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Preventive Effect of Endoscopic Sphincterotomy on Post-Endoscopic Retrograde Cholangiopancreatography Pancreatitis: A Systematic Review and Meta-Analysis of Randomized Controlled Trials

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ADMINISTRATIVE INFORMATION**Support** - N/A.**Review Stage at time of this submission** - Completed but not published.**Conflicts of interest** - None declared.**INPLASY registration number:** INPLASY202550033**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 13 May 2025 and was last updated on 13 May 2025.**INTRODUCTION**

Review question / Objective To investigate the preventive effect of endoscopic sphincterotomy (EST) on post-endoscopic retrograde cholangiopancreatography (ERCP) pancreatitis (PEP).

Rationale Post-ERCP pancreatitis (PEP) remains the most common and significant adverse event associated with ERCP. Endoscopic sphincterotomy (EST) has been proposed as a potential strategy to reduce PEP risk by facilitating biliary drainage and minimizing pancreatic duct manipulation. However, the evidence regarding its preventive effect remains inconsistent, with some studies reporting protective benefits while others suggest a potential increased risk. Therefore, we performed a systematic review and meta-analysis of randomized controlled trials (RCTs) to evaluate the preventive effect of EST on PEP.

Condition being studied The current meta-analysis was based on the following PICO framework:

Population (P): Patients undergoing ERCP
Intervention (I): Endoscopic sphincterotomy (EST)
Comparison (C): No EST or sham procedure
Outcome (O): Incidence of post-ERCP pancreatitis (PEP).

METHODS

Search strategy Two independent authors (P.-F.H. and J.-C.L.) systematically searched the electronic databases PubMed, Embase, Cochrane CENTRAL, Web of Science, and ClinicalTrials.gov from inception to 31 March 2025. The following keywords were used: (“Endoscopic Sphincterotomy” OR “EST”) AND (“Post-ERCP Pancreatitis” OR “PEP”) AND (“ERCP” OR “endoscopic retrograde cholangiopancreatography”).

Participant or population Patients undergoing ERCP for various indications, including difficult biliary cannulation, choledocholithiasis (especially large common bile duct stones ≥ 10 mm), malignant or benign biliary strictures (both distal and proximal), sphincter of Oddi dysfunction.

Intervention Endoscopic sphincterotomy (EST), performed prior to or during ERCP.

Comparator No EST or sham procedure.

Study designs to be included Randomized controlled trials (RCTs).

Eligibility criteria Inclusion criteria included: (1) RCTs involving human participants, (2) Trials comparing Endoscopic sphincterotomy with no endoscopic sphincterotomy in post-ERCP pancreatitis, and (3) Studies providing data on post-ERCP pancreatitis. Exclusion criteria were: (1) Non-RCT studies, (2) Studies lacking data on post-ERCP pancreatitis rate, and (3) Studies with participant overlap from previously published trials.

Information sources The literature search was performed in PubMed, Embase, Cochrane CENTRAL, Web of Science, and ClinicalTrials.gov, using a combination of medical subject headings (MeSH) and free-text terms relevant to ERCP, EST, and PEP.

Main outcome(s) The primary outcome was the incidence of post-ERCP pancreatitis (PEP) following EST or control intervention. Diagnosis and grading of PEP followed the Cotton criteria or similar validated definitions in each trial.

Data management Two authors (P.-F.H. and J.-C.L.) independently extracted study data, including sample size, patient demographics, indications for ERCP, type of comparator, technique of EST, and outcome measures. Discrepancies or uncertainties in the data were resolved through discussion and consensus between the two authors.

Quality assessment / Risk of bias analysis Risk of bias was assessed using the Cochrane Risk of Bias Tool (RoB 2), which evaluates randomization, deviations from intended interventions, missing outcome data, outcome measurement, selection of reported result, and overall bias. The per-protocol approach was adopted given the procedural nature of the intervention.

Strategy of data synthesis A random-effects model was used to account for potential clinical and methodological heterogeneity. Risk ratios

(RRs) and their 95% confidence intervals (CIs) were calculated for dichotomous outcomes. Heterogeneity was assessed using the I^2 statistic and Cochran's Q test. An I^2 of 25%, 50%, and 75% was considered low, moderate, and high heterogeneity, respectively.

Subgroup analysis Prespecified subgroup analyses were performed based on stent placement (yes vs. no), indication for ERCP (e.g., distal malignant biliary obstruction), and type of stent used (plastic vs. metal). These analyses aimed to assess whether the preventive effect of EST varied across clinical contexts.

Sensitivity analysis To ensure the robustness of the findings, sensitivity analyses were conducted by sequentially omitting each study to observe the impact on the pooled estimates.

Country(ies) involved Taiwan.

Keywords endoscopic sphincterotomy, post-ERCP pancreatitis, PEP, ERCP, randomized controlled trial, meta-analysis, systematic review.

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