

Endoscopic retrograde cholangiopancreatography in the elderly: Some considerations and approaches

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ABSTRACT

Introduction: Cholelithiasis is an old age disease but old age is not a disease. Biliary tract disorders are increasingly seen in elderly patients and this is related to the aging of the global population. In the current study, our main concern was to communicate the message that the ERCP is a safe procedure in elderly patients with signs of biliary sepsis and adverse comorbid conditions.

Materials and Methods: Between June 2014 and May 2018, endoscopic retrograde cholangiopancreatography (ERCP) was carried out on patients in our hospital with obstructive jaundice and acute cholangitis. There were 154 patients over 80 years of age, 236 patients in the 65–79-year age group, and 422 patients under the age of 65, who served as the control group.

Results: Our study was conducted on three age groups: under 65 years, from 65–79 years, and 80 years and older. The length of hospital stays and cost among the groups was compared. Duodenal diverticula were significantly more common in patients over 65 years of age ($p>0.001$). Significantly lower costs were found for patients under 65 years of age (Group A) in comparison with both Groups C and B (both $p=0.001$). The average length of hospital stay differed significantly among age groups and was significantly shorter in patients under 65 years of age than the 65–79-year age group as well as patients 80 years of age and older ($p=0.001$).

Conclusion: In conclusion, ERCP is a safe and effective procedure in patients from 65 to 79 years of age and patients aged 80 and older. We suggest that emergency or early ERCP should be performed within 24–48 hours in elderly patients with acute cholangitis and biliary sepsis irrespective of the severity of the disease unless there are major contraindications.

Keywords: Elderly patients, comorbid, cholangitis

Introduction

Old age is a period that describes the changes in the late period of human life. Cholelithiasis is an old age disease but old age is not a disease. Biliary tract disorders are in-

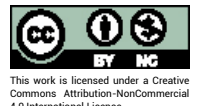
creasingly seen in elderly patients and this is related to the aging of the global population. In elderly patients, decreased physiological reserve due to age-related physical, social and physiological impairment is associated



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with significant morbidity and mortality. ERCP is a safe procedure, but it carries certain risks in elderly patients.^[1,2] According to another authors, ERCP is an invasive procedure which is not associated with an increased rate of complications in the elderly.^[3] Even in cases requiring complex interventions, the ERCP procedure saves elderly patients from surgical intervention with the use of mechanical, laser or electrohydraulic lithotripsy.^[4] The aim of this study was to determine the safety of ERCP in elderly patients by retrospectively comparing characteristics and outcomes of patients in different age groups (<65, 65-79, >80 years). At the same time, to determine the safety of ERCP in elderly patients with signs of biliary sepsis and unfavorable comorbid (cardiopulmonary) conditions.

Materials and Methods

For the study, prospectively collected medical records of patients undergoing ERCP in a single hospital were reviewed retrospectively. Between June 2014 and May 2018, ERCP was carried out in our hospital for patients with obstructive jaundice and acute cholangitis. There were 154 patients over 80 years and older of age (group C), 236 patients in the 65-79-year age (group B) and 422 patients under the age of 65 served as the control (group A). Demographic characteristics, medical history, clinical features, laboratory data, ERCP findings, details of ERCP procedures, hospital stay, cost, ERCP related complications and mortality were evaluated. In cases of unsuccessful ERCP, surgical treatment was considered if selective biliary cannulation failed despite second attempt for ERCP. Additionally, patients with large stones that could not be removed from the common bile duct and patients with failed ERCP due to duodenal diverticula were also evaluated for surgical treatment. The sedation was performed in the endoscopy unit or operating room under deep sedation and general anesthesia by an anesthesiologist. ERCP procedure was planned within 24-48 hours for patients with poor general condition due to cholangitis. Detailed information was given to the relatives of the patients about the procedure, and the ERCP procedure was carried out without delay after obtaining written informed consent.

