

## The safety and efficacy of ERCP in octogenarians: a comparison of two geriatric age cohorts

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### Abstract

**Background/Aims :** The application of endoscopic retrograde cholangiopancreatography (ERCP) in the octogenarian population is limited. The aim of the study was to compare the clinical characteristics and outcomes of ERCP in octogenarian patients with non-octogenarian elderly patients.

**Materials and Methods :** A total of 1044 patients who underwent ERCP for the first time and are over the age of 65 were enrolled in this study. Data regarding demographic characteristics, medical history of patients, indications, technical success rate, final clinical diagnosis and complications were analyzed. 284 patients and 760 patients composed the octogenarian and non-octogenarian group, respectively.

**Results :** The mean ages in octogenarian and non-octogenarian groups were  $83.99 \pm 3.85$  and  $71.50 \pm 4.27$  years of age respectively. Both groups had similar values with regards to chronic concomitant diseases (96.6% vs. 96.5%). The most common indication of ERCP in the two groups was common bile duct stones. There was no significant difference in technical success and failure of cannulation in procedures of either group ( $p > 0,05$ ). The duration of overall ERCP procedure was shorter in length in the non-octogenarian group in comparison to the octogenarian group ( $p = 0.004$ ). The overall complication rate was similar in both groups ( $p > 0.177$ ). The most common complication in either group was post-ERCP pancreatitis.

**Conclusions :** ERCP is an effective and safe procedure in both octogenarian and non-octogenarian patients with naive papilla when performed by experienced endoscopists. (*Acta gastroenterol. belg.*, 2017, 80, 263-270).

**Key words :** ERCP, octogenarian, ERCP-related complication, geriatric ERCP

### Introduction

A significant increase of the geriatric population has been observed in both developing and developed countries in recent years (1, 2). Benign and malignant biliary disorders are seen more commonly in these patients and may need invasive interventional procedures such as endoscopic retrograde cholangiopancreatography (ERCP) (3-5). ERCP is a safe and effective diagnostic and therapeutic modality with a relatively low complication rate. Co-morbidities and other age-related health problems may increase the risk of the procedure. The safety and efficacy of ERCP for elderly patients have been evaluated and compared with non-geriatric patients in different studies (6-16). The number of studies evaluating the use of ERCP specifically on octogenarian patients (80 years or older), are limited. In previous studies, rates of complication risks and efficacy with the use of

ERCP between the octogenarian and non-octogenarian geriatric populations (ages 65-79 years) have not been well established. The purpose of this study was the investigation and comparison of the rates of complication risks and efficacy of ERCP among octogenarian and non-octogenarian geriatric populations (6-16).

### Patients/Materials and Methods

This chart and computer-based study was approved by the Gaziantep University Institutional Review Board. This study took place between October 2010 and January 2014, and 7835 ERCP procedures were performed at the Gaziantep University Hospital Department of Gastroenterology ERCP laboratory. The number of the patients included in this study over the age of 65 was 2055. 363 patients with a history of a previous endoscopic sphincterotomy and 648 patients with a referral to our hospital for ERCP while hospitalized at another centre were excluded from this study with an intention to observe and standardize the possible complications. 1044 patients diagnosed with naive papilla were included in this study. Patients were divided into two groups according to age ; octogenarians (>80 years of age) and non-octogenarians (65 to 79 years of age). Data regarding demographic characteristics and medical history of chronic concomitant diseases, indications, technical success rates, duration of cannulation and overall procedures, final clinical diagnosis, ERCP interventions performed, and complications were retrieved from the university hospital electronic medical record database and analyzed retrospectively.

