

# Increased severity of complications after therapeutic ERCP in geriatric patients with chronic pancreatitis An observational study

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#### Abstract

Studies of therapeutic endoscopic retrograde cholangiopancreatography (ERCP) in geriatric patients have mainly examined patients with biliary diseases, rather than chronic pancreatitis (CP). This study aimed to evaluate the safety and success rate of therapeutic ERCP in geriatric patients with CP.

The medical records of patients with CP aged over 65 years (group A) were retrospectively collected in a tertiary hospital from January 2013 to December 2018. Sex-matched CP patients under 65 years (group B) were randomly selected into the control group (matching ratio = 1:2). The success rate and the complication rate of therapeutic ERCP in 2 groups were compared. The risk factors for post-ERCP pancreatitis were investigated by univariate and multivariate analyses.

A total of 268 ERCPs were performed in 179 patients of group A and 612 ERCPs in 358 patients of group B. The success rate of ERCP in group A was similar to that of group B (92.16% vs 92.32%; P = .936). The overall incidence of post-ERCP complications was 7.09% (19/268) and 5.72% (35/612) in group A and B, respectively (P = .436). However, geriatric patients had a significantly increased occurrence of moderate to severe complications (2.61% vs 0.16%; P = .002). Female gender (odds ratio [OR] = 3.40; P = .046), pancreas divisum (OR = 7.15; P = .049), dorsal pancreatogram (OR = 7.40; P = .010), and lithotripsy (OR = 0.15; P = .016) were significantly associated with risk of post-ERCP pancreatitis in geriatric patients.

Therapeutic ERCP is safe and feasible in elderly patients with CP. However, occurrence of moderate to severe complications after ERCP increased in geriatric patients.

**Abbreviations:** CBD = common bile duct; CI, confidence intervals; CP = chronic pancreatitis; ERCP = endoscopic retrograde cholangiopancreatography; ESWL = extracorporeal shock wave lithotripsy; MPD = main pancreatic duct; OR = odds ratios; PD = pancreatic duct; PEP = post-ERCP pancreatitis.

Keywords: chronic pancreatitis, complications, ERCP, feasibility, geriatric

# 1. Introduction

Chronic pancreatitis (CP) is characterized by long-standing inflammation of the pancreas resulting in progressive damage to the pancreatic parenchyma; it ultimately causes failure of exocrine and endocrine pancreatic function.<sup>[1,2]</sup> The incidence of CP increases with increasing age (20–74 years), with the highest prevalence among those aged 45 to 74 years.<sup>[3]</sup> Due to improvements in health care, human longevity continues to rise. The World Health Organization Report 2013 highlighted

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the problems associated with aging of the global population.<sup>[4]</sup> Importantly, with aging of the population, more people will develop CP worldwide.

The latest guidelines recommend endoscopic retrograde cholangiopancreatography (ERCP) as the first-line therapy for patients with uncomplicated painful CP.<sup>[5,6]</sup> Elderly patients often present with chronic concomitant diseases, such as cardiovascular diseases, respiratory diseases, and neurological diseases, as well as weakened body function and geriatric syndromes.<sup>[7,8]</sup> Thus, the risk of ERCP-related adverse events may

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increase with age, and the consequences may be more severe and long-lasting in the elderly.

Several studies have shown that ERCP can lead to serious complications in elderly patients,<sup>[7,9,10]</sup> including hemorrhage, perforation, acute pancreatitis, and cholangitis, among others. Moreover, elderly patients had higher rates of chronic concomitant diseases, and the risk of complications may be associated with chronic obstructive pulmonary disease.<sup>[10]</sup> However, there are few relevant studies in the context of CP and the studies that are available involve relatively small numbers of elderly CP patients or mixed CP patients with biliary diseases.

Thus, we conducted this study to evaluate the safety and success rate of therapeutic ERCP in CP patients aged  $\geq 65$  years. The ERCP success rate and complication rate were analyzed and were compared with those of younger patients.

