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Effectiveness of prophylactic pancreatic stents in preventing post-endoscopic retrograde cholangiopancreatography pancreatitis in high-risk patients: a 16-year comprehensive study

Gregorios Paspatis[a], Ioannis Psaroudakis[a], Magdalini Velegraki[a], Maria Fragaki[a], Despoina-Eleni Arna[a], George Tribonias[a], Evangelos Voudoukis[a], Angeliki Theodoropoulou[a], Gregorios Chlouverakis[b], Emmanouil Vardas[a]

Venizeleion General Hospital; Department of Social Medicine, School of Medicine, University of Crete; Heraklion, Greece

Abstract

Background Cannulation of the common bile duct (CBD) during endoscopic retrograde cholangiopancreatography (ERCP) can be technically challenging, especially when repeated unintended pancreatic duct cannulation occurs. We evaluated the effectiveness of prophylactic pancreatic stent (PS) placement in preventing post-ERCP pancreatitis (PEP) under such conditions. This is the first comprehensive study of its kind conducted in Greece, and one of the few in Europe.

Methods This retrospective study included patients who underwent their first ERCP between January 1, 2008, and March 1, 2024, and received a PS after inadvertent pancreatic duct cannulation on 3 or more attempts. From 2015 onward, rectal diclofenac was administered to all patients as a preventive measure for PEP.

Results In a total of 6080 ERCP procedures, 421 patients met the inclusion criteria (46.1% male; mean age 67.8±15.8 years). The most common indications were choledocholithiasis (57.7%), malignant obstruction (26.6%), and benign CBD strictures (5.7%). Successful CBD cannulation during the initial session was achieved in 86.4% of cases. Additional techniques included transpancreatic sphincterotomy (2.6%) and needle-knife precut (1.4%). A second ERCP was performed in 7.8% of cases, achieving successful CBD cannulation in all. PEP occurred in 4.9% of patients, with severe cases accounting for only 0.7%. PEP was significantly more frequent in women (P=0.001), while diclofenac did not significantly reduce its incidence (P=0.4). There were 3 deaths, 1 related to PEP (0.2%).

Conclusion PS placement effectively reduces severe PEP risk following difficult CBD cannulation and supports high success rates in repeat ERCP, while diclofenac showed no significant additional benefit.

Keywords Endoscopic retrograde cholangiopancreatography, pancreatitis, pancreatic stents, prevention

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[a]Department of Gastroenterology, Venizeleion General Hospital, Heraklion, Crete, Greece; [b]Department of Social Medicine, School of Medicine, University of Crete, Heraklion, Greece

Conflict of Interest: None

Correspondence to: Gregorios A. Paspatis, MD, Department of Gastroenterology, Venizeleion General Hospital, Knossou Ave., Heraklion 71409, Crete, Greece, e-mail: gpaspatis@gmail.com

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Introduction

During the last 50 years, therapeutic endoscopic retrograde cholangiopancreatography (ERCP) has substantially improved the outcomes of patients with biliary–pancreatic diseases. Post-ERCP pancreatitis (PEP) constitutes the riskiest complication, creating legitimate fear among endoscopists—mainly because of its unpredictable outcome. It occurs with an incidence ranging from 6.5-14%, being higher in high-risk cases [1,2]. More specifically, PEP is one of the most severe and potentially fatal complications of ERCP, particularly when compared with other risks, such as bleeding [3]. The incidence in older studies was estimated to be approximately 3.5% [4]. In the last decades preventive measures against PEP have been evaluated. These measures comprise wire-guided cannulation, prophylactic placement of pancreatic stents (PS), aggressive hydration with

lactate Ringer's solution, and treatment with nonsteroidal anti-inflammatory drugs (NSAIDs), administered rectally, and they have been encapsulated in the guidelines of the European Society for Gastrointestinal Endoscopy (ESGE) and American Society for Gastrointestinal Endoscopy (ASGE) [3,5].

