

Endoscopic retrograde cholangiopancreatography in the elderly: outcomes, safety and complications

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ABSTRACT

Introduction: As the population ages, the incidence of biliary tract pathologies also increases, leading to an increase in the demand for endoscopic retrograde cholangiopancreatography (ERCP) interventions. Our aims are to assess the outcomes, safety and complications associated with ERCP performed in an elderly population.

Methods: Patients aged 80 years or over referred for ERCP from January 1999 to September 2002, were identified and retrospectively reviewed.

Results: 103 patients (68 females, mean age 84.6 ± 3.9 years old) underwent 144 procedures (1-6 procedures/patient). The main indications were cholangitis (51.4 percent), choledocholithiasis (19.4 percent) and blocked stents (14.6 percent). Malignancies represented 5.6 percent of indications. The mean procedure time was 38 ± 16 minutes. The overall success rate was 80.5 percent. Minor events occurred in 23 percent (tachycardia 13, desaturation six, transient hypotension six, self-limiting bleed four, extravasations three, and mild pancreatitis one). Major events were post sphincterotomy bleeding (five days post-procedure) one, duodenal perforation one (Billroth-II gastrectomy, survived after surgery), cholangitis two, and one death was probably procedure-related (acute myocardial event five days post-stenting in a patient with Klatskin tumour). Seven deaths occurred within one month of ERCP, due to advanced malignancies (four), sepsis (two) and acute myocardial infarction (one). Patients who died within one month had significantly higher serum urea (p-value equals 0.001), and creatinine (p-value equals 0.007) levels, and lower haemoglobin (p-value equals 0.014) level. More patients had an underlying malignancy (p-value less than 0.001). In addition, they were given significantly less conscious sedation (midazolam [p-value equals 0.002] and fentanyl [p-value equals 0.018]).

Conclusion: Our study showed that ERCP is safe in an elderly Asian population. Minor complications

are usually transient and related to sedation, and mortality is usually related to severity of illness and underlying malignancies.

Keywords: biliary tract diseases, elderly patients, endoscopic retrograde cholangiopancreatography, endoscopy complications

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INTRODUCTION

As the population ages, the incidence of biliary tract pathologies also increases⁽¹⁾, leading to an increase in demand on the medical services to provide care for these patients. Common bile duct (CBD) exploration in patients 80 years or older reportedly has a high mortality rate at 9%⁽¹⁾. In addition, presentations can be atypical in the elderly patients leading to difficulty in diagnosis^(2,3) and delay in giving appropriate treatment, which can increase the risks of complications. Endoscopic retrograde cholangiopancreatography (ERCP) is increasingly being used to manage biliary tract diseases. Studies have shown that the complications and mortality of ERCP to be lower compared to surgical interventions^(4,5). In addition, complications of ERCP have been shown to be similar between the elderly and the young patients^(6,7).

Recent studies have shown that ERCP is safe in the elderly populations but these data are mainly from the West⁽⁸⁻¹²⁾. The yield and success rate of ERCP has been shown to be very good especially for biliary stone clearance of up to 98% and malignant biliary obstruction decompression of up to 73%⁽⁸⁾. A recent Japanese study showed that ERCP and sphincterotomy are safe for treating choledocholithiasis in the population aged over 90 years⁽¹³⁾. They also showed that stenting is a good and safe alternative for managing difficult biliary stones. Data from the East is scarce and our study aims to assess the outcomes, safety and complications of ERCP performed in elderly Asian populations.

METHODS

Patients aged 80 years and over and underwent ERCP at the Gastroenterology Unit, Tan Tock Seng Hospital

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for various indications from January 1999 to September 2002, were identified from the endoscopy register and retrospectively reviewed. Patients referred for ERCP were routinely assessed by a member of the Gastroenterology Unit to assess the appropriateness of the indications. Patients or family members were informed of the indications and the risk associated with the intended procedures. Consent was obtained from patients, or family members if patients were unable to give written consents. Conscious sedation with intravenous midazolam (dormicum) and fentanyl were routinely used for the procedures. Additionally, intravenous glucagon or buscopan (hyoscine hydrobromide) were used to reduce bowel peristalsis when indicated.

All procedures were performed by experienced gastroenterologists in the Endoscopy Unit using the Olympus endoscopic system. Therapeutic endoscopes were used for all procedures. All patients who had stone clearance had endoscopic sphincterotomy performed unless there were contraindications (coagulopathy, thrombocytopenia or anti-platelet agents). For stone clearance, the biliary mechanical lithotripter (BML, Olympus®) was routinely used under fluoroscopic guidance to crush big CBD stones (>1cm or smaller stones if sphincterotomy size was limited). Stone clearances were also done using basket (Dormia basket, Olympus®) and balloon catheter (Extractor XL triple lumen retrieval balloon, Boston Scientific Microvasive®). The latter was also routinely used to obtain a check cholangiogram to ensure complete clearance at the end of procedures.

