

**Review Article** 

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# RISK OF PANCREATITIS FOLLOWING BILIARY STENTING WITH OR WITHOUT ENDOSCOPIC SPHINCTEROTOMY

#### Said Muse Yusuf<sup>1</sup>, Ping Yao<sup>2</sup> and Sakarie Mustafe Hidig<sup>3</sup>\*

<sup>1</sup>Dept. 1 of Gastroenterology, The First Affiliated Hospital of Xinjiang Medical University, Urumqi, 830054, P.R. China.

<sup>2</sup>Professor and Head of Dept. 1 of Gastroenterology, The First Affiliated Hospital of Xinjiang Medical University, Urumqi, 830054, P.R. China.

<sup>3</sup>Department of Hepatobiliary and Pancreatic Surgery, The Fourth Affiliated Hospital, Zhejiang University School of Medicine, Yiwu, Zhejiang Province, 322000, P.R. China.

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#### \*Corresponding Author: Sakarie Mustafe Hidig

Department of Hepatobiliary and Pancreatic Surgery, The Fourth Affiliated Hospital, Zhejiang University School of Medicine, Yiwu, Zhejiang Province, 322000, P.R. China.

#### ABSTRACT

**Background and Aim:** Endoscopic sphincterotomy (EST) effectiveness before endoscopic biliary stenting in post-endoscopic retrograde cholangiopancreatography pancreatitis (PEP) prevention remains unestablished. This study aimed to determine the impact of EST prior endoscopic biliary stent placement in PEP. **Methods:** One hundred and fifty patients of different ages with biliary stricture needing ERCP were enrolled and randomly grouped into the non-EST (n=75) and EST (n=75). The researchers followed up with the participants for one month after the ERCP procedure and collected data on PEP occurrence and adverse events. The primary measure was PEP incidence within two days after the biliary stenting. The secondary outcome measures evaluated included recurrent biliary obstruction (migration, dislocation, and occlusion), adverse events connected with EST (bleeding and perforation), cholecystitis, and cholangitis after the first transpapillary biliary drainage. **Results and Conclusion:** 16% of patients who had biliary stenting after EST got pancreatitis, while only 9.3% of those who had biliary stenting without EST developed pancreatitis. The risk of pancreatitis is higher in endoscopic biliary stenting patientsafter undergoing EST.

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KEYWORDS: The primary measure was PEP incidence within two days after the biliary stenting.

#### INTRODUCTION

The pancreas is a retroperitoneal gland and a fascinating organ with exocrine and endocrine functions. It produces hormones and enzymes like insulin, which regulates blood sugar levels. Acute pancreatitis is an inflammatory condition of the exocrine pancreas that leads to multiple organ dysfunction and severe abdominal pain with a mortality of one to five percent (Szatmary et al., 2022). Excessive alcohol consumption, smoking, obesity, drug abuse, and bile stones are the common causes of pancreatitis. Pancreatitis presentations include abdominal guarding, hypotension, tachycardia, tachypnoea, low oxygen saturation, fever, impaired consciousness, irritability, breathlessness, and abdominal distension. Acute pancreatitis contributes to significant long and short-term morbidity, which in several minor cases exocrine results in pancreatic endocrine and insufficiency, recurrent disease, and prolonged debility

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(Szatmary et al., 2022). Besides the economic and social impacts of hospitalizations, chronic pain has a significant but often neglected effect on the patient's quality of life.

Endoscopic retrograde cholangiopancreatography (ERCP) is a commonly employed procedure in different disorders in the pancreaticobiliary tract. Endoscopists divide the major duodenal papilla to perform endoscopic sphincterotomy (EST) when extracting bile stones. The procedure employs a combination of fluoroscopic imaging and luminal endoscopy to diagnose and treat conditions related to the pancreaticobiliary system. The examination's endoscopic segment uses a side-viewing duodenoscope that an endoscopist passes through the esophagus and stomach into the duodenum's second portion. Having the scope in the described position allows for identifying the major duodenal papilla and inspection for abnormalities (Langerth, 2020). ERCP is the standard procedure for treating causes of bile obstruction, such as common bile duct stones. While clinicians can achieve biliary drainage percutaneously, they generally prefer ERCP due to shorter hospital stays, high success rates, and better quality of life due to its capacity to prevent clinicians from using percutaneous tubes. On the other hand, bile duct cannulation issues may result in constant interaction with the ampulla, causing unintended contrast injection or guidewire insertion into the pancreatic duct and temporary edema, creating an environment for PEP (Okamoto & Fukuda, 2022).