Recent data, coming mainly from the United States of America (USA), have clearly shown an increase—or at least stability—in the incidence of PEP among hospitalized patients, and more alarmingly, an increase in mortality among those patients, despite the use of preventive methods, and particularly the placement of rectal NSAIDs [1,2,6,7]. Furthermore, doubt has recently arisen regarding the effectiveness of aggressive hydration with lactate Ringer's solution and treatment with rectal NSAIDs for the prevention of PEP. In contrast, there is recent accumulating evidence demonstrating that PS placement, in combination with rectal NSAIDs, definitely reduces the rate of PEP [8-11]. The data for PS prophylaxis from randomized controlled trials (RCTs) are very limited. So far, only 1 RCT [8] has randomized patients for PS prevention, possibly because of difficulties in study design. More specifically the stent vs. indomethacin (SVI) trial [8] has been a benchmark study. In addition, data from the USA have demonstrated a substantial decrease in PS utilization [7]. A notable subset of endoscopists, especially those with less experience, feel uncomfortable about placing a PS, taking into account the potential complications and the technical difficulties that might arise. Frequent guidewire passage into the pancreatic duct has definitely been associated with higher rates of PEP in high-risk patients, and it has been considered by ESGE and ASGE as a definite risk factor [3,5,9,12].

In this retrospective analysis of prospectively collected data, we primarily assessed the incidence of PEP in patients who underwent prophylactic PS placement following unintended pancreatic duct cannulation on 3 or more attempts. This 16-year historical cohort study presents real-world data from a large patient population. Given the recently published evidence from RCTs on the efficacy of prophylactic PS in preventing PEP, long-term real-world studies such as this one may offer valuable insights. A reassessment of PS placement based on real-world data could enhance clinical management. Notably, data on this topic remain limited in Europe.

Patients and methods

Study population

The study was conducted in the Gastroenterology Department of the Venizeleio General Hospital between January 1, 2008, and March 1, 2024. Eligible patients were those who underwent ERCP procedures with prophylactic PS placement and had a naive papilla. Cases were identified from a prospectively collected ERCP database. In cases where unintended pancreatic duct cannulation occurred during 3 or more attempts, a pigtail PS (5 Fr, 5 cm Boston Scientific, Marlborough, MA, USA) was immediately placed, regardless of the further success of common bile duct (CBD) cannulation. After the PS placement, cannulation of the CBD was performed through a standard endoscopic biliary sphincterotomy (EBS) technique, or alternative techniques, including needle-knife or transpancreatic sphincterotomy and endoscopic papillary balloon dilation (EPBD), after limited EBS. In cases of failure to cannulate the CBD the procedure was rescheduled within a reasonable time period, taking advantage of the presence of the PS in the pancreatic duct. Since 2015, all patients have received NSAID suppositories, apart from those with a contraindication.

Cases with bleeding tendency (receiving anticoagulant therapy, platelet count <100,000/mm^3, or prothrombin time >30% above control) were excluded. Patients receiving anticoagulant or antiplatelet therapy for noncritical problems, such as cardiovascular and cerebral disorders, were instructed to discontinue the use of that medication for 3-7 days, depending on the type, before the endoscopic procedure.

All ERCP procedures were performed using side-viewing endoscopes (TJF-160 or 190; Olympus Optical, Tokyo, Japan), under deep propofol sedation provided by an anesthetist, and were carried out by 2 experienced pancreaticobiliary endoscopists (GP and EV; each one with an experience of >1000 ERCPs at the initiation of the study). A generator with an automatically controlled cutout system (Endocut mode, ICC200, VIO 200D, Erbe Elektromedizin GmbH, Tubingen, Germany) was used. All patients were administered Ringer's lactate infusion during and for 4 h after the ERCP procedure (3 mL/kg/h during ERCP, 20 mL/kg bolus after ERCP, 3 mL/kg/h for 4 h after ERCP).

Demographic data, patient and procedural related risk factors for PEP, and technical features of the ERCP procedure were recorded on a predetermined electronic case record form.

All complications within 30 days post ERCP were recorded in the electronic case record. In addition, the patients were thoroughly instructed to contact their attending gastroenterologist if they faced any persistent or deteriorating symptoms.

Complications were evaluated and graded according to the standards established by Cotton *et al* [13], as follows: (a) bleeding: clinical evidence of bleeding, such as melena or hematemesis, with an associated decrease of at least 2 g/dL in hemoglobin concentration or the need for a blood transfusion; (b) PEP: persistent epigastric pain for >24 h with a more than 3-fold elevation in serum amylase levels after the procedure; (c) cholangitis: fever >38°C >24 h and liver biochemistry suggestive of biliary obstruction.

