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ERCP in patients over 90 years old: Safety and efficacy comparison with a younger cohort

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ABSTRACT

Background and study aims As life expectancy increases worldwide, so does the prevalence of biliary tract and pancreatic disorders, resulting in rising demand for invasive procedures such as endoscopic retrograde cholangiopancreatography (ERCP) in the elderly. Few studies have assessed the safety of ERCP in patients 90 years and older, particularly among the Hispanic population. The primary aim of this study was to determine the technical success and adverse events (AEs) associated with ERCP in patients 90 years of age or older in comparison to a younger cohort of patients.

Patients and methods A retrospective analysis of all ERCPs done at our institution from 2012 to 2018 was performed. Three hundred ERCPs in patients < 90 years old and all 28 ERCPs done in patients ≥ 90 years old were included in the analysis.

Results ERCPs were successfully completed in 96.4% of patients > 90 years old and 96.3% of the < 90-year-old cohort (realtive risk [RR] 1.00, confidence interval 0.92-1.07). There was no difference in the rate of periprocedural AEs. Post-ERCP AEs occurred in 7.1% and 3.0% in patients aged < 90 and > 90 years, respectively (RR 2.38, 0.54-10.48). No deaths were directly attributed to the procedure; however, inpatient mortality was higher in the group aged > 90 years.

Conclusions ERCP is safe and effective in nonagenarian patients, and advanced age should not be considered an independent risk factor for AEs nor a contraindication for the procedure.

Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) has predominantly become a therapeutic procedure for management of multiple pancreatic and biliary disorders. Because life expectancy is increasing worldwide, as is the prevalence of biliary tract and pancreatic disorders, there is a rising demand for invasive procedures such as ERCP in the elderly. In 2010, an estimated 524 million people were aged 65 or older, comprising 8% of the world's population. This number is expected to nearly triple to about 1.5 billion by 2050, representing 16% of the world's population [1]. Life expectancy in Puerto Rico was 79.3 years in 2012 and increased to between 85.4 and 89.4 years in 2015 [2]. As the proportion of the elderly population rises, so do healthcare expenditures. It is estimated that 75% of spending in healthcare by the year 2030 will be focused on the elderly [3]. As the population ages and individuals of advanced age are increasing in number, it is imperative to recognize the unique

challenges that specific medical interventions pose for this population.

Few studies have assessed the safety of ERCP in patients over 90 years old, particularly among the Hispanic population. The overall reported incidences of short-term adverse events (AEs) for ERCP range from 5% to 10% according to various prospective studies, even though the data might vary depending on the definition and method of data collection [4, 5, 6, 7, 8]. Post-ERCP AEs are considered to be 20-fold more common and have a four-fold increased severity as compared to standard endoscopic procedures, but the risks are still lower when compared to its surgical counterpart [8].

The primary aim of this study was to determine the technical success and AEs associated with ERCP in patients 90 years of age or older in comparison to a younger cohort of patients.

Patients and Methods

A retrospective cohort database review of all patients who underwent ERCP at Hospital Bella Vista from January 2012 through July 2018 performed by a single interventional endoscopist (C.G.M.) was performed. The sample was divided into those less than 90 years old and 90 years and older. Information about patient comorbidities, indication for ERCP, procedural success, findings, and AEs during and after the procedure was collected.

All procedures were performed with the assistance of a nurse anesthetist or anesthesiologist under monitored anesthesia care or general anesthesia. Wire-guided cannulation was attempted in all cases with a native papilla using a pull-type sphincterotome preloaded with a 0.035-inch guidewire. Pancreatic stents and indomethacin suppositories were utilized at the discretion of the endoscopist to prevent post-ERCP pancreatitis after the procedure ended. Patients were monitored in recovery for 30 to 60 minutes before being discharged home or returned to the ward. All outpatients were contacted by phone the following day by the endoscopy unit staff and any AEs were documented in the chart.

Post-ERCP pancreatitis was defined as new or worsening abdominal pain with an increase in serum amylase or lipase of at least three times the upper limit of normal 12 to 24 hours after the procedure as defined by the American Society of Gastrointestinal Endoscopy [9]. Bleeding was defined as the occurrence of melena, hematemesis, or hematochezia and one or more of the following: a drop in hemoglobin of 2 g/dL or more from baseline, bleeding that required a blood transfusion, or a need for endoscopic intervention [10]. Severity of pancreatitis and bleeding was defined according to previously published criteria [9]. Acute cholangitis was defined as the presence of fever, jaundice, and abdominal pain after the procedure, excluding those where cholangitis was the indication. Hypotension and altered mental status represent severe cholangitis [11].

