# Incidence, Clinical Presentation and Management of Type IV Perforations After Sphincterotomy Among Post Ercp Patients

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# **Abstract**

**Objective/Background:** ERCP related perforation is an endoscopic emergency. Presence of retroperitoneal air after ERCP always is not an indication for emergency surgery. Aim of this study is to determine the incidence of Type IV perforations and management of patients with Type IV perforation.

**Methods:** This is a prospective hospital based study, in these study 111 consecutive patients after fulfilling the inclusion and exclusion criteria were enrolled.

**Results:** Incidence of Type IV perforation in the study is 7.2%. All patients with Type IV perforation were managed conservatively.

**Conclusion:** ERCP related Type IV perforations occur in a significant number of patients undergoing ERCP. Patients in whom an ERCP related perforation is suspected should undergo an urgent CECT abdomen with oral contrast to rule out extravasation of contrast. Patients with contrast extravasation should be managed by emergency surgery. Patients with type IV perforation should be managed conservatively.

**Keywords:** Choledocholithiasis; Sphincterotomy; ERCP; Perforation

# Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) is a common, well established procedure that is being used with increasing frequency for the evaluation and treatment of biliary tract and pancreatic duct disease. In the recent years the therapeutic use of ERCP has increased 30 fold [1]. The success rate of ERCP varies markedly between institutions [2]. The short term complication rate of ERCP is around 10% and includes acute pancreatitis, bleeding, cholangitis and perforation [3]. In of an expert, endoscopic retrograde cholangiopancreatography (ERCP) and endoscopic sphincterotomy (ES) are associated with high rates of success and few complications, most of which can be treated

conservatively [4]. The most common complication of ERCP is post ERCP pancreatitis, which is reported to occur in 2-10% of patients [5]. PEP manifests with pain abdomen and elevation of serum amylase and serum lipase levels. But serum amylase levels may be elevated in upto 75% of patients, regardless of the symptoms [6]. The severity of post ERCP pancreatitis is classified as per cottons classification [7].

ERCP is also associated with a mortality rate between 0.1 and 6% [8]. Post ERCP cholangitis is one of the complications of ERCP. However the risk factors of post ERCP cholangitis are not well established. Cholangitis is one of the common complications of ERCP and has an incidence rate of 1%-5% [9]. High biliary obstruction is one of the risk factors for post ERCP cholangitis [10]. Bleeding is one of the most frequent complications following endoscopic sphincterotomy ES [11]. The incidence of ERCP related bleeding varies from 1% -48% [12]. ERCP related perforations are rare but serious complications. Perforations are one of the most dreaded complications of ERCP, with a reported incidence of 0.3–6%7 [13]. Perforation is defined as the presence of oral contrast or air in the retroperitoneal space with or without frank visualization of peritoneum during the procedure [14].

Although ERCP related perforations have been classified by various researchers based on the location of perforation and mechanism of injury, the most popular of these classifications was proposed by Stapfer et al [15]. ERCP related perforations have been classified into three types as per Howard classification: type I, guide wire perforation; type II, periampullary perforation; type III, duodenal perforation remote from the papilla [14].ERCP related perforations have been classified into four types as per Stapfer classification [15], Type I, lateral or medial wall duodenal perforation; type II, paravaterian injuries; type III, distal bile duct injuries related to guide wire-basket instrumentation and type IV, retroperitoneal air alone [15].presence of Free air after an ERCP has been found to be present in 13-29% of asymptomatic patients[16].

Many patients with ERCP related perforations may be managed conservatively or may need an emergency surgical intervention [17]. ERCP related perforation although rare can have a mortality rate of as high as 37.5% [18]. The causes of perforation include patient related factors such as Billroth II gastrectomy and technical factors such as inexperienced

endoscopist, difficult cannulation, precut, and sphincterotomy [19]. Early diagnosis and prompt treatment are important for better outcome [7, 20]. The diagnosis of perforation can often be suspected or made during the endoscopic procedure, but is usually confirmed radiologically by demonstrating open air cavity or leakage of contrast.

Often the physical examination can help assess the patient, but not all abdominal perforations present with an acute abdomen [21]. Post ERCP perforations can be managed conservatively or may need an emergency exploration .Proper management of post ERCP perforation depends on type of injury and time of diagnosis of perforation after ERCP. Majority of cases are retroperitoneal perforations due to papillotomy, whereas intra peritoneal perforations are less common and caused by endoscope itself. Type I perforations are large, usually discovered during the ERCP procedure. They require immediate surgery or urgent endoscopic treatment, both type II and III perforations may be managed non surgically but require close surveillance, Type IV perforations which are not true perforations require no surgical intervention and are usually managed successfully by conservative management [22]. With the availability of non-invasive diagnostic modalities such as magnetic resonance cholangiopancreatography (MRCP) and endoscopic ultrasonography (EUS), ERCP has largely become a therapeutic modality [23].

