

## Original Research Article

# Indications, outcomes and complications of therapeutic endoscopic retrograde cholangiopancreatography procedures in a tertiary care centre in North East India

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## ABSTRACT

**Background:** Therapeutic endoscopic retrograde cholangiopancreatography (ERCP) is one of the most complex endoscopic procedures in the management of several pancreatobiliary diseases. There is no comprehensive data available till date about ERCP procedures from North East India. The aim of this study was to review the indications, outcomes and complications of endoscopic retrograde cholangiopancreatography (ERCP) procedures in a tertiary care centre of North East India.

**Methods:** We retrospectively analysed the clinical records of all patients undergoing ERCP between July 2011 and November 2019. ERCP was performed under sedation (Midazolam + Pentazocine). Patient's demographic characters, ERCP indications, outcome and post-ERCP complications were reviewed. Potential important patient and procedure related risk factors for overall post-ERCP complications were investigated.

**Results:** A total 1038 patients were included in the study. Cannulation of the desired duct was successful in 89.2% of ERCPs. Among them male patients were 392 and females were 646. Mean age was 45 years and the age range were 7 to 92 years. Commonest indication was choledocholithiasis followed by malignancy. Overall Success rate was 82.66% with 84.64% in CBD stone and 75.65% in stenting of malignancy. Post ERCP complications developed in 96 patients (9.2%) and pancreatitis was the most common post-ERCP complication. Sedation related complications occurred only in few cases.

**Conclusions:** Despite its associated morbidity and risk of mortality, ERCP is an important method for managing the pancreatic-biliary diseases. Indications, outcomes, and complications of therapeutic ERCPs in our centre are comparable to those reported from other centres.

**Keywords:** Cholangitis, Choledocholithiasis, Endoscopic retrograde cholangiopancreatography, Haemorrhage, Pancreatitis, Perforation, Sphincterotomy

## INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) is used in the treatment of benign and malignant pancreatic and biliary diseases. It is a technically demanding procedure with a long learning curve and a risk of serious and life-threatening complications. The most common indications of ERCP are removal of

common bile duct (CBD) stones, relieving bile duct obstruction by stent insertion in benign and malignant strictures and postoperative management of biliary perioperative complications.<sup>1</sup> Diagnostic procedures are now being replaced by mostly non-invasive magnetic resonance imaging (MRI) or endoscopic ultrasound. Although ERCP is an important therapeutic tool in biliary and pancreatic diseases, there is some risk for

complications.<sup>2</sup> ERCP complications can occur in upto 10% of patients with an overall mortality of about 0.1-0.5%.<sup>3</sup>

Common complications of ERCP are pancreatitis, bleeding, infection, perforation and sedation-related events. Pancreatitis is the most common adverse event after ERCP and its incidence varies between 1-7% and can reach values up to 25% in some high-risk patients. Most of post-ERCP pancreatitis are mild to moderate but sometimes few patients may develop severe pancreatitis, which can result in prolonged hospitalization and the need for endoscopic or surgical procedures.<sup>4</sup>

Bleeding in ERCP is most commonly the result of endoscopic sphincterotomy. Sometimes, bleeding may be caused by mechanical trauma to the ampulla or fresh sphincterotomy site during balloon extraction of large or jagged stones. The rate of post-sphincterotomy bleeding after ERCP is estimated to be 0.3% to 2%.<sup>5,6</sup> The cotton consensus criteria divide bleeding into three categories of mild, moderate and severe.<sup>7</sup>

#### **An objective classification has been defined as follows**

- Mild bleeding - haemoglobin drop <3 gm/dL
- Moderate bleeding - transfusion requirements ≤4 units of packed red blood cells (PRBCs) with no intervention
- Severe haemorrhage - transfusion requirements >4 units of PRBCs or intervention (angiographic/surgical).<sup>8</sup>

A total 70% of the bleeding episodes are mild and the risk of severe haemorrhage (i.e. requiring ≥5 units of blood, surgery, or angiography) is estimated to occur in less than 1 per 1000 sphincterotomies.<sup>9</sup>

Perforation during ERCP may occur due to duodenoscope related trauma, sphincterotomy and intraductal guidewire manipulation. Perforations can occur in 0.3% to 0.6% of ERCP cases.<sup>10</sup> Post-ERCP cholecystitis in 0.5% and cholangitis in 1 to 3% may occur. Overall ERCP-specific mortality is 0.33%.<sup>11</sup>

## **METHODS**

Consecutive patients undergoing ERCP procedure from July 2011 to November 2019 at the department of gastroenterology of Gauhati Medical College and Hospital were included in the study. All ERCPs were performed by a team lead by a senior medical gastroenterologist.

