**Pancreatitis**

ERCP, or endoscopic retrograde cholangio-pancreatogram, is a procedure performed by threading an endoscope through the mouth to the opening in the duodenum where bile and pancreatic digestive juices are released into the intestine. ERCP is helpful for treating blockages of flow of bile (gallstones, cancer), or diagnosing cancers of the pancreas, but has a high rate of complications (15-25%). The occurrence of post-ERCP pancreatitis is a common and feared complication, as pancreatitis can result in multisystem organ failure and death, and can occur in ~ 16% of ERCP procedures. The inflammatory cytokine storm that can result from this procedural complication can be quite severe.

Several small randomized trials suggested that anti-inflammatory NSAID therapies at the time of ERCP could reduce the rate of this complication. Elmunzer, Higgins, and colleagues found in a meta-analysis that indomethacin could reduce post-ERCP pancreatitis. The investigators confirmed this in a multicenter RCT comparing placebo to indomethacin. Now, you want to re-use this data source to create a clinical risk prediction model for post-ERCP pancreatitis, taking into account treatment (indomethacin or placebo) and other patient characteristics.

The dataset is based on the results of a randomized, placebo-controlled, prospective 2-arm trial of rectal indomethacin (100 mg) vs. placebo prevent post-ERCP pancreatitis in 602 participants, as reported by Elmunzer, Higgins, et al. in 2012 in the New England Journal of Medicine. It is an altered and augmented version of the real patient data. The in/exclusion criteria and measurement procedures can be found in the original article.

The inclusion criteria selected patients with an elevated baseline risk of post-ERCP pancreatitis. Patients were eligible if they met one or more of the following major criteria: clinical suspicion of sphincter of Oddi dysfunction, a history of post-ERCP pancreatitis, pancreatic sphincterotomy, precut sphincterotomy (a procedure performed to facilitate biliary access when standard cannulation techniques are unsuccessful), more than eight cannulation attempts (as determined by the endoscopist), pneumatic dilatation of an intact biliary sphincter, or ampullectomy. Patients were also eligible for inclusion if they met two or more of the following minor criteria: an age of less than 50 years and female sex, a history of recurrent pancreatitis (≥2 episodes), three or more injections of contrast agent into the pancreatic duct with at least one injection to the tail of the pancreas, excessive injection of contrast agent into the pancreatic duct resulting in opacification of pancreatic acini, or the acquisition of a cytologic specimen from the pancreatic duct with the use of a brush.

The exclusion criteria were intended to exclude patients in whom ERCP was unsuitable and those who had active pancreatitis, had a contraindication to the use of NSAIDs (e.g., creatinine level, >1.4 mg per deciliter [124 μmol per liter] or active peptic ulcer disease), were already taking NSAIDs (other than cardioprotective aspirin), or had an anticipated low risk of post-ERCP pancreatitis (e.g., those with chronic calcific pancreatitis or a pancreatic-head mass or those undergoing routine biliary-stent exchange).

Eligible patients who provided written informed consent underwent randomization at the conclusion of the ERCP procedure, because patients without risk factors could be included in the study on the basis of procedure-related factors alone.

The primary outcome of the study was the development of post-ERCP pancreatitis, which was defined according to consensus. Briefly, post-ERCP pancreatitis was diagnosed if there was a new onset of pain in the upper abdomen, an elevation in pancreatic enzymes of at least three times the upper limit of the normal range 24 hours after the procedure, and hospitalization for at least 2 nights. Patients were observed in the recovery area for at least 90 minutes after the procedure. Patients in whom abdominal pain developed during this observation period were admitted to the hospital (or for current inpatients, kept in the hospital). Decisions regarding evaluation of complications after the procedure and in-hospital care were left to the discretion of the endoscopist and clinical-service staff members, who were unaware of study-group assignments. Serum amylase and lipase were measured in hospitalized patients at least once 24 hours after the procedure and subsequently at clinical discretion.

Patients who were discharged after an uneventful ERCP were contacted by telephone within 5 days to capture delayed occurrence of the primary end point. Patients were again contacted at 30 days to assess for delayed adverse events and to determine the severity of post-ERCP pancreatitis, which was defined in part by the length of hospitalization for pancreatitis. The original study protocol stated that the primary end point would be assessed within 48 hours after the procedure. Although post-ERCP pancreatitis generally occurs within this period, we contacted patients up to 5 days after ERCP to ensure capture of delayed cases of the primary end point.

Patient demographics, risk factors, ERCP procedural elements, and follow-up data were recorded on standardized data-collection forms by an investigator or coordinator who was unaware of study-group assignments. All data were subsequently entered into a Web-based database, Velos eResearch, and managed by an independent data-management service. Pre-treatment risk of post-ERCP pancreatitis was determined by assigning one point for each major inclusion criterion and 0.5 points for each minor inclusion criterion.