ESGE recommendations were followed for the management of complications [3,14]. All patients were scheduled for removal of the PS within a reasonable time period (<15 days) if the PS had not been dislodged, proven radiologically.

Secondarily, we looked at cannulation rates, as well as several other parameters, including those potentially implicated in the development of PEP.

This study was approved by the hospital's scientific committee. All patients gave oral and written consent. Written informed consent was obtained from all patients before the initiation of the study. In the general ERCP consent form, the patients were asked to grant permission for their data to be published for scientific/research purposes.

Statistical analysis

Categorical data are expressed as percentages, whereas continuous data are reported as means with standard deviation. Categorical variables were compared using the corrected χ^2 or 2-sided Fisher's exact test. Continuous data were compared using unpaired Student's *t* or Mann-Whitney tests, as appropriate. All analyses were 2-sided and P-values <0.05 were considered statistically significant. Variables that were significantly associated with the presence of PEP at the univariate level were entered into a multivariate stepwise logistic regression model to identify those that contain independent prognostic information. The threshold values for entry into and removal from the model were 5% and 10%, respectively.

Results

Of the 6080 patients who underwent ERCP, 421 were included in the study (male: 46.1%). The mean age was 67.8±15.8 years. The main indications were choledocholithiasis (57.7%), biliary-pancreatic malignancies (26.6%), benign stenosis of the CBD (24, 5.7%) and bile leak (13, 3.1%). In 364 patients (86.4%), bile duct cannulation was achieved in the first session; of these patients 11 (2.6%) underwent transpancreatic sphincterotomy and 6 (1.4%) needle-knife. In 33 patients (7.8%) a second ERCP was attempted, with 100% success in catheterization of the CBD. In other words, in 397 of the 421 patients having PS placement, the CBD was eventually cannulated. EPBD was performed in 39 cases (9.3%) (Table 1, Fig. 1).

A total of 21 patients experienced PEP (4.9%), which was severe in 3 (0.7%) (Fig. 1). The incidence was higher in women compared to men (18/227 vs. 3/194, P=0.001), while rectal NSAIDs administration did not significantly affect the incidence of PEP (12/202 vs. 9/219, P=0.4). Apart from sex, the other patient and procedure-related likely risk factors evaluated were not significantly associated with the development of PEP (Tables 2,3).

A multivariate stepwise logistic regression analysis revealed that the sex of the patient was significantly associated with the presence of PEP. More specifically, female sex increased the chance of PEP 5.7 times compared to males, even after the placement of a PS (Table 4).

Three ERCP-related periampullary perforations Stapfer's type II [15] were observed, and all were treated conservatively without any other intervention. In 1 of the 3 patients a fully covered stent was placed.

Overall, 3 deaths were recorded, of which 1 was associated with PEP (0.2%). The other 2 were due to carcinomatosis and sepsis existing prior to the ERCP procedure.

In 356 (84.6%) cases the PS was endoscopically removed in a repeated endoscopy. The PS were removed 3-7 days after the procedure if they had not spontaneously dislodged.

In 1 case the PS was accidentally dislocated into the pancreatic duct during the procedure; it was removed endoscopically in a second laborious ERCP attempt, without a PEP episode. In 7 cases the PS was accidentally removed during

Table 1 Patient and procedural characteristics

Characteristics	Value
Patients	No=421
Age (y) mean±SD	67.8±15.8
Male (%)	194 (46.1)
Indications (%)	
CBD stones	243 (57.7)
Malignancy	112 (26.6)
Benign CBD strictures	24 (5.7)
Bile leak	13 (3.1)
SOD	0 (0)
Other	29 (6.9)
Periampullary diverticulum (%)	63 (15)
Naive papilla	421
Successful cannulation (%)	397 (93.6)
1st ERCP (%)	364 (86.5)
Repeated ERCP (%)	33 (7.8)
Failed CBD cannulation (%)	24 (5.7)
Accidental removal of PS	7
Sphincterotomy (%)	397 (93.6)
Endoscopic papillary balloon dilation (%)	39 (9.3)
Balloon diameter 10-12 mm	12
Balloon diameter 12-15 mm	20
Balloon diameter 15-18 mm	5
Combination 12-15 plus 15-18 mm	2
Needle knife (%)	6 (1.4)
Trans-pancreatic sphincterotomy (%)	11 (2.6)
CBD cannulation time (min)	19.7±8.4
History of pancreatitis (%)	26 (6.2)
Rectal NSAIDs (%)	202 (48)

