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Comparative efficacy of various advanced techniques for difficult biliary cannulation between different ages in ERCP: network meta-analysis and validation with real world data in Taiwan

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ADMINISTRATIVE INFORMATION

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Review Stage at time of this submission - Preliminary searches.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 4 January 2026 and was last updated on 4 January 2026.

INTRODUCTION

Review question / Objective We performed a network meta-analysis combining direct and indirect evidence comparing the relative efficacy of all advanced adjunctive techniques for patients with difficult biliary cannulation in ERCP practice.
The primary focus of our study was the success rate of biliary cannulation and the incidence of adverse events such as PEP, bleeding, perforation, etc. Secondary aims included meta-regression with subgroup analysis according to different ages and validation with real world data from PTVGH with retrospective fashion.

Condition being studied Endoscopic retrograde cholangiopancreatography (ERCP) is still the cornerstone therapeutic procedure for managing the majority of pancreaticobiliary disorders. Achieving successful ERCP depends on effective deep cannulation of the common bile duct and, less frequently, the main pancreatic duct. Nevertheless, selective cannulation of the major papilla remains one of the most technically demanding steps of the procedure. Overall cannulation failure has been reported in up to 18% of ERCP procedures, although the rate decreases to below 5% in high-volume centers. The criteria used to define “difficult biliary cannulation” vary considerably among studies, and no universally accepted definition currently exists. In a prospective study involving 907 ERCP procedures performed by experienced endoscopists, the most recent European Society of Gastrointestinal Endoscopy guideline defined difficult biliary cannulation as failure after five minutes, five attempts, or more than one unintended pancreatic duct cannulation. In contrast, an international consensus group proposed a purely time-based definition, using ten minutes of cannulation attempts as the threshold. Prolonged manipulation of the papilla and repeated attempts at selective biliary cannulation—particularly when inadvertent pancreatic duct cannulation with contrast injection occurs—are well recognized risk factors for post-ERCP pancreatitis. Consequently, several alternative cannulation strategies have been

developed to improve success rates in cases of difficult biliary cannulation, including pancreatic duct stent–assisted techniques and various cutting-based approaches such as conventional precut sphincterotomy, transpancreatic sphincterotomy, and fistulotomy.

METHODS

Participant or population Studies included in this network meta-analysis were RCTs published in any language that met the following inclusion criteria: (1) patients: adults (age >20 years) undergoing ERCP for any biliary indication and presenting a difficult biliary cannulation

Intervention Application of needle-knife techniques (conventional precut sphincterotomy or fistulotomy), pancreatic guidewire- or double-guidewire–assisted techniques, pancreatic stent-assisted technique, or transpancreatic sphincterotomy

Comparator Another of the above reported methods or persistence with standard cannulation techniques.

Study designs to be included Network meta-analysis, meta-regression, cluster analysis.

Eligibility criteria NMA search method:
Noncomparative observational and retrospective studies, trials comparing different approaches within the same technique, trials assessing cannulation techniques in index ERCPs and studies not fully published were excluded
Inclusion criteria of validation cohort
Between January 2023 and July 2025, all consecutive outpatients and inpatients who underwent ERCP at the department of gastroenterology of PingTung Veterans General Hospital, Taiwan, were recruited in this study. Those with positive HIV serology results, history of receiving pancreatico-biliary surgery, gastrectomy, gastroduodenal bypass surgery, ERCP with sphincterotomy or balloon dilation, or age under 20 were excluded.

Information sources Electronic databases: online PubMed, Cochrane, Embase, and OVID.

Main outcome(s) Rate of successful biliary cannulation and incidence of complications such as PEP, bleeding, perforation, etc.

Quality assessment / Risk of bias analysis The methodological quality of the included randomized controlled trials will be assessed using the Cochrane Risk of Bias 2.0 tool, evaluating bias arising from the randomization process, deviations from intended interventions, missing outcome data, measurement of outcomes, and selection of the reported result. Each outcome will be rated as low risk, some concerns, or high risk of bias.

Strategy of data synthesis A network meta-analysis will be conducted within a frequentist/Bayesian framework to compare all available interventions simultaneously. The network plot will be generated to illustrate the direct and indirect comparisons. Effect estimates will be reported as odds ratios (ORs) or mean differences (MDs) with 95% confidence/credible intervals. Ranking probabilities will be calculated using the surface under the cumulative ranking curve (SUCRA). Statistical heterogeneity and inconsistency will be assessed using I^2 and node-splitting methods. Sensitivity analyses will be performed to explore the robustness of the results.

Subgroup analysis Subgroup analyses will be performed according to key covariates, including patient characteristics (age, gender, baseline disease severity, etc.), or intervention features (endoscopic procedure, procedure duration, etc.). Network meta-regression will be used where appropriate to assess the impact of these factors on treatment effect estimates.

Sensitivity analysis It will be performed to assess the robustness of the network meta-analysis results. Methods included such as excluding studies with high risk of bias, studies with small sample sizes, or studies with other methodological limitations. The impact of these exclusions on effect estimates and treatment rankings will be evaluated.

Country(ies) involved Taiwan, ROC.

Keywords Complication; Difficult biliary cannulation; ERCP.

Contributions of each author
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