# 2. Methods

#### 2.1. Study design

This study was an retrospective observational study that aimed to evaluate the outcomes of CP patients aged  $\geq 65$  years who were treated with ERCP and to compare these ERCP outcomes to those of CP patients aged < 65 years. The study involving human participants has been approved by the Changhai Institutional Review Board and has been performed in accordance with the ethical standards laid down in an appropriate version of the Declaration of Helsinki (as revised in Brazil 2013). Written informed consent was obtained from all patients participating in the study.

#### 2.2. Patients and data collection

We recruited 179 consecutive patients aged  $\geq 65$  years (defined as group A) who underwent therapeutic ERCP for the management of CP at the Changhai Hospital between January 2013 and December 2018. A total of 358 sex-matched patients with CP aged <65 years who also underwent therapeutic ERCP for the management of CP were recruited into the control group (defined as group B) using the incidence density sampling method (ie, 2 consecutive controls selected within 1 week of recruitment of 1 index patient),<sup>[11,12]</sup> with consideration for changes in diagnostic and therapeutic modalities over time.

The diagnosis of CP was established based primarily on computed tomography, magnetic resonance imaging, or endoscopic ultrasound examinations.<sup>[13-15]</sup> All patients suffered abdominal or back pain associated with pancreatitis. Indications of ERCP were the presence of ductal stones, strictures, or both stones and strictures in the head/body of the pancreas that induced a dilated duct on imaging.<sup>[5,6]</sup> Patients who had undergone pancreatic surgery or gastrectomy with Billroth II reconstruction prior to the ERCP procedure, received a diagnostic-only ERCP, or suspected of malignant tumors were excluded from this study. A diagnostic ERCP was defined as an injection of contrast medium into the bile duct or pancreatic duct (PD) during endoscopy without any therapeutic procedure. Therapeutic ERCP was defined as any interventional procedure performed, aside from cholangiopancreatogram or pancreatogram. Therapeutic ERCP included endoscopic sphincterotomy, dilation of PD stricture, pancreatic stone extraction, and pancreatic stent placement.<sup>[15,16]</sup>

Detailed data on each patient were obtained from an endoscopy center database. Collected data included demographic data, important chronic concomitant diseases, endoscopic findings, interventions, success, and complications. All patients were classified according to the M-ANNHEIM clinical staging.<sup>[17]</sup> Chronic concomitant diseases were classified as follows: cardiovascular (ischemic or valvular heart disease, congestive heart failure, significant cardiac arrhythmia), neurologic (previous cerebrovascular event, severe dementia, multiple sclerosis), pulmonary (chronic obstructive pulmonary disease, bronchial asthma, lung resection), diabetes mellitus, chronic renal failure, and liver cirrhosis.<sup>[18]</sup>

#### 2.3. Treatment strategy

Before performing the ERCP procedure, extracorporeal shock wave lithotripsy (ESWL) was performed for the clearance of radiopaque obstructive main pancreatic duct (MPD) stones >5 mm located in the head/body of the pancreas as indicated in guidelines.<sup>[5,6]</sup> ESWL was performed using a third-generation electromagnetic lithotripter (Compact Delta II; Dornier Med Tech, Wessling, Germany). The patients received intravenous analgesia (flurbiprofen and remifentanil) before the procedure. One or more sessions of ESWL were performed for adequate stone fragmentation in all patients. Successful stone fragments  $\leq 2$  or 3 mm or by the demonstration of a decreased stone density at x-ray, an increased stone surface, and heterogeneity of the stone that may fill the MPD and adjacent side branches.<sup>[5]</sup>

Therapeutic ERCP was performed under conscious sedation with intravenous administration of diazepam 5 to 10 mg and pethidine 25 to 50 mg. All endoscopic treatments were performed by experienced endoscopists who had each performed >1000 ERCP procedures. If necessary, endoscopic sphincterotomy was performed. A dilating bougie or balloon was used to dilate the stenosis after sphincterotomy. Standard techniques (ie, extraction basket, extraction balloon, or both) were used for stone removal. A PD stent was used for drainage and nasopancreatic catheters were inserted for temporary drainage if necessary. Blood pressure, pulse, and oxygen saturation were closely monitored during all procedures. All patients were observed in the ward for 24 hours after ERCP treatment to monitor for the occurrence of complications following the intervention.