SD, standard deviation; CBD, common bile duct; SOD, sphincter of Oddi dysfunction; ERCP, endoscopic retrograde cholangiopancreatography; PS, pancreatic stent; NSAIDs, nonsteroidal anti-inflammatory drugs

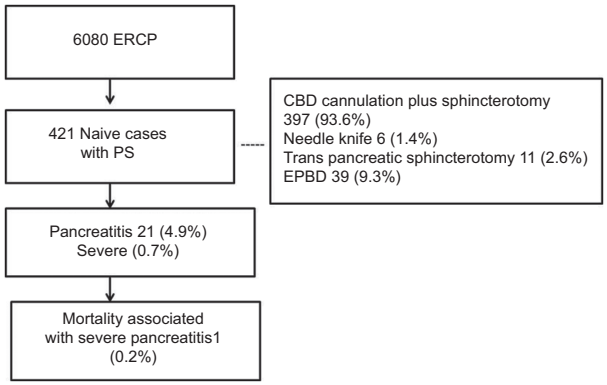

Figure 1 Flow diagram illustrating the study population examined and treated

ERCP, endoscopic retrograde cholangiopancreatography; PS, pancreatic stents; CBD, common bile duct; EPBD, endoscopic papillary balloon dilation

Table 2 Summary of post ERCP complications

Complications	Value
Patients	No=421
No complications	363 (85.5)
Pancreatitis (%)	21 (4.9)
Severe	3 (0.7)
Moderate	2 (0.5)
Mild	16 (3.8)
Cholangitis (%)	23 (5.5)
Severe	1 (0.2)
Moderate	2 (0.5)
Mild	20 (4.7)
Bleeding (%)	11 (2.6)
Severe	1 (0.2)
Moderate	5 (1.19)
Mild	5 (1.19)
Perforation (%)	3 (0.7) (All treated conservatively)
Mortality associated with PEP	1 (0.2%)

ERCP, endoscopic retrograde cholangiopancreatography; PEP, post-ERCP pancreatitis

Table 3 Univariate analysis of patient and procedural factors correlating with PEP

Factors	PEP group N=21	No PEP group N=400	P-value
Age (y)	62±21	68±16	0.1
Sex (F/M)	18/3	209/191	0.003
BMI ≥30 kg/m^2	3	44	0.7
Rectal NSAIDs	12	190	0.4
History of pancreatitis	2	24	0.5
Pancreatic injection	2	26	0.6
Needle knife	1	5	0.3
Trans-pancreatic sphincterotomy	0	11	>0.99
EPBD	2	37	0.9
Cannulation time	17.8±6	18.8±8.5	0.3

PEP, post-ERCP pancreatitis; BMI, body mass index; NSAIDs, nonsteroidal anti-inflammatory drugs; EPBD, endoscopic papillary balloon dilation

Table 4 Results of the multivariate analysis of risk factors correlating with post-endoscopic retrograde cholangiopancreatography pancreatitis

Risk factor	P-value	Odds ratio	95% confidence interval
Sex	0.006	5.67	1.6-19.6
Age	0.085	0.98	0.95-1

the ERCP procedure; however, no episode of PEP was seen. The post-ERCP complications are summarized in Table 2.

Two patients of the 24 in whom CBD cannulation was unsuccessful were treated surgically, and 15 were treated with percutaneous transhepatic biliary drainage. The remaining 7 patients were lost from the long-term follow-up. In all these 24 patients the PS was endoscopically removed in a repeated endoscopy, if it had not spontaneously dislodged.