For patients who had incomplete clearances of CBD stones or had strictures (either benign or malignant), biliary drainage were achieved by stent placements under fluoroscopic guidance. Plastic stents (Cotton-Leung biliary stent, Wilson Cook®), mostly 10Fr 10cm were inserted using the Oasis System stent delivery accessory (Wilson Cook®). The length can be variable depending on the level of obstruction. Patients with malignant strictures who were expected to survive beyond three months were offered placement of self-expandable metal stent (Biliary WallStent, Boston Scientific Microvasive®). Otherwise, plastic stents were used. Patients who failed endoscopic interventions were offered percutaneous intervention by the radiology department, or surgical intervention if they were deemed fit for the procedures.

Routine monitoring of pulse, blood pressure and saturation were performed before, during and after the procedures. Blood pressure was monitored at five minutes intervals during procedures and fifteen minutes interval after procedures until patients left

Table I. Demographics and baseline laboratory results.

Age *	84.64 ± 3.90 years
Gender (male: female)	35: 68
Activities of daily living	
Dependent	52%
Co-morbidities (≥2)	71%
Blood investigations at presentation or prior to procedures*	
Alkaline phosphatase (IU/L)	335 ± 281
Alanine transferase (IU/L)	133 ± 139
Bilirubin (mmol/L)	75 ± 91
Albumin (g/L)	33.74 ± 8.02
Leukocyte counts (x 10 ⁹ /L)	11.8 ± 5.9
Haemoglobin (g/L)	11.6 ± 2.25
Creatinine (mmol/L)	105 ± 68
Urea (µmol/L)	7.8 ± 6.4

* expressed in mean and standard deviation

the Endoscopy Unit. Pulse and saturation monitoring were monitored continuously during the procedures and then at fifteen minutes intervals after procedures in the recovery area. Any adverse events occurring during procedures were addressed immediately by the performing endoscopist.

Patients were monitored closely for the first 24 hours post-procedure and during the duration of the in-patient stay. Any adverse events deemed to be related to the procedures were reported to the gastroenterology team. Post-discharge, all patients were followed-up in the gastroenterology outpatient clinic. All patients who had gallstone disease and were deemed fit for cholecystectomy surgery, were referred to the surgical department. Patients who had stenting for failed stone clearance or strictures were followed-up in the clinic and rescheduled for repeat ERCP in three to six months, in an attempt to achieve complete clearance or replacement of stents. Patients were discharged from follow-up if they had remained well after complete clearance.

Data on patients' demography, indications, blood investigations (white cell counts, haemoglobin, serum creatinine, urea, serum alkaline phosphatase, serum bilirubin and serum alanine aminotransferase), outcomes, events, complications and one month mortality were retrieved from case records and computer database. Events were considered minor (if they were self-limiting and required minor treatments such as supplemental oxygen and fluid therapy), or major (if the events led to mortality or required interventions such as transfusion, endoscopy and a course of antibiotics).

Table II. Indications for ERCP (n=144).

Indications	% (n)
Cholangitis	51.4 (74)
Blocked stent*	14.6 (21)
Obstructive jaundice	
CBD stones	19.4 (28)
Malignancy**	2.7 (4)
Cause unknown	3.5 (5)
Gallstone pancreatitis	3.5 (5)
Dilated biliary system	
Abnormal LFT	4.2 (6)
Normal LFT/fever	0.7 (1)

LFT: liver function test

* Stents were inserted previously for large CBD stones (n=18), malignant stricture (n=1) and benign stricture (n=2).

Overall malignancy accounted for 8 procedures (Pancreatic head tumour [n=3], Klatskin tumour [n=1], ampullary tumour [n=2], advanced gall bladder tumour [n=1], colorectal tumour with portal hilar metastasis [n=1]). ** Four cases were diagnosed to have underlying malignancies before ERCP (obstructive jaundice) while the other four cases were diagnosed after ERCP (indications were obstructive jaundice [n=1], blocked stent [n=1] and dilated CBD [n=2]).

Data were entered into the Statistical Package for Social Sciences (SPSS) version 11.0 (Chicago, IL, USA) for analysis. Data were expressed as absolute numbers, percentages, means and standard deviations. Differences between those who died within and those who survived beyond one month were compared using the Fisher's exact test and the Mann-Whitney test. Significance level was taken when $p < 0.05$.

