

Risk factors of pancreatitis after endoscopic sphincterotomy. Review of literature and practical remarks based on approximately 10,000 ERCPs

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ABSTRACT:

Post-endoscopic pancreatitis (PEP) is the most common complication of endoscopic retrograde cholangiopancreatography (ERCP). Depending on the presence of risk factors, PEP can occur in 4.1% to about 43% of patients. According to the European Society of Gastrointestinal Endoscopy (ESGE) guidelines, only three to patient-associated risk factors have been identified: suspected sphincter of Oddi dysfunction (SOD) (OR 4.09), female gender (OR 2.23), and previous pancreatitis (OR 2.46). Another three procedure-associated factors include cannulation attempt duration > 10 minutes (OR 1.76), more than one pancreatic guidewire passage (OR 2.77, CI: 1.79 – 4.30), and pancreatic injection (OR 2.2, CI: 1.60 – 3.01). Importantly, analyses of cumulative risk due to coexistence of several factors emphasize the importance of female sex, difficult cannulation, CBD diameter <5 mm, young age, and many other factors. Unfortunately, studies performed to date have included only small numbers of patients with several co-existing risk factors. Therefore, further analysis of other risk factors and the cumulative risk related to their co-occurrence is necessary. Based on current evidence, special care must be given to patients with several risk factors. Also, care should be given to proper qualification of patients, use of guidewires, early pre-cut incision, protective Wirsung's duct stenting, and rectal NSAID administration.

KEYWORDS:

ERCP, pancreatitis, endoscopic sphincterotomy, risk factors

INTRODUCTION;

Post-endoscopic pancreatitis (PEP) is the most common complication of endoscopic retrograde cholangiopancreatography (ERCP). The diagnosis of PEP is based on the presence of abdominal pain - typical for acute pancreatitis, and serum lipase and/or amylase activity at least three times greater than the upper limit of normal at 24 hours after the procedure (1, 2). PEP occurs in 4.1%-5.4% of patients, but depending on the prevalence of risk factors, it may vary from 0.4%-3.6% to 7.8%-29.2%, with an odds ratio (OR) of 14.9 (1, 3, 4). Additionally, risk factor co-occurrence may increase the prevalence of PEP to 40%-43% of patients (4, 5). The risks of PEP are both patient- and procedure-associated. Therefore, knowing the risk of each endoscopic maneuver is important for selecting the best strategy for each patient. However, such selection is possible under two conditions. First, all existing risk factors must be identified. Second, the risk associated with co-existence of several factors should be determined. Currently, there are no generally accepted evidence-based guidelines for choosing an optimal treatment for a given patients, and many decisions are operator-dependent (1,2, 3-6).

RISK FACTORS ASSOCIATED WITH THE PATIENT

Knowing patient-associated risk factors allows to exclude patients with greater risk than potential benefit of treatment. Based on the ESGE guidelines, only three definite risk factors have been identified as follows: suspected sphincter of Oddi dysfunction (SOD) (OR 4.09), female gender (OR 2.23), and previous pancreatitis (OR 2.46). Another five likely risk factors include previous PEP (OR 8.7), younger age (OR 1.09 – 2.87), non-dilated extrahepatic biliary duct (OR 4,4,- 5,35)3.8% vs. 2.3%), absence of chronic pancreatitis (OR 1.87), and normal serum bilirubin level (OR 1.89) (1-3, 6-10).

Suspected SOD increases PEP risk from 3.9% to 10.3% (OR 4.09, CI: 3.37 – 4.96) (1-2, 5,7, 10). However, indications for endoscopic treatment in patients with SOD are still discussed. According to the Milwaukee classification, only type I SOD is a clear indication for endoscopic sphincterotomy (ES); complete pain relief 1.5 years after ES in this type of SOD has been reported in 91% of patients, compared with 75% and 0-50% in type II and type III SOD, respectively (11, 12). Sphincter of Oddi manometry (SOM) is the most objective method for the diagnosis of type II and type III SOD. Unfortunately, no correlation exists between clinical symptoms and SOM, which was confirmed in the EPISODE multicenter trial. (13,14). As SOM is associated with a particularly high risk of PEP, non-invasive methods of SOD diagnosis such as functional CBD ultrasound examination or secretin-enhanced magnetic resonance cholangiopancreatography (MRCP) should be considered before qualification for ES (1,11, 12). Therefore, ES for type II and type III SOD raises many doubts, and should be performed only in centers with substantial ERCP experience (1, 2).