Discussion

The data of the present study clearly show a low incidence of PEP (4.9%) in patients who are at increased risk for PEP due to unintentional pancreatic duct cannulation. Notably, the rate of severe PEP was even smaller (0.3%). A recent meta-analysis [1] evaluating 145 RCTs detected an overall incidence of PEP up to 10.2%, and 14.1% among patients at high risk for PEP. In the same meta-analysis [1] the cumulative incidence of severe pancreatitis was 0.8% and the mortality rate 0.2%, among patients at high risk for PEP. A very recent comprehensive systematic review including more than 2 million cases depicted an overall rate 6.5% of PEP in naive cases, with a mortality rate of 0.2% [2]. Interestingly, the mortality rate in our study (0.2%) aligns with the findings of both meta-analyses, although they reported a higher PEP rate compared to the present study. This suggests that PS placement may help to prevent the onset of pancreatitis, though its impact on the progression of severe pancreatitis, once established, appears to be limited.

Real world-based data, derived from 26,820 ERCPs performed between 2009 and 2018 in the USA, revealed a PEP rate of 8.6% [7]; unfortunately, PEP rates did not decrease progressively as time went on. These findings were further reinforced in a recent meta-analysis that evaluated the time period 2000-2023 [2]. Over this period, despite the increasing adoption of rectal NSAIDs, the placement of prophylactic PD stents declined rapidly, from a rate of over 40% to less than 4% [7]. Four years later a benchmark RCT, performed in 20 North American referral centers and including 1950 patients, depicted the beneficial effect of PD placement plus indomethacin compared to indomethacin alone among those patients found to be at high risk of PEP; this ultimately encouraged PS use [8].

Additional data from China have raised doubt about the efficacy of rectal NSAID administration in patients at high-risk for PEP who received prophylactic PS, since its use did not reduce the incidence or severity of PEP [10]. Our data concerning PS placement are in line with recently published retrospective data from China [10], and of course with the milestone data coming from the SVI randomized trial [8]. Similarly to the Chinese retrospective data [10], the PEP rate in the present study was <5%, and the beneficial effect of NSAID administration was not clearly proved. Moreover, a multicenter RCT from the Dutch pancreatitis study group revealed that aggressive periprocedural hydration did not reduce the incidence of PEP in patients who were at moderate to high risk of developing this complication and routinely received prophylactic rectal NSAIDs [16].

Given the accumulating evidence regarding the weak preventive effect of NSAID suppositories [8,10] and aggressive lactate hydration in PEP [16], in the absence of PS placement

in high-risk cases, the placement of these prophylactic stents becomes important. Conversely, there is certain evidence suggesting the use of PS in cases at high risk for PEP. We should emphasize that PEP is the most common reason for lawsuits after an ERCP procedure [17].

Acknowledging the heterogeneity in defining "difficult" CBD cannulation [16,18], in the present study we defined the unintentional passage of the guidewire 3 times into the pancreatic duct as the cutoff point for PS placement. A *post hoc* analysis of RCT data and a secondary analysis of the SVI trial have shown that repeated guidewire passage into the pancreatic duct has been significantly associated with a higher risk of PEP [9,12].

Prospective data have shown that failed PS placement is associated with an increased risk of PEP, which strengthens the importance of proper training of endoscopists in placing PS [19]. Pancreatic instrumentation that is not followed by proper duct drainage via PS placement might increase the risk for PEP, particularly in patients at high risk for PEP. Fatal complications have been reported after a dislocation of PS into the pancreatic duct [11]. The rate of proximal PS migration in the present cohort (0.2%) was similar to that reported in the literature [20]. The difficulty of PS placement might be the reason why this approach is obviated by medical and nursing personnel, even in cases when it could be indicated. Therefore, training of ERCP personnel to place PS effortlessly when appropriate is essential. The Hippocrates exhortation to "do no harm" should be strictly abided by endoscopists [21].

PS of 5-Fr diameter were routinely placed in all patients throughout the study period. This size is considered potentially more effective in preventing PEP compared to 3-Fr stents, probably because the larger diameter achieves superior drainage of the pancreatic duct—an essential factor in reducing PEP risk [3,5,22,23]. The preferred stent length was typically 5 cm, as this provides adequate ductal coverage while still maintaining a high rate of spontaneous dislodgment. In contrast, 7-cm stents, although useful in anatomically long or tortuous ducts, were avoided in most cases given the higher risk of ductal injury. All the PS were placed immediately before the cannulation of the CBD, since the double guidewire technique has not been routinely adopted in our unit. Recent evidence enforces the early placement of PS in order to reduce the PEP rate [23]. Despite the new data coming from RCTs [8], there is room for more information to clarify the best scenario for the indication and the timing of PD placement, and whether they should be placed intentionally, or after inadvertent access to the PD.

