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**Post-endoscopic retrograde cholangiopancreatography cholecystitis: A review of incidence, risk factors, prevention, and management**

Giri S *et al* Post-ERCP Cholecystitis

**Abstract**

Post-endoscopic retrograde cholangiopancreatography (ERCP) cholecystitis (PEC) is a recognized adverse event associated with ERCP. The incidence of PEC is low in patients undergoing ERCP, but is high in specific subgroups, such as those receiving fully-covered self-expandable metallic stents (SEMS). Several risk factors contribute to PEC, including gallbladder (GB)-related factors like tumor involvement of the orifice of the cystic duct (OCD) or feeding artery, and associated gallstones. Stent-related factors, such as covered stent placement and high axial force stents, and procedure-related factors, including stent placement across the OCD and contrast injection into the GB, further elevate the risk. Prevention strategies focus on modifying techniques, such as careful contrast administration and stent selection (uncovered or low axial force SEMS), and considering prophylactic GB drainage through endoscopic transpapillary GB drainage (ETGBD) or endoscopic ultrasound-guided GB drainage (EUS-GBD), especially in high-risk patients. Treatment options for PEC range from conservative management with antibiotics to more invasive interventions like percutaneous transhepatic GB aspiration or drainage, endoscopic techniques (ETGBD, EUS-GBD), and cholecystectomy. The choice of treatment depends on the severity of cholecystitis, the patient's condition, and other factors. The present review summarizes the currently available literature on the incidence, predictors, prevention, and management of PEC.

**Key Words:** Cholecystitis; Endoscopic Retrograde Cholangiopancreatography; Gallbladder stenting; Percutaneous gallbladder drainage; Endoscopic ultrasound-guided gallbladder drainage

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**Core Tip:** The incidence of cholecystitis after ERCP is usually low but can increase up to 33% in high-risk individuals. Prevention in these cases involves careful contrast administration and stent selection, and considering prophylactic endoscopic gallbladder drainage. A step-up approach may be acceptable in mild cases, which include conservative treatment or percutaneous aspiration followed by drainage if needed. Endoscopic drainage after stent removal is often the first line for moderate to severe cases after covered metal stent placement. Endoscopic ultrasound-guided or percutaneous drainage is preferred in cystic duct obstruction. Treatment strategies should be tailored to the patient's condition, cholecystitis severity, and prognosis.

## **INTRODUCTION**

Endoscopic retrograde cholangiopancreatography (ERCP) is the primary modality for diagnosing and treating biliopancreatic disorders, particularly for managing benign and malignant biliary obstruction (MBO). However, ERCP is not without risks and is associated with multiple adverse events (AE).[1] Post-ERCP cholecystitis (PEC) is a recognized AE associated with ERCP, though often less discussed than post-ERCP pancreatitis.[1] PEC can lead to significant morbidity, requiring further interventions, extending hospitalization, and potentially affecting the patient's quality of life and overall prognosis.[2] The reported incidence of PEC varies from 0.5% to 5.2% in patients undergoing ERCP, with a mortality rate of 0.04%.[1] This variability may be attributed

to differences in patient populations, definitions of cholecystitis, and the specific ERCP techniques employed.

Notably, the incidence appears to be higher in specific subgroups, such as those receiving biliary duct metallic stents, particularly fully-covered self-expandable metallic stents (FC-SEMS), where rates as high as 15.7% have been reported.[3-5] In one study, the incidence of cholecystitis after CSEMS was significantly higher than that observed with uncovered SEMs (UC-SEMS) (7.8% vs. 1.2%).[6] Numerous other risk factors for PEC have been identified across various studies.[7,8] Given the potential for severe outcomes, identifying patients at high risk for PEC is crucial for implementing preventive measures and ensuring timely management.

While post-ERCP pancreatitis has been extensively studied, PEC has received comparatively less attention, possibly due to its historically reported lower incidence.[1] However, the increasing use of FC-SEMS for malignant biliary strictures has heightened the clinical relevance of PEC.[9] Apart from this, the treatment of PEC will often require invasive treatment like <sup>6</sup>percutaneous transhepatic gallbladder drainage (PTGBD), endoscopic transpapillary GB drainage (ETGBD), endoscopic ultrasound-guided GB drainage (EUS-GBD) or cholecystectomy.[10,11] There is a lack of data on the step-wise approach to the management of PEC. Understanding the incidence, risk factors, steps for prevention, and optimal management strategies for PEC is essential for improving patient outcomes and the safety of ERCP procedures. Thus, the present review was undertaken to summarize the current literature on PEC.

