

A Year of Endoscopic Retrograde Cholangiopancreatography (ERCP) At a Glance. Indications, Interventions, Complications

Syed Kumail Hasan Kazmi, Rao Saad Ali Khan, Laima Alam*, Farrukh Saeed

Pak Emirates Military Hospital/National University of Medical Sciences (NUMS) Rawalpindi Pakistan, *Bahria International Hospital Rawalpindi, Pakistan

ABSTRACT

Objective: To determine the demographics, indications and frequency of interventions and complications endoscopic retrograde cholangiopancreatography (ERCP).

Study Design: Cross-sectional study.

Place and Duration of Study: Department of Gastroenterology, Pak Emirates Military Hospital, Rawalpindi Pakistan, from Jan to Dec 2019.

Methodology: The study included all the elective and emergency ERCP procedures from January 2019 to December 2019.

Results: Out of 1030 patients who underwent endoscopic retrograde cholangio-pancreaticography, 903 were enrolled. Sixty-one percent of the participants were males. The mean age was 56 ± 16 years, with the majority of the patients lying in the age range of 41-65 years. The most common indication for ERCP in this study was choledocholithiasis (47%), the most common complication encountered was acute pancreatitis (2.1%), and a mortality rate of 0.2% was reported. The complication rate was statistically related to the intervention rather than the age and gender of the patients.

Conclusion: The most common indication for ERCP remains choledocholithiasis, with the most common ERCP complication being acute pancreatitis followed by stent migration. Biliary fistulae, post-surgical biliary leaks and strictures, pancreatic pseudo cysts, acute cholangitis, choledocholithiasis and cholestasis secondary to as cariasis were found in a relatively younger group. The success rate was above 95% for high volume centres.

Keywords: Complications, choledocholithiasis, Endoscopic retrograde cholangiopancreatography (ERCP), Haemorrhage, pancreatitis.

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INTRODUCTION

Endoscopic retrograde cholangio-pancreatography (ERCP) was introduced in 1968 to diagnose benign and malignant biliary and pancreatic conditions. Though used mainly as therapeutic rather than diagnostic utility these days, ERCP is one of the more technically challenging procedures requiring a high set of skills and a steep curve of practice under supervision. The complication rate for ERCP is relatively high, ranging from 3-15% in good centres. 48,000 ERCPs were performed in the United Kingdom alone in one year with a complication rate of 5-10% and a mortality rate of 0.3-1% throughout thirty days. Where as, more than 500,000 ERCP procedures with a complication rate of 4-10% and a death rate of 0.05-1% were reported for 2007 from the United States.

Post-ERCP complications are variable, and a meta-analysis reported 5.4% post-procedure pancreatitis and 2% haemorrhage requiring re-hospitalization.⁶

Another study reported a rate of 4-7% acute cholangitis post-ERCP.⁷ Coagulopathy, sepsis, surgical modification of anatomy, pre-cut sphincterotomy, multiple attempts at cannulation, poor cardiovascular reserve and sedation have been recognised as predisposing conditions for overall complications during and post-ERCP.⁸ However, elderly age as a risk factor for complications is still controversial.⁹

The development of quality improvement initiatives requires an elaborate database of procedural outcome measurements for setting guidelines.¹⁰

This study described the demographic distribution, indications, and outcomes in terms of intervention(s) and complications from Pakistan's high volume specialised centre, with the largest study population.

METHODOLOGY

This cross-sectional study was carried out in the Department of Gastroenterology Pak Emirates Military Hospital, Rawalpindi, Pakistan from January 2019 to December 2019 after taking ethical approval (A/28/07/BC/122).

Correspondence: Dr Syed Kumail Hasan Kazmi, Department of Gastroenterology, Pak Emirate Military Hospital, Rawalpindi Pakistan
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Inclusion Criteria: All the patients undergoing elective and emergency ERCP procedures were included in the study.

Exclusion Criteria: Patients who were in septic or cardiogenic shock were excluded.

All the patients undergoing elective ERCP were admitted overnight before the procedure. In contrast, the emergency procedures were carried out within 12-72 hours of initial presentation, depending upon the hemodynamic stability and urgency of the procedure. All the patients were thoroughly examined, and the indication of ERCP was confirmed with the demographic data and co-morbidities duly noted.

All the patients received a local anaesthetic Lido-caine throat spray with either balanced Mida-zolam and Propofol based sedation or general anaesthesia,¹¹ led by an anaesthetist depending on patient factors. Blood pressure, pulse, oxygen saturation, ECG tracing and level of sedation was noted every five minutes,¹² by either a trained endoscopy nurse or a resident gastroenterologist. Duodenal peristalsis were reduced with intravenous Hyoscine Butyl Bromide where required.¹³ Rectal indomethacin was used as a prophylaxis against post ERCP pancreatitis. Patients with cholangitis, purulent discharge upon cannulation without fever and those deemed high risk for infective endocarditis were given prophylactic antibiotics.