All procedures were performed by five endoscopists with appropriate training and expertise in ERCP. Procedures were conducted at Gaziantep University Hospital, a tertiary level facility with expertise in the assessment and treatment of hepatobiliary diseases. Informed written consent was obtained from the legal

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guardians of the patients. Prior to the patients undergoing ERCP, investigations with one or more non-invasive techniques were used including ultrasonography, computed tomography (CT) and magnetic resonance cholangiopancreatography (MRCP) when therapeutic interventions were intended. Coagulation profiles were checked and corrected in all patients before their procedures. Topical pharyngeal anesthesia was administered in all patients with 10% lidocaine spray. All patients were placed under deep sedation by an anesthesiologist and the procedures were performed in the left-sided prone position. Hyoscine N-butylbromide was administered in cases with an overactive duodenum to slowdown intestinal motility. Hyoscine N-butylbromide was not used if elderly patients had any of the following ; severe coronary heart disease, paralytic ileus, megacolon, myasthenia gravis, an enlarged prostate, or narrow angle glaucoma. Blood pressure, heart rate, and oxygen saturation were continuously monitored with automated pulse oximetry. For all patients, a diagnostic adult duodenoscope (TJF-160 ; Olympus America Corp., Melville, NY,USA) with an insertion diameter of 10.8 mm or a therapeutic duodenoscope (TJF-100 ; Olympus

America Corp., Melville, NY, USA) with an insertion diameter of 12.5mm was used at the discretion of the endoscopists. Technical success was defined as successful deep cannulation of the bile duct or pancreatic duct along with completion of any planned diagnostic or therapeutic procedure. Cannulation was achieved using a standard sphincterotome catheter with a guide wire. A non-ionic contrast medium, iopamidol diluted to half strength, was used to lessen the risk of post injection pancreatitis. Sphincterotomy was performed in a standardized fashion (a small cut for benign or malignant stenosis, and in the case of common bile duct stones, a cut according to the stone size). Stone removal was achieved with the help of a retrieval balloon and/or a basket catheter, with the addition of mechanical lithotripsy after sphincterotomy and/or endoscopic papillary balloon dilatation (EPBD). Individual patient status and the judgment of the endoscopists were factors that influenced the use of sphincterotomy and/or EPBD. Ductal clearance was documented with a balloon occlusion cholangiogram. For patients in whom ductal clearance was not achieved, a plastic biliary stent was placed in a standardized fashion, also a plastic biliary stent was inserted to achieve relief of obstruction in malignant stenosis and after the balloon dilatation of benign stenosis. All patients were hospitalized for 24 hours after therapeutic ERCP to assess the incidence of post-procedural complications.

Complications were defined as occurring within a 4 week time period of the procedure and was further characterized as minor bleeding (settled spontaneously, controlled endoscopically at the time of ERCP), major bleeding (requiring further procedure, surgery, or blood transfusion), perforation, post-ERCP pancreatitis, infections (cholangitis) and mortalities associated with ERCP .

SPSS (Statistical Package for Social Sciences) for Windows 18.0 program was used for statistical analyses. All data were entered into a database and were verified by a second independent person. The variables were analysed using visual (histograms, probability plots) and analytical methods (Kolmogorov–Simirnov test) to determine whether or not they are normally distributed. Data are presented as mean and  $\pm$ S.D. for normally distributed variables (age, sedative drug amount) and as median (minimum-maximum) for skewed distributed continuous variables (cannulation time, overall procedure time). Categorical variables are shown as frequencies (gender, chronic diseases, indications of ERCP, final diagnosis and outcomes of ERCP, complications of ERCP and details of ERCP procedures). For group comparisons, the independent samples t tests were used if the data were normally distributed, and Mann-Whitney U tests were used for non-normally distributed data. Two-sided values of  $p < 0.05$  were considered as statistically significant.

## Results

A total of 1044 elderly patients were enrolled in this study including 284 octogenarian and 760 non-octogenarian participants. Of note, 24 (8.5%) patients were 90 years of age or older. The octogenarian and non-octogenarian group had similar values in regards to chronic concomitant diseases. However, there were significantly higher incidences of biliary or pancreatic malignancy and chronic liver disease in the non-octogenarian group in comparison to the octogenarian group (Table 1).

Indications for ERCP are also summarized in Table 1. In some cases multiple indications were recorded. The most common indication of ERCP in both groups was common bile duct stones (CBDS) which were confirmed by different radiological imaging techniques.