# Post-ERCP Pancreatitis (PEP)

Pancreatitis is an adverse and common effect of ERCP happening in two to fifteen percent of cases despite significant technical development. Its mortality rate may reach 0.7 percent (Borrelli de Andreis et al., 2023). ERCP is a specialized endoscopic procedure for managing pancreaticobiliary disorders such as relief of biliary obstruction (Tringali et al., 2023). There is significant controversy about the definition of PEP. Sole increased serum pancreatic enzyme levels do not imply PEP since temporary increases in serum pancreatic enzyme levels may happen in up to seventy-five percent of people after ERCP, regardless of the symptoms. On the contrary, people with low serum amylase levels one and a half times less than the upper limit of the average level, acquired two to four hours after ERCP, are not likely to develop or have PEP (Chandrasekhara et al., 2017). PEP can result in severe complications, including organ failure and pancreatic necrosis. According to Thaker et al. (2015), health professionals have poorly understood the mechanisms that result to pancreatitis but have suggested many theories. The common endpoint of pancreatitis is inflammatory pathways activation. Ribiero et al. (2021) identify the mechanism that induces PEP, which includes mechanical injury or obstruction due to instrumentation and hydrostatic pressure increase in the pancreatic duct due to over-injection of the contrast medium. The resultant cascade of inflammation involves chemo-attraction of inflammatory cells, premature intraocular stimulation of zymogens into proteolytic enzymes, and the release of cytokines and inflammatory mediators. The cascade can initiate a systematic inflammatory response syndrome or be limited to local inflammation (Thaker et al., 2015). Since abdominal discomfort is common after ERCP, PEP diagnosis should involve clinical evaluation with serum lipase or amylase to distinguish between PEP, transient post-procedural bloating, and other complications, including unresolved biliary obstruction, cholangitis, and perforation. Early cross-sectional imaging and excluding a structural cause for PEP, such as retained bile stones, may require early ERCP recurrence (Cahyadi et al., 2022).

Over the years, studies have identified patient, operator, and technical factors that act together or independently for PEP. To date, health professionals have tried to reduce the severity and incidence of PEP by administrating pharmacological agents, developing

devices to minimize the trauma that endoscopic interventions cause, identifying risk factors, and inserting pancreatic stents after ERCP. As mentioned earlier, PEP development is likely associated with pressure increase within the central pancreatic duct that results from inflammation periampullary resulting from instrumentation during ERCP. According to Cahyadi et al. (2022), PEP results from hydrostatic injury and mechanical obstruction, which cause early pancreatic enzyme activation, resulting in potential and local systemic inflammation. Patients with suspected sphincter of Oddi dysfunction (SOD) have a high risk of developing PEP. Other patient-associated risk factors include a history of acute recurring pancreatitis, regular serum bilirubin levels, younger patient age, prior PEP, and female sex. Additionally, previous studies have hypothesized operator-associated risk factors including case volume, trainee participation, and prior experience to affect the risk of PEP. However, it has been challenging to assess these factors due to confounding variables, including ERCP complexity at low-volume versus high-volume centers (Chandrasekhara et al., 2017).