#### **Inclusion criteria**

- Patients undergoing therapeutic ERCP
- Patients with partial CBD clearance
- Patients with all data of pre, intra and post-ERCP reports

- Patients with details record of 1-month post-ERCP follow up to recognize any adverse events.

#### **Exclusion criteria**

- Refusal for consent
- Unstable vitals
- Gastric outlet obstruction
- Previous gastrojejunostomy
- Massive ascites
- On antiplatelets and anticoagulants for last 5 days
- Very low platelets and coagulopathy.
- Insufficient data.

ERCP was performed with patients under conscious sedation with midazolam and pentazocine administered by gastroenterologist. Arterial oxygen saturation, heart rate and blood pressure were monitored using automated devices. Data contained demographics, clinical history, blood test results, procedural details, technical procedures, procedural findings, diagnosis, type and grade of severity of post-ERCP complications. All patients were admitted for at least 24 hours for observation.

Successful ERCP were defined as clearance of CBD in choledocholithiasis and CBD worm, passage of stents along the stricture with relief from jaundice in malignant and benign stricture.

Complications of ERCP were defined as any adverse events related to the ERCP procedure that required more than one night of hospitalization. The severity of complications was graded according to the length of hospitalization and the degree of intervention required. Severe complications required more than 10 days of hospitalization, requiring surgical or invasive radiologic intervention, or leading to death.<sup>7</sup>

Post-ERCP pancreatitis was defined as new-onset or worsening abdominal pain and elevation of serum amylase three times above normal at 24 hours post procedure requiring hospitalization more than 24 hours. The severity of Post-ERCP pancreatitis was defined by using the consensus grading as mild post-ERCP Pancreatitis resulting in hospitalization (or prolongation of the existing hospitalization) for ≤3 days. Moderate post-ERCP pancreatitis resulted in hospitalization (or prolongation of existing hospitalization) for 4-10 days. Severe post-ERCP pancreatitis results in hospitalization (or prolongation of existing hospitalization) for >10 days, or leads to the development of pancreatic necrosis or pseudocyst, or requires additional endoscopic, percutaneous, or surgical intervention.<sup>7</sup>

Haemorrhage was defined as mild when there was a decrease of <3 gm in haemoglobin level, moderate when transfusion was required (≤4 units), and severe when ≥5

units of blood transfusion were needed or when intervention was required.

Cholangitis was defined as an elevation in body temperature to greater than 38°C for more than 48 hours after the procedure. Cholecystitis was defined as clinical evidence of an inflamed gallbladder such as local signs of inflammation, including Murphy's sign, right upper abdominal quadrant pain or tenderness, fever, and imaging finding characteristic of acute cholecystitis.<sup>12</sup> Perforation was graded as mild if there was no leakage or limited leakage of contrast and conservative treatment (intravenous fluids, nasogastric suction) was required for 3 or fewer days; as moderate when treatment was required for 4 or more days; and as severe when intervention like surgery was necessary.

Other sedation related or procedure interrupting events such as hypoxia (decrease in oxygen saturation to below 90% for 2 minutes), hypotension (decrease in systolic blood pressure to below 90 mmHg for 2 minutes) and bradycardia (decrease in heart rate to less than 50 beats per minute for 2 minutes) were included as ERCP complications.

Data collected by the endoscopist conducting the procedures comprised: specific details concerning the procedure including the type of papilla and presence of periampullary diverticulum; method of CBD cannulation (wire guided, precut access or trans pancreatic sphincterotomy) CBD diameter, inadvertent PD cannulation or pancreatic opacification.

### Statistical analysis

Frequencies and percentages were calculated for categorical variables, and continuous variables were summarized using median and range. Patients with Post-ERCP complications and without complications were compared statistically in multiple factors, including demographics, indications, prior cholecystectomy, associated comorbidity, pre-cut access and stenting. A probability of <0.05 was regarded as significant.

## RESULTS

A total of 1345 ERCPs reviewed, 1038 procedures were included in the study. Three hundred and seven patients were excluded because of insufficient data regarding the type of complications and follow up. Demographic profile was shown in Table 1.

Among 1038 cases included for study, 765 (73.7%) were benign aetiology while 273(26.3%) were malignant aetiology. Among benign causes (N=765), 261 (34.12%) were male and 504 (65.88%) were female.