Another risk factor of PEP is female sex, which has been confirmed in 20 studies (OR from univariate regression analyses from 0.09 to 2.23; OR for multi-factor analyses from 1.84 to 3.5; OR = 2.23 according to the ESGE guidelines); the difference in percent prevalence was 1.9%-20.6%. However, other studies did not find female sex to be a significant risk factor of PEP. According to the ESGE recommendations, female sex is a definite risk factor, with an OR value of 2.23 (1.75 - 2.84) and an incidence of 4.0% compared to 2.1% in men. An effect of estrogens on the sphincter of Oddi likely explains the increased risk of PEP in women. However, we should take into account the coexistence of other factors such as young age and SOD (15).

According to the ESGE guidelines, the incidence of PEP in patients with a history of pancreatitis is increased (OR 2.46;

CI: 1.93 – 3.12), with a prevalence of 3.8%–6.7% (1, 2). In my opinion, reducing the risk of PEP in these patients can be achieved by implementing adequate non-invasive diagnosis. The available imaging methods such as HD-MRCP, EUS, and functional examination of the bile ducts can differentiate between SOD, pancreas divisum, small pancreatic tumors, and abnormal pancreatic–biliary duct union (APBDU). If the diagnosis is based on such non-invasive methods, the risk associated with ERCP is obviated. Patients with a history of PEP are at an even higher risk (OR 8.7, CI:3.2 – 23.86), with a prevalence of 30% in comparison to 3.5% in patients without prior PEP. This can potentially be due to a relatively long, separate, hyperactive sphincter of the pancreatic duct that cannot be cut during ES. ERCP may provoke an excessive contraction with subsequent PEP. Therefore, if we perform ERCP in these patients, we should implement additional preventive measures, such as shortening the period of unsuccessful cannulation, protective prostheses for the Wirsung's duct, and rectal NSAID administration (1,2).

Young age is another risk factor of PEP (OR of 1.09-2.87, prevalence of 6.2% vs. 2.6%). A decreased risk of PEP associated with aging is most likely a consequence of progressive degradation of the pancreatic parenchyma, which results in a less pronounced response of this organ to irritations caused by endoscopic procedures (6). This is confirmed by the fact that 57% of all severe cases of acute pancreatitis affect young people. However, data pertaining to this issue are not consistent in the age range of 20-70 years (5). The importance of young age for PEP was confirmed in 19 publications, with OR values ranging from 0.8 to 6.68 (1, 2). However, Cotton and Testoni (3, 10) drew contrary conclusions. As regards the relationship between age and the risk of PEP, OR decreases by 0.75 for each 20 years or by 1.09 for each 5 years. In terms of percentage values, the frequency of PEP in patients younger than 30 years of age ranges from 6.2%-8%, 4.7%-36% in the 30-49 age group, 4.7%-36%; in the 50-69 age group, 4.4%-33%; and 2.9%-22% in patients over 70 years of age (3). The particular percentage values may differ due to demographic and/or procedural differences in individual studies (2, 3, 16).

Non-dilated extrahepatic bile ducts increase PEP frequency, with OR values from 0.8 to 2.6. Potentially, cannulation of a wide CBD with high pressure is easier. When the duct is non-dilated, the endoscopist has to make more attempts at deep CBD cannulation. Lack of an accepted definition of normal CBD diameter is problematic. In various publications, 5-10-mm bile duct diameters are considered narrow. In patients with bile ducts narrower than 5 mm, PEP frequency is 19.6%, and it is 2.0% in patients with bile ducts wider than 14 mm. The importance of bile duct diameter has not yet been precisely established, and further analyses are needed to establish clear criteria (3).