RESULTS

103 patients with a mean age of 84.6 ± 3.9 years (range 80-98 years) underwent 144 procedures. This represented 20% of all ERCPs done during this period. 75 patients underwent one procedure, and the remaining 28 patients had more than one procedure, namely: two procedures (n=21), three procedures (n=4), four procedures (n=1), five procedures (n=1) and six procedures (n=1), respectively. Multiple procedures were mainly for stent replacement. Majority of the patients were Chinese (92%). Patients' demographics and blood investigations are shown in Table I. The indications for ERCP are shown in Table II. The mean procedure time was 38 ± 16 minutes. The mean dose of conscious sedation given were midazolam 2.7 ± 1.7 mg and fentanyl 46 ± 27 μ g. Seventeen of the procedures required flumazenil to reverse the effects of midazolam.

Table III. Outcome of ERCP procedures (n=144).

	% (n)
Overall success of initial procedure	80.5 (116)
Outcomes	
CBD stone diseases	51.6 (73)
Complete clearance	39 (56)
Successful stenting [†]	11 (16)
Declined further intervention [‡]	0.7 (1)
Overall stenting	37.5 (54)
Blocked stent	20.1 (29)
Stenting for incomplete CBD stone clearance [†]	11 (16)
Stenting for strictures	6.25 (9)
Benign	2.1 (3)
Malignant	4.9 (6)
Dilated ducts and sphincterotomy*	2.8 (4)
Normal CBD and no sphincterotomy	1.4 (2)
Overall incomplete/abandoned initial procedures	19.4 (28)
Outcomes	
Successful repeat ERCP	6.3 (9)
PTC**	4.9 (7)
Surgery	5.6 (8)
Conservative medical treatment	5.6 (8)

CBD: common bile duct

* Dilated duct without obvious cause except for periampullary diverticulum, treated with endoscopic sphincterotomy

** One patient with head of pancreas tumour had PTC stenting. Four other patients subsequently had surgery.

[†] Same cases

[‡] Included in incomplete procedures (conservative medical treatment)

The overall success rate for the various indications was 80.5%. The outcomes of ERCP are shown in Table III. Complete clearance of CBD stones was achieved in 76.7% (56/73). Reason for failed clearance was mainly large CBD stones (>1cm). Overall, stents were inserted in 37.5% (54/144) procedures, of which 53.7% (29/54) were replacements for blocked stents. 16 cases of incomplete CBD stones clearance had stents inserted. The remaining nine cases were for stenting of strictures (benign three and malignant six). Four patients with underlying malignancies (ampullary tumour two and pancreatic head tumour two) and who underwent stenting, survived beyond two months and none needed repeat ERCP. 28 procedures (19.5%) were incomplete or abandoned due to various reasons (Table IV).

Table IV: Reasons for incomplete or abandoned procedures and outcomes (n=28).

Reasons	n	Outcomes
Failure to reach ampulla		
Billroth II gastrectomy	4	2A, C, E
Pyloric stenosis (peptic ulcer disease)	2	2B
Failure to achieve cannulations/ deep cannulations		
Periampullary diverticulum	9	A, 3C, 2D, 3E
Submucosal injection (extravasations)	3	2D, E
Advanced malignancies	3	B, D (stenting), E
Migrated impacted stent	1	D (stenting)
Floppy papilla	1	A
Failure to achieve adequate biliary drainage		
Failed clearance and stenting	1	E
Technical failures with fluoroscopy machine during the procedure	3	3D
Uncooperative patient despite sedation	1	E

A: surgery; B: percutaneous cholangiography (PTC);
C: PTC followed by surgery; D = successful repeat ERCP;
E: conservative management.

There were 33 minor (23%) and 5 major (3.5%) events related to the procedures. Most minor events were self-limiting, without requiring any major treatment. Bleeding associated with sphincterotomy occurred in four procedures. These were treated immediately with adrenaline injections (1mg in 10ml of water: 1/10,000 dilution) and did not require further interventions. Transient desaturation, hypotensive episodes and tachycardia occurred in six, six and 13 procedures, respectively. These responded

to fluid and oxygen supplements. Three cases of sub-mucosal extravasations occurred and led to the incompleteness of procedures. Mild self-limiting pancreatitis occurred in one patient. This settled with conservative treatment.