#### 2.4. Outcome measures

There were 2 main outcomes of this study: the success rate of ERCP and the complication rate of ERCP. The calculation of post-ERCP complication and success rate was based on the procedures. According to the classifications described by Bernica et al,<sup>[19]</sup> ERCP can be classified as a complete success, partial success, or failure. ERCP complete success is achieved if all expected diagnostic and therapeutic measures are performed, including complete stone removal or PD drainage. ERCP is considered a partial success if only some of the expected procedures are performed successfully. If none of the planned objectives are completed, ERCP is considered a failure.

This study also compared the ERCP complication rate in CP patients aged  $\geq 65$  years with that of younger patients. ERCP was performed only once in most patients during hospitalization. If the second ERCP procedure was performed due to the failure of the first one, ERCP complications involved all ERCP procedures performed during hospitalization. Post-ERCP complications and their severity were defined according to the Consensus Criteria reported by Cotton et al.<sup>[20]</sup> Major post-ERCP complications included pancreatitis, bleeding, infection, perforation, and basket impaction and were classified as mild, moderate, or severe depending mainly on the length of hospitalization and the need for invasive treatment (**Supplementary Table 1** http://links.lww.com/MD/G799). Post-ERCP pancreatitis (PEP) was defined as new or worsening abdominal pain and a serum concentration of amylase 3 times greater than the normal upper limit >24 hours after the procedure.

#### 2.5. Statistical analyses

Statistical analyses were performed to compare the various parameters between geriatric patients and younger patients.

Depending on their distributional properties, continuous variables are expressed as mean  $\pm$  standard deviation or median and range, whereas categorical data are expressed as percentages. Normally distributed quantitative data were analyzed with the Student *t* test. Categorical data were analyzed with the chi-square test, with Yates correction when appropriate, or Fisher exact test whenever applicable. A *P* value (2-tailed) <.05 was considered statistically significant. Variables with *P* value <.10 in univariate analyses were included in multivariate logistic regression analysis using the "Enter" method. Risk factors included in the final model are presented as odds ratios (ORs) with 95% confidence intervals (CIs). All statistical analyses were performed using IBM SPSS Statistics version 23.0 (IBM Corp., Armonk, NY).

# 3. Results

# 3.1. Baseline characteristics of patients

A total of 268 ERCP procedures were performed in 179 patients (77.09% males) aged ≥65 years (group A). The mean age of group A was 69.12 ± 4.65 years. In group B, a total of 612 ERCP procedures were performed in 358 patients aged <65 years (mean age 42.68 ± 12.97 years). There were statistically significant differences between the groups in terms of age of onset of CP, incidence of pancreatic stones, and incidence of chronic concomitant diseases (Table 1). Compared with the control group, geriatric patients had an older age of onset of CP  $(63.51 \pm 10.29 \text{ vs } 37.63 \pm 13.71 \text{ years};$ P < .001). Herein, age at disease onset was defined as the age at onset of abdominal pain or in patients who did not experience prior symptoms, as age at diagnosis of CP. The incidence of pancreatic stones was also higher in group A (94.97% vs 77.93%; P < .001). Chronic concomitant diseases, including cardiovascular diseases (10.06% vs 1.40%; P < .001), neurologic diseases (5.03% vs 0.84%; P = .005), pulmonary diseases (7.26% vs 2.23%; P = .005), liver disease (8.38% vs 2.51%; P = .002), diabetes mellitus (34.64% vs 24.02%; P = .009), and hypertension (34.08% vs 10.06%; P < .001), were more prevalence in group A than in group B. According to the M-ANNHEIM classification, the proportion of CP patients at different stages was not statistically different for group A and group B (all P > .05).