Statistical analysis

The 90 years and older (≥ 90 y/o) cohort was composed of all 28 patients in this age range who underwent ERCP during the study period. The sample size for the < 90 y/o cohort aged 21 to 89 was calculated based on a preliminary estimate of the incidence rate of AEs of 3% (+ /- 1.5) with a 95% confidence interval (CI), which resulted in the random selection of 300 patients for analysis. Descriptive data analysis included means and standard deviations of continuous variables, and frequency distributions of categorical variables. Comparisons between different groups were tested for statistical significance using estimates of relative risks (RRs) with their 95% CIs. All statistical analyses were computed using IBM SPSS Statistics for Windows, Versions 24.0. (Armonk, New York, United States). This study was reviewed and approved by the Institutional Review Board (protocol N. 180806-CM).

Results

A total of 897 ERCPs were performed during the study period and 328 patients were included in the study. The ≥ 90 y/o cohort had 28 patients, ranging from 90 to 98 years of age with a mean of 92.1 ± 1.98. The < 90 y/o cohort included 300 patients, with ages ranging from 18 to 89 years old with a mean of 61.48 ± 17.3. The majority of ERCPs were performed in women in both groups (67.9% ≥ 90 y/o, 56% < 90 y/o). Most patients in the ≥ 90 y/o group had a normal body mass index (57.1% ≥ 90 y/o, 44% < 90 y/o), and obesity was seen more frequently in the younger patients. There was an increased rate of hypertension and chronic kidney disease in the ≥ 90 y/o group (▶ **Table 1**).

The indications for performing ERCP were similar in both age groups, with a trend for a higher incidence of obstructive jaundice in patients ≥ 90 y/o, (53.5% ≥ 90 y/o vs 37.6% < 90 y/o, RR 1.42, 0.97–2.06) (▶ **Table 2**), The second most common indication was choledocholithiasis, seen in almost one-third of ≥ 90 y/o and 19% of < 90 y/o. Acute and recurrent pancreatitis, pancreatic or biliary leak, ampullary mass or adenoma, cholangitis, and primary sclerosing cholangitis were only an indication in patients < 90 y/o.

Technical success was achieved in completion of ERCP and its intended intervention was achieved in 96.4% of patients in the ≥ 90 y/o and 96.3% in the < 90 y/o cohorts (RR 1.00, 0.92–1.07). Sphincterotomy was the most common intervention performed overall. This was performed more frequently in the ≥ 90 y/o group than in the younger group. Half of the patients in the ≥ 90 y/o underwent stone removal, compared to 45.3% in the < 90 y/o (RR 1.10, 0.74–1.63). Biliary stricture dilation was performed more frequently in the ≥ 90 y/o group (21.4% vs 9.3% in ≥ 90 y/o vs < 90 y/o, RR 2.29, 1.03–5.06). Although there was no significant difference in biliary stent placement, there was almost a nine-fold higher rate of biliary self-expanding metal stent (SEMS) placement in the ≥ 90 y/o cohort. There was a trend toward placement of a higher number of pancreatic stents in < 90 y/o cohort (3.5% vs 7.7% in ≥ 90 y/o vs < 90 y/o, RR 0.46, 0.06–3.32), but the difference was not statistically significant. There was one direct single-operator pancreatoscopy performed in a patient 72 years of age. Biliary drainage was achieved via endoscopic ultrasound (EUS)-guided choledochoduodenostomy during the same ERCP session after a failed transpapillary attempt in two patients from the overall cohort (▶ **Table 3**).

▶ **Table 1** Baseline characteristics.

	≥ 90	< 90	95% CI	P value
	n = 28(%)	n = 300 (%)		
Age (mean)	92.1	61.48		
Female	19 (67.9)	169 (56.0)		
Male	9 (32.1)	131 (43.7)		
BMI groups				
Underweight	2 (7.1)	16 (5.3)	1.33 (0.32, 5.53)	0.68
Normal weight	16 (57.1)	133 (44.4)	1.38 (0.99, 1.92)	0.05
Overweight	8 (28.5)	77 (25.6)	1.11 (0.60- 2.06)	0.73
Obese	2 (7.1)	62 (20.7)	0.34 (0.08–1.33)	0.12
Morbid obesity	0 (0)	12 (4.0)	0.41 (0.02, 6.83)	0.54
Social				
Smoking	2 (7.14)	26 (8.6)	0.82 (0.20, 3.29)	0.78
Alcohol use	0 (0)	26 (8.6)		
Medical history				
Diabetes	6 (21.4)	79 (26.3)	0.81 (0.39–1.69)	0.58
Hypertension	19 (67.8)	154 (51.3)	1.32 (1.00–1.74)	0.04
Chronic kidney disease	13 (46.4)	47 (15.6)	2.96 (1.8, 4.77)	< 0.0001
Heart disease*	8 (28.5)	50 (16.6)	1.71 (0.90, 3.24)	0.09
Cancer	7 (25.0)	39 (13.0)	1.92 (0.95, 3.89)	0.06

*coronary artery disease, heart failure.

