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Clinical Profile of Patients Undergoing ERCP in a Tertiary Care Centre in Eastern India

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ABSTRACT

Endoscopic Retrograde Cholangiopancreatography (ERCP) is one of the most technically demanding interventional procedures used by the gastroenterologists and interventional endoscopists both for the diagnosis and treatment of hepatopancreatic biliary diseases. The aim of this study was to assess the clinical profile of patients undergoing ERCP and its associated complications. The study retrospectively reviewed 373 patients data of ERCP performed by the experienced gastroenterologists at a single tertiary care center between January, 2019 to December, 2021. The data was entered into Microsoft excel and statistical analysis was done with SPSS 25 version in terms of clinical profile of patients undergoing ERCP and its associated complications. Out of 373 participants, 41.82% (156) were males while 58.18% (217) were females; mean age was 49.6 years. Majority of the patients i.e., 81.23% complained of pain abdomen followed by jaundice (41%). The most common indication for ERCP procedure was choledocholithiasis (73.72%). The most common complications were pancreatitis 35(9.38%), cholangitis 12(3.21%), perforation 3(0.8%) and bleeding 2(0.53%). Mortality occurred in 0.8% of the patients. For the treatment of the diseases of the biliary tract, ERCP undoubtedly is a technically advance procedure. However, it is associated with risk of severe pancreatitis, perforation, bleeding and even death.

INTRODUCTION

Endoscopic Retrograde Cholangiopancreatography (ERCP) plays a very vital role in the management of diseases especially those involving the bile duct and pancreatic duct^[1]. In recent scenario, it is one of the most technically demanding procedures carried out by the gastroenterologist and interventional endoscopists. Despite being an invasive and time-consuming procedure, it is one of the most preferred procedures in diseases involving bile duct and pancreatic ducts like choledocholithiasis, pancreatic duct strictures due to its high sensitivity and specificity which ranges to around 95% and 100%, respectively^[2]. Other indications include obstructive jaundice, biliary or pancreatic ductal system disease treatment or tissue sampling, suspicion for pancreatic cancer, pancreatitis of unknown cause, manometry for Sphincter of Oddi, hepatobiliary drainage, biliary stenting for strictures and leakage, drainage of pancreatic pseudo cysts and balloon dilatation of the duodenal papilla and ductal strictures. From 1968, the year when ERCP was introduced, to till date ERCP has evolved from being a diagnostic modality of pancreaticobiliary system to therapeutic modality thanks to availability of better non-invasive diagnostic modalities like MRCP, multi-detector computed tomography – MDCT and endoscopic ultrasound-EUS^[3].

ERCP has got its own set of complications. The first multicentre study which evaluated the prevalence of ERCP related complications in the United States that included more than 10,000 patients at a time when ERCP procedures were largely diagnostic, complications ranged from injection pancreatitis in just 1%, to other complications like pancreatic sepsis, pseudo cyst and instrumental injury in <1%^[4]. In a systematic survey of prospective studies comparing old (1977-1996) and new (1997-2005) studies it was found that the morbidity rates following ERCP increased significantly from 6.27% to 7.51%^[5]. Therefore, with the evolution of ERCP from a diagnostic to therapeutic modality the prevalence and spectrum of post-ERCP complications have changed too.

Although complication rates following ERCP vary widely due to variation in definitions, different protocols for detection of complications, patients with different risk factors and differences in spectrum of technical approach, post ERCP pancreatitis remains one of the most common complications following the procedure^[6]. In a systematic review including 108 RCTs, an overall incidence of PEP of 9.7%, with an incidence of 14.7% in high-risk patients was found^[7]. Unusual complications such as perforation, pneumothorax, air embolism, splenic injury and basket impaction are rare but if develops may require surgical intervention and, or if not managed properly can lead to permanent disability and even death^[8]. Therefore preventing such

complications using various methods like assessment of patients with high risk factors for alternative therapeutic and diagnostic techniques, pre-procedural administration of pharmacological agents and following proper procedural techniques becomes utmost important^[9].