Of major events, one of the deaths was probably related to the procedure. This patient presented with obstructive jaundice secondary to Klatskin tumour. She underwent metal stent placement without any complication. She died of an acute myocardial event five days post-procedure. One case of post-sphincterotomy bleeding occurred five days post-procedure. The patient had to be transfused and underwent endoscopic injection therapy. One patient with Billroth II gastrectomy developed duodenal perforation. He underwent emergency laparotomy repair and CBD exploration. This showed complete transection of the afferent loop and CBD stones. Two cases developed cholangitis (patients with CBD stones stented and who had documented transient worsening of clinical states and liver function tests consistent with cholangitis after an initial improvement) and were treated with a course of intravenous antibiotics. Both cases occurred within the second week post-stenting. All remaining four patients were alive on follow-up.

Seven deaths occurred within one month of procedures (Table V). Four deaths occurred in patients with underlying advanced malignancies with underlying sepsis. Two patients died despite having successful biliary clearance due to overwhelming sepsis (cholangitis and aspiration pneumonia occurring two weeks after biliary clearance). Patients who died within one month of procedures had significantly higher levels of serum

Table V. Details of patients who died within one month of procedures.

Age/ gender	Admission diagnosis	Co-morbid conditions	Final clinical diagnosis	Outcomes	Cause of death	Time from procedure
84/F	Cholangitis	COPD/CRF/HT	CBD stones	Successful clearance	Sepsis/acute myocardial infarction	3 days
89/F	Jaundice	Nil	Klatskin tumour	Stented (metal stent)	Acute myocardial event	5 days
86/F	Cholangitis/ liver abscess	Billroth II/CVA/HT	CBD stones	PTC stenting	Pneumonia/ liver abscess	8 days
84/F	Blocked stent	DM/IHD/CRF	Blocked stent/ pancreatic tumour	Re-stented (metal stent)	Advanced pancreatic tumour	10 days
95/F	Cholangitis	DM/CVA	CBD stones	Successful clearance	Aspiration pneumonia	23 days
87/M	Cholangitis	Nil	Malignant hilar stricture	Stented (plastic stent)	Gall bladder tumour/ portal vein thrombosis	<30 days
86/F	Cholangitis/jaundice	IHD/depression	Malignant hilar stricture	Declined intervention Conservative management	Advanced ceacal tumour with hilar lymphadenopathy	30 days

COPD: chronic obstructive pulmonary disease; IHD: ischaemic heart disease; DM: diabetes mellitus; CRF: chronic renal failure;
HT: hypertension; CVA: cerebrovascular accident; PTC: percutaneous transhepatic cholangiography.

F: female; M: male.

Table VI. Comparison between patients who died within one month and those who survived beyond one month after procedures.

	Alive (n=96)	Death (n=7)	p-value
Age (years) [†]	84.6 ± 3.9	87.3 ± 3.82	0.081
Underlying malignancies [‡]	3% (4)	57% (4)	<0.001
Co-morbid conditions [†]	2.4 ± 1.3	2.6 ± 1.8	0.604
Procedure time (minutes) [†]	38.0 ± 16.3	37.9 ± 13.5	0.856
Midazolam (mg) [†]	2.8 ± 1.7	1.1 ± 0.9	0.002
Fentanyl (µg) [†]	52 ± 24	32 ± 19	0.018
Laboratory investigations [†]			
Albumin (g/L)	33.4 ± 5.6	29.5 ± 3.1	0.061
Alkaline phosphatase (IU/L)	332 ± 284	400 ± 240	0.254
Alanine aminotransferase (IU/L)	130 ± 131	187 ± 248	0.834
Bilirubin (mmol/L)	73 ± 90	103 ± 99	0.261
Leukocyte count (x10 ⁹)	11.7 ± 5.9	14.1 ± 4.9	0.182
Haemoglobin (g/L)	11.7 ± 2.2	9.7 ± 1.9	0.014
Serum urea (mmol/L)	7.3 ± 4.8	19.2 ± 17.7	0.001
Serum creatinine (mmol/L)	99 ± 54	217 ± 173	0.009

[†]: expressed in mean and standard deviation; [‡]: expressed in percentage and absolute number in bracket.

urea (19.2 ± 17.7 mmol/L versus 7.3 ± 4.8 mmol/L, $p=0.001$) and serum creatinine (217 ± 173 mmol/L versus 99 ± 54 mmol/L, $p=0.009$) and lower haemoglobin level (9.7 ± 1.9 versus 11.7 ± 2.2 , $p=0.014$), respectively. Significantly more had an underlying malignancy (57% versus 3.3%, $p<0.001$). In addition, they were given significantly less conscious sedation; midazolam (2.8 ± 1.7 mg versus 1.1 ± 0.9 mg, $p=0.002$) and fentanyl (52 ± 24 µg versus 32 ± 19 µg, $p=0.018$) (Table VI).