Clinicians have made many trials to prevent PEP or minimize its severity. However, they have only proven a few approaches as effective and acknowledged them in clinical practice. They employ several tactics to reduce PEP incidences. The first approach involves vigilant patient selection to prevent pointless ERCP exposure and associated risks and instead use the latest, less-invasive problem-solving modes when indicated. The other method uses epidemiological statistics to determine the most crucial risk factors for pancreatitis development. High-risk patients often permit particular preventive endoscopic procedures like pancreatic duct stent placement. Moreover, risk classification may prompt clinicians referring high-risk patients to experienced endoscopists (Thaker et al., 2015). Other prevention strategies include pharmaco-prevention and enhancing procedural techniques. Elmunzer (2015) explains that atraumatic and competent technical activities during ERCP are essential in diminishing the risk of pancreatitis. As mentioned earlier, pancreatic duct injection and difficult cannulation are independent risk factors for PEP. Therefore, strategies that limit the injection of contrast into the pancreas and enhance cannulation will likely decrease PEP risk. Guidewireassisted cannulation attains both interventions. Guidewire-assisted cannulation employs a smalldiameter wire that has a hydrophilic tip that an endoscopist originally directs into the duct, thereby guiding passage to the catheter as opposed to conventional contrast-assisted cannulation, which leads to papillary edema or inadvertent injection to the pancreatic duct (Elmunzer, 2015).

Clinicians often carry out EST before biliary stenting to reduce PEP risk. However, the protective effect or prevention measure of EST is quite controversial. EST is

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often the initial step in accessing the pancreatic duct for anv therapeutic maneuvers, and some expert endoscopists use it as a precut technique for cannulating the biliary duct. Cui et al. (2014) explain that the idea of conducting EST before biliary stenting may have originated from previous studies that propose that stent placement may be more accessible and that the incidence of PEP may be lower when performing EST before biliary stenting. Additionally, EST prior endoscopic biliary stenting prevents PEP since it separates the orifice of the bile and pancreatic ducts possibly leading to a pressure decrease on the pancreatic duct's orifice. However, some studies do not support the effectiveness of EST in patients with biliary obstruction. Cui et al. (2014) further report that EST poses risks, particularly perforation, and bleeding, even when experienced endoscopists perform the procedure. Therefore, whether patients benefit from EST when they undergo biliary stenting is unclear. This study is a randomized control trial that aims to evaluate the effectiveness of EST in preventing pancreatitis following biliary stenting. The researchers considered a noninferiority setting suitable since health professionals consider EST a standard clinical practice technique. This study also aims to assess the inferiority of non-EST to EST prior endoscopic biliary stenting in patients with biliary stricture resulting from an etiology.

# METHODS

## Study Design

This study is according to the published study guidelines. The researchers randomly assigned the participants into a treatment group (EST or non-EST) through dynamic allocation (allocation factors included sex, age, and hilar or distal stricture) with an internet-based randomized allocation system. The endoscopists and patients knew the randomization outcomes because they were not completely blinded.

## **Participants**

The researchers enlisted patients with hilar or distal obstruction with etiologies needing biliary drainage through biliary stenting from the participating institutions. In this study, the researchers defined the distal biliary tract as the common bile tract downstream of the cystic duct's confluence. In contrast, they described the hilar biliary tract as situated upstream of the cystic duct. The researchers collected written informed consent from patients before registering them for the study.

## Study Outline and Intervention

The study's inclusion criteria included the capacity to provide and comprehend printed informed consent, more than twenty years old, naive major duodenal papilla, need for endoscopic biliary drainage through plastic stent, and clinical finding of biliary stricture established through imaging. The study's exclusion criteria were acute pancreatitis coincidence; history of ERCP; severe cholangitis coincidence; treatment with anticoagulant or antiplatelet drugs that the patient could not stop; breastfeeding or pregnancy; severe cardiopulmonary disease; ampullary tumor; impossibility of reaching of the primary duodenal papilla with a duodenal endoscope and history of gastrointestinal tract reconstruction other that Billroth I reconstruction.