Table 2 demonstrates the final diagnosis and outcomes after the ERCP. Normal cholangiography results were observed more often in the non-octogenarian group rather than octogenarian group. There were no significant differences in technical success and failed cannulation of procedures in either group.

The percentage of patients who underwent biliary sphincterotomy was also similar in both groups (70.7% vs. 68.7% ;  $p = 0.794$ ). There was no significant difference between the two groups in regard to the type of sphincterotomy procedure used such as classic sphincterotomy or needle- knife pre-cut (Table 3). While the complete stone clearance rate was insignificant between two groups, there was a significant difference concerning the mechanical lithotripsy requirement between the two groups. Additionally, 30 of the 284 patients in the octogenarian group and 47 of the 760 patients in the non-octogenarian group underwent multiple endoscopic sessions for stone clearance. The rate for endoscopic biliary stent insertion was higher in the octogenarian group (31.3% ;  $p = 0.004$ ). However,

Table 1. — Demographics, clinical characteristics of patients and indications of ERCP

	Non-octogenarians < 80 years n=760	Octogenarians > 80 years n=284	p
Age (years)	71.50±4.27	83.99±3.85	<0.001
Men / Women (n%)	329 (43.3)/431(56.7)	109 (38.4)/175(61.6)	0.153
Chronic Diseases	734 (96.5%)	274(96.6%)	0.875
Hypertension	486 (63.9%)	203 (71.5%)	0.022
Diabetes mellitus	42 (5.5%)	25 (8.8%)	0.050
Hypertension and diabetes mellitus	54 (7.1%)	13 (4.6%)	0.727
Cardiovascular diseases	11 (1.4%)	9 (3.2%)	0.071
Chronic obstructive pulmonary disease	11 (1.4%)	8 (2.8%)	0.141
Stroke	1 (0.1%)	1 (0.4%)	0.468
Dementia	4 (0.5%)	2 (0.7%)	0.735
Chronic renal disease	5 (0.7%)	3 (1.1%)	0.511
Biliary or pancreatic malignancy	55 (7.2%)	5 (1.8%)	0.001
Malignancy other than biliary and pancreatic	27 (3.6%)	4 (1.4%)	0.690
Hematologic malignancy	3 (0.4%)	1 (0.4%)	0.921
Chronic liver disease	35 (4.6%)	0(0%)	<0.001
Indications			
CBD stones	392 (51.6%)	144 (50.9%)	0.842
Obstructive jaundice	100 (13.2%)	40 (14.1%)	0.681
Jaundice without cause	57 (7.5%)	22 (7.8%)	0.882
Dilated bile duct	44 (5.8%)	23 (8.1%)	0.171
Acute and chronic pancreatitis	58 (7.6%)	16 (5.7%)	0.192
Biliary or pancreatic malignancy	72 (9.5%)	31 (11%)	0.476
Cystic disease	14 (1.8%)	0 (0%)	0.022
*Others	33 (4.3%)	7 (2.5%)	0.162

\*Others: Biliary leak, primary sclerosing cholangitis, pancreaticolithiasis

Table 2. — Final diagnosis and outcomes of ERCP

	Non-octogenarians < 80 years n = 760	Octogenarians > 80 years n = 284	p
<u>Final diagnosis</u>			
Normal ERCP	101 (13.3%)	16 (5.7%)	<0.001
CBD stones	354 (46.6%)	156 (54.9%)	0.018
Malign biliary stenosis	141 (18.6%)	67 (23.6%)	0.073
Benign biliary stenosis	21 (2.8%)	8 (2.8%)	0.968
Dilated CBD. no obvious causes	43 (5.7%)	8 (2.8%)	0.057
Bile leak	12 (1.6%)	2 (0.7%)	0.273
Failed ERCP	53 (7%)	19 (6.7%)	0.864
*Anatomical causes	14 (1.8%)	3 (1.1%)	0.370
†Others	19 (2.5%)	5 (1.8%)	0.425
<u>Outcomes</u>			
Technical success	707 (93%)	265 (93.3%)	0.829
Failed cannulation	53 (7%)	19 (6.7%)	0.864
Duration of cannulation (minute) Median (minimum-maximum)	3 (1-45)	3 (1-45)	0.410
Duration of overall procedure (minute) Median (minimum-maximum)	15 (1-75)	16(2-70)	0.004
Sedative drug (propofol mg)	89 ± 9.7	70.5 ± 7.21	0.031
Periampullary Diverticulum	85 (11.2%)	49 (17.3%)	0.009