Aim: The aim of this study was to assess the clinical profile of patients undergoing ERCP and its associated complications.

MATERIALS AND METHODS

Study Design: Retrospective study.

Study Duration: Two years (Jan. 2019-Dec. 2021).

Study Place: Endoscopy Unit of Indian Institute of Gastroenterology and Hepatology Hospital, Cuttack, Odisha.

Methodology: A retrospective study was carried out at the Endoscopy Unit of Indian Institute of Gastroenterology and Hepatology Hospital, Cuttack, Odisha using a universal sampling technique over a period of 2 years i.e., from January, 2019 to December, 2021 to assess the clinical profile of patients undergoing ERCP and its associated complications.

All the ERCP procedures done in the endoscopy unit were included in the study regardless of their age, gender or ethnicity. The ERCP procedures which had incomplete data were excluded from the study.

All the procedures of ERCP were performed by experienced gastroenterologists only after taking informed written consent. All patients were observed for complications of ERCP and if there was any complication during or after the procedure it was handled by the hospital itself. Severity of pancreatitis was graded according to the Cotton criteria^[10]. A Therapeutic Olympus Side View duodenoscope TJF-Q180V was used to carry out the ERCP.

Pre-requisites for the procedure included routine blood tests, LFT, PT-INR, UGI endoscopy, viral markers and imaging studies like USG of the abdomen, CT and MRI, which were available. All the ERCP procedures were carried out under total intra-venous anesthesia (TIVA). During the procedure incidentally if the guide wire passes into the Main Pancreatic Duct (MPD) then rectus suppository like diclofenac was given immediately or within 15mins after the procedure. All data were collected and entered into Microsoft excel and statistical analysis was done with SPSS 25 version.

RESULTS AND DISCUSSIONS

Out of 373 participants, average age is 49.6 years. 41.82% (156) were males and 58.18% (217) were females. Average BMI of the patients came to be about

22.66. Only 13.4% of the patients were obese. About 14.2% of the patients had DM. About 6.1% of the patients were addicted to alcohol and only 3.2% of the patients had smoking history. Most patients were from central division of Odisha i.e., 273 which accounted to 73.2%. About 12.6% were from northern division of Odisha, 4.8% were from southern division of Odisha and only 9.4% were from outside Odisha (Table 1).

Majority of the patients i.e., 81.23% complained of pain abdomen followed by jaundice (41%). About 25.46% of the patients had pain abdomen along with jaundice. About 93.3% of the patients had benign lesion which accounted to 348 of the total patients. The benign lesions included CBD stone, CBD stricture, hepatic SOL, duct injury, dilated CBD and mild ascites. In contrast, only 6.7% (25 patients) had malignancy which included carcinoma gall bladder, cholangiocarcinoma and carcinoma pancreas and periampullary carcinoma.

Out of 373 patients, 22 had large stones more than 10 mm. Among which 14 had undergone lap CBD exploration and in 8 patients repeat ERCP was done and calculus was retrieved successfully. In 7 patients ERCP wasn't possible due to deformed duodenum and failed cannulation. Thirty five (9.38%) patients developed pancreatitis (hyperamylasaemia) out of which 21 were mild and were discharged within 48 hours. Fourteen patients had severe pancreatitis out of which 12 recovered after prolonged hospitalization and 2 succumbed to the disease due to severe post ERCP pancreatitis with multi organ failure. Twelve (3.21%) patients presented with fever and pain abdomen and were diagnosed as cholangitis. Three (0.8%) patients developed small perforation which was cured with conservative management. Two (0.53%) presented with post ERCP bleeding but only 1 died due to severe bleeding.

Out of 25 malignant patients, 18 were diagnosed with carcinoma gall bladder, 6 with cholangiocarcinoma and 1 patient with pancreatic carcinoma. Plastic stent was given to 19 patients. Rest was given metallic stent. Patients who have undergone

plastic stent developed cholangitis after 3-5 days in comparison to patients who had undergone metallic stents.