Statistical Analysis

The normality of distribution of continuous variables was tested using the Shapiro-Wilk test and Normal Q-Q plot. Because none of the numerical data was followed normal distribution based on the graphical evaluation

and Shapiro-wilk test, nonparametric test were applied for age group comparisons of numerical data. The Mann-Whitney U test was used to compare two independent groups for non-normal data. Kruskal Wallis test was performed to compare non-normal data when there are more than 2 groups. The Chi-square test applied to investigate the relationship between two categorical variables and Fisher exact test was applied when more than 20% of the expected values are less than 5. Furthermore Multivariate linear regression analyses were performed to adjust impact of confounding factors and mean differences and bootstrap 95% confidence intervals were given for numerical outcomes. Statistical analysis was performed using the SPSS for Windows version 24.0 program, and P values <0.05 were accepted as statistically significant.

Results

In our study conducted in three age groups and compare the lengths of hospital stay and cost among the groups. Group C consisted of 154 patients including 58 males and 96 females and Group B consisted of 236 patients including 118 males and 118 females. Following cholecystectomy, bile leak was detected in 0 (0%) patients in group C, 7 (1.7%) patients in group B and 1 (0.4%) patient in group A and there was no significant difference among the age groups. Among patients 80 years of age and older, 32 (20.8%) patients had duodenal diverticula ($p < 0.001$) and 39 (25.3%) patients required second ERCP, with a statistically significant difference versus other age groups (Table 1). According to results given in Table 1 rates of having Cholecystectomy and Duodenal diverticulum were significantly different between groups so these two variables were considered as potential confounders. Adjusted p values from multivariable modeling are also given in Table 2. In all cases the rate of successful biliary cannulation during the second ERCP session was 97%. The ERCP procedure was deferred due to hypertension in 6 patients from group C and due to an upper respiratory tract infection in 4 patients from group B. The treatment regimens for these patients were managed by the respective departments and they were operated after full recovery. A significant difference was observed between the age groups regarding the cost ($p = 0.004$). Significantly lower costs were found for patients under 65 years of age (group A) in comparison to both group C and group B (both $p = 0.001$). Additionally, 65-79-year age group showed a lower cost compared to ≥ 80 -year age group. The average length of hospital stay differed significantly among age groups and was signif-

Table 1. Comparison among age groups (<65, 65-79 and ≥80 years of age)

	Age groups			65-79 years vs <65 y OR [95%CI]	80 years and older vs <65 years OR [95%CI]	p
	Group A <65 years (n=422)	Group B 65-79 years (n=236)	Group C 80 years and older (n=154)			
Gender						
Male	195 (46.2)	118 (50)	58 (37.7)	0.86 [0.62-1.18]	1.42 [0.97-2.08]	0.055
Female	227 (53.8)	118 (50)	96 (62.3)			
Cholangiocellular carcinoma						
Yes	10 (2.4)	4 (1.7)	3 (1.9)	0.71 [0.22-2.29]	0.82 [0.22-3.01]	0.837
Duodenal diverticulum						
Yes	19 (4.5)	41 (17.4)	32 (20.8)	4.46 [2.52-7.89]	5.56 [3.05-10.16]	0.001*
Suspicion of malignant disease						
Yes	15 (3.6)	11 (4.7)	6 (3.9)	1.33 [0.6-2.94]	1.1 [0.42-2.89]	0.782
Bile leak						
Yes	7 (1.7)	1 (0.4)	0 (0)	0.25 [0.03-2.06]	NC	0.119‡
Need for second ERCP						
Yes	100 (23.7)	38 (16.1)	39 (25.3)	0.62 [0.41-0.93]	1.09 [0.71-1.67]	0.039*
Status: Exitus (Ex)	0 (0)	1 (0.01)	1 (0.01)	NC	NC	0.306‡
Stent placement						
Yes	74 (17.5)	57 (24.2)	32 (20.8)	0.67 [0.45-0.99]	0.81 [0.51-1.29]	0.123
Cholecystectomy						
Yes	56 (13.3)	20 (8.5)	11 (7.1)	1.65 [0.97-2.83]	1.99 [1.01-3.91]	0.046*
Sphincterotomy						
Yes	396 (93.8)	224 (94.9)	145 (94.2)	0.82 [0.4-1.65]	0.95 [0.43-2.07]	0.851
Sclerotherapy						
Yes	10 (2.4)	4 (1.7)	5 (3.2)	1.41 [0.44-4.54]	0.72 [0.24-2.15.]	0.611