\*Anatomical causes:Mirizzi syndrome, choledochoduodenal fistula, choledochobulber fistula, ectopic opening of choledochus to duodenal bulb

†Others: Fasciola hepatica, liver cysts, pancreatic lithiasis

there was no significant difference between the two groups with regard to the necessity of the endoscopic biliary stent placement etiology (Table 3).

A summary of all complications is given in table 4. There was no significant difference in complication rates between two groups as shown in table 4. The most common complication in both groups was post-ERCP pancreatitis. All post-ERCP pancreatitis cases were graded as mild pancreatitis according to the consensus classification of post-ERCP pancreatitis by Cotton et al and all cases resolved with conservative treatment (17). Minor bleeding was the second most frequent ERCP related complication in our study. All cases in both groups were treated successfully by endoscopic intervention

and no blood transfusion was needed. A case of major bleeding occurred and required surgical intervention in one octogenarian patient. This octogenarian patient unexpectedly developed sepsis and respiratory arrest, the patient died one week after surgery. The other four patients were treated with subsequent endoscopic management and multiple blood transfusions. No delayed bleeding was noted.

In the present study, there were no significant differences in the rate of perforation between the two groups. One patient who had type I perforation (according to Stapfler et al) was treated surgically ; other patients who had type IV perforations, were surgically treated with a biliary stent, kept in a fasting state and were given antibiotics

Table 3. — Therapeutic intervention and details of ERCP procedures

	Non-octogenarians < 80 years n = 760	Octogenarians > 80 years n = 284	p
CBD stone clearance	309 (40.6%)	125 (44%)	0.418
Balloon sweep and/or basket	331 (43.5%)	141 (49.6%)	0.217
By Basket and Mechanical lithotripsy	33 (4.34%)	28 (9.8%)	0.021
Stent	172 (22.6%)	89 (31.3%)	0.004
Obstructive malignancies	87 (11.4%)	48 (16.9%)	0.608
Benign stenosis Failed	15 (1.9%)	4 (1.4%)	0.213
stone clearance	45 (5.9%)	31 (10.9%)	0.144
Sphincterotomy			
Classic (Std. sphincterotomy)	462 (60.8%)	167 (58.8%)	0.309
Needle knife	21 (2.8%)	10 (3.5%)	0.519
Combined	39 (5.1%)	24 (8.5%)	0.045
Papillary balloon dilatation	68 (8.9%)	46 (16.1%)	0.001

(18). Patients recovered fully within 2-3 days. In non-octogenarians, one patient had a type III perforation and subsequently died after surgical intervention because of cardiopulmonary complications and multiorgan failure in the intensive care unit. The other two patients who had type II and IV perforations recovered with biliary stents, antibiotics and supportive therapy. One patient in octogenarians developed sepsis, respiratory arrest, and subsequently died after surgery because of major bleeding. Two patients in the non-octogenarian group died, one after surgery due to perforation and the other due to cholangitis followed by sepsis.

## Discussion

Studies on the therapeutic success of ERCP in the elderly have grown in popularity, partly due to the prevalence of pancreaticobiliary disease and the increasing risk of surgical complications due to aging. There have been several reports from various countries and populations regarding safety and efficacy of

therapeutic ERCP in elderly patients (19-22). In these studies, elderly patients were compared with non-elderly patients (under 65 years) or a heterogeneous aged group of patients (ranging from 17-80 years of age) as a control group. In an attempt to make a direct comparison with a closer age group, patients between the ages of 65 and 79 were selected as the control group. In this study, the aim was to compare the clinical characteristics and outcomes of ERCP in octogenarian patients (over 80 years) with non-octogenarian elderly patients (aged between 65 and 79 years).