The aim of this study was to determine the incidence of type IV perforations in the patients undergoing ERCP and also to determine the management of the patients with type IV perforations.

# **Experimental Design**

A hospital based observational analytical study was done. This study was conducted in the department of gastroenterology and hepatology, Government Medical College Srinagar (J&K) over a period of 2 years from May 2018 to June 2020. Informed consent of the study participants was obtained in all cases. The study had approval of College ethical committee.

A total of 111 patients were included in our study. Patients of all the ages and both the genders who were subjected to ERCP for the first time were included in the study. All the patients admitted in our hospital during the 2 year period satisfying the inclusion and exclusion criteria and underwent ERCP first time in our hospital were included in the study. All ERCPs were performed by experienced consultants in our department. All the patients who were included in our study were admitted to hospital on the day of ERCP. Drugs such as midazolam and hyoscine were used as premedication and during the procedure. All the patients after undergoing ERCP were observed for 24 hours. The enrolled patients were subjected to history and physical examination before and after ERCP. The following laboratory and imaging tests were done before the commencement of ERCP,

The nature of the procedure and possible complications were explained to the patients and their attendants.

All patients will be subjected to clinical examination to look for signs of peritoneal irritation, abdominal distension, subcutaneous emphysema and Pneumomediastinum. Serum amylase levels will be measured 6 hours after the procedure. NC CT chest abdomen pelvis with oral contrast was done in all patients within 24 hours after the procedure. The presence of Pneumomediastinum, retroperitoneal air, contrast extravasation and its location was recorded.

#### **Exclusion Criteria:**

- Billroth II and Roux en Y gastrojejonostomy.
- Recent Paracentesis.
- · Recent surgery.
- Pregnancy.
- Previous ERCP.
- · Biliary malignancy.
- Pancreatic head malignancy.

#### **Ethical consideration**

The study design, method of data collection, consent form and patient information sheets were analyzed by the institutional ethics committee at Government Medical College Srinagar, as a part of the procedure necessary for the approval of researches that involve the human interventions. The study was conducted after approval by the institutional ethics committee.

#### Informed consent forms

Appropriate consent forms were designed for seeking written consent which was approved by the institutional IEC. Patients and attendants were explained the nature of the procedure, risks involved, possible complications. After explaining the procedure clearly, the participants were requested to sign the consent form for the study. A patient information sheet was also signed by each participant after explaining the protocol and its requirements.

# Participant confidentiality

Patient confidentiality was fully maintained. Every patient was given an ID for further reference .All the data entries were made by using patient IDs .The data collected stayed with the researcher and was filed regularly by the researcher to be kept under safety.

#### **Results**

This is an observational analytical study. The data was entered in Microsoft Excel sheet. Chi-square test was used to analyze the relationship between the categorical variables and post ERCP type IV perforation. A p-value of < 0.05 was considered statistically significant.

This is a prospective, hospital based study conducted in the department of medical gastroenterology SMHS Srinagar conducted from June 2018 to June 2020. All patients with history of biliary pain, cholangitis, and acute pancreatitis secondary to stone disease were enrolled in this study. During the study period 111 patients of all ages, sexes were enrolled. Out of 111 patients one patient (0.9%) developed duodenal perforation with evidence of contrast extravasation (Stauffer type1) and 8(7.2%) patients showed evidence of only air leak

without evidence of contrast extravasation (Stauffer type IV) (see Figure 1).

**Figure1**: Relative proportion of various types of perforations Thus total incidence of perforations in our study is 10 % (see Figure 2).

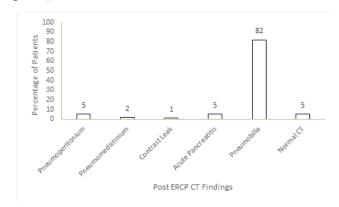
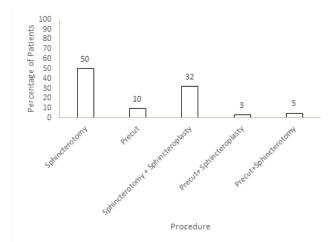


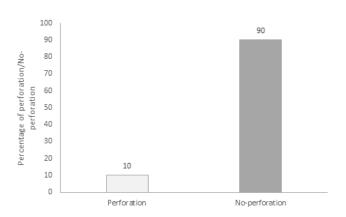
Figure2: Percentage of perforations post ERCP.