It is known that if a PS remains in place for a long time, this might trigger the formation of a stricture in the pancreatic duct [22]; thus, they should be removed 2-4 weeks after their placement, if necessary. In the present cohort, most of the PS were endoscopically removed 1 week after their placement. The primary reason for the prompt removal of the PS was the nature of our unit as a referral center for the island of Crete. Managing stent removal outside our facility would have posed significant challenges. Therefore, the decision was made to perform endoscopic stent removal at the safest and most convenient time for the patients.

Our data did not confirm, at a statistically significant level, the well-known risk factors for PEP, such as young age or needle-knife technique [24]. This observation is in line with recently published epidemiological data [6]. Future stronger data might indicate a changing profile for PEP nowadays, taking into account several new factors, such as the exclusive invasive and complex nature of modern ERCP procedures, the preventive methods used, and the level of expertise among the operating endoscopists. As long as the issue of PEP persists, efforts to identify individual susceptibility to PEP, including genetic factors, will be important. However, until today, these trials have not been satisfactory [25,26].

Although ESGE guidelines [3] suggest the Atlanta classification [27] for the grading of the severity of PEP, we used the ASGE lexicon [13], since the database was designed on this grading system.

This study had several limitations. First, it was a historical cohort based on prospectively collected data that were retrospectively analyzed, and it was conducted at a single high-volume referral center for ERCP. Therefore, the findings may not be generalizable to other settings or broader patient populations. Importantly, the retrospective design evaluated the incidence of PEP in the context of an already implemented prophylactic strategy, thereby reflecting a best-case scenario. Second, the study lacked randomization, and the absence of a control group was a notable limitation. Without a comparator arm, it is not possible to definitively conclude that pancreatic duct stenting alone is responsible for the observed reduction in PEP incidence. Nonetheless, the real-world nature of the data supports the practical benefit of PS placement in routine clinical practice.

Of course, we acknowledge that PS placement may also prolong the ERCP procedure: it increases the use of devices, and often necessitates a second endoscopic session for PS removal, thereby imposing a significant financial burden. In addition, this study further contributes by providing real-world evidence from a large public hospital specializing in advanced gastrointestinal endoscopic procedures. The findings suggest that early PS placement effectively prevents the development of PEP in high-risk patients. Interestingly, PS placement in patients with a failed CBD cannulation at the first ERCP, definitely facilitates the CBD cannulation in a repeated ERCP. This finding is in accordance with the established knowledge that PS placement facilitates bile duct access, aiding the orientation of the cannulation, with low rates of precut sphincterotomy [28]. This may partly explain the low number of precut cases observed in our study. Additionally, the limited experience with precut techniques in our unit during the early years of the study probably contributed to their infrequent use.

In conclusion, the use of PS was associated with a low incidence of PEP, while rectal NSAID administration did not significantly affect PEP incidence. Additionally, PS placement in patients who had a failed CBD cannulation facilitated successful CBD cannulation in a second ERCP in all cases.

Summary Box

What is already known:

- Recent data, coming mainly from the United States, have clearly shown an increase, or at least stability, in the incidence of post-endoscopic retrograde cholangiopancreatography pancreatitis (PEP) among hospitalized patients, and more alarmingly an increase in the mortality among those patients, despite the use of preventive methods, and in particular rectal nonsteroidal anti-inflammatory drugs (NSAIDs)
- There is recent accumulating evidence demonstrating that pancreatic stent (PS) placement in combination with rectal NSAIDs definitely reduces the rate of PEP
- A notable subset of endoscopists, especially those with less experience, feel uncomfortable about placing a PS, taking into account the potential complications and the technical difficulties that might arise

What the new findings are:

- The use of PS was associated with a low incidence of PEP, while rectal NSAID administration did not significantly affect PEP incidence
- PS placement in patients who had a failed common bile duct (CBD) cannulation facilitated successful CBD cannulation in a second ERCP in all cases

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