In the present study, majority belonged to the middle age group. Females (58%) outnumbered males (42%). In our study, 4/5th of the patients complained pain abdomen whereas only 2/5th presented with jaundice.

Only a minority (5.63%) presented with complains like fever, swelling of the abdomen etc.

The mean age of the benign participants was 49 years with a standard deviation of 15.51 years whereas the mean age of the malignant patients was 55 years with a standard deviation of 9.57 years and this was found to be statistically significant ($p = 0.04$) which means increasing age is associated with more chance of malignancy (Table 2).

Although obesity is considered as a risk factor for carcinoma gall bladder, with the risk being increased by 4% for each 1 kg m^{-2} increment in BMI, the mean BMI of our patients (including both benign and malignant) was 22.66 and therefore no such association was found^[11]. A study from north India reported both benign and malignant conditions of gall bladder i.e. gallbladder cancer with stones, gallbladder cancer without stones and calculus cholecystitis had highly significant positive correlation with levels of serum glutamic oxaloacetic transaminase (SGOT) and serum glutamic pyruvic transaminase (SGPT). (2) But in our study among liver enzymes, only the level of serum alkaline phosphatase (SAP) was found to be positively associated with increased risk of malignancy with a p -value <0.001 ^[12] in accordance to a study where they showed in patients with obstructive jaundice, bilirubin levels in isolation represent an important tool for discriminating between benign and malignant underlying causes^[13]. Levels of other liver enzymes like serum glutamic oxaloacetate transaminase (SGPT) and serum glutamic pyruvic transaminase (SGPT) didn't have any association with the presence of malignancy which means liver parenchyma has not been injured. Apart from that total leucocyte count was also found to have no association with the presence of malignancy in our study.

In our study out of 373 patients, 153 patients (41%) had jaundice as presenting symptom whereas in a study from Pakistan, conducted among 161 patients,

Table 1: Clinical parameters of all subjects (n = 373)

| Parameter | Frequency | Percentage |
|-------------------|-----------|------------|
| Age (<20 Years) | 6 | 1.6 |
| Age (21-40 Years) | 105 | 28.15 |
| Age (> 40 Years) | 262 | 70.24 |
| BMI | 50 | 13.40 |
| Male | 156 | 41.82 |
| Female | 217 | 58.17 |
| DM | 77 | 20.64 |
| Hypertension | 46 | 12.33 |
| Obesity | 50 | 13.40 |
| Total Bilirubin | 213 | 57.10 |
| SGOT | 242 | 64.87 |
| SGPT | 228 | 61.12 |
| ALP | 321 | 86.05 |
| USG | 336 | 90.08 |
| Pain Abdomen | 303 | 81.23 |
| Jaundice | 153 | 41.01 |

Other symptoms (Fever, Swelling of abdomen etc) 21 (5.63%)

Table 2: Clinical parameters of patients

| Parameter | Mean±SD |
|-----------------|---------------|
| Age | 49.60±15.281 |
| BMI | 22.6±93.45 |
| Total Bilirubin | 6.65±8.96 |
| SGOT | 102.34±105.70 |
| SGPT | 103.33±101.91 |
| ALP | 469.08±429.39 |

Table 3: Post ERCP complications

| Parameter | Frequency | Percentage |
|--------------|-----------|------------|
| Pancreatitis | 35 | 9.38 |
| Cholangitis | 12 | 3.21 |
| Perforation | 3 | 0.8 |
| Bleeding | 2 | 0.53 |
| Death | 3 | 0.8 |