### **INCIDENCE OF PEC**

The incidence of PEC varies significantly based on procedural techniques, patient characteristics, and preventive measures. Newly diagnosed cholecystitis after ERCP was seen in 1.5% (11/2347 patients undergoing biliary sphincterotomy) of patients up to 16 days after ERCP in a study by Freeman *et al.*[12] A subsequent study reported a PEC incidence rate of 0.96% among 1345 ERCP procedures.[2] In a recent study based

on a prospective multicenter biliary endoscopy registry, the incidence of PEC was as low as 0.38%, developing after a median duration of 5 days.[13]

However, studies on ERCP with self-expandable metallic stents reported a higher rate of cholecystitis. This again depends on the type of stent, with covered SEMS reporting a higher PEC rate of 4-15.7% [3,5,6,14,15] compared to uncovered SEMS reporting a PEC rate of 1.2-4%.[6,15] The rate of PEC increases significantly with the involvement of the orifice of the cystic duct (OCD). Suk *et al*[16] reported a PEC rate of 33% with uncovered SEMS and 27% with covered SEMS in those with OCD involvement. Based on the site of obstruction, the incidence of cholecystitis after SEMS placement for distal MBO and hilar MBO were comparable (7.5% vs. 5.9%).[8] Thus, there is a significant variation in the incidence of PEP, depending on the type of stent and involvement of OCD.

### **RISK FACTORS OF PEC**

Several factors have been identified as predictors of cholecystitis following biliary stent placement. These can broadly be classified into GB-related, stent-related, and procedure-related factors (**Figure 1**).

#### **Gallbladder-related factors**

*Involvement of the orifice of the cystic duct:* Multiple studies have shown that tumor involvement of OCD was an independent risk factor for the development of PEC, with odds ratio (OR) varying from 3.17 to 47.2.[3,7,8,15-23] Tumor growth around the OCD can directly narrow or obstruct the opening of the cystic duct. This blockage prevents the normal outflow of bile from the GB, leading to bile stasis within the GB. The resulting bile stasis can lead to inflammation and infection of the GB, manifesting as cholecystitis. Also, tumor invasion can cause the OCD to lose its normal elasticity. In a healthy state, the elastic nature of the OCD allows space for bile to pass through the cystic duct. When this elasticity is lost due to tumor involvement, the orifice may become rigid and less able to accommodate bile flow, especially if there is additional compression from the SEMS.[18]

### ***Tumor invasion of the feeding artery of the gallbladder:***

In a study by Sogabe *et al*,[19] tumor invasion of the feeding artery of GB was an independent predictor of PEC with OR 22.13 (95%CI: 3.57-137.18). These may be due to the fact that tumor invasion around the arteries that supply blood to the GB, such as the cystic artery or its origin (often the right hepatic artery), can narrow or obstruct these vessels, leading to ischemia. The ischemic damage and potential necrosis trigger an inflammatory response in the GB, which, coupled with potential bile stasis due to other factors like cystic duct obstruction (which may or may not be present concurrently), can lead to the development of acute cholecystitis.[24] Placing a biliary SEMS can potentially compress the feeding arteries of the GB, especially if they lie close to or across the common bile duct (CBD), such as the right hepatic artery.[19] This is distinct from the mechanism of cholecystitis related to OCD involvement, which primarily involves obstruction of bile outflow. Apart from predicting PEC, the absence of tumor invasion of the feeding artery of GB has also been shown to be associated with a higher success rate of percutaneous transhepatic gallbladder aspiration (PTGBA).[25]

**Gallbladder stone:** Most cases of acute cholecystitis are caused by the obstruction of the cystic duct due to an impacted gallstone. Similarly, gallstones can predispose to PEC in patients undergoing ERCP and stent placement by obstructing the bile flow. Three studies have shown that the presence of gallstones increased the risk of PEC after SEMS placement.[4,16,22] Another study by Ting *et al*[2] reported that cystic duct stone was an independent predictor of PEC.