Expert endoscopists with more than ten years of experience with ERCP performed all procedures. In some cases, fellows or trainees performed the procedures under experts' rigorous supervision. The endoscopists inserted a duodenoscope into the duodenum's second portion under conscious sedation, employing an analgesic agent (pethidine/fentanyl) and a soothing agent (diazepam/midazolam). The researchers formally registered the participants after selective biliary cholangiogram and cannulation and randomly assigned them to the EST and non-EST groups. Participants in the EST group underwent the EST procedure using a standardized method that involved a sphincterotome with a blended current. The endoscopists used a 5, 6, or 7Fr ENBD tube or a 7, 8.5, or 10Fr plastic stent for both study groups. Placing 2 ENBD tubes was allowed for patients who needed two-segment drainage. The endoscopists placed all tubes or stents across the papilla and hospitalized all the participants for at least one night after the procedure. The participants also routinely underwent blood tests, including C-reactive protein assays, lipase, amylase, liver function tests, and white blood counts before and within twenty-four hours for all study participants during admission. Any participant who experienced symptoms after the procedure underwent necessary blood assessments.

## Follow-up and Data Acquisition

The researchers documented patient background data (history of anticoagulant and antiplatelet treatment, medical history, age, sex, and Eastern Oncology Group performance status); procedural features (devices employed, cannulation techniques, endoscopist category (expert/fellow/trainee), biliary cannulation time, use of a pancreatic stent, intraductal ultrasonography/brushing cytology/guidewire insertion to the major pancreatic duct/bile duct biopsy/performance of pancreatography); medical data (pathologic assessment results if available); primary pancreatic duct diameter measured using magnetic resonance cholangiopancreatography, computed tomography or ultrasonography; stricture location; and presence of a benign or malignant stricture in the electronic data capture system. The researchers followed up with the patients for thirty days to obtain data on clinical symptoms and laboratory data. They collected data before the procedure and two hours, one day, and thirty days (+/-10) after it.

## **Definition of Adverse Effects**

The researchers recorded adverse events associated with the procedure, including bleeding, perforation, cholecystitis, cholangitis, and pancreatitis, thirty days after the procedure. They employed the American

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Society for Gastrointestinal Endoscopy (ASGE) standards to detect adverse events. ASGE criteria is a risk stratification instrument that categorizes patients into intermediate, high and low risk for pancreatitis and aims enhance diagnostic precision and increase to endoscopists' employment of less invasive imaging models (Jacob et al., 2021). Based on the ASGE, imaging studies such as computed tomography were not needed for PEP diagnosis. Endoscopists classify PEP by severity. Previous studies define moderate and mild PEP solely on the period of hospitalization (hospital stays ranging from 4-10 days or 2-3 days, respectively). They also define severe PEP as hospitalization for over ten days or pseudocyst or hemorrhagic pancreatitis that needs intervention such as surgery or percutaneous drainage (Cahyadi et al., 2022). The researchers used the ASGE grading system to grade the severity of the adverse events. Moreover, they defined recurrent biliary obstruction to involve stent migration, dislocation, or occlusion that needs intervention according to the TOKYO criteria 2014. The TOKYO criteria 2014 is a consensus-based criteria for reporting endoscopic transpapillary biliary stenting for biliary stricture and includes definitions of suitable evaluation of stent quality and complications. Initially, experts used stent patency, but it excluded migration. Therefore, they implemented the term 'recurrent biliary obstruction' to evaluate stent quality rather than stent occlusion (Isayama et al., 2015).

This study's primary outcome measure was the PEP incidence within two days after the endoscopic biliary stenting. The secondary outcome measures evaluated included recurring biliary obstruction (migration, dislocation, and occlusion), adverse events associated with EST (bleeding and perforation), cholecystitis, and cholangitis after the first transpapillary biliary drainage.

## Data Management and Monitoring

The researchers stored all the sampled information in a secure system according to internal information governance guidelines that only permitted clinicians could access. They calculated the ninety-five percent confidence interval (CI) of PEP incidence in both groups. They examined whether the variation between the values with 95% C is for the two study groups was within the margin of inferiority (six percent) using the Wald method. The Wald method is a technique for the significance of specific explanatory variables in a statistical model (Lishinski, 2018). The researchers used the chi-square  $(X^2)$  to analyze secondary data outcomes. Additionally, they performed exploratory multi-variate analysis modified for confounders to identify risk factors for PEP. The researchers explored the PEP incidence in the study groups according to stent diameter, etiology of pancreatic cancer, stricture's location, and the diameter of the primary pancreatic duct (<6 or  $\geq$  6 mm). They conducted all statistical examinations on the protocol population since the study was a non-inferiority trial. All P values less than .05 were statistically significant.