*Significant at 0.05 level based on Chi-square test. ‡Fisher exact test, OR: Odds Ratio; CI: Confidence Interval, NC: Not calculable.

icantly shorter in patients under 65 years of age than 65-79-year age group as well as patients 80 years of age and older ($p=0.001$). The values of MN and MX GGT among the groups ($p<0.003$ and $p<0.006$, respectively) were statistically significant. Bilirubin levels were high in patients with cholangitis. However the difference between MN and MX direct bilirubin values was not statistically significant between the groups ($p=0.181$, $p=0.089$, respectively) (Table 2). The most common indication for ERCP was choledocholithiasis (Figs. 1, 2), by bile leak, malignant biliary stricture and suspected malignancy. Of 12 patients with septic shock in the elderly group, a dramatic improvement was observed in the general condition of 10 patients. There were no patients with septic shock due to cholangitis in the other groups. During the ERCP, non-severe bleeding due to sphincterotomy occurred in 9 patients in the elderly groups and it was stopped by sclerotherapy. Only one patient was reoperated due to bleeding requiring blood transfusion and bleeding was stopped with endoscopic sclerotherapy. One patient in the 65-79 age group developed massive pulmonary embolism after ERCP and died despite all interventions. A 80-year-old patient died of multiorgan failure with renal failure and sepsis due to cholangitis despite successful endoscopic biliary drainage. Two patients in the 65-79 age groups had type II perforations and one patient had air in the retroperitoneum. Two patients over 80 years of age had type II perforations (perivaterian injury) and one patient had retroperitoneal air. For patients exhibiting clinical manifestations of sepsis due to cholangitis, emergency or early (within 24-48 hours) biliary drainage was performed via endo-

Table 2. Hospital stay, cost and blood values comparison between three age groups

Variables	Group A	Group B	Group C	Adjusted MD [95%CI]	Adjusted MD [95%CI]	P	P _{adjusted}
	<65 years (n=422) Median (25%-75%)	65-79 years (n=236) Median (25%-75%)	80 years or older (n=154) Median (25%-75%)				
Cost (USD)	287.85 [168.9-412.35]	346.96 [213.44-517.82]	402.43 [268.55-644.26]	167.2 [71.9-262.4]	131.6 [49.6-213.5]	0.004*	0.001*
Hospital stay (days)	5 [3 -7]	5.5 [3-8]	6 [4-8]	0.9 [-0.1-1.9]	0.9 [0-1.7]	0.001*	0.044*
MN WBC x10 ³ cells/uL	6.09 [5.1-7.69]	5.72 [4.75-6.92]	6.13 [5.02-7.94]	0.4 [-0.1-0.8]	-0.3 [-0.7-0.1]	0.018*	0.335
MX WBC x10 ³ cells/uL	9.91 [7.87-13.81]	10.67 [8.26-14.84]	12.39 [9-15.71]	2.9 [1.6-4.3]	1.8 [0.6-2.9]	0.001*	0.001*
MN GGT	164 [66-296.5]	133 [45-270]	121 [54-212]	-49.8 [-87.3-12.4]	-3.6 [-36-28.8]	0.003*	0.019*
MX GGT	306 [159.5-515]	260 [107-538]	227 [118-391]	-79.5 [-142.2-16.7]	1.5 [-52.7-55.8]	0.006*	0.030*
MN direct bilirubin	0.41 [0.19-0.97]	0.36 [0.17-0.89]	0.41 [0.22-0.97]	-0.1 [-0.4-0.2]	0 [-0.3-0.2]	0.181	0.512
MX direct bilirubin	2.59 [0.56-4.83]	2.18 [0.45-5]	3.29 [0.55-5.18]	0.4 [-0.3-1.1]	-0.1 [-0.7-0.5]	0.089	0.320
MN ALT U/L	57 [24-108]	31 [14-62]	24.5 [12-46]	-41.7 [-54.2-(-)29.2]	-33.8 [-44.5-(-)23.1]	0.001*	0.001*
MX ALT U/L	184 [76-351]	130 [42-242]	106.5 [52-199]	-65.9 [-111.3-(-)20.5]	-55.4 [-94.4-(-)16.3]	0.001*	0.001*
MN AST U/L	32 [20-57]	27 [19-41.5]	25 [18-41]	-8.4 [-16.3-(-)0.5]	-8.4 [-15.2-(-)1.6]	0.001*	0.013*
MX AST U/L	123 [60-237]	122 [58-246]	131.5 [61-264]	-176.9 [-304.5-(-)49.4]	8.9 [-101-118.7]	0.480	0.243

