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Frequency of Post Endoscopic Retrograde Cholangiopacreatography Pancreatitis in Patients with Pancreatic Disease

Maqsood Ahmad[1], Shafaq Farooq[2], Akash Kumar[3], Muhammad Adil Raza[4], Khair Muhammad[5], Asma[6], Moeen-Ul-Haq[7]

[1]Senior Registrar, Department of Gastroenterology /Medical Unit 1, Jinnah Hospital, Lahore, Pakistan

[2]Senior Registrar, Gastroenterologist and Hepatologist, Holy Family Hospital, Rawalpindi, Pakistan

[3]Trainee Resident Medical Officer Gastroenterology, Jinnah postgraduate Medical Center, Karachi, Pakistan

[4]Consultant Gastroenterologist, Department of Gastroenterology, Naimat Begum Hamdard University Hospital, Karachi, Pakistan

[5]Specialist, Clinical Imaging Department, Hamad General Hospital, Doha Qatar 0009-0007-1308-0686

[6]Assistant Professor Gastroenterology, Medicare Cardiac and General Hospital (JMDC), Karachi, Pakistan

[7]Assistant Professor, Department of Gastroenterology, Gomal Medical College, Dera Ismail Khan, Pakistan

Corresponding author:

Moeen-Ul-HAQ,

Assistant Professor, Department of Gastroenterology, Gomal Medical College, Dera Ismail Khan

Email ID: moeen81@gmail.com

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ABSTRACT

Endoscopic retrograde cholangiopancreatography (ERCP) is a technique that combines the use of endoscopy and fluoroscopy to diagnose and treat certain problems of the biliary or pancreatic ductal systems. Post-ERCP pancreatitis (PEP) is diagnosed when patients develop signs and symptoms of acute pancreatitis in addition to elevation of pancreatic enzymes.

Objective: To determine the frequency of post ERCP in patients undergoing endoscopic retrograde cholangiopancreatography for pancreatic disease

Methodology: This descriptive case series study was conducted at the Gastroenterology Unit of Lahore General Hospital, Lahore, over a duration of six months following the approval of the synopsis, from May 2023 to June 2024. Patients were prepared for the procedure by overnight fasting and received antibiotic prophylaxis with an injection of Ceftriaxone 1 gram. The ERCP procedure was performed under regional anesthesia by a single senior gastroenterologist with a minimum of four years of residency experience. Post-ERCP outcomes were carefully documented. All collected data were entered and analyzed using SPSS version 20.

Results: The mean age of patients was 37.19±10.54 years. Abdominal pain was observed in 44(14.33%) patients and PEP was found in 44(14.33%) patients.

Conclusion: The frequency of PEP was 14.33% in patients with pancreatic disease

Keywords: *Endoscopic Retrograde Cholangiopancreatography, Pancreatitis, Pancreatic Disease,*

1. INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) is a technique that uses a combination of luminal endoscopy and fluoroscopic imaging to diagnose and treat conditions associated with the pancreatobiliary system. The endoscopic portion of the examination uses a side-viewing duodenoscope that is passed through the esophagus and stomach and into the second portion of the duodenum. Based on data from 2004, it is estimated that about 500,000 procedures are performed annually in the United States.[1]

ERCP has evolved into an almost exclusively therapeutic procedure. The main reason for this evolution is that diagnostic modalities have been developed that are less invasive. Routine ERCP before laparoscopic cholecystectomy is not indicated. The first step in preventing post-ERCP complications is to identify those patients who are most likely to experience adverse events. Patients at higher risk for development of PEP, the most common serious complication associated with this procedure, include patient-related factors, procedure-related factors, operator-dependent factors, and underlying disease or indication for performing ERCP.[2]

ERCP is an advanced endoscopic technique that carries a higher risk of procedure-related complications than other endoscopic procedures do. Besides the risks associated with most other endoscopic procedures, ERCP also carries a risk for the following specific complications: Post-ERCP pancreatitis, Postsphincterotomy bleeding, Infection (cholangitis, bacteremia) & retroperitoneal perforation.[3]

Despite important advances over the last several decades, post-ERCP pancreatitis (PEP) remains the most frequent complication of ERCP, occurring in 2-15% of cases, and accounting for substantial morbidity, occasional mortality, and increased healthcare expenditures. Approximately 10% of those who develop PEP will follow a severe clinical course that results in prolonged hospitalization and/or additional interventions, leading to significant patient suffering.[4]

Regardless of the advancement and improvement in ERCP techniques, post-ERCP acute pancreatitis remains the most feared and common complication, being associated with high morbidity and mortality. The figures cited in literature vary from 3.3 – 6.7%.[5, 6] In a local study, the frequency of PEP was 3.6%,[7] which may increase up to 40%.[8]

This study was conducted to determine the frequency of PEP in patients underwent ERCP for pancreatic disease. PEP is a serious complication associated with significant morbidity and mortality. Variable incidence rates of PEP have been reported in previous literature. Therefore, this study was designed to assess the magnitude of the problem in the local population. The aim was to provide updated local data on the frequency of PEP, which could inform modifications in ERCP techniques or management protocols to reduce its occurrence**.** Furthermore, the findings were intended to contribute to the improvement of clinical practice.