Another risk factor of PEP is non-elevated bilirubin; according to the ESGE guidelines, OR is 1.89 (CI: 1.22 - 2.93) and prevalence is 4.15% compared to 1.43% in patients with elevated bilirubin (1, 2). This can be potentially related to hypertension in the bile ducts. In the case of altered anatomy, one can often observe bile flow, indicating a CBD orifice. When bilirubin level is not raised, this phenomenon does not occur, and access to the bile ducts can be more difficult.

RISK FACTORS ASSOCIATED WITH THE PROCEDURE

According to the ESGE guidelines, there are only three definite risk factors associated with the procedure: cannulation attempt duration > 10 minutes (OR 1.76), more than one guidewire pancreatic passage (OR 2.77) (1.79 – 4.30), and pancreatic injection (OR 2.2) (1.60 – 3.01) (1, 2)

Difficult cannulation increases PEP risk, with OR values ranging from 1.76 to 14.9 and prevalence ranging from 1.4% to 14.9%, depending on the definition of difficult cannulation; in particular, with regard to the time from the beginning of the procedure (10 minutes to 30 minutes), number of failed bile duct catheterizations (from 3 to 20) (17), or number of unplanned catheterizations of the pancreatic duct (from 2 to 5) (1, 2). Two studies showed that PEP risk was 3.0% for fewer than 3 attempts, and for more than 20 attempts, the risk was 14.9% (3). In analyses using logistic regression, OR was 4.4 for 10-15 catheterization attempts and 9.4 for more than 15 attempts; each catheterization attempt increased the OR value by 1.39. Therefore, the ESGE guidelines suggest changing the technique after 10-15 catheterization attempts or after 10 minutes from the beginning of the procedure. Unfortunately, these suggestions have not been commonly accepted, and individual centers use different approaches. We change the access method to pre-cut incision already after two unsuccessful cannulations. However, the decision also depends on the anatomy of the papilla of Vater, risk factors, and indications for ERCP (1, 2).

The next factor influencing PEP's development is the use of the guidewire. Many studies have shown that this technique shortens both cannulation and fluoroscopy times. In addition, a meta-analysis of 12 RCTs (3,450 patients) demonstrated that the wire-guided method significantly decreased the incidence of PEP, increased primary cannulation success (RR 1.07; 95% CI 1.00-1.15), reduced the need to use precut sphincterotomy (RR 0.75; 95% CI 0.60-0.95), and did not increase other ERCP-related complications (1, 2, 18). However, Kobayashi did not confirm these findings (19). Apparently, guidewire cannulation can also prevent unintended contrast enhancement of the pancreatic duct. However, some studies show that unintended multiple pancreatic guidewire passages (> 1) increase PEP risk, with OR of 2.77 (1.79 - 4.30; 2.9% vs. 9.5%) because this procedure can damage the orifice of the Wirsung's duct (2). In addition, pancreatic duct catheterization increases the risk of PEP from 2.4% to 9.2%. Moreover, Ito showed that protective Wirsung's duct stenting post unintended insertion decreases the incidence of PEP from 23% to 2.3%. Therefore, the ESGE guidelines recommend this approach; however, in daily practice in most endoscopic centers, its implementation is relatively rare (1, 2). In conclusion, guidewire use decreases the incidence of PEP, but if the unintended insertion of a guidewire into the pancreatic duct occurs, protective stent placement should be considered. However, it is still not clear which of the three existing guidewire cannulation techniques should be used. At first only the guide-wire is inserted into the orifice of the papillae. In the second before use guide-wire, the tip of the sphincterotom is fixed in the orifice. In the third the duct is first opacified, and the guidewire is then used to access the duct (hybrid method) (1, 2). In my practice, I first fix the sphincterotomy tip in the papillae orifice; if deep guidewire cannulation is impossible, the next step is an early pre-cut, but the technique, i.e., pre-cut pull or needle knife, is dependent on

the papillae shape. If the guidewire gets into the Wirsung's duct, the Goff technique is applied. Very rarely, because of the risk of intramural injection with subsequent tissue edema and PEP, the hybrid technique is used.