The most common indication of ERCP in our study is biliary pain (73%) followed by acute cholangitis (20%) and acute pancreatitis (7%). Next, we calculated the incidence of type IV perforations, 7.27% of the patients showed evidence of type IV perforations. The average age of patients in perforation group is 54.37 with SD of 9.42. Out of 8 patients who developed post ERCP type IV perforation one patient has undergone precut and 7 patients have undergone sphincterotomy.

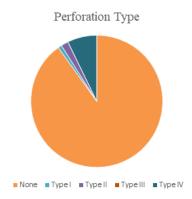
Out of 111 patients, sphincterotomy alone was done in 50% patients, sphincterotomy and sphincteroplasty was done in 32% patients, precut alone was done in 10%, precut and sphincterotomy was done in 5% patients, precut and sphincteroplasty was done in 3% patients (see Figure 3).

**Figure3:** Various procedures done for cannulation and their respective percentages.



Most common finding in post ERCP CT chest abdomen pelvis with oral contrast is pneumobilia (82%) (see Figure 4). CT was unremarkable in 5% patients. Pneumoperitoneum without evidence of contrast leak was found in 7.2% patients Pneumomediastinum without evidence of contrast leak was found in 1.8% patients. Pneumoperitoneum, pneumomediastinum with evidence of contrast leak was found in 0.9% patients. Thus incidence of type IV perforation in our study is 6.3%.The incidence of post ERCP acute pancreatitis in our study is 5%.

**Figure4**: CT findings post ERCP and their percentages across the sample.



All patients with type IV perforation in our study were managed conservatively with NPO, broad spectrum I/V antibiotics. All patients with type IV perforation improved after conservative management, although the number of hospitalization days was prolonged in patients who developed type IV perforation. One patient in our study, who developed type I perforation was shifted to surgical side and was managed by emergency surgical exploration and was later discharged.

### Discussion

ERCP is an important therapeutic modality for the treatment of a number of biliary and pancreatic diseases. Since ERCP is an invasive procedure, with the advent of MRCP, ERCP has largely been used as a therapeutic modality. During a routine ERCP session we encountered a 53-year-old female patient with history of biliary pain and MRCP documented choledocholithiasis was admitted for an elective ERCP. The

patient underwent ERCP and after the procedure, the patient complained of pain in the abdomen and vomiting. ERCP related perforation is a serious complication and has several important implications such as cost of treatment, length of hospital stay, morbidity and mortality.

We conducted a prospective observational, hospital based study in the department of gastroenterology and hepatology for a period of 2 years from May 2018 to May 2020.A total of 111 patients were included in our study after fulfilling the exclusion criteria. The average age of patients in this study was 50.19. Majority of the subjects were female compared to males. This can be attributed to the fact that biliary tract stone disease is more common in females than males.

Majority of patients in our study was from rural areas in comparison to patients from urban areas. The most common indication of ERCP in our study is biliary pain followed by cholangitis and acute pancreatitis. Several researchers have classified ERCP related perforations according to the location and mechanism of injury. Stapfer et al classified perforations into four types according to the location and mechanism of injury (1 )Type I, lateral or medial duodenal wall perforation, **ERCP** scope related.(2) ΙΙ, periampullary type paravaterian ,sphincterotomy related. (3) type III, Ductal perforations due wire manipulation to instrumentation during stone retrieval and occur in distal CBD (4) type IV, tiny retroperitoneal perforations caused by the use of compressed air during endoscopy. Second classification system has been proposed by Howard et al, which includes three groups (1) Group I, guide wire perforations (2) Group II, periampullary perforations and (3) Group III, Duodenal perforations. Third classification system has been proposed by Enns et al. Group I: esophageal, gastric, duodenal perforations, Group II sphincterotomy related perforations, Group III guide wire related perforations [33].

ERCP has been widely practiced for more than 35 years, progressively evolving from a diagnostic to a therapeutic role. The risk of serious complications has been identified early and has been the focus of many studies and reviews [17]. Noninvasive imaging, such as MRCP and EUS, have largely superseded diagnostic ERCP, and the safety profile of surgery has greatly improved [18]. Subcutaneous emphysema after an ERCP is a rare but well-recognized complication [19]. Prolonged air insufflation leads to dissection of air through the tissues. An alternative explanation is the leakage of air along the perineural and perivascular sheaths [20]. The type of post ERCP perforation should guide towards operative or non-operative management.