2. METHODOLOGY

This descriptive case series was conducted at the Gastroenterology Unit of Lahore General Hospital, Lahore, over a period of six months from May 2023 to June 2024. A sample size of 307 patients was calculated using a 95% confidence level, a 2% margin of error, and an expected incidence of post-ERCP pancreatitis (PEP) of 3.3%. Non-probability consecutive sampling was employed to enroll patients aged 18–55 years of either gender undergoing ERCP for pancreatic disease, as documented in the medical record. Exclusion criteria comprised patients undergoing redo ERCP, those with liver pathology such as carcinoma, cirrhosis, or hepatitis, and patients with co-morbid conditions including hypertension (BP ≥140/90 mmHg), diabetes (BSR >186 mg/dL), or renal disease (creatinine >1.2 mg/dL or on dialysis). A total of 307 eligible patients were enrolled from the gastroenterology wards. Informed consent was obtained, and demographic details such as name, age, sex, BMI, and diagnosis were documented. All patients were prepared with overnight fasting and received prophylactic antibiotics (Injection Ceftriaxone 1g). ERCP was performed under regional anesthesia by a single senior gastroenterologist with at least four years of residency experience. Following the procedure, patients were monitored in the gastroenterology ward for 24 hours. After this period, a blood sample was drawn using a 3cc BD syringe and sent to the hospital laboratory for serum amylase assessment. PEP was diagnosed according to the operational definition if the serum amylase level was ≥300 U/L and the patient reported abdominal pain with a Visual Analogue Scale (VAS score) >4/10. All relevant data were recorded using a structured proforma.

Statistical Analysis

Data was entered and analyzed using SPSS.v.20.0. Mean & SD was calculated for quantitative variables (age, BMI and serum amylase). Frequency & percentages were calculated for qualitative variables (gender and PEP). Effect modifier like age, gender, BMI and diagnosis of pancreatic disease was controlled through stratification. Post stratification, chi- square test was applied by taking $p \leq 0.05$ as significant.

3. RESULTS

Our study included 307 patients who underwent ERCP for pancreatic disease. The participants had a mean age of 37.19±10.54 years (range: 18-55 years). The gender distribution was nearly equal, with 156 males (50.8%) and 151 females (49.2%), resulting in a male-to-female ratio of 1.03:1. The mean BMI of participants was 25.33±3.99 kg/m² (range: 18.5-32.2 kg/m²). Patients had a mean pain score of 2.79±2.34 (range: 0-10) and mean serum amylase level of 2.79±2.34 (range: 0-10), as shown in **Table 1**. Post-ERCP pancreatitis (PEP) was diagnosed in 44 patients, representing 14.33% of the study population. Notably, abdominal pain was reported in exactly the same number of patients (44, 14.3%) as shown in **Figure 1.**

Table 1: Descriptive Statistics of Study Participants (n = 307)

Parameter	Mean ± SD	Minimum	Maximum	n (%) / Ratio
Age (years)	37.19 ± 10.54	18	55	–
Gender	–	–	–	Male: 156 (50.8%) Female: 151 (49.2%) Male:Female = 1.03:1
BMI (kg/m²)	25.33 ± 3.99	18.5	32.2	–
Pain Score	2.79 ± 2.34	0	10	–
Serum Amylase (U/L)	2.79 ± 2.34	0	10	–
Abdominal Pain	–	–	–	Present: 44 (14.3%) Absent: 263 (85.7%)

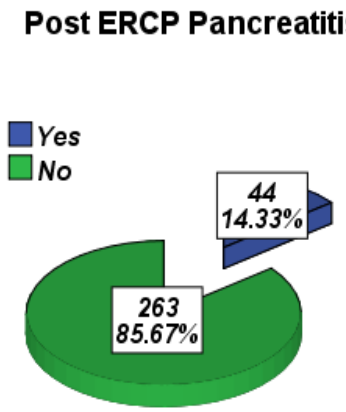

Figure 1: Frequency distribution of Post ERCP Pancreatitis

When analyzing potential risk factors for PEP, we found that among patients aged ≤30 years, 16 developed PEP, while 28 patients in the >30 years group experienced this complication. This age-related difference was not statistically significant (p=0.291). Regarding gender, PEP occurred in 28 male patients compared to 16 female patients. Despite this apparent difference, statistical analysis did not show significance (p=0.066). BMI classification showed PEP in 18 patients with normal BMI and 26 patients with abnormal BMI, but this difference also lacked statistical significance (p=0.295). The most striking finding was the perfect correlation between abdominal pain and PEP. All 44 patients diagnosed with PEP experienced abdominal pain, while none of the 263 patients without PEP reported pain. This association was highly statistically significant (p=0.001), confirming abdominal pain as a reliable clinical indicator of post-ERCP pancreatitis as shown in **Table 2.**