Most common indication for ERCP was choledocholithiasis (N=664, 63.97%) followed by malignant obstruction (N=273, 26.3%). Among the

malignant obstructions, carcinoma GB was the most common hilar obstruction and periampullary carcinoma among the distal biliary obstruction. Among the benign obstruction, benign biliary stricture (BBS) of chronic pancreatitis was the cause of distal obstruction and post-operative stricture for benign upper biliary obstruction. Indications for ERCP procedure are listed in Table 2.

**Table 1: Demographic profile of patients.**

Characteristic	Number of patients
Total number of patients	1038
Male	392 (37.76%)
Female	646 (62.24%)
Age range	7-92 years
Age (mean)	45±28 years

**Table 2: Indications for ERCP.**

Indications	No. 1038 (%)
Choledocholithiasis	664 (63.97%)
Carcinoma GB	75 (7.2%)
Periampullary carcinoma	89 (8.5%)
Carcinoma of head of pancreas	37 (3.6%)
Cholangiocarcinoma	70 (6.7%)
Chronic pancreatitis with BBS	41 (3.9%)
Post-operative biliary leak	19 (1.83%)
Post-operative biliary stricture	14 (1.35%)
Biliary ascariasis	20 (1.9%)
Choledochal cyst	4 (0.38%)
PSC/RPC	3 (0.29%)
Lymphoma/ portal metastatic nodes	2 (0.19%)

Complete CBD clearance of stone was possible in 520 (78.3%) cases in initial attempt. While in 62 cases there was failure in complete extraction of stone in first attempt and in these patients CBD stenting by a plastic biliary stent was done and 40 cases were subsequently taken for repeat ERCP after 6 to 8 weeks. In these 62 cases repeat ERCP resulted in complete retrieval of stones in 42 cases and the rest 20 cases were referred for surgery.

**Table 3: Success rate of ERCP.**

Total	Successful outcome	%	
Choledocholithiasis	664	562	84.64%
Malignant stricture	Hilar 118	81	68.64%
	Lower CBD 153	124	81.05%
Benign stricture	58	53	91.4%
Bile leak	19	18	94.7%
Biliary ascariasis	20	20	100%

Retrospective chart review was continued for up to 30 days after the procedure or to the end of longer hospitalization. Patient status after 30 days could be confirmed in 91.5% of ERCPs.

**Table 4: Overall complication rate of the 1038 therapeutic ERCPs.**

Complications	No. (%)
Overall	98 (9.4%)
Pancreatitis	68 (6.6%)
Mild	51 (75.0%)
Moderate	15 (22.1%)
Severe	2 (2.9%)
Bleeding	9 (0.86%)
Mild	5
Moderate	3
Severe	1
Cholangitis	7 (0.6%)
Perforation	4 (0.4%)
Acute cholecystitis	2 (0.19%)
Sedation related	6 (0.58%)

The overall rate of complications in this study was 9.4%, occurring in 96 patients. The most common complication was acute pancreatitis 68 (6.6%), majority of which were mild and two had developed severe pancreatitis. Two patients developed both bleeding and acute pancreatitis. 7 patients developed cholangitis, out of which 4 had severe cholangitis requiring urgent repeat ERCP.

Rest of the cholangitis patients were responding to conservative management with antibiotics and IV fluids. Bleeding occurred in 9 patients with one severe bleeding occurring 3 days after discharge and he died. Perforation occurred in 4 cases of which one case required surgery for scope induced perforation at D1. Sedation related complication caused failed ERCP in 6 cases where there were drop of saturation during the procedures. All patients with sedation induced complications recovered and discharged on same day.

**Table 5: Characteristics of the patients with and without complications.**

	Patients without complications N	Patients with complications N	p-value
Number of patients	942	96	
Sex (male/female)	349/593	43/53	NS
Age			
7-20	97	8	NS
20-40	308	49	NS
41-60	434	33	NS
>60	103	6	NS
Prior cholecystectomy	263	13	<0.05
Indications for ERCP			
Choledocholithiasis	617	61	NS
Malignant hilar stricture	104	12	NS
Malignant distal stricture	128	21	NS
Benign stricture	56	2	NS
Associated comorbidity	148	11	NS
Pre-cut access	328	30	NS
Stenting	356	9	<0.005

When the patients with complications are compared with those without complications, it is seen that precut access, comorbidity and extreme of age were not associated with increased rate of complications. Concomitantly stenting (biliary/pancreatic) with ERCP and post cholecystectomy were associated with decrease rate of complications.