### **Stent-related factors**

**Covered stent placement:** Theoretically, the open interstices of the uncovered SEMS can allow sufficient GB drainage and avoidance of cholecystitis. However, cholecystitis is well-documented after placement of both covered and uncovered SEMS. Studies suggest that covered SEMS are associated with a higher incidence of PEC than uncovered SEMS,[6,20,22] with a shorter median time in covered vs. uncovered SEMS

(22 vs. 124 days).[20] This is often attributed to the impermeable barrier created by the covering material, potentially obstructing the OCD, thereby impeding the outflow of bile from the GB with subsequent inflammation. A recent meta-analysis reported higher odds of PEC in patients with covered SEMs than with uncovered SEMs placement (OR 1.78, 95%CI: 1.03–3.07).[9] Thus, covered SEMs should be avoided as much as possible in patients with other risk factors for PEC.

#### ***High axial force stent:***

A high axial force can contribute to cholecystitis in both covered and uncovered SEMs by causing compression of the OCD, especially when the OCD is compromised by the tumor. This compression can impede or block the bile outflow from GB, leading to bile stasis and subsequent inflammation, manifesting as cholecystitis. A shorter SEMs length ( $\leq 60$  mm) may have a shorter distance from its ends to the stricture, leading to an increased axial force.[26] Nakai *et al*[18] reported SEMs with high axial force as an independent predictor of PEC (OR 6.34, 95%CI: 1.15–118.36). The authors suggested that a strong axial force might cause a deviation of the OCD from the longitudinal axis of the CBD.[18] However, this factor has become less important, with the currently available stents having low axial force.

#### **Procedure-related factors**

##### ***Stent placement across the orifice of the cystic duct:***

Placing a biliary stent across the OCD can directly obstruct the bile outflow from the GB, particularly with covered SEMs. This mechanical blockage leads to bile stasis and inflammation, resulting in PEC, as evidenced by multiple studies.[5,8,27,28] The risk is amplified by factors like high stent axial force and pre-existing tumor involvement at the OCD. Avoiding stent placement across the OCD, when feasible, is a key consideration to minimize this complication. Prophylactic GB drainage is also considered in situations where covering the OCD is unavoidable.[27]

*Contrast injection into the gallbladder:* Contrast injection into the GB during ERCP is recognized as a predictive factor for the development of PEC, as reported by multiple studies.[3,5,7] There are multiple mechanisms for PEC after contrast injection into the GB. First, if the contrast is nonsterile, it can introduce bacteria and other contaminants into the GB lumen, leading to infection and subsequent cholecystitis, especially if bile outflow is already compromised due to stent placement or other factors. Second, manipulation during ERCP can lead to the retrograde entry of enteric bacteria into the biliary tract and subsequently into GB with contrast injection.[28] Third, the involvement of the OCD and covered SEMS placement may impede the GB emptying, leading to prolonged contrast retention and subsequent PEC.[7] Thus, avoiding unnecessary and large amounts of contrast injection into the GB and aspirating as much bile as possible before cholangiography may prevent PEC.

## **PREVENTION OF PEC**

### **Modification of techniques**

PEC prevention focuses on reducing the risk of GB inflammation following ERCP. Several strategies, including procedural modifications and additional drainage techniques, have been proposed to mitigate PEC incidence. Unintentional GB opacification during ERCP has been linked to increased cholecystitis risk.[3,5,7] Thus, careful contrast administration techniques should be employed, including aspirating bile before cholangiography and limiting the volume of contrast injected.[20] Stent selection also plays a crucial role in PEC prevention. Covered SEMS and SEMS with high axial force are associated with higher cholecystitis rates due to cystic duct obstruction.[18] Consequently, the use of uncovered SEMS or low axial force SEMS has been suggested to minimize the risk of PEC. Recently introduced multi-hole fully-covered SEMS for prevention of stent migration and recurrent biliary obstruction has been shown to have a low PEC rate of 2.7%.[29] Another study, comparing the outcome of multi-hole fully-covered SEMS with covered SEMS, reported comparable PEC rates between the two stents (0% vs. 5.6%).[30] However, the study was underpowered to

analyze the difference in PEC. Thus, while theoretically, a multi-hole fully-covered SEMS may reduce the risk of PEC, the same remains to be proved in future studies. High-risk patients should be closely monitored post-ERCP to facilitate early cholecystitis detection. Imaging modalities such as ultrasound and computed tomography (CT) can help identify early signs of GB inflammation, allowing for timely intervention before severe complications arise.