Based on Elmunzer BJ et al.

Dataset content:

* id subject id
* site study site (center), factor, 1 = University of Michigan, 2= Indiana University, 3 = University of Kentucky, 4 = Case Western
* age age in years, numeric, range: 19-90
* risk pre-treatment risk score, numeric, range: 1-5.5
* gender male or female, factor, levels: 1\_female, 2\_male
* sod sphincter of oddi dysfunction was present, a risk factor favoring post-ERCP pancreatitis, factor, levels: 0\_no, 1\_yes
* pep previous post-ERCP pancreatitis (PEP), a risk factor for future PEP, factor, levels: 0\_no, 1\_yes
* recpanc Recurrent Pancreatitis, a risk factor for future PEP, factor, levels: 0\_no, 1\_yes
* psphinc a Pancreatic Sphincterotomy was performed, a risk factor for PEP, factor, levels: 0\_no, 1\_yes
* precut a sphincter pre-cut was needed to enter the papilla, a risk factor for PEP, factor, levels: 0\_no, 1\_yes
* difcan Cannulation of the papilla was difficult, a risk factor for PEP, factor, levels: 0\_no, 1\_yes
* pneudil Pneumatic dilation of the papilla was performed, a risk factor for PEP, factor, levels: 0\_no, 1\_yes
* amp An Ampullectomy was performed for dysplasia or cancer, which could be a risk factor for PEP, factor, levels: 0\_no, 1\_yes
* paninj Contrast was injected into the pancreas during the procedure, a risk factor for PEP, factor, levels: 0\_no, 1\_yes
* acinar The pancreas appeared to have acinarization on imaging, which could be a risk factor for PEP, factor, levels: 0\_no, 1\_yes
* brush Brushings were taken from the pancreatic duct, a possible risk factor favoring post-ERCP pancreatitis. factor, levels: 0\_no, 1\_yes
* asa81 Aspirin was used at a dose of 81 mg per day, which may increase the risk of bleeding. factor, levels: 0\_no, 1\_yes
* asa325 Aspirin was used at a dose of 325 mg per day, which may increase the risk of bleeding. factor, levels: 0\_no, 1\_yes
* asa Aspirin was used (at a dose of 325 mg per day(at any dose), which may increase the risk of bleeding. factor, levels: 0\_no, 1\_yes
* prophystent A pancreatic duct stent was placed at the end of the procedure per the judgement of the endoscopist (more often in high-risk cases), a potential protective effect against PEP, factor, levels: 0\_no, 1\_yes
* therastent A pancreatic duct stent was placed in order to treat a clinically significant narrowing of the pancreatic duct, a potential protective effect against PEP, factor, levels: 0\_no, 1\_yes
* pdstent A pancreatic duct stent was placed at the end of the procedure for any reason, a potential protective effect against PEP, factor, levels: 0\_no, 1\_yes
* sodsom Sphincter of oddi manometry was performed during the procedure for SOD, a risk factor for PEP, factor, levels: 0\_no, 1\_yes
* bsphinc A biliary sphincterotomy was performed, which could be a risk factor for PEP, factor,

levels: 0\_no, 1\_yes

* bstent A biliary stent was placed to relieve significant biliary obstruction, factor, levels: 0\_no,

1\_yes

* chole Choledocholithiasis (gallstones blocking the biliary duct) was present, factor, levels: 0\_no, 1\_yes
* pbmal Malignancy of the biliary duct or pancreas was found, factor, levels: 0\_no, 1\_yes
* train A trainee participated in the ERCP, which could be a risk factor for PEP, factor, levels: 0\_no, 1\_yes
* outcome outcome of post-ercp pancreatitis, 0=no, 1=yes
* status outpatient status, factor, levels: 0\_inpatient, 1\_outpatient
* type Sphincter of Oddi dysfunction type/level - higher numbers are more severe with greater association with PEP, factor, levels: 0\_no SOC, 1\_type 1, 2\_type 2, 3\_type 3
* rx treatment arm, factor, levels: 0\_placebo, 1\_indomethacin
* bleed A gastrointestinal bleed occurred (which could be a complication of indomethacin therapy), factor, levels: 1. no, 2. Yes

**References**

Higgins P (2021). medicaldata: Data Package for Medical Datasets. https://higgi13425.github.io/medicaldata/.

Elmunzer BJ, Scheiman JM, Lehman GA, et al (2012). A Randomized Trial of Rectal Indomethacin to Prevent Post-ERCP Pancreatitis. N Engl J Med;366(15):1414-22. doi: 10.1056/NEJMoa1111103