Table 2: Comparison of PEP with Age, Gender, BMI, and Abdominal Pain

Variable	Category	PEP		Total	Chi-square	p-value
		Yes	No			
Age (years)	≤ 30	16	75	91		
	> 30	28	188	216	1.113	0.291
Gender	Male	28	128	156		
	Female	16	135	151	3.38	0.066
BMI	Normal	18	130	148		

(kg/m²)	Abnormal	26	133	159	1.096	0.295
Abdominal Pain	Yes	44	0	44		
	No	0	263	263	307.00	0.001

4. DISCUSSION

This present descriptive case series study was carried out at Gastroenterology Unit, Lahore General Hospital, Lahore to determine the frequency of PEP in patients undergoing ERCP for pancreatic disease. ERCP is increasingly used for therapeutic management of various biliary and pancreatic diseases. PEP remains the most common and serious complication after ERCP. The reported incidence of PEP is around 5%. This rate may increase up to 20%-40% in high risk patients.[9,10]

In our study the PEP in patients undergoing ERCP for pancreatic disease was present in 44(14.33%) patients. This aligns with the study by Pande H and Thuluvath P who reported that incidence of clinically significant pancreatitis after ERCP ranged from 1-13.5%.[11] It is more common after therapeutic procedures such as sphincterotomy or balloon dilatation of the sphincter, and diagnostic procedures such as biliary or pancreatic manometry. The severity of PEP may vary from very mild to extremely severe disease with multiple organ failure and fatal outcome.

Ayman El Nakeeb et al. enrolled 996 patients in their study. They showed that the overall PEP after ERCP occurred in 102 (10.2%) patients of the study population; eighty (78.4%) cases were of mild to moderate degree, while severe pancreatitis occurred in 22 (21.6%) patients.[12]

Despite advanced accessories and novel techniques in ERCP, complication rate after ERCP remained unchanged over the last decade. According to previous reports, the incidence of PEP ranges from 5% to 40%.[13,14]

Despite significant advances over the last several decades, PEP remains the most frequent complication of ERCP, occurring in 2-15% of cases, and accounting for substantial morbidity, occasional mortality, and increased healthcare expenditures. Approximately 10% of those who develop PEP will follow a severe clinical course that results in prolonged hospitalization and/or additional interventions, leading to significant patient suffering.[4] In a local study, the frequency of PEP was 3.6%,[7] which may increase up to 40%.[8]

A recent meta-analysis of 108 randomized, controlled trials reported an overall incidence of 9.7%, with a mortality rate of 0.7%.[4] Another study by Adarsh M. Thaker et al. resulted that the overall incidence of PEP was 9.7%, of which 8.6% of cases were mildly severe, 3.9% were moderate, and 0.8% were severe. The incidence of all-severity PEP in high-risk patients was 14.7%.[15]

Although asymptomatic elevation of serum amylase is a common occurrence after ERCP, the incidence of clinically significant PEP ranges from 1-15.7%.[6,16 -19]Several studies and reviews have identified several risk factors. High PEP rates have been reported after interventional ERCP, especially those involving extensive biliary or pancreatic manipulation, after which PEP rates can approach 30%.[20-22]In a large, prospective, multicenter US study, the risk of PEP after a difficult cannulation increased from 4.3-11.3%.56 In another study, the risk of PEP increased from 3.3-14% when difficulty was encountered using standard cannulation methods.[23]

5. LIMITATIONS

This single-center study may have limited generalizability to other healthcare settings or populations. Our sample size, while statistically adequate, may have been insufficient to detect some significant associations between risk factors and PEP. By focusing exclusively on patients with pancreatic disease and excluding those with certain comorbidities, we created a homogeneous population that might not represent the full spectrum of ERCP indications. The 24-hour follow-up period might have missed cases of delayed-onset PEP. We did not assess all potential PEP risk factors such as specific cannulation techniques, procedure duration, or prophylactic interventions. Finally, our study design did not evaluate preventive strategies or management approaches for PEP.

6. CONCLUSION

According to our study results the frequency of PEP was 14.33% in patients undergoing ERCP for pancreatic disease. Now we have got the local evidence and got updated data regarding PEP in local population

Conflict of Interest: None

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