### **Prophylactic gallbladder drainage**

There are limited studies on the drainage technique for preventing PEC, and only endoscopic methods have been described. Prophylactic GB drainage by ETGBD has emerged as a viable approach to prevent PEC, particularly in patients receiving SEMS. Gosain *et al*[27] conducted the first study on the role of prophylactic GB drainage in reducing PEC. Patients in whom the OCD was expected to be covered by the SEMS underwent ETGBD with a 7 Fr single pigtail plastic stent. PEC occurred in 20% (2/10) of those without any prophylactic GBD compared to none among the 11 patients undergoing ETGBD.[27] Subsequently, Ishii *et al*[31] reported a significantly lower incidence of PEC with ETGBD (21.4% vs. 4.2%,  $P = 0.045$ ) among those undergoing covered SEMS placement for distal malignant biliary obstruction (DMBO). In the study by Kozakai *et al*,[32] prophylactic GB stenting was a significant factor in preventing PEC on multivariable analysis (Hazard ratio 0.61; 95%CI: 0.37-0.99;  $P = 0.045$ ). This indicates that prophylactic ETGBD significantly reduces the risk of PEC by maintaining GB drainage, thereby preventing stasis and subsequent infection. However, there are certain technical issues with the placement of the GB stent, like the presence of cystic duct stones and stricture of the cystic duct secondary to tumor invasion, reducing technical success.[33] Additionally, if the cystic duct opening is close to the distal bile duct obstruction, then manipulation of the guidewire and cannulation would be difficult. This is evidenced by the lower technical success rates reported in the three studies (58%-75%), with procedure-related AE rates of 9.4% to 23.3%.[27,31,32] Thus, technical challenges and AEs limit the feasibility of prophylactic ETGBD.

Endoscopic ultrasound-guided gallbladder drainage (EUS-GBD) is another promising prophylactic strategy with limited data. In a study, patients with unresectable MBO with obstruction of OCD were randomized to SEMS with or without EUS-GBD using lumen-apposing metal stents (LAMS). PEC was observed in 22.7% of the patients in the control group compared to none in the intervention group. The 1-year acute cholecystitis-free survival rate was 100% in the EUS-GBD group and 75% in the control group ( $p = .023$ ). Also, there were no AEs related to EUS-GBD.[34] While highly effective, EUS-GBD is a technically demanding procedure requiring specialized expertise. **Table 1** summarizes the strategies for the prevention of PEC.

### TREATMENT OF PEC

Multiple options are available for the management of PEC, varying from medical management to percutaneous radiological techniques, endoscopic techniques, and surgery. Treatment choice depends on various factors, including the severity of cholecystitis, the patient's comorbidities and overall condition, the type and location of the biliary stent, and the availability of specialized techniques.

#### Conservative management

For some patients with mild cholecystitis, treatment may involve intravenous antibiotics, intravenous hydration, and administration of analgesics if needed. In the study by Shimizu *et al*,[17] two out of four patients with PEC after SEMS placement improved with conservative antibiotic therapy, while the other two patients required percutaneous GB drainage. In the study by Ishii *et al*,[4] watchful waiting with antibiotic therapy was used in 7 out of 51 cases of PEC, of which six improved and one patient expired. However, conservative treatment might not be sufficient for moderate to severe cases.