MD: Mean Difference, CI: Bootstrap Confidence Interval *Significant at 0.05 level. Kruskal-Wallis test. P adjusted: Multivariate linear regression analysis results by adjusting having Duodenal diverticulum and Cholecystectomy; Maximum (MX) and minimum (MN) values during hospitalization, white blood cells (WBC), alanine aminotransferase (ALT), aspartate aminotransferase (AST), gamma-glutamyl transferase (GGT), US dollars (USD).

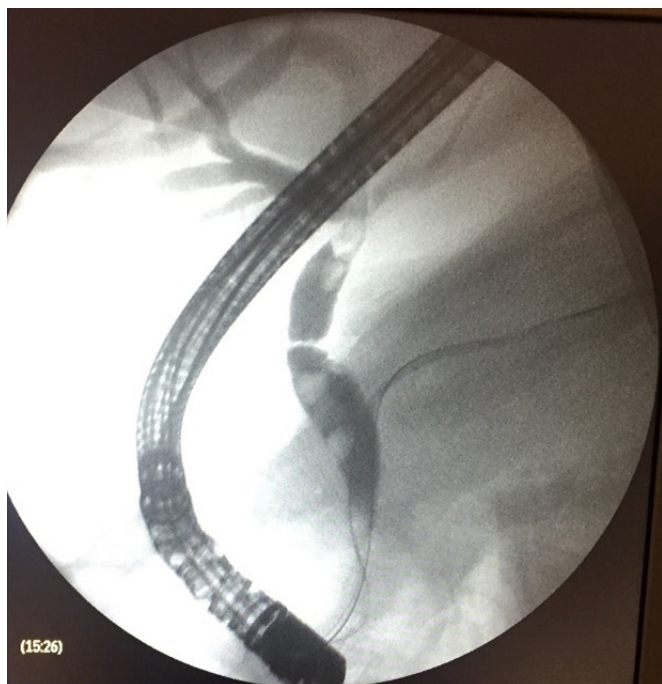


Figure 1. Common bile duct stones in cholangiography.

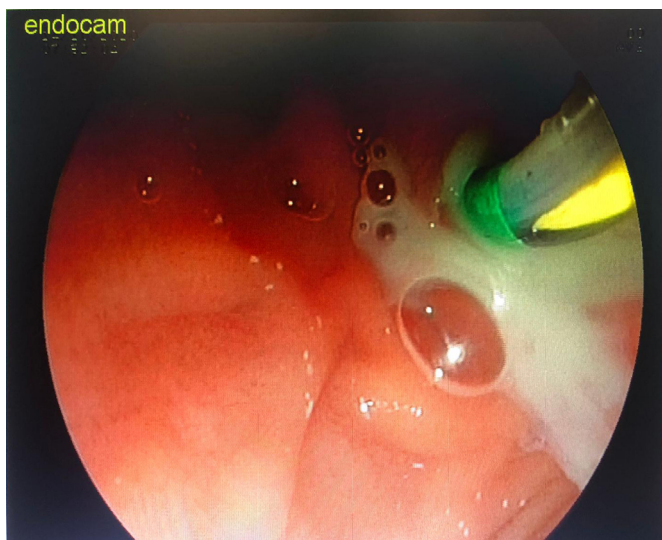


Figure 2. Stones extracted from the common bile duct.

scopic sphincterotomy (ES) regardless of their general condition. Biliary drainage resulted in a dramatic clinical improvement in elderly patients.