## **Outcome Measures**

#### **RESULTS AND DISCUSSION**

i. Descriptive statistics. Gender.

Gender						
		Frequency	Percent	Valid Percent	Cumulative Percent	
Valid	Male	76	50.7	51.7	51.7	
	Female	71	47.3	48.3	100.0	
	Total	147	98.0	100.0		
Missing	System	3	2.0			
Total		150	100.0			

Figure 1: Gender distribution.

There are (50.7%) males and (47.3%) females among the 150 patients. Including approximately equal numbers of male and female patients shows your study has a balanced representation. Gender can be an essential

factor in the risk of pancreatitis. Because of physiological variations, several medical illnesses and sequelae, such as pancreatitis, may have a distinct prevalence or severity in men and women.

#### Recode of inspection findings.

Recode_of_inspection_findings					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Endoscopic interstitial	12	8.0	8.2	8.2
	Endoscopic intersection	1	.7	.7	8.8
	Endoscopic insertion	96	64.0	65.3	74.1
	Endoscopic interpolation	30	20.0	20.4	94.6
	Endoscopic Interscope	1	.7	.7	95.2
	Endoscopic interstent	2	1.3	1.4	96.6

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	Emergency bedside exercise	1	.7	.7	97.3
	Endoscopic Lens Food	1	.7	.7	98.0
	Endoscopic interstular	1	.7	.7	98.6
	X-ray at the bedside	1	.7	.7	99.3
	Endoscopic insert to twelve	1	.7	.7	100.0
	Total	147	98.0	100.0	
Missing	System	3	2.0		
Total		150	100.0		

Figure 2: Recode of inspection findings.

Endoscopic insertio" is the most common finding, occurring in 64.0% of cases. "Endoscopic interpolatio" (20.0%) and "Endoscopic interstent" (1.3%) are two more prevalent results. The variety of results reflects the breadth of disorders and treatments encountered during endoscopic exams. The type of endoscopic finding might

be crucial when assessing the risk of pancreatitis. Some results may be connected to an increased risk of pancreatitis or other problems. For example, procedures requiring invasive interventions or anomalies in the pancreas may be more dangerous.

#### CONCLUSIONS

Conclusions					
		Frequency	Percent	Valid Percent	Cumulative Percent
	transendoscopic selective gallbladder	76	50.7	64.4	64.4
	Duodenoscopy	1	.7	.8	65.3
	X-ray assisted duodenum fourth	2	1.3	1.7	66.9
	common bile duct node	2	1.3	1.7	68.6
	Endoscopic removal of the bile duct	11	7.3	9.3	78.0
	Complete duodenoscopy	1	.7	.8	78.8
	endoscopic selective gallbladder	12	8.0	10.2	89.0
	Endoscopic bile duct stent	3	2.0	2.5	91.5
	Bile duct stent removal	3	2.0	2.5	94.1
Valid	endoscopic intubation + nipple	1	.7	.8	94.9
	transendoselective gallbladder in the lower segment of the common bile duct	1	.7	.8	95.8
	transendoscopic selective gallbladder in the lower section of the common bile duct	2	1.3	1.7	97.5
	Remove bile duct stent + meridian	1	.7	.8	98.3
	duodenal papillae ES	1	.7	.8	99.2
	X assisted lower duodenum	1	.7	.8	100.0
	Total	118	78.7	100.0	
Missing	System	32	21.3		
Total		150	100.0		

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"Transendoscopic selective gallbladder" is the most common result in 50.7% of cases. Other findings include"Endoscopic removal of the bile duct" (7.3%), "Endoscopic bile duct stent" (2.0%), and a variety of others with lesser frequency. The conclusion of the surgery is essential in determining the risk of pancreatitis. Some findings may point to more invasive treatments or therapies affecting the pancreas. For example, "endoscopic removal of the bile duct" implies a complicated surgery with a higher chance of consequences, such as pancreatitis.