#### 3.2. ERCP findings and interventions

Endoscopic findings on ERCP included dilation of the MPD in 218 ERCPs (81.34%), periampullary diverticula in 19 ERCPs (7.09%), and common bile duct (CBD) stricture in 11 ERCPs (4.10%; Table 2). There were no significant differences between the 2 groups (all P > .05).

Among those patients with radiopaque pancreatic stones  $\geq 5 \text{ mm}$ , 142 (52.99%) and 337 (55.07%) ESWL procedures were performed before ERCP in group A and B, respectively (P = .569). There were 13 (4.85%) and 34 (5.56%) dorsal pancreatogram procedures in group A and B, respectively (P = .669). Of the 6 patients with pancreas divisum in group A, 5 underwent dorsal pancreatogram; 1 did not due to failed cannulation. There were no statistically significant differences between the groups in terms of endoscopic papillotomy, dilation of PD stricture, stone extraction, and pancreatic stent, respectively (all P > .05; Table 2). Additionally, only 1 patient underwent the second ERCP due to the failure of the first ERCP, whereas 5 patients in the control group. No ERCP-related complications occurred in these 6 patients during their hospitalization.

# 3.3. Success rate of ERCP

The ERCP success rate was 92.16% (247/268) in group A and 92.32% (565/612) in group B; there was no statistically significant difference between the 2 groups (P = .936; Table 3). There were also no differences in complete (85.07% vs 84.97%; P = .967) or partial success (7.09% vs 7.35%; P = .890) between the 2 groups. In group A, there was a total of 21 ERCP failures, 8 of which were caused by abnormal duodenal papilla (4 due to swelling of the papilla, 1 due to a small opening of the papilla, and 3 due to no identification of the papilla). Another main reason for ERCP failure was abnormal MPD, including MPD distortion (2/21), stricture (1/21), or stone blockage (2/21). Other causes of failure included duodenal stenosis (1/21), pancreas divisum (2/21), and unknown causes (5/21).

# 3.4. Complications of ERCP

The overall incidence of post-ERCP complications was similar in the 2 groups (7.09% [19/268] vs 5.72% [35/612]; P = .436; Table 4 and Figure 1). There were no statistical differences in

# Table 1

Demographic and clinical characteristics of the geriatric group and the control group.

	Geriatric group (N = 179)	Control group (N = 358)	P value	
Male, n (%)	138 (77.09)	276 (77.09)	1	
Age at enrollment (y)	$69.12 \pm 4.65$	42.68±12.97	<.001	
Age at onset of chronic pancreatitis (y)	$63.51 \pm 10.29$	$37.63 \pm 13.71$	<.001	
Prior acute pancreatitis, n (%)	115 (64.25)	240 (67.04)	.519	
Pancreatic stones, n (%)	170 (94.97)	279 (77.93)	<.001	
Steatorrhea, n (%)	25 (13.97)	59 (16.48)	.45	
Pancreas divisum, n (%)	6 (3.35)	16 (4.47)	.538	
Chronic concomitant diseases, n (%)				
Cardiovascular	18 (10.06)	5 (1.40)	<.001	
Neurologic	9 (5.03)	3 (0.84)	.005	
Pulmonary	13 (7.26)	8 (2.23)	.005	
Renal	3 (1.68)	3 (0.84)	.663	
Liver	15 (8.38)	9 (2.51)	.002	
Diabetes mellitus	62 (34.64)	86 (24.02)	.009	
Hypertension	61 (34.08)	36 (10.06)	<.001	
M-ANNHEIM clinical staging, n (%)				
0	10 (5.59)	28 (7.82)	.341	
	98 (54.75)	208 (58.10)	.46	
	57 (31.84)	91 (25.42)	.116	
III	12 (6.70)	27 (7.54)	.724	
IV	2 (1.12)	4 (1.12)	1	

#### Table 2

Findings and interventions of all endoscopic retrograde cholangiopancreatography procedures.