Type I perforations can be diagnosed during the procedure as a result of direct visualization of the retroperitoneal space or the abdominal cavity [24]. In cases with bleeding and lack of a clear view, fluoroscopy with or without contrast injection can help in diagnosis [22]. Type II perforations can be suspected after a sphincterotomy and confirmed by fluoroscopy,the later showing the presence of retroperitoneal air, especially around the right kidney [23] . contrast injection can also depict contrast leaking at sphincterotomy site [25]. Type III perforations can be picked up by the unusual passage of the guidewire [26]. Pre-cutting is dangerous and thus ERCP including pre-cutting needs to be done

by experienced endoscopists [27]. After every ERCP, the patient should be examined carefully and appropriate laboratory investigations should be done to detect any perforation . The duodenum should be inspected carefully while doing the procedure and X-ray abdomen should be done to look for the presence of retroperitoneal air.

Patients with air leaks can present hours after procedure with pain, fever and leukocytosis. In type I perforations, the diagnosis is usually obvious with severe pain and signs of peritonitis [27] When a patient complains of severe pain after ERCP, acute pancreatitis and perforation need to be ruled out [28]. In retroperitoneal perforations the diagnosis is not straight forward [28]. The patient may report epigastric pain but no signs of peritonitis [29]. Subcutaneous emphysema may be evident from the first hours after the procedure[30]. Leucocytosis and fever are often seen several hours after completion of the procedure [31]. In patients with suspected perforation, a CT scan with oral contrast should be done. retroperitoneal air can be picked up by plain films, but CT scan is more sensitive [32].

Free perforation indicates a serious complication; with associated high mortality approaching 25%. The diagnosis of free perforation can be made by the demonstration of air in the peritoneum and evidence of contrast leak on CT abdomen with oral contrast. Physical examination can be helpful in identifying the patients who develop ERCP related perforation, however all patients with perforation do not present with an acute abdomen.

In our study 8 patients developed type IV ERCP related perforation .Out of these 8 patients 5 patients were having pain abdomen in the Post ERCP period and one patient was having subcutaneous emphysema in the cervical region. Of these 8 patients who developed type IV perforation, the diagnosis of perforation was made immediately in the post ERCP period in only one patient because of the presence of subcutaneous emphysema in the cervical and thoracic regions on physical examination. The length of procedure lasted less than 60 minutes in all the cases. The finding of retroperitoneal air is not associated with the duration of the procedure. Among these 8 patients who developed type IV perforation, endoscopic sphincterotomy was done in 6 patients and precut was done in 2 patients. Thus in our study more number of patients who developed type IV perforation has undergone endoscopic sphincterotomy as compared to precut but it is not statistically significant. Of these 8 patients who developed type IV perforation serum amylase was above the upper limit of normal in only 2 patients. Thus hyperamylasemia has no association on the incidence of type IV perforation. Of these 8 patients who developed type IV perforation 6 patients were complaining of abdominal pain that lasted for 3-4 days and other 2 patients were completely symptom free. Thus patients with type IV perforation can have pain in the post ERCP period that lasts for few days or these patients may be completely asymptomatic. All the patients in our study who developed type IV perforation were managed conservatively by I/V fluids, antibiotics, analgesics, parenteral nutrition. All the patients who developed type IV perforation were successfully discharged from the

hospital, although the length of hospital stay was prolonged in this group of patients (7-10 days).

## Conclusion

ERCP is an invasive procedure used for the treatment of a number of biliary and pancreatic disorders. Due to its invasive nature, it may be associated with a number of complications including post ERCP pancreatitis, cholangitis, perforation and bleeding .Successful management of ERCP related perforations requires immediate diagnosis and early decision to decide whether to manage conservatively.

Endoscopic retrograde cholangiopancreatography (ERCP) is an invasive procedure used for the treatment of a number of biliary and pancreatic disorders. Due to its invasive nature, it may be associated with a number of complications including PEP, cholangitis, and perforation and bleeding. The objectives of this were to determine the incidence of type IV ERCP related perforations, and to determine the clinical profile and management of these patients with type IV perforation.

This is a hospital based prospective study conducted in the Department of Gastroenterology, Government Medical College Srinagar. Patients of all ages and both sexes who were subjected to ERCP and after fulfilling the exclusion and inclusion criteria were enrolled in this study. One hundred eleven consecutive patients who underwent ERCP and were fulfilling the exclusion and inclusion criteria were enrolled in this study. CBC, LFT, KFT, coagulogram, chest x-ray, ECG, HBSAg. IgG anti HCV were done prior to ERCP. Patients were monitored carefully in post ERCP period for 24 hours. Serum amylase levels were evaluated at 6 hours NCCT abdomen with oral contrast was done within 24 hours of ERCP in all the patients. NCCT abdomens with oral contrast were reported by the experienced radiologists.

Out of 111 patients who underwent ERCP, 8 patients developed type IV ERCP related perforations. Out of 8 patients 7 were female and 1 patient was male. All the patients with type IV perforation were managed conservatively, although the length of hospital stay is longer.

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