The present study has one of the largest series to date and demonstrated that the efficacy and complication rate of ERCP was similar in both groups despite the high prevalence of comorbidity of extremely elderly patients. Similarly, CBDS and obstructive jaundice were the most common indication for ERCP in previous reports. (8, 11, 19-23).

The rate of technical success of cannulation in previously reported studies were 80.5%-100% (6-16, 19-23). Some of these studies had significantly lower

Table 4. — Complications of ERCPs

	Non- octogenarians < 80 years n=760	Octogenarians > 80 years n=284	p
None	689 (90.6%)	262 (92.2%)	0.323
Post ERCP pancreatitis	32 (4.2%)	7 (2.5%)	0.186
Minor bleeding	23 (3%)	8 (2.8%)	0.859
Major bleeding	3 (0.4%)	2 (0.7%)	0.519
Perforation	3 (0.4%)	2 (0.7%)	0.541
Infection (Cholangitis)	10 (1.3%)	4 (1.4%)	0.842
Exitus	2 (0.3%)	1 (0.35%)	0.874
Total Complications	73 (9,6%)	24 (8.5%)	0.177

percentages of successful cannulation rates in elderly patients when compared to control groups (24). In this study technical success of cannulation rates were high and there were no significant difference between the two groups. There was no significant difference of duration of cannulation between two groups similarly to the study reported by Yun DY et al. (21). Periapillary diverticulum prevalence increases with age, potentially causing bile-duct stone formation and pancreatitis due to pancreatobiliary reflux (11, 25). This study reinforced findings in previous reports stating that, periampullary diverticulum were more frequently observed in octogenarian patients (7, 19, 22). There is presently conflicting results in scientific literature regarding the presence of periampullary diverticulum as a restrictive factor for successful cannulation. According to the findings of this study, periampullary diverticulum was not the cause of the failure of cannulation. Similar findings were also reported by other authors (11, 19, 25). However, periampullary diverticulum may have an effect on the duration of cannulation and the overall procedure in octogenarian patients. The discrepancy between the reported successful cannulation rates and the duration may be due to the existing periampullary diverticulum and the differences in operator experience when performing this procedure.

Patients undergoing ERCP often require deep sedation because the procedure has a typically long duration and requires less spontaneous patient movement to achieve technical success. Several studies have shown that propofol based sedation could provide a better recovery profile during ERCP. Propofol has been shown to be superior to midazolam and meperidine in high risk octogenarians (26, 27). Aspiration, laryngospasm, apnea, transient oxygen desaturation, hypotension, and

eventually cardiorespiratory suppression caused by sedative agents are a matter of concern. Prone position, growing prevalence of overt or subclinical obstructive sleep apnea, obesity and patients over the age of 60 are some of the most common predictive factors cited for high risk patients in sedation related adverse events during ERCP (28, 29). Subsequently, more attention should be paid to the assessment and evaluation of pre-procedural risk and also determining the optimal approach not only in elderly patients more sensitive to anesthetic agents but also their adverse effects in sedation during ERCP. Similarly, Obana et al reported that a minimal dosage of sedative drug was required for the octogenarian patient during the entire length of the procedure (30). There were also no serious adverse events such as cardiorespiratory suppression specifically related to deep sedation despite the high prevalence of comorbidity in two groups. Phillips et al suggested that large doses of propofol cause hypotension in elderly patients (31). The reason for the lack of adverse effects in their patients may be due to the fact that the adverse effect of propofol is dose dependent in elderly patients. Further investigation is necessary to establish an optimal method of administration and dosage of sedation for elderly patients in both surgical and non-surgical procedures.

There was no significant difference in the frequency of malign biliary stenosis between octogenarian and non-octogenarian groups, similar to the findings in Katsinelos et al (11).