Discussion

Cholangitis and biliary sepsis due to biliary obstruction may result in mortality in elderly patients if not treated endoscopically. Sphincterotomy with ERCP, which can convert emergency situations such as choledocholithiasis and cholangitis to elective conditions, is safely performed in elderly patients.^[5] It has shown that patient monitoring during deep sedation is important in elderly

patients.^[6] Controlled deep sedation increases the quality of upper gastrointestinal endoscopy and ERCP. In the geriatric population, conscious sedation practices are modified by administering fewer agents at a lower cumulative dose and slower rate.^[7] Cholecystectomy is a commonly used procedure for patients with cholecystolithiasis and choledocholithiasis at 4-6 weeks post-ERCP. However, as reported in the literature, ERCP and laparoscopic cholecystectomy (LC) have been increasingly performed in the same session or during the same hospitalization period in evidence-based studies.^[8] At the same time, this approach provides economic advantages by preventing morbidity and reducing the cost.^[9] Biliary drainage via ERCP may be in elderly patients with low physiological reserve in the case of obstructive jaundice and cholangitis. Dramatic improvement was achieved even in patients with symptoms of septic shock when the ERCP was performed within the first 24-48 hours following preoperative preparation. Complications related to ERCP and sedation should not be forgotten. Post-ERCP cholangitis occurs when cholangitis is absent before the procedure according to clinical and/or radiographic evidence, but in this case, emergency intervention is required after the ERCP.^[4, 10, 11] None of our patients achieving biliary drainage through a successful ERCP developed postoperative cholangitis. Cardiopulmonary complications secondary to sedation include acute myocardial infarction, stroke, respiratory failure, arrhythmia, pulmonary thromboembolism, and aspiration.^[12] Early biliary drainage prevents unfavorable outcomes in elderly patients with cholangitis. Therefore, we performed emergency endoscopic biliary drainage in patients with severe acute cholangitis, biliary obstruction and biliary sepsis or septic shock. Patients with poor general condition due to cholangitis underwent early ERCP without delay (within the first 24-48 hours). A biliary stent was placed with or without ES for biliary drainage. ERCP was repeated to remove gallstones as the patients' clinical condition improved.

Mortality increases by 9% in the presence of biliary sepsis in elderly patients.^[10] This is due to cholangitis and particularly sepsis related to reduced physiological reserves in the elderly. The risks of surgery should be taken into account in patients over the age of 80. Endoscopic treatment is effective even in a high-risk geriatric population.^[10] Many studies on the surgical treatment of biliary disease have shown that elderly patients have higher postoperative morbidity and mortality rates and longer hospital stay compared to younger patients.^[11,12] Ramzi M et