Table 4: Comparison between benign and malignant group

| Parameters | Benign (Mean±SD) | Malignant (Mean±SD) | p-value |
|------------|------------------|---------------------|---------|
| AGE | 49.18±15.51 | 55.64±9.57 | 0.0408 |
| SBP | 115.77±16.15 | 117.60±20.05 | 0.591 |
| DBP | 75.10±10.85 | 74±10.40 | 0.6238 |
| BMI | 22.7±3.4 | 22.64±6.50 | 0.9373 |
| FBS | 111.1±39.61 | 119.04±38 | 0.3324 |
| TLC | 11248.45±5569.90 | 11844±6141 | 0.6084 |
| SGOT | 101.27±107.01 | 117.19±85.73 | 0.4677 |
| SGPT | 102.81±103.05 | 110.47±85.86 | 0.7171 |
| ALP | 449.44±406.90 | 742.5±616.88 | 0.0009 |
| Total BIL. | 5.93±6.92 | 11.43±7.64 | 0.0002 |

obstructive jaundice was the main indication of ERCP in 65.8% of the patients^[2]. In a meta-analysis of prospective studies regarding diabetes and risk of gall bladder disease, the overall relative risk of developing gall bladder disease in diabetics was 1.56, supporting the view of increased risk of gall bladder diseases in diabetes patients^[14]. However in our study only 20% of the patients undergoing ERCP had diabetes. In a study by Zhang *et al.*^[15] they showed that hypertension was significantly associated with the risk of gallstone diseases and gallstones and the association between hypertension and gallstone disease was stronger in women than in men. However, in our study only 12% of the patients who underwent ERCP had hypertension.

In malignant obstructive jaundice, most patients preferred plastic stent due to low socioeconomic status. A study done by Alvi *et al.*^[1] 9.74% were malignant patients requiring ERCP and the result was similar to our study where 6.7% had malignancy. In a study done in Peshawar, Pakistan by Anwar *et al.*^[2] 20.9% of patients had malignancy of the hepatobiliary tree whereas in our study only 6.43% of the patient had cancer of the hepatobiliary tree^[2]. This difference could be attributed to referral bias. In the present study, only 6.70% of the patients had malignant biliary obstruction but, in a study, done in Korea 22.8% have malignant biliary obstruction^[16].

In a systematic review done by Andriulli *et al.*^[5] The incidence rate of post ERCP pancreatitis was 3.5% and 1.34% had bleeding. A study from USA by Cotton *et al.* done on 11,497 patients showed that only 2.6% had pancreatitis and 0.3% had bleeding. A study by Mascietal^[17]. Reported that the post ERCP pancreatitis was 1.8% and bleeding was 1.13%. But in our study the post ERCP complication rate was a bit high. i.e., 14.74% developed complication. About 9.38% presented with pancreatitis, out of this 3.75% had severe pancreatitis and 0.53% had bleeding after the procedure^[19]. The

difference in the incidence rate could be due to small sample size of our study.

The post-ERCP cholangitis rate was 3.21% in our study which corroborated with the finding of the study done in Singapore by Ong *et al.*^[19] where the rate was 2.4%. In another study from China on the risk factor analysis of post ERCP cholangitis by Chen *et al.*^[20] on 4234 patients also reported a similar incidence of 2.4% with old age, previous ERCP history and hilar obstruction being independent risk factors for this complication (Table 3).

Our study showed that the risk factor for post-ERCP pancreatitis were female gender (54.28%) and younger age (42.8%) and this result was similar to a study done in Turkey by Arslan *et al.*^[21] where 60.9% of the patients of post-ERCP pancreatitis were females and 42.3% of the patients were in younger age. However, in many systematic reviews and meta-analyses of risk factors for post ERCP pancreatitis only female gender was shown to be one of the major risk factors among patient related risk factors and not age (Table 4)^[23,24].

CONCLUSION

ERCP is a technically advance treatment for diseases of the biliary tract. The most common indication remains choledocholithiasis with or without cholangitis^[24]. CBD stones are commonly seen in females compared to males. With the increase in the use of outpatient and inpatient ERCP, the rate of post-ERCP complications are also increasing. Among all the complications, post ERCP pancreatitis remains the most common. In case of malignant pancreaticobiliary diseases, metallic stent is preferable over plastic stent to avoid early cholangitis. Despite appropriate measures and interventions, there is a risk of severe pancreatitis, perforation, bleeding and death post ERCP.

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