▶ **Table 2** Indications for ERCP.

	Total	≥ 90	< 90	(95% CI)	P value
	n = 328(%)	n = 28 (%)	n = 300 (%)		
Obstructive jaundice	128 (39)	15 (53.5)	113 (37.6)	1.42 (0.97, 2.06)	0.0651
Choledocholithiasis	65 (19.8)	9 (32.1)	56 (18.6)	1.72 (0.95, 3.09)	0.0699
Dilated bile duct	41 (12.5)	3 (10.7)	28 (9.3)	1.14 (0.37, 3.53)	
Acute pancreatitis	26 (7.9)	0	26 (8.6)		
Pancreatic/biliary leak	18 (5.48)	0	18 (6.0)		
Elevated liver enzymes	15 (4.5)	0	15 (5.0)		
Recurrent pancreatitis	15 (4.5)	0	15 (5.0)		
Chronic pancreatitis	9 (2.7)	1 (3.6)	8 (2.6)	1.33 (0.17, 10.32)	0.7792
Ampullary mass/adenoma	10 (3)	0	10 (3.3)		
Cholangitis	6 (1.8)	0	6 (2.0)		
Primary sclerosing cholangitis	3 (0.91)	0	3 (1.0)		

ERCP, endoscopic retrograde cholangiopancreatography.

▶ **Table 3** Interventions performed.

	Total	≥ 90	< 90	(95% CI)	P value
	n = 328(%)	n = 28 (%)	n = 300 (%)		
Sphincterotomy	218 (66.4)	23(82.1)	195 (65.0)	1.26 (1.04, 1.53)	0.016
Stone removal	150 (45.7)	14 (50.0)	136 (45.3)	1.10 (0.74, 1.63)	0.623
Dilation	38 (11.5)				
Biliary		6 (21.4)	28 (9.3)	2.29 (1.03, 5.06)	0.039
Pancreatic		1 (3.5)	3 (1.0)	3.57 (0.38, 33.20)	0.263
Stent placement	117 (35.6)				
Biliary plastic		8 (28.5)	74 (24.6)	1.15 (0.62, 2.14)	0.641
Biliary SEMS		5 (17.8)	6 (2.0)	8.92 (2.90,27.41)	0.0001
Pancreatic duct		1 (3.5)	23 (7.66)	0.46 (0.06,3.32)	0.445
Biliary & pancreatic		0	6 (2.0)		
Ampullectomy	10 (3.0)	0	10 (3.3)		
Cholangioscopy	13 (3.9)	1 (3.5)	12 (4.0)	0.89 (0.12, 6.62)	0.911
Lithotripsy	8 (2.4)	1 (3.5)	7 (2.3)	1.53 (0.20, 12.00)	0.685
Tumor ablation	9 (2.74)	2 (7.1)	7 (2.3)	3.06 (0.67, 14.04)	0.149
Choledochoduodenostomy (EUS-guided)	2 (0.60)	1 (3.5)	1 (0.3)	10.71 (0.68, 166.7)	0.090
Pancreatoscopy	1 (0.30)	0	1 (0.3)		
Success rate	316 (96.3)	27 (96.4)	289 (96.3)	1.00 (0.92, 1.07)	0.979

SEMS, self-expanding metal stent; EUS, endoscopic ultrasound.

There was no statistically significant difference in the overall rate of AEs between in the two groups. (7.1% ≥ 90 y/o vs 6.6% < 90 y/o, RR 1.07, 0.26–4.34). There were no serious AEs reported during the procedure in either group. Intraprocedural AEs were only seen in the < 90 y/o cohort, with bleeding occurring in 3.3% and hypoxia in 0.3%.

Post-ERCP AEs occurred in 7.1% and 3.0% in the ≥ 90 and < 90 cohorts, respectively (RR 2.38, 0.54–10.48). Post-procedural AEs in the ≥ 90 y/o cohort were as follows: one patient (3.6%) had bleeding and one (3.6%) was diagnosed with pancreatitis, graded as mild. In comparison, the < 90 y/o group had five patients (1.7%) with mild pancreatitis, one (0.33%) with bleeding, and three (1.0%) with cholangitis. None of the patients suffered from severe pancreatitis.