#### Radiological techniques

***Percutaneous transhepatic gallbladder aspiration:*** PTGBA is a minimally invasive modality for managing acute cholecystitis that involves aspirating bile from the GB percutaneously, particularly in patients with high surgical risk. PTGBA is a technically feasible procedure with high success rates. Multiple studies reported a 100% technical success rate for PTGBA, which is defined as sufficient aspiration of gallbladder contents. However, it may have a poor long-term drainage effect, reducing its clinical efficacy. Ohno *et al*[21] reported a low clinical success rate of 54% with the first session of PTGBA, with the success rate increasing to 70% after repeated aspiration. The authors reported obstruction of the OCD as an independent predictor of poor response to ETGBA.[21] Three other studies also reported a lower clinical success rate of 57.1%-65% with PTGBA.[25,35,36] Also, cholecystitis can frequently recur after aspiration alone, with reported recurrence rates ranging from 14.3% to 36.7%.[3,8,25,35,36] The reported AEs with PTGBA are rare, with only one study reporting a moderate AE (intraabdominal bleeding requiring blood transfusion).[36] Thus, PTGBA is associated with lower clinical success and a higher risk of recurrence. PTGBA might be considered when obstructive cholecystitis is thought to improve without a drainage tube, especially in the absence of severe cholecystitis findings.

***Percutaneous transhepatic gallbladder drainage:*** PTGBD is an easy, well-established, and frequently utilized treatment for cholecystitis and PEC. PTGBD is generally a technically successful procedure with a 95-100% rate of successful catheter placement. The efficacy of PTGBD for PEC is also high, with clinical success rates of 91-95%. PTGBD is often used as a first-line treatment, especially in patients with unresectable malignant biliary strictures who develop PEC. Although the Tokyo guidelines have mentioned PTGBD as the standard treatment in patients who are unfit for surgery, it requires long-term external catheter/drainage tube management, which in turn decreases the quality of life of patients.[10,35] Migration or accidental catheter dislodgement can occur in approximately 6.5% of patients undergoing PTGBD.[36] Other reported AEs include pleural effusion, pneumothorax, bile leak with or without biliary peritonitis, and intrahepatic hemorrhage.[8,36,37] Also, prolonged external

drainage with PTGBD in patients with biliary tract cancer is associated with the risk of tumor seeding of the puncture pathway, as reported with percutaneous transhepatic biliary drainage.[38] While PTGBD effectively resolves acute cholecystitis, recurrence can occur after catheter removal, with incidence varying from 10% to 33%. Thus, PTGBD is a highly effective and technically successful procedure for treating PEC, but the burden of the external drainage tube on the patient's quality of life and the potential for AEs and recurrence after tube removal are essential considerations.

**Comparison between percutaneous transhepatic gallbladder aspiration vs. drainage:** Two studies have compared the outcome of PTGBA and PTGBD in PEC. Kozakai *et al*[25] reported a higher clinical success rate with PTGBD than with PTGBA (92% vs. 65%). However, it was not statistically significant, which may be due to the study's small sample size and, thus, being underpowered to show significant differences.[25] Subsequently, Imai *et al*[36] reported a significantly higher clinical efficacy with PTGBD than with PTGBA (100% vs. 57%,  $P < 0.01$ ). Thus, PTGBD may be associated with a higher efficacy than PTGBA, but further studies are required before recommending one over the other.

### **Endoscopic techniques**

**Endoscopic transpapillary gallbladder drainage:** ETGBD involves accessing the GB through the papilla of Vater and the cystic duct during an ERCP procedure to establish drainage, which is an effective treatment option for PEC. ETGBD can achieve prompt internal drainage by placing a stent or a nasobiliary tube into the GB, avoiding the need for an external tube, and potentially offering a better quality of life compared to PTGBD.[38] Another advantage of ETGBD is that it is feasible in patients with ascites or coagulopathy, where percutaneous approaches may be contraindicated.[38] However, ETGBD is generally considered technically challenging, and the success rate can vary. Among all the interventions available for managing PEC, ETGBD has the lowest technical success rate, varying from 75% to 83.3%, as access into the gallbladder through the cystic duct may be difficult or even impossible in some cases.[8,38] In cases of

uncovered SEMs, ETGBD may be successfully performed through the stent mesh.[38] However, PEC developing after covered SEMs will require removal of the SEMs, followed by ETGBD with simultaneous biliary stent (either plastic or SEMs) placement.[38] However, ETGBD has a very high clinical success rate, and no recurrence has been reported. Thus, despite ETGBD having high efficacy and offering the benefits of internal drainage, it is technically challenging, requiring specialized techniques and careful patient selection.