A side-viewing doudenoscope was used for all patients. A team of four consultant gastroenterologists with over seven years of experience in interventional and therapeutic endoscopies carried out all the procedures. A primary method of using sphincterotome and guidewire led cannulation was done with a pre-cut sphincterotomy using a needle knife at 11 to 12 o'clock. Some of the difficult cannulations were tackled using the double-guide-wire technique.¹⁴ Serum blood samples for haemoglobin, total leucocyte count, CRP and amylase at 6-10 hours were carried out for all patients, and post-procedure stay for at least 24 hours was applied to all.¹⁵

Bleeding was defined as ≥ 3 g/dl of haemoglobin drop with or without hemodynamic instability and requirement of transfusion.¹⁶ Pancreatitis was defined as abdominal pain with at least a threefold increase in pancreatic enzymes 24-48 hours post-intervention.¹⁴ Perforation was defined as the presence of free air in the peritoneal or retroperitoneal cavity confirmed either by an erect (or left lateral) abdominal X-ray or CT scan at the time of ERCP or later during recovery. ERCP related cholangitis was defined as sepsis confir-

med by physical, biochemical and pathological parameters lasting more than 24 hours with no other source of infection. Death was defined as mortality related to either a complication of ERCP or sedation within 30 days of procedure.¹⁷ Failed cannulation was defined as failure to cannulate CBD deeply after 10-15 attempts and using needle-knife and double-guide-wire technique.¹⁷

All the complications were managed in our set-up, with surgical referral required in case of perforation only. Statistical Package for Social Sciences (SPSS) version 23.0 was used for the data analysis. Data was statistically described as mean \pm SD for continuous data, frequencies and percentages for qualitative variables. The chi-square test and Fisher exact test were used to compare qualitative data. The *p* value of ≤ 0.05 was considered statistically significant.

RESULTS

Out of 1030 patients who underwent ERCP in 2019, 903 were enrolled in the study, and the rest were excluded due to either incomplete data or loss to follow up status. Sixty-one percent of the participants were males. The mean age was 56 ± 16 years, with the majority of the patients lying in the age range of 41 to 65 years (Table-I).

The most common indication for ERCP in this study was choledocholithiasis 424 (47%), followed by benign distal CBD stricture 180 (20%), peri-ampullary growths 90 (10%) and carcinoma head of the pancreas 54 (6%), respectively (Table-I). Biliary fistulae, post-surgical biliary leaks and strictures, pancreatic pseudocysts, acute cholangitis, choledocholithiasis and cholestasis secondary to ascariasis were found in a relatively younger population (<55 years). At the same time, biliary obstruction secondary to malignancies and benign CBD strictures were seen in the older population.

Tumours (gall bladder, klatskin, ampullary, cholangiocarcinoma and Ca head of the pancreas) were a common finding among the male gender. However, post-surgical biliary leaks and other findings were predominantly seen in the females. A statistically significant relation was seen about age and gender distribution for ERCP indication.

Seventy-nine percent of the patients had no co-morbidities since most of the patients belonged to the younger age group. Diabetes mellitus and hypertension were the commonest co-morbid conditions in our setting (Figure).

Endoscopic Retrograde Cholangiopancreatography

Table-I: Indications for ERCP in the study population in relation to age and gender.