al.^[13] reported that early ERCP is associated with considerably lower 30-day mortality and in-hospital mortality in patients with acute cholangitis. In that study, ERCP performed within 48 hours of admission was found to be associated with shorter duration of hospitalization as well as reduced costs.^[13] In our study, we employed aggressive endoscopic approaches to elderly patients with obstructive jaundice. Emergency biliary drainage and the use of ES for extraction of common bile duct stones were considered on the basis of the general condition of individual patients. The updated Tokyo Guidelines (TG18) recommends biliary drainage irrespective of the severity of acute cholangitis (excluding mild acute cholangitis). In some mild acute cholangitis cases, antibiotic therapy and general supportive measures are effective. There are three types of biliary drainage: (1) surgical, (2) percutaneous transhepatic, and (3) endoscopic transpapillary drainage. In recent years, endoscopic ultrasonography-guided biliary drainage (EUS-BD) was recommended as an alternative drainage technique when standard endoscopic transpapillary drainage fails.^[14] Biliary drainage via ERCP is less invasive and better tolerated than the surgical method. Emergency ERCP can be safely performed for acute cholangitis even in patients 80 years of age or older.^[15] In our study, patients with mild cholangitis associated with obstructive jaundice received antibiotic therapy and supportive care and underwent elective ERCP during the same hospital stay. There are studies reporting that ERCP is a safe and effective procedure in patients aged 80, 90 years and older.^[2,3,16] In order to perform ERCP safely in older patients, obtaining informed consent, monitoring the patient closely during and after ERCP and prompt recognition and management of complications are of utmost importance. Moderate and severe complications might increase the mortality rate particularly in high-risk patients.^[17] Timely and effective interventions may reduce the rates of morbidity and mortality. Early ERCP and early use of antimicrobial therapy have been reported to reduce mortality significantly even in older patients with sepsis.^[18] In a study by Galeazzi M et al.^[19] involving 363 patients, 190 patients were aged 70-79 and 173 were aged over 80 years. The older group (those ≥ 80 years old) showed significantly more patients with ASA Classes III-IV than the younger one (those ≤ 79 years old). The overall complication rate was 17.3% without inter-group differences. Older age, sex and intra-ERCP procedures were not related to a higher risk of complications. In this study, (as in the age of 70-79) ERCP appears to be safe in patients

80 years and older.^[19] In the present study, although the anesthesiologists anticipated the need for intensive care based on pre-ERCP American Society of Anesthesiologists (ASA) scores, intensive care was not needed in most of our patients. Dramatic improvements were seen at follow-up 12 h and 24 h postoperatively. Our ERCP suite is equipped with appropriate devices meeting established standards and allows for implementation of general anesthesia when necessary, facilitating overall patient management. In Parra V et al.'s^[20] study involving a total of 171 patients, the presence of comorbidities (e.g. diabetes and hypertension), direct bilirubin and transaminase levels were the variables that were significantly associated with patients aged 70 years or older. The most common procedure-related complications were post-ERCP pancreatitis and post-papillotomy bleeding but these were not related to patient age.^[20] In the current study, direct bilirubin, transaminase and GGT values were significant variables in the age groups. Maximum and minimum values of these parameters were recorded before and after ERCP. Postoperative biochemical analyses showed reductions in direct bilirubin and transaminase values in all age groups. Elderly patients are at an increased risk of developing cardiopulmonary adverse events. The use of anticoagulant drugs, the presence of duodenal diverticulum and large stones that require a larger sphincterotomy have been reported to be associated with increased risk of bleeding in the elderly.^[21] While the risk of post-ERCP pancreatitis is low in older patients, there are certain risk factors in the elderly including suspected sphincter of Oddi dysfunction (SOD) and difficult cannulation of the common bile duct.^[21] In patients aged between 65 and 79 years and patients aged 80 or older, the incidence of pancreatitis was 2% and mild and moderate pancreatitis occurred in 8 patients each; this finding supports the low risk of pancreatitis in elderly patients as reported in the literature. The fact that the study is retrospective and a single-center study can be counted as the limitation of this article. However, all data were collected prospectively.

Conclusion

ERCP is a safe and effective procedure in elderly patients. Emergency and early ERCP prevents morbidity and mortality in patients at an advanced age with poor general condition due to biliary obstruction. A multidisciplinary approach, early ERCP and post-ERCP monitoring are very important for older patients. Delivering detailed information to patients and their relatives about the risks and ben-

efits of the ERCP procedure helps them make informed decisions. We suggest that emergency or early ERCP should be performed within 24-48 hours in elderly patients with acute cholangitis and sepsis irrespective of the severity of the disease unless there are major contraindications.

Disclosures

Ethics Committee Approval: Kahramanmaraş Provincial Health Directorate, Scientific Study Evaluation Form, Public Hospitals Services Directorate, 25.06.2019. 1351197-601.99e.17402.

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Conflict of Interest: None declared.

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