Pancreatic injection also increases PEP risk, with OR ranging from 1.35 to 6.1 and PEP prevalence of 15% vs. 1.6% in patients without pancreatic injection (1, 2). Additionally, the risk is dependent on the extent of pancreatic injection, e.g. involving only the pancreatic head, the pancreatic head and body, or the pancreatic tail (16, 20). Importantly, guidewire use helps avoid accidental contrast injection into the pancreatic duct. Based on my experience, a specific situation exists when the distal portion of the Wirsung's duct runs parallel to the common bile duct (CBD). Under such circumstances, the endoscopist may mistake the Wirsung's duct for the CBD and inject contrast into the pancreatic duct. Nevertheless, it seems that guidewire use should be recommended to decrease the risk associated with unintended pancreatic injection.

Another maneuver that should be considered is pre-cut sphincterotomy, although data regarding its influence on PEP risk are ambiguous. Some studies showed an increased PEP risk, with OR of 2.3 (CI: 1.4 – 3.7; 5.3% vs. 20%). Other studies either did not find any significant relationship or showed a protective effect of early pre-cutting. Importantly, there is no agreement on the time after which the technique should be switched to a pre-cut incision, varying from a few minutes to 30 minutes in different studies (21). Conceivably, the risk associated with pre-cut incision may be due to papillary damage caused by multiple inefficient cannulations (22). Based on this, some authors emphasize the significance of an early change of the access technique to a pre-cut incision, which reduces PEP risk from 6.4% to 2.8% (1, 2). Another question regards the differences between various sphincterotomy methods and cutting techniques. There is pull sphincterotomy for the classic or Goff technique and needle sphincterotomy when cutting can be initiated from the orifice or from the top of the papillae (fistulotomy) (23). All of these parameters may affect the risk of PEP. Some centers emphasize the importance of operator experience so that pre-cut incisions should be performed by operators with more than 500 ERCPs, successful cannulation ratio of 85%-90%, and performing at least 40-100 procedures per year (22, 24). These factors may translate into different frequencies of using this technique, from 3.8% to 44%. Current evidence suggests that early pre-cut incisions and persistent cannulation attempts have similar overall cannulation rates when performed by an experienced operator, and early pre-cut incisions reduce PEP risk but not the overall complication rate. A meta-analysis showed that the pre-cut technique did not increase the primary cannulation rate. However, the technique reduced the risk of post-ERCP pancreatitis compared with the conventional technique. In conclusion, these data suggest that a pre-cut incision should be considered in the early stage of the procedure, depending on other existing risk factors and indications for the procedure (19, 23). Additionally, in my opinion, the technique should be tailored to the anatomy of a given patient, i.e., the shape of the papillae or existing duodenal diverticulum (1, 2, 22, 23, 26).

Stenting of the Wirsung's duct ensures proper outflow of the pancreatic juice despite sphincter of Oddi contraction and tissue edema around the post-ERCP opening. Consequently, this maneuver is most effective in preventing acute pancreatitis, particularly in