Both patients who bled after the procedure were classified as moderate and required blood transfusions. No perforations occurred in either group. No deaths were directly attributed to the procedure. All-cause mortality during hospitalization was significantly higher in the ≥ 90 y/o cohort (7.1% ≥ 90 y/o vs 1.0% < 90 y/o, RR 7.14, 1.24–40.97). Three patients from the younger group died 2, 3, and 5 days after the procedure due to AEs unrelated to the procedure. One patient had advanced pancreatic cancer and later developed bacteremia and respiratory failure. Another died from progressive metastatic pancreatic cancer. The third one died from hepatorenal syndrome. Two patients in the ≥ 90 y/o cohort died 13 and 15 days after the procedure from multiorgan failure, sepsis, and advanced pancreatic cancer, which were unrelated to the ERCP.

Discussion

Invasive procedures such as ERCP have become an integral element for diagnosis and management of pancreaticobiliary disorders. As the proportion of individuals in a population having advanced age increases, so do the complexity and risks associated with medical procedures. Factors such as frailty, multiple comorbidities, and polypharmacy play an important role in the care of geriatric patients. ERCP is considered one of the most invasive endoscopic procedures, but is generally accepted as safe in the elderly population [5, 12]. However, published data are largely limited to septuagenarian and octogenarian patients, with very few nonagenarians included in these series. Endoscopic intervention often obviates the need for emergency biliary tract surgery in the elderly, is better tolerated, and is associated with significantly less morbidity and mortality [12].

The safety and efficacy of ERCP in patients of advanced age has largely been focused on reporting in patients over the age of 80, but is very limited in subjects past their ninth decade of life [13]. We found that rates of successful ERCP completion were not statistically significantly different between patients over 90 years old and their younger counterpart. Furthermore, overall AEs occurred at a similar rate between both groups, re-

sults which are comparable to those from previously published series, which reported a rate of 6.3% to 14.0% [14, 15].

A recent systematic review found a significantly higher rate of bleeding, cardiopulmonary AEs, and mortality among nonagenarians who underwent ERCP compared to younger patients [16]. Our series found a nearly two and a half-fold higher rate of post-procedural AE in the group ≥ 90 y/o, which was not statistically significant different than in the younger group, and could represent a type 2 error of statistics attributable to the small number of patients in the ≥ 90 y/o cohort. However, there was a significantly higher in-hospital mortality rate in the ≥ 90 y/o group, not directly attributed to the procedure, but as a result of decompensation of their underlying comorbidities. These deaths occurred at 2, 3, and 5 days after the procedure in the younger group, in contrast to the nonagenarians, in whom deaths occurred later, at 13 and 15 days after the ERCP. These results are in agreement with a recent study by Sobani et al, which found that age over 90 was an independent predictor of inpatient mortality following ERCP. Interestingly, they report a 12% mortality rate despite the indication for ERCP being choledocholithiasis or cholangitis in 85% of cases [15]. The authors speculate that this may reflect less aggressive care for patients over the age of 90 with tumors or abnormal radiologic findings. In comparison, we found a 7% inpatient mortality in nonagenarian patients undergoing advanced procedures such as cholangioscopy, SEMS placement, lithotripsy, and even EUS-guided choledochoduodenostomy to salvage a failed transpapillary stent placement.

Finkelmeyer et al found a higher risk of sedation-related AEs, but decreased rate of post-ERCP pancreatitis in patients older than 80 [17]. There was no statistically significant difference in the rates of post-ERCP pancreatitis and intraprocedural AEs in our series. Moreover, no patient older than age 90 years suffered a cardiorespiratory adverse event while getting moderate anesthesia under the supervision of a nurse anesthetist or anesthesiologist.

We acknowledge that this study has several limitations. First, it was performed in a single center and all procedures were performed by a single endoscopist, which are factors that reduce the generalizability of the results. Second, as with any retrospective cohort study, there is a risk of selection bias and missing data. However, the chances of having incomplete or missing data were less in the ≥ 90 y/o cohort because the majority of ERCPs were done while the patients were hospitalized. Furthermore, it is routine practice in our endoscopy unit for the staff to call every outpatient and inpatient transferred from another institution to document any AEs the day after an endoscopic procedure. Third, the use of pancreatic stents or indomethacin suppositories was not standardized, but rather, used at the discretion of the endoscopist. However, there was no difference between the ≥ 90 y/o and <90 y/o groups in the rate of pancreatic stents placed or indomethacin suppositories used.

Conclusions

In summary, ERCP can be safely and effectively performed in nonagenarian patients, and age alone should not be considered an independent risk factor for AEs or a contraindication to the procedure. Procedural success in nonagenarian patients was similar to those in the younger cohort, despite differences in the kinds of interventions that were being performed. Ultimately, it is important to recognize that inpatient mortality in this population may be higher as a result of their complex medical condition and comorbidities.

Conflict of Interest

The authors declare that they have no conflict of interest.

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