Indications /Diagnosis	Age (years)				Mean Age (Total=56 ± 16)	Gender	
	15-40 n (%)	41-65 n (%)	66-90 n (%)	>90 n (%)		Female n=349 (39%)	Male n=554 (61%)
Acute cholangitis Alone (10)	7 (70)	-	3 (30)	-	52 ± 20.2	5 (50)	5 (50)
Choledocholithiasis (18)	6 (33)	7 (39)	5 (28)	-	47 ± 17	5 (28)	13 (72)
Benign CBD Stricture (8)	2 (25)	6 (75)	-	-	54 ± 13.3	4 (50)	4 (50)
Klatskin Tumour (2)	-	2 (100)	-	-	53 ± 9	-	2 (100)
Ampullary Growth (2)	-	2 (100)	-	-	53 ± 9	2 (100)	-
Choledocholithiasis Alone (378)	80 (21)	188 (50)	103 (27)	103(27)	55.4 ± 17	170 (45)	208 (55)
Benign CBD Stricture (37)	10 (27)	17 (46)	9 (24)	1(3)	52 ± 17	170 (45)	208 (55)
Post cholecystectomy Biliary Stricture (3)	-	2 (66.6)	1 (33.3)	-	57 ± 7.4	1 (33)	2 (67)
Ampullary Growth (3)	-	3 (100)	-	-	64 ± 7	2 (67)	1 (33)
Benign Distal CBD Stricture Alone (179)	27 (15)	105 (59)	47 (26)	-	57 ± 15	68 (38)	111 (62)
Ampullary Growth (2)	-	1 (50)	1 (50)	-	62 ± 21	2 (100)	-
GB Tumor (12)	2 (17)	5 (42)	5 (42)	-	57 ± 15	5 (42)	7 (58)
Klatskin Tumor (13)	-	7 (54)	6 (46)	-	64 ± 9	5 (38)	8 (62)
Distal CDB Cholangiocarcinoma (18)	2 (11)	8 (44)	8 (44)	-	61 ± 13	1 (6)	17 (94)
CA Head of Pancreas (52)	-	32 (62)	20 (38)	-	63 ± 9	10 (19)	42 (71)
Ampullary Growth (91)	3 (3)	46 (51)	42 (46)	-	63 ± 12	25 (27)	66 (73)
Biliary Fistulas* (3)	3 (100)	-	-	-	30 ± 0.6	-	3 (100)
Biliary Leak (16)	5 (31)	4 (25)	7 (44)	-	57 ± 18.6	10 (63)	6 (37)
Post Cholecystectomy Biliary Strictures (18)	6 (33)	9 (50)	3 (17)	-	49 ± 17.4	6 (33)	12 (67)
Post LT Biliary strictures (6)	3 (50)	3 (50)	-	-	47 ± 9	1 (17)	5 (83)
Biliary Ascariasis (4)	2 (50)	2 (50)	-	-	46 ± 22.5	2 (50)	2 (50)
Pancreatic Pseudocyst (4)	2 (50)	1 (25)	1 (25)	-	47 ± 25	-	4 (100)
Others£ (23)	9 (39)	12 (52)	2 (9)	-	45 ± 18.6	12 (52)	11 (48)
p-value	<0.001	-	0.004	-	-	-	-

CBD common bile duct, CA carcinoma, LT liver transplant *fistulous tracts with liver cysts £including Primary Sclerosing Cholangitis, Caroli's disease, unexplained cholestatic jaundice, choledochal cysts, biliary tree trauma.

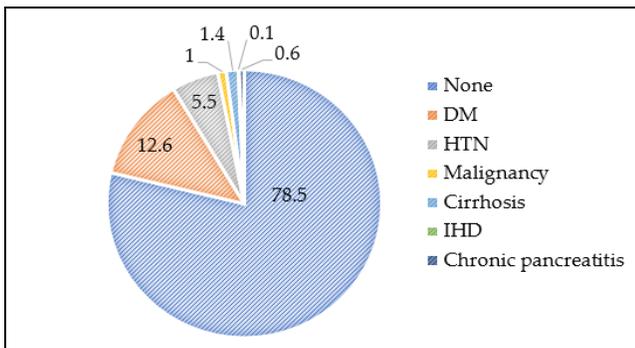


Figure: Distribution of comorbidities, DM diabetes mellitus, HTN hypertension, IHD Ischemic heart disease, malignancy refers to cholestasis secondary to mass at porta hepatis or biliary invasion.

Sphincterotomy 769 (85%), plastic stent placement 653 (72%), plastic stent replacement 346 (38%) and balloon trawling 276 (31%) were the most common

interventions carried out, correlating to the aetiology (Table-II).

Table-II: Different interventions carried out during ERCP.

Intervention	n (%)
None	58 (6.4)
Precut	54 (6)
Sphincterotomy	769 (85)
Sphincteroplasty	37 (4.1)
Balloon Trawling	276 (31)
Plastic Stent Replacement	346 (38)
Plastic Stent Placement	653 (72)
Brush Cytology	15 (2)
Adrenaline Injection/Spray	4 (0.4)
Bile for Culture and Sensitivity	15 (2)
Biopsies	59 (6.5)
SEMS	12 (1.3)
PD Stent	18 (2)

SEMS self-expanding metal stent, PD pancreatic duct

Acute pancreatitis 19 (2.1%), followed by stent migration 4 (0.4%) and bleeding 2 (0.2%) were the most common complications observed, whereas failed cannulation, though not a direct complication was seen in 9 (1%) patients (Table-III). The complications had a statistical relationship with the type of intervention performed.

Table-III: Complications that occurred during ERCP.

Complications £	n(%)
None	866 (96)
Alone	19 (2.1)
With Failed Cannulation	17 (2)
with Failed Cannulation	2 (0.2)
Bleeding	2 (0.2)
Stent Migration	4 (0.4)
Duodenal Perforation	1 (0.1)
Failed Cannulation	9 (1)
Death	2 (0.2)

Total complications=37 (4.1%). *EP* values for complications in relation to intervention, gender and age were <0.001, 0.93 and 0.1, respectively using chi square statistics. *One secondary to acute pancreatitis and one related to sedation.