In this study, mechanical lithotripsy and EPBD were used more frequently in octogenarians. Additionally, a higher frequency of combined multiple procedures were required in octogenarian patients. The incidence of plastic biliary stent placement because of failed stone clearance was not significantly different in the two groups. Similar

results regarding the incidence of plastic biliary stent placement between the two groups were reported by Katsinelos et al (11). Although there are some conflicting results in the safety of EPBD, several studies showed no significant increased risk of pancreatitis or bleeding rates in older patients (mean age of 60 years or older) (32). In the present study, EPBD was performed on 46 octogenarian patients (16.1%) and 68 (8.9%) non-octogenarians patients after standard sphincterotomy. EPBD was chosen for patients who failed to complete stone clearance after standard sphincterotomy or those undergoing anticoagulant therapy. Takashi et al and Nishikawa et al chose EPBD in a small number of cases and reported insignificant change in the risk of pancreatitis or the bleeding rate in elderly patients (30, 33). No reports suggested complications in patients such as pancreatitis or bleeding were associated with EPBD. The results of this study strongly suggest the use of EPBD for the removal of CBDS in elderly patients.

In the present study, there was no significant difference regarding the rate of ERCP related overall complications and ERCP related deaths between two elderly age cohorts. In previously reports, the occurrence rate of ERCP related overall complication was between 1.65% and 15.9%, mild pancreatitis was between 0.1% and 8.7%, bleeding was between 0.55% and 6.2%, infection (cholangitis) was between 0% and 2.2%, perforation was between 0.1% and 2.9% and death was between 0% and 3% in elderly patients (8, 11, 29-21, 23, 30, 33).

Post-ERCP pancreatitis (PEP) is the most common adverse event of ERCP in the general population. PEP was the most frequently observed complication in our study, too. PEP was seen in 2.5% of octogenarian patients and 4.2% of non-octogenarian patients. Similar findings were reported in previous studies (8, 13, 23, 30, 33). Atrophy of pancreatic parenchyma and decreased activity of pancreatic enzymes termed "Aging Associated Pancreatic Exocrine Insufficiency" seems to play a protective role against the development of PEP in elderly patients (13, 21). All patients were graded as mild cases of pancreatitis and resolved with conservative treatment.

Bleeding and perforation rates reported in this study were concordant with related literature (11, 19-21, 23, 30, 33). Death from overall ERCP-related mortality is rare (0.33%) and most often due to cardiopulmonary complications (34). Fisher L et al reported that 8% (6/74) of patients older than 65 years of age sustained myocardial injury in ERCP procedures compared with none (0 of 56) of the patients younger than 65 years of age. Most injuries had occurred during prolonged procedures (>30 minutes) (35). Cardiopulmonary problems may also arise from medications used for sedation and analgesia. This study may demonstrate a correlation between the rarity of death from ERCP and the short duration of the procedure along with medication selection administered for sedation. The mortality rate must be considered in light of the underlying patient co morbidity and development of sepsis in the intensive care

unit after a successful surgical operation rather than old age in the present study.

This study has several limitations that should be noted. This study had a retrospective design, therefore the anesthesiologic risk score and the need for urgent procedures could not be properly measured in all patients. Another limitation is the short follow-up time because of the fact that the facility was a referral centre. Short follow-ups consequently led to limited information retrieval on the effect of ERCP in octogenarian survival and recurrence of the presenting disease which required ERCP. The findings of this study cannot be generalized, as our department is a tertiary referral centre and the ERCPs were performed by endoscopists who perform at least 10 therapeutic ERCPs per week. Thus, the complication rate in this study may not be applicable to other centres, because ERCP related complications have been observed to be associated with the experience of the endoscopists' and ancillary staff (36).

In conclusion, ERCP is an effective and safe procedure in this cohort with naive papilla when performed by experienced endoscopists at high-volume centers. Outcomes of ERCP for therapeutic success rates are similar with octogenarian and non-octogenarian patients except for the duration of the overall procedure that may have been accomplished in a shorter time in non-octogenarian patients. ERCP related adverse events were frequently minor and comparable between two elderly age cohorts, as is evident by the low complication rate observed. Finally, advanced age (80 years or older) should not be considered a contraindication or an exclusion criteria for performing ERCP in elderly.

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