.0)	0.075
No	14(4.1)	19(8.8)	7(6.0)	
History of blood pressure				
Yes	22(9.6)	20(13.8)	13(15.5)	0.274
No	206(90.4)	125(86.2)	71(84.5)	
History of diabetes				
Yes	15(6.7)	17(11.6)	2(2.5)	0.035
No	208(93.3)	129(88.4)	78(97.5)	
History of ischemic disease				
Yes	9(4.1)	17(12.1)	8(9.8)	0.015
No	212(95.9)	124(87.9)	74(90.2)	
Number of ERCP sessions				
1	3(6.4)	1(2.3)	1(4.5)	
2	37(78.7)	35(81.4)	16(72.7)	0.821
3	7(14.9)	7(16.3)	5(22.7)	
Smoking history				
Yes	23(10.2)	19(12.9)	3(3.7)	0.078
No	202(89.7)	128(87.1)	79(96.3)	

Table 3. Effect of initial variables on the failure rate of ERCP procedure

Variable	Univariate analysis				Multivariate analysis			
	Odds Ratio	p-value	95% CI Lower limit	95% CI Upper limit	Odds Ratio	p-value	95% CI Lower limit	95% CI Upper limit
Age	1.023	0.026	1.003	1.043	1.008	0.556	0.982	1.035
Gender (woman)	0.787	0.466	0.414	1.498	1.300	0.578	0.515	3.281
Acute cholangitis	1.737	0.318	0.588	5.134	1.156	0.828	0.312	4.286
Diverticulum	2.455	0.022	1.139	5.289	4.060	0.006	1.486	11.088
History of blood pressure	0.253	0.183	0.033	1.916	0.654	0.709	0.070	6.088
History of diabetes	0.456	0.450	0.059	3.498	1.168	0.893	0.122	11.211
History of ischemic disease	0.463	0.459	0.060	3.556	-	0.998	-	-
Number of ERCP sessions	1.145	0.833	0.327	4.013		-		
Smoking history	0.763	0.721	0.172	3.378	1.637	0.562	0.310	8.658

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Discussion

Our study findings showed that among 774 patients with a mean age of 62.02±13.46 years (range of 18-97 years), more than half of them (60.3%) were women. Less than 6% of patients had acute cholangitis and diverticula were reported in less than 25% of patients. In the studied years, more than 90% of these procedures were successful and only 40 ERCP procedures performed due to choledocholithiasis failed. Most patients did not have any specific underlying disease and did not report a significant history of smoking.

A study by Galeazzi et al. showed that in the older group (80 years and older), the number of female patients was significantly higher, which is probably due to the different life expectancy between men and women (26). This finding was also confirmed by the study by Han et al. (18). A study by Colmenero Gargari et al. showed that adverse events after ERCP occurred in 1.7% of patients <90 years of age and 3% in patients 90 years of age and older. This finding is similar to our study, as the incidence of complications after ERCP was reported to be less than 10%, as in our study. They also noted that in both age groups, more than 90% of the procedures performed were successful, which is also similar to our study (13). Another study by Saito et al. reported that ERCP was successful in more than 90% of patients and there was no significant difference in the incidence of complications after ERCP between patients aged 75–89 years and those aged over 90 years (27).

Another study by Takahashi et al. reported that the very elderly group (aged over 90 years) had fewer comorbidities but reported more adverse events (28). In our study, the very elderly group (aged over 80 years) reported more comorbidities than the group aged less than or equal to 65 years but had fewer comorbidities than the group aged 66–79 years. In our study, it was reported that in patients aged over 80 years, female gender, periampullary diverticulum, and acute cholangitis were statistically more common. Regression analysis also revealed that with each year of age, the chance of ERCP failure in patients with choledocholithiasis increases by 2%, and periampullary diverticulum is an independent risk factor predicting ERCP failure in these patients. A study by Tohda et al. showed that periampullary diverticulum was more common in the elderly group than in the control group (24.5% vs. 13.3%) (29).

A study by Lobo et al. showed that periampullary diverticula (PAD) is associated with biliary disease and leads to failure of endoscopic retrograde cholangiopancreatography (ERCP), especially in elderly patients (30). The presence of PAD and the causes of failure of ampullary cannulation were observed in 1211 consecutive patients undergoing ERCP. The overall prevalence of PAD was 9%, and the prevalence in patients older than 75 years was nearly 4 times higher than in patients younger than 75 years. This finding is also similar to our study. Another study by Zavaleta et al. reported that the presence of periampullary duodenal diverticula (PDD) during ERCP is associated with higher failure (failure of cannulation) and treatment failure (persistent biliary obstruction) (31). Therefore, it is suggested that in these conditions, biliary endoscopic procedures be performed by experienced endoscopists to minimize the possibility of treatment failure and complications.

In a study by Chan et al., mortality in patients with acute cholangitis with gallstones was not significantly different between the elderly and non-elderly (16). Similar findings were reported in a study by Antypas et al., which reported that ERCP in the elderly is a safe procedure with a high rate of success for the treatment of difficult gallstones (32). A study by Saito et al. suggested that ERCP for choledocholithiasis in elderly patients over 90 years of age is a safe and effective procedure (27). However, endoscopists should select appropriate strategies after considering the medical conditions and history of each patient.

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A study by Galeazzi et al. noted that although older patients are able to tolerate ERCP, older patients with comorbidities are at higher risk for some complications compared with those without comorbidities (26). However, understanding this issue goes beyond a collection of medical history and physical condition of the patient. They ultimately stated that when dealing with older adults, a Comprehensive Geriatric Assessment (CGA) should be considered as the preferred method to assess their health status before performing ERCP (26).

One of the most important reasons why studies have shown that ERCP can be safe and appropriate for very elderly patients is that the dependent variable in most of these studies is mortality, not the success or failure of ERCP. Therefore, since not every failure in ERCP leads to mortality, we suggest that considering the failure variable as an important initial factor to investigate the importance and safety of ERCP in elderly patients, this procedure should be decided based on the patient's condition at older ages. In this study, we reported that increasing age is associated with a higher chance of ERCP failure. Similar to the results of this study, Takahashi et al. stated that age over 90 years, duodenal papillary cancer, and gallbladder carcinoma are among the factors that significantly contribute to the occurrence of adverse events in ERCP therapy (28). Finally, Mohapatra et al. reported that elderly patients are more likely to have multiple comorbidities and, therefore, may be more susceptible to complications during endoscopic procedures (33). Furthermore, complications in older patients may be more severe than in younger patients due to reduced physiologic reserve, the presence of systemic comorbidities, and potential serious drug interactions. Therefore, endoscopists should be aware of the risks before performing endoscopic procedures in older patients and should carefully weigh the risks against the benefits.

One of the limitations of our study is that this study was conducted in only one medical center. Therefore, generalizing these data to the entire population requires a study with a larger sample size and multiple centers at the provincial level. Another important point is the status of patient follow-up, which may affect the results due to missing data. Also, a number of variables have missing data, so these cases were not adequately and appropriately investigated in the study.

In the 10-year follow-up of patients undergoing ERCP with common bile duct stones, we concluded that more than 90% of ERCP procedures were successfully performed during the years 2011-2021, and with each year of age, the chance of failure in ERCP in patients with common bile duct stones increases by 2%, and diverticulum is also an independent risk factor predicting failure in the ERCP procedure in these patients. These findings indicate that when performing ERCP for common bile duct stones, specialists should pay attention to the patient's age and the presence or absence of diverticula, in addition to paraclinical and clinical findings, and should try to subject elderly patients to ERCP by considering all aspects, including life expectancy, patient tolerance, and other factors.

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