DISCUSSION

In this large study population, male preponderance was apparent and in accordance to a few local,⁶ and international,¹⁸ studies but in contrast to studies from Brazil,¹⁹ India,²⁰ and the United Kingdom.²¹

The mean age for our sample was 56 ± 16 years which was higher than a study by Jain *et al.*²⁰ Approximately 79% of the patients had no co-morbidities that corresponded positively to the younger population and probably to a high success rate.

Patient selection and the operator's expertise dictate the success rate and outcome of high-risk procedures like ERCP. The success rate was 92% for our study, which was higher than a local study that reported failed cannulations at 58%.²² The effect of high volume versus low volume centres and endoscopists' expertise (with a current ERCP volume of >40/year) and its relation to the success rate and complications was studied by Testoni *et al.* Their study reported a lower rate of complications like pancreatitis and haemorrhage for high volume centres with highly skilled operators mainly because of a high single attempt cannulation rate.²³

Choledocholithiasis, like many similar studies,^{6,18,20,21} was the most common indication for ERCP reported in this setting. The frequency of cholestatic jaundice secondary to malignancy treated by ERCP was lower than a study from India where carcinoma head of the pancreas, peri-ampullary tumours, chola-

ngiocarcinomas and gall bladder carcinomas amounted to more than 57%.²² This percentage was higher in comparison to many descriptive studies.^{2,6,21}

Twenty-one (2.3%) post-cholecystectomy CBD strictures and 16 (1.7%) post-cholecystectomy biliary leaks were dealt with in our setting over one year, the largest patient population ever treated for these surgical complications locally.^{6,24} Only six post-liver transplant biliary strictures were treated at our centre that was lower than a study from Shaikh Zayed Hospital, Pakistan,²⁵ due to the lower burden of liver transplant candidates at our set up.

The overall complication rate was 4.1%, with 0.2% mortality and 1% failed cannulations in our study. The complication rate was lower than two of the local studies (6-9%),⁶ and some of the international studies (6-6.3%)²¹ and in accordance to the international guidelines (5-15%).^{3,14,19} The mortality rate was significantly lower than (1.4-5.8%),¹³ and the success rate was similar to many studies from large centres.^{2,13,21}

The most common complication for our study was acute pancreatitis, accounting for 2.1% of all the cases, followed by stent migration (0.4%), bleeding (0.2%) and duodenal perforation (0.1%). This was per almost all the studies searched where post-ERCP pancreatitis ranged from 1.9-6.5%.^{2,6,19,20} The haemorrhage and duodenal perforation rates were lower than the reported rates.^{6,19-21} The rate of stent migration was lower than a similar study from Karachi that showed a frequency of 4.14% in 1229 stentings done throughout three years.²⁵

American and European Society of Gastrointestinal Endoscopy emphasises pooling data from many different centres to formulate benchmark data, against which outcomes and success rates of different centres should be compared as an integral part of a region's quality assessment.¹⁰ The lack of a national registry, which is a direct indicator of a lack of interest in research and establishing local guidelines, hampers the implementation of quality checks at our centres.

Endoscopic retrograde cholangiopancreatography is an effective and relatively safe intervention in the hands of an experienced team and well-established centre. The success rate was above 95% for high volume centres. The most common indication for ERCP remains choledocholithiasis, with the most common ERCP complication being acute pancreatitis followed by stent migration. Biliary fistulae, post-surgical biliary leaks and strictures, pancreatic pseudocysts, acute cholangitis, choledocholithiasis and cholestasis secon-

dary to ascariasis were found in a relatively younger group. The complication rate is related to the intervention done, statistically.

LIMITATIONS

The study has its limitations, the most important one being the retrospective nature of the data, and as a result, many of the variables like BMI, socioeconomic class, ASA level, time to deep cannulation, total intervention time, endoscopist's satisfaction score etc. were missed that would have contributed to the outcome and quality assessment scores.

CONCLUSION

The most common indication for ERCP remains choledocholithiasis, with the most common ERCP complication being acute pancreatitis followed by stent migration. Biliary fistulae, post-surgical biliary leaks and strictures, pancreatic pseudocysts, acute cholangitis, choledocholithiasis and cholestasis secondary to ascariasis were found in a relatively younger group. The success rate was above 95% for high volume centres.

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Authors' Contribution

SKHK: contributed to idea, literature review and data collection, RSAK: contributed to idea and critical review, LA: contributed to manuscript gifting and data analysis, FS: contributed to idea and critical review.

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