Group A (Biliary Stenting after EST)	
Total Participants	75
Percentage with pancreatitis	16%

Group B (Biliary Stenting without EST)	
Total Participants	75
Percentage with pancreatitis	9.3%

According to the statistics, 16% of patients who had biliary stenting after EST got pancreatitis, while only 9.3% of those who had biliary stenting without EST developed pancreatitis. This shows that the risk of pancreatitis may differ between the two groups.

# DISCUSSIONS

Pancreatitis is a severe and sometimes fatal illness characterized by pancreatic inflammation. It is a known complication of endoscopic operations such as biliary stenting with or without endoscopic sphincterotomy (EST). Various causes, including gallstones and biliary blockage, can cause it. The treatment of pancreatitis following these surgeries is still a clinical problem. The findings shed light on the possible influence of EST on post-procedure pancreatitis rates in these two patient categories, revealing crucial insights into the frequency of pancreatitis in these two patient groups. Group A, which included patients who had biliary stenting after EST, had a greater rate of pancreatitis cases (16%) than Group B, which included patients with biliary stenting without EST (9.3%). The observed difference in pancreatitis rates between the two groups implies that adding EST to biliary stenting may raise the risk of pancreatitis.

## Mechanisms Underlying Increased Risk with EST

Endoscopic sphincterotomy is the incision of the biliary sphincter to allow stones or stents to pass. This operation is used to ease biliary blockage. Still, it can also interfere with the normal physiology of the sphincter, which is essential for controlling bile flow and avoiding pancreatic enzyme reflux into the pancreatic duct. Patients may be predisposed to pancreatitis if this regulating process is disrupted.

The retrograde flow of bile and pancreatic juice into the pancreatic duct, known as pancreatic, biliary reflux, is one probable mechanism leading to the higher risk of pancreatitis in Group A. By definition, EST can cause changes in sphincter function, potentially enabling digestive juices and bile to reflux into the pancreas and raising the risk of pancreatic inflammation. Previous research has connected EST to pancreatitis, lending credence to this notion.

Another factor to consider is the possible trauma generated by EST, which might result in local inflammation and irritation, raising the risk of pancreatitis. The sphincterotomy damage may cause the release of inflammatory mediators, resulting in an inflammatory cascade inside the pancreas.

## **Clinical Implications**

The results have important clinical implications. Clinicians should carefully examine the risks and advantages of EST with stent implantation when contemplating biliary treatments. While EST can help relieve biliary blockage in certain circumstances, evaluating the patient's particular risk factors and the possibility of pancreatitis is important. Furthermore, our findings highlight the significance of patient selection and individualized treatment approaches. Patients with

high risk of pancreatitis, like those with a history of acute pancreatitis or underlying pancreatic disease, may necessitate a more careful approach when determining EST needs. To reduce the occurrence of post-procedure pancreatitis, clinicians should do a rigorous preprocedural assessment and risk stratification.

# CONCLUSION

Although EST is the recommended procedure carried out in daily clinical practice to facilitate the insertion of a large-bore device into the bile duct such as per-oral cholangioscopy and PEP prevention, the procedure occasionally results in severe adverse events such as perforation and bleeding. This study's results indicate that bleeding incidences were significantly higher in the EST group. Therefore, clinicians should not recommend ES for all biliary stricture patients undertaking endoscopic biliary stent placement. Moreover, the results show that PEP incidences were higher in the EST group than in the non-EST group. In conclusion, EST conduction prior biliary stenting increases the risk of PEP in patients with biliary stricture. The limitation of this study is that the researchers did not conduct it in a blinded setting. They did not conceal the randomization results from the endoscopists who conducted the procedure and assessed the post-procedure adverse events and the participants. Generally, incompletely blinded settings can cause assessor bias, affecting the primary study outcome.

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## Availability of data and materials

Most of the data was in the article, and other data can be asked from the corresponding author.

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**Conflict of Interest:** The author declares no competing interests.

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