high-risk patients with SOD, difficult cannulation, pre-cut incision, or unintended opacification of the pancreatic duct. In these patients, inserting a prosthesis into the pancreatic duct reduces the risk of PEP from 34% to 2%, with an OR of 0.3 and NNT of 4-11 (27-29). Additionally, the combination of early sphincterotomy and early preventive prosthetics in the Wirsung's duct in high-risk patients reduces the frequency of PEP from 42% to 0% (30). Similar conclusions were drawn by other researchers, implying that early prosthetics may protect from acute pancreatitis in a manner similar to *ad hoc* sphincterotomy performed in the case of pancreatitis induced by gallstones (31, 32, 33). Importantly, due to a high failure rate of inserting pancreatic duct prostheses, even experienced endoscopists have difficulties in entering the pancreatic duct in 10% of patients, and after a failed attempt, the risk of acute pancreatitis increases dramatically (OR value of 16.1; frequency of 65%) (2, 34, 35). Therefore, this maneuver should be performed by or under the supervision of an experienced operator, although the level of failure may still reach 3.2% to 10%. The ESGE recommends that 5-Fr pancreatic stents should be used in patients with a high risk of PEP. Spontaneous passage should be evaluated within 5 to 10 days after the procedure, and retained stents should be removed endoscopically. However, a recent study emphasized the effect of early stent migration on PEP (36, 37). As regards PEP prophylaxis, there are no clear guidelines for ideal stent characteristics, optimal duration of stent placement, and the benefit of re-intervention in case of migration (26, 30, 36, 38 -40).

RISK OF PEP DUE TO COEXISTENCE OF SEVERAL RISK FACTORS

In order to choose the best technique during ERCP, it is necessary to know the risks associated with the coexistence of several risk factors in one patient. The results presented in a multi-center study by Freeman (1,963 patients) showed that accumulation of risk factors was related to an increased PEP risk. For instance, the risk of PEP was 5% in women with elevated bilirubin levels and easy CBD access; if cannulation was difficult, the risk increased to 16%; and it was 42.1% in patients with no gallstones in the bile duct, suspected SOD, and a history of acute pancreatitis (25). Tarnasky reported that the risk of PEP was three times higher in patients with a CBD diameter <5 mm in comparison to the remaining patients (relative risk, RR=3.1); in patients with an overactive sphincter, RR was 10.3; and if both risk factors were present, RR was 18.1 with a frequency of 57% (31). Mehta found that PEP risk after sphincterotomy was 27% in patients under 59 years of age and without gallstones in the common bile duct (39); if narrow CBD (distal diameter < 5 mm) and SOD co-occurred, PEP can occur in 37% with a mortality rate of 1.7% .. It was shown in further studies that acute pancreatitis may occur in 31%-46.3% of patients with co-occurrence of suspected SOD, difficult cannulation, and normal bilirubin levels (OR=16.8). The risk of PEP is nearly twice as high in young patients compared with older patients. In addition, performance of the procedure in a patient with suspected SOD increases the risk by nearly five times. Coexistence of these two factors translates into a 10-fold increase in the risk regardless of difficulties during cannulation (25). From a practical point of view, special care must be given to patients with co-existence of these factors. Unfortunately, the numbers of patients with multiple risk factors were small in studies performed to date, precluding firm conclusions.

PHARMACOLOGICAL PREVENTION OF PEP

Another method of avoiding PEP is pharmacotherapy. Rectal administration of 100 mg diclofenac or indomethacin immediately before or after ERCP decreases PEP risk from 12.5% to 4.4%, with an estimated pooled RR of 0.36 (95% CI: 0.22–0.60) and NNT to prevent one episode of PEP of 15 (41). Therefore, this type of prevention is recommended in all patients without contraindications (1, 2). However, according to a study from 2012, only 35% of endoscopists use NSAIDs (18). Also, NTG (42) and somatostatin (43) provide some benefit with regard to PEP risk. Therefore, administration of an intravenous bolus of somatostatin (250 mg) or sublingual NTG (2 mg) should be considered in patients for whom NSAIDs are contraindicated (24).

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CONCLUSION

Based on the presented data, the following factors are important for reducing PEP risk: proper qualification, guidewire use to avoid unintended pancreatic injection, early pre-cut incisions, protective Wirsung's duct stenting, and rectal administration of 100 mg of diclofenac in high-risk patients. However, these preventive methods are still suboptimal and not widely accepted. Therefore, it seems necessary to conduct further analyses to determine the importance of each risk factor and protective method so that evidence-based rules for choosing the best strategies during ERCP can be created for each patient and used even by inexperienced operators.

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