DISCUSSION

ERCP is a potentially life-saving intervention in the elderly population. Our study showed that ERCP is safe in the elderly Asian populations. This is in agreement with previous published studies from the West^(7-10,12). The indications in our study are comparable to these published studies, with stone disease being the commonest. This reflects the high prevalence of stone disease in the East. Despite the appropriateness of the indications in our study, our success rate is slightly lower than published data at 80.5%. Similarly, clearance rate of CBD stones was only achieved in 76.7% of cases. Main reason for failed stone clearance in our patients was mainly due to large CBD stones. These low rates may be partly explained by the presence of altered anatomies, such as periampullary diverticulum, and altered anatomies secondary to surgery, and chronic ulcer disease, making access to the common bile duct difficult. This may also be contributed by the health of our patients as indicated by the high dependency and co-morbid conditions, leading to a less aggressive approach.

Generally, adequate drainage of the obstructed biliary system can be achieved with endoscopic sphincterotomy⁽¹³⁾ or placement of stents^(11,14-16). However, use of stents as temporary or long-term measures will lead to an increase in the cases presenting with obstructed stent requiring replacement, as shown in our study (20.1%). This is inevitable as stent placement usually require a shorter time to achieve and is seen a safer alternative for the elderly population⁽¹³⁾, particularly those with multiple co-morbid conditions. This is supported by studies done showing that temporary or long-term stent placement is safe^(11,14-16). This is also reflected in our study by the percentage (37.5%) of procedures having stents inserted.

The major concerns with ERCP or endoscopies in the elderly, particularly in those with multiple co-morbid conditions, as seen in our patients, have been shown to be related to sedation^(17,18). Hypoxaemia and hypotension are particularly common. These are however transient, requiring only supportive treatment. The rate of minor events (23%) in our study were high when compared to published data. This difference may be due to differences in definitions of events. The 13 cases of tachycardia had been given buscopan which may have contributed to this. However, the majority of these minor events was not clinically significant and was only transient, needing fluid or additional increase in the oxygen supplements. Despite this, caution should always be exercised to prevent, detect and deal with these events to prevent morbidity and mortality.

Major or significant events, which are those that could cause significant morbidity and mortality, were uncommon in our study. Of the five major events that occurred, one death secondary to acute myocardial event was probably related to procedure. This occurred five days after placement of a self-expandable metal stent for hilar cholangiocarcinoma. The patient had been stable post-procedure. It was possible that the patient had undetected underlying ischaemic heart disease due to her age. Bowel perforation occurred in a patient with altered anatomy (Billroth II gastrectomy). Billroth II gastrectomy is known to make ERCP difficult^(19,21). All four patients with Billroth II gastrectomy in our study failed ERCP and needed alternative therapies.

The case of post-sphincterotomy bleeding was easily treated with endoscopic haemostasis. Older series have reported a post-sphincterotomy bleeding complication rate that is slightly higher at 2-5%. However with more experience and better techniques, the current level is 1-2%⁽⁶⁾. The risk is higher in those with coagulopathy, thrombocytopenia, cholangitis, large stones, presence of periampullary diverticulum and large sphincterotomy. Cholangitis post-procedure is usually associated with incomplete stone clearance or contamination of undrained systems, particularly those with high hilar strictures. The two cases of cholangitis post-stenting for CBD stones probably occurred as a result of passage of sediment, sludge, or stones leading to transient blockage. This settled with antibiotic treatment without needing any further endoscopic interventions.

Mortality has been shown to be often related to severity of illness. Our study showed that abnormal renal function, low haemoglobin level and underlying malignancy were significant predictors for death within one month of ERCP. In addition, those patients who died within one month were given significantly less conscious sedations. These factors probably reflected the severity of the underlying condition of our patients. Of the seven deaths that occurred within one month of ERCP, four patients had advanced malignancies in addition to underlying sepsis. Previous studies have also shown that malignancies are often associated with poor outcomes regardless of successful procedures^(8,22). Due to the small number of patients with underlying malignancies in our study, we are unable to draw any conclusion regarding palliative procedures in such patients. However, palliative endoscopic decompression of obstructed system has been shown to improve jaundice, pruritus, biochemical markers and patients' quality of life^(8,22).

In conclusion, our study showed that ERCP is safe in the elderly Asian population. Minor complications are usually transient and related to sedation, and mortality is usually related to severity of illness and underlying malignancies. ERCP should be considered when indicated in the elderly population as this may be life saving.

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