## DISCUSSION

Therapeutic ERCP is an important procedure that is frequently done in the management of a variety of pancreatobiliary disorders. ERCP is generally considered to be effective and safe but with risk of some complications. In this study, we reviewed 1038 patients who underwent therapeutic ERCPs in our institute. The

success rate of ERCP varies from 76.0%-80.3% in low volume centres to 86.9%-94.3% in high volume centres.<sup>13-15</sup> The success rate in our study was 82.66% which is almost similar with previous reports. The success rate in benign and malignant diseases were 85.14% and 75.65% respectively. The success rate of hilar stricture is less than distal biliary stricture.

In this study, choledocholithiasis was the most common indication for ERCP (63.9%) followed by malignant biliary obstruction. Other indications in small numbers of cases were post-operative biliary injury, benign biliary stricture of chronic pancreatitis, CBD worm and choledochal cyst. Biliary stenting was successfully used in preoperative drainage or palliative treatment of pancreaticobiliary malignancies and when complete bile

duct clearance was not achieved as in some cases with large or multiple bile duct stones that could not be removed in a single session. In 14% cases with incomplete clearance of CBD stones, repeat ERCPs were done after 4 to 8 weeks of initial attempt where 67.7% complete clearance was achieved.

In the present study, overall complication rate was 9.4%. The overall complication rates and mortality rates of ERCP have been reported to range from 5% to 13.6% and from 0.1% to 0.87% respectively in various earlier reported studies.<sup>16-19</sup>

Post-ERCP pancreatitis (PEP) is one of the most serious complications and the overall incidence of PEP is estimated to be 3% to 10% in systematic reviews.<sup>11,19,20</sup> A recent meta-analysis of 108 randomized, controlled trials involving 13,296 patients, reported a 9.7% overall incidence of PEP [95% confidence interval (CI), 8.6%-10.7%], with an increased incidence of 14.7% (95% CI, 11.8%-17.7%) in high-risk patients.<sup>19</sup> The majority of PEP cases were mild, with a mortality rate of 0.7%. In this study, 6.6% of patients developed post-ERCP pancreatitis, which is completely consistent with previous studies. PEP was mild in 51 patients (75.0%), moderate in 15 patients (22.1%), and severe in 2 patients (2.9%). Mild and moderate cases were managed with conservative treatment but the severe two cases required radiological drainage. Of the 68 patients of post-ERCP pancreatitis 47 patients (69.11%) had cholelithiasis with choledocholithiasis, 12 patients (17.65%) had choledocholithiasis, 7 patients (10.29%) had extrahepatic biliary obstruction and 2 patients (2.9%) had bile duct stricture.

In a meta-analysis of 21 prospective trials, the bleeding rate as a complication of ERCP was 1.3% where 70% of bleeding episodes were mild.<sup>11</sup> In this study, bleeding occurred in 0.86% of patients of which 80% were mild and death due to bleeding occurred in 1 patient. Freeman et al reported clinically significant bleeding in 2% of 2347 patients undergoing ERCP and bleeding was mild in 0.6%, moderate in 0.9%, and severe in 0.5% with death in 2 cases.<sup>5</sup>

Seven (0.6%) patients developed cholangitis after ERCPs in this study which is comparable to previously reported studies.<sup>5,21</sup> As a serious complication after ERCP, perforations have been reported to occur in 0.1% to 0.6% of patients.<sup>5,21</sup> Perforation was observed in 4 (0.3%) patients in this study. One case was caused by a duodenoscope who required surgery. Perforation occurred in other 3 (2.0%) procedures with standard sphincterotomy (NS) which were managed with conservative management and radiological drainage in one case.

Cardiopulmonary events or anesthetic complications range from mild transient hypoxia and hypotension to critical myocardial infarction, pulmonary embolism,

respiratory failure and cardiac arrest. In our study there were drop of saturation in 4% patients during the procedure for which complete procedure could not be done in 6 patients. There was no mortality from sedation or sedation related events.

The principal limitations of our study are that the data were collected retrospectively. Some patients were taken for multiple times repeat procedure which may cause excess financial burden.

## CONCLUSION

Therapeutic ERCP is now a highly effective and safe procedure in the hands of experienced endoscopist. The indications and success rates as well as morbidity and mortality are acceptable compared to those in earlier reports and published guidelines. Sedation required in ERCP may be adequate and safe when administered by gastroenterologist also.

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