	Geriatric group (N = 268)	Control group (N = 612)	<i>P</i> value
Endoscopic findings, n (%)			
MPD dilation	218 (81.34)	520 (84.97)	.179
Periampullary diverticula	19 (7.09)	32 (5.23)	.277
CBD stricture	11 (4.10)	13 (2.12)	.097
ESWL procedure, n (%)	142 (52.99)	337 (55.07)	.569
Difficult cannulation, n (%)	47 (17.54)	99 (16.18)	.617
Dorsal pancreatogram, n (%)	13 (4.85)	34 (5.56)	.669
Endoscopic papillotomy, n (%)	( )	( <i>'</i> ,	
Major	135 (50.37)	321 (52.45)	.570
Minor	9 (3.36)	24 (3.92)	.686
Pancreatic duct stricture	( )	( <i>'</i> ,	
dilation, n (%)			
Bougie dilation	49 (18.28)	122 (19.93)	.569
Balloon dilation	16 (5.97)	58 (9.48)	.084
Stone extraction, n (%)			
By balloon	173 (64.55)	417 (68.14)	.298
By basket	10 (3.73)	24 (3.92)	0.893
Pancreatic stent, n (%)	179 (66.79)	413 (67.48)	.840
Stent diameter (F), n (%)			
5	79 (29.48)	144 (23.53)	.062
7	75 (27.99)	186 (30.39)	.572
8.5	19 (7.09)	64 (10.46)	.116
10	6 (2.24)	19 (3.10)	.477

CBD = common bile duct, ESWL = extracorporeal shock wave lithotripsy, MPD = main pancreatic duct.

#### Table 3

# Success rate of therapeutic endoscopic retrograde cholangiopancreatography.

	Geriatric group (N = 268)	Control group (N = 612)	P value
Success, n (%)	247 (92.16)	565 (92.32)	.936
Complete*	228 (85.07)	520 (84.97)	.967
Partial <sup>+</sup>	19 (7.09)	45 (7.35)	.890
Failure‡, n (%)	21 (7.84)	47 (7.68)	.936

\*All expected diagnostic and therapeutic measures are performed.

<sup>†</sup>Only some of the expected procedures are performed successfully

\*None of the planned objectives is completed.

# Table 4

# Complications of therapeutic endoscopic retrograde cholangiopancreatography.

	Geriatric group (N = 268)		
Type, n (%)			
Post-ERCP pancreatitis	13 (4.85)	28 (4.58)	.858
Bleeding	3 (1.12)	2 (0.33)	.341
Infection	3 (1.12)	4 (0.65)	.761
Perforation	0	0	_
Basket impaction	0	1 (0.16)	1.000
Severity, n (%)			
Mild	12 (4.48)	34 (5.56)	.508
Moderate	5 (1.87)	1 (0.16)	.017
Severe	2 (0.75)	0	.093
Moderate + severe	7 (2.61)	1 (0.16)	.002
Total complications, n (%)	19 (7.09)	35 (5.72)	.436

ERCP = endoscopic retrograde cholangiopancreatography.

the incidence of PEP (4.85% [13/268] vs 4.58% [28/612]), bleeding (1.12% [3/268] vs 0.33% [2/612]), infection (1.12% [3/268] vs 0.65% [4/612]), or basket impaction (0 [0/268] vs

0.16% [1/612]) between the 2 groups (all P > .05). Although the incidence and type of complications were similar, the risk of moderate to severe complications in elderly patients was significantly increased compared to younger patients (2.61% [7/268] vs 0.16% [1/612];  $\hat{P} = .002$ ); almost all complications in group B were mild (4.48% [12/268] vs 5.56% [34/612]; P = .508). All complications were resolved with conservative medical treatment, except for 2 cases of moderate bleeding in group A. Additionally, we further analyzed the complications of the first ERCP between the geriatric group and the control group. The complication results of the first ERCP were similar to that of all ERCP procedures (Supplementary Table 2 http:// links.lww.com/MD/G799). There were no statistical differences in the complication types of the first ERCP between the 2 groups (all  $\bar{P} > .05$ ), whereas the incidence of moderate to severe complications in elderly patients was significantly higher compared to younger patients (2.79% [5/179] vs 0 [0/358]; P = .007).