*Endoscopic ultrasound-guided gallbladder drainage:* EUS-GBD has emerged as an efficacious treatment option for acute cholecystitis, including those occurring after ERCP. EUS-GBD involves visualizing the GB using an echoendoscope, typically from the duodenum or the gastric antrum, followed by GB puncture, confirmation of position (bile aspiration or contrast injection), the passage of a guidewire, tract dilatation, and stent placement (either plastic or LAMS). An electrocautery-enhanced LAMS can reduce the procedure duration by bypassing the need for guidewire passage and tract dilatation.[39-41] EUS-GBD has been reported to have a high technical and clinical success rate of 90-100%.[5,8,35] However, the AE rates are also high with EUS-GBD, including pneumoperitoneum, bile leak, bile peritonitis, and stent migration,[5] with reported rates up to 40%.[35] Inoue described a modified version of EUS-GBD, which used a naso-drainage tube in place of LAMS in 30 patients of PEC. The technical and clinical success rates were 96.7% and 96.6%, respectively, with only one procedure-related AE (biliary peritonitis).[42] Thus, EUS-GBD offers the benefits of internal drainage with high technical and clinical success rates. However, it is a technically demanding procedure that requires expertise and awareness of potential complications.

### **Surgery**

In acute calculous cholecystitis, surgical cholecystectomy is the recommended standard treatment. For PEC, cholecystectomy can be performed as an urgent or delayed treatment depending on the patient's condition and the severity. In the study by Khan *et al*,[13] 10 out of 17 patients with PEC were initially treated with urgent

cholecystectomy, and one received antibiotics followed by delayed cholecystectomy. Cholecystectomy offers a high technical and clinical success rate and eliminates the risk of cholecystitis recurrence.[24] However, many patients who develop PEC, particularly those with MBO requiring stent placement, often have unresectable malignancy and a poor performance status.[16] In such cases, the invasiveness of surgery makes cholecystectomy usually not feasible or associated with high risk.

**Table 2** summarizes the reported outcomes of various modalities for treating PEC. **Figure 2** shows the step-wise approach to the prevention and management of PEC.

### **LIMITATIONS AND FUTURE PERSPECTIVES**

There is a lack of prospective studies regarding the incidence, prevention, and management of PEC, suggesting the risk of selection bias. Most of the studies had a relatively small number of patients, which can hinder the ability to perform meaningful multivariate analyses or detect statistically significant differences. There is a paucity of data comparing the outcome of various treatment modalities available for the prevention and treatment of PEC. Some studies have relatively short follow-up periods, limiting the assessment of late complications like late-onset cholecystitis or long-term stent patency. Lastly, the evaluation of certain factors, such as tumor involvement of the OCD or flow of contrast into the GB, may rely on visual interpretation of imaging, potentially introducing observer bias. There is a strong emphasis on the need for future prospective, randomized controlled trials with larger numbers of patients to accurately evaluate the efficacy and safety of different modalities for the prevention and treatment of PEC. Developing predictive models could help clinicians identify high-risk patients who might benefit from prophylactic interventions or closer monitoring. Future studies should also consider the cost-effectiveness of different stent types and management strategies, especially as newer and potentially more expensive technologies like LAMS for EUS-GBD become more widespread.

### **CONCLUSION**

The overall incidence of PEC remains low but increases significantly in the high-risk group. The risk factors include tumor involvement of the OCD or feeding artery of GB, stent across the OCD, covered SEMS placement, associated GB stones, and flow of contrast into the GB. Identification of the risk factors for PEC is the key to adapting preventive strategies for PEC and keeping a close watch on the early identification and treatment of PEC. While preventive strategies such as EUS-GBD and prophylactic ETGBD show promise, further studies are needed to refine treatment protocols and enhance patient safety. Several treatment options are available for PEC, ranging from conservative measures to percutaneous techniques like PTGBA and PTGBD, endoscopic techniques like ETGBD and EUS-GBD, and lastly, cholecystectomy. <sup>4</sup> The choice of treatment depends on the severity of the condition, the patient's overall health, and the presence of any complicating factors. There is a need for prospective and well-controlled studies to overcome the limitations of current retrospective data and provide clearer guidance on the optimal selection of techniques for preventing and managing PEC.

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