PEP is the main post-ERCP complication. In this study, PEP was documented in 13 cases in group A, including 8 mild cases, 3 moderate cases, and 2 severe cases. In comparison, there were 28 PEPs in group B, of which almost all were mild (27/28) and only 1 case of PEP was moderate. The risk of moderate to severe PEP in elderly patients was significantly higher compared to younger patients (1.87% [5/268] vs 0.16% [1/612]; P = .017). In group A, no PEP occurred among CP patients at stage 0, III, and IV, and the incidence of PEP among CP patients at stage I and II was 9.18% (9/98) and 7.02% (4/57), respectively. In group B, with increasing stage, the incidence of PEP was 7.14% (2/28), 7.69% (16/208), 4.40% (4/91), 3.70% (1/27), and 0% (0/4), respectively.

Three of 268 (1.12%) ERCP procedures in group A developed post-ERCP bleeding. Two of 612 (0.33%) ERCP procedures in group B developed mild post-ERCP bleeding. No patients with bleeding had a history of antiplatelets/anticoagulants prior to procedure. In group A, there was 1 mild case of bleeding caused by pancreatic pseudocyst. The patient was treated by placing a pancreatic plastic stent for drainage of the pseudocyst in the tail of the pancreas. On the second day after ERCP, the patient presented abdominal pain. An emergency upper abdominal CT scan showed bleeding from the pseudocyst in the tail of the pancreas. The bleeding was successfully treated by intravenous injection of hemocoagulase agkistrodon. There were 2 moderate cases of bleeding caused by mucosal laceration of the cardias. Two patients with MPD stones were treated by extraction of the stone fragments at ERCP. When the endoscopy was withdrawn, the mucosal laceration of the cardias and bleeding was observed. The patients' hemoglobin levels declined significantly requiring blood transfusion treatment. For these 2 cases, bleeding was successfully stopped utilizing intraoperative and postoperative placement of hemostatic clips under the endoscope, hot probe hemostasis, and local injection of hemostatic drugs. The infections or basket impaction in both groups were mild. There was no ERCP-related perforation or death events.

#### 3.5. Risk factors for PEP

Given the high incidence of PEP in our geriatric cohort, we performed a risk factor analysis for PEP (Table 5). Univariate analysis showed that 3 patient-related factors and 2 intervention-related factors were significantly associated with PEP, including female gender (P = .047), pancreas divisum (P = .031), pancreatic stones (P = .099), dorsal pancreatogram (P = .007), and ESWL (P = .015). Factors with P values <.10 were used to establish a multivariate model. After multivariate analysis, 4 factors were determined to be independently related to PEP. Female gender (OR = 3.40; 95% CI: 1.02–11.31; P = .046), pancreas divisum (OR = 7.15; 95% CI, 1.01–50.62; P = .049), and dorsal pancreatogram (OR = 7.40; 95% CI, 1.63–33.64; P = .010) significantly increased the risk of PEP and ESWL prior



Figure 1. Comparison of type (A) and severity (B) of post-ERCP complications between geriatric and control groups. \*P < .05. ERCP = endoscopic retrograde cholangiopancreatography.

to ERCP significantly reduced the risk of PEP (OR = 0.15; 95% CI, 0.03–0.70; P = .016).

# 4. Discussion

The incidence of CP increases with increasing age.<sup>[3]</sup> Thus, the need for therapeutic ERCP as a first-line treatment strategy for CP will continue to increase with the aging population. For this reason, it is important to recognize the risks and benefits of ERCP in geriatric patients with CP. There have been few studies of ERCP in geriatric patients, and there have been none that have reported specifically on CP patients. Therefore, this study

aimed to investigate the safety and success rate of ERCP in geriatric patients with CP and to explore the risk factors related to complications.

In the current study, the success rate of ERCP was found to be similar in the 2 groups (92.16% vs 92.32%; P = .936), such that ERCP was highly feasible in elderly patients. The success rate of 92.16% in geriatric patients is similar to the success rates reported in other studies,<sup>[7,21-23]</sup> which range from 88.0% to 96.9%. Galeazzi et al<sup>[21]</sup> analyzed the clinical records of patients aged  $\geq 65$  years undergoing ERCP. The main indication for ERCP was CBD stone (32.9% vs 40.0%) in patients aged 65 to 79 years and those aged 80 years or older; the success rate

Table 5	
Univariate and multivariate analyses of factors affecting incidence of PEP in geriatric patients with CP.	

Variables		Univariate		•	Multivariate		
	n (%)	OR	95% CI	P value	OR	95% CI	P value
Patient factors (N = $179$ )							
Female gender	41 (22.91)	3.21	1.01-10.16	.047	3.40	1.02-11.31	.046
Pancreatic divisum	6 (3.35)	7.32	1.21-44.45	.031	7.15	1.01-50.62	.049
Pancreatic stones	170 (94.97)	0.24	0.05-1.31	.099			
Prior acute pancreatitis	115 (64.25)	1.27	0.38-4.31	.698			
Intervention factors ( $N = 268$ )							
ESWL	142 (52.99)	0.15	0.03-0.69	.015	0.15	0.03-0.70	.016
Difficult cannulation	47 (17.54)	0.77	0.17-3.58	.743			
Dorsal pancreatogram	13 (4.85)	7.35	1.75-30.92	.007	7.40	1.63-33.64	.010
Endoscopic papillotomy	144 (53.73)	1.40	0.45-4.40	.564			
Dilation of stricture	65 (24.25)	1.48	0.44-4.97	.529			
Pancreatic stent	179 (66.79)	0.79	0.25-2.48	.681			

CI = confidence interval, CP = chronic pancreatitis, ERCP = endoscopic retrograde cholangiopancreatography; ESWL = extracorporeal shock wave lithotripsy, PEP = post-ERCP pancreatitis, OR = odds ratio.

of ERCP was 94.6% and 93.7%, respectively. Han et al<sup>[7]</sup> analyzed patients aged ≥80 years and those <65 years who underwent ERCP. CBD stone combined with gallbladder stone was the most common indication for ERCP (42.6% vs 46.8%). The success rate (94.9% vs 97.4%; P = .096) was not significantly different between the 2 groups.

The incidence of post-ERCP complications in both groups in this study was very low, at 7.09% and 5.72% for group A and B, respectively (P = .436). The complications rate in geriatric patients was similar to those reported previously in studies that have shown that ERCP is safe for elderly patients (complications rates ranging from 4.8% to 8.4%).<sup>[7,22,24]</sup> Katsinelos et al<sup>[24]</sup> analyzed patients aged ≥90 years and those 70 to 89 years of age who underwent ERCP. The rates of post-ERCP complications (6.3% vs 8.4%; P > .05) were low and not significantly different between the 2 groups. Fritz et al<sup>[22]</sup> analyzed the clinical records of patients aged ≥80 years and those <80 years undergoing ERCP. There was no significant difference in the complications rate between the 2 groups (6.8% vs 5.1%). ESGE guideline for PEP prophylaxis in 2014<sup>[25]</sup> indicates that older age is considered a protective factor for PEP, which mainly involved patients with biliary tract disease, whereas our study focused on patients with CP. One possible explanation for the lack of difference in the complications rate between the 2 groups is that the clinical staging of the disease, not patient age, plays a major role in the occurrence of complications. In this study, there was no difference in clinical staging between the 2 groups (P > .05). Further, the incidence of PEP showed a decreasing trend with increasing CP stage in both groups. The above hypothesis can be proved by a previous study that CP patients at stage Ia had the highest PEP incidence among all CP patients.<sup>[26]</sup> The pathophysiology behind this phenomenon may include a decrease in pancreatic enzyme secretion or further atrophy of the pancreas with disease progression and increasing clinical stage.<sup>[27,28]</sup>

Although the incidence and types of complications were similar in the 2 groups in this study, 7 geriatric patients had moderate to severe complications, whereas only 1 patient in the control group experienced moderate complications (P = .002). The risk of moderate to severe PEP in elderly patients was also significantly higher compared to younger patients. Several studies have reported similar results whereby elderly patients had increased severity of complications after ERCP.<sup>[29,30]</sup> This might be due to a physiological decline in immune system competence in the elderly compared to young patients, which increases the risk of inflammation.<sup>[29]</sup> Nonetheless, PEP can be prevented by routine rectal administration of diclofenac or indomethacin, which is recommended for all patients receiving ERCP without contraindication.<sup>[25]</sup> However, patients undergoing ERCP do not routinely receive diclofenac or indomethacin for prevention in clinical practice in China, including this study. Based on this study, elderly patients are at highest risk of moderate to severe PEP, and the use of preventive drugs should be recommended prior to ERCP. In addition, the type of procedural sedation used in our study was determined by clinical practice in China and differed from sedation used in western populations.

Risk factors for PEP identified in the literature include female sex, a history of acute pancreatitis or PEP, multiple cannulation attempts, and precut sphincterotomy.<sup>[22,26,31-33]</sup> In this study, we further confirmed that pancreatic divisum can increase the risk of PEP (OR = 7.15; 95% CI, 1.01–50.62; P = .049). Pancreatic divisum can increase the possibility for associated operations on the accessory PD or minor papilla, including dorsal pancreatogram.<sup>[34]</sup> For this reason, dorsal pancreatogram was also significantly associated with increased risk of PEP (OR = 7.40; 95% CI, 1.63–33.64; P = .010).

ESWL is the standard of care for large pancreatic stones (>5 mm), especially for those in the head and body region.<sup>[35,36]</sup> The clinical guidelines state that for painful uncomplicated CP with stones >5 mm in the MPD, ESWL should be the first step in management, followed by extraction of the stone fragments at a subsequent ERCP.<sup>[5,6]</sup> A large study of 5124 patients with CP who underwent ESWL and ERCP, of whom 548 patients were >60 years of age, confirmed the safety and efficacy and short-term pain relief of ESWL for large calculi in the MPD.<sup>[37]</sup> In addition to helping to remove large stones that were not amenable for extraction by ERCP, our analysis showed that patients with prior ESWL had a significantly lower risk of PEP (OR = 0.15; 95% CI, 0.03–0.70; P = .016). This is probably due to the reduced difficulty of cannulation following ESWL.

There are several limitations of this study that should be noted. First, because this was a retrospective study, we could not evaluate the long-term therapeutic effects of ERCP due to a lack of enough follow-up data after patient discharge. Second, all procedures were performed by experienced endoscopists, and thus, our results may not be generalizable to other contexts. Third, the definition of ERCP success is considered somewhat subjective in this study and may be a confounding factor in these results. Nonetheless, it should be considered that there are no widely accepted definitions of complete success, partial success, or failure.

In conclusion, this is the first study to compare the safety and success rate of therapeutic ERCP in elderly patients and younger patients only suffering from CP. The success rate of therapeutic ERCP in elderly patients with CP was identical to that of younger patients. However, in comparison to younger patients, occurrence of moderate to severe complications after therapeutic ERCP increased in geriatric patients, although there was no obvious difference in the overall incidence of complications between the 2 groups. This study indicates that therapeutic ERCP is safe and feasible in elderly patients with CP. However, there is a need for improved awareness of the severity of complications among geriatric patients; this may be of benefit in perioperative management of these patients. In the future, there is a need for the development of assessment tools to make careful periprocedural assessment of ERCP risks in elderly patients in order to predict and prevent the occurrence of complications.

# Author contributions

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