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Comparison of different trans-gastric stents for drainage of necrotic collection in patients with necrotizing pancreatitis: a systematic review and network meta-analysis of randomized control trials

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ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - Completed but not published.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY2023120086

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 21 December 2023 and was last updated on 21 December 2023.

INTRODUCTION

Review question / Objective In order to figure out which intervention (DPPS, FCSMES or LAMS) is better for the patients with necrotizing pancreatitis, we perform a network meta-analysis.
The PICO of this s (1) Participants: Adults with necrotizing pancreatitis with complication of pancreatic fluid collection. (2) Interventions and comparisons: endoscopic approach trans-gastric stenting, such as FCSEMS, DPS, and LAMS. (4) Primary outcome: clinical improvement. The clinical improvement is defined as either improvement of organ systems, SIRS resolution, or PFC resolution detected by images.

Rationale Among the current evidence, the recommended type of stent is still under debate and research. To our knowledge, there are many RCT studies comparing the safety and efficacy among different stent, but none of which compared FCSEMS and LAM head-to-head in an RTC study. To compare the three types of stents, there is only one meta-analysis trying to answer this question, but has a potential heterogeneity due to the study selection method, which included not only RCTs but also retrospective studies for the meta-analysis.

Condition being studied Acute pancreatitis (AP) is a disease of broad spectrum of clinical course. While most APs are usually self-limiting and can be treated with conservative strategy, some may develop shock followed by multiorgan failure which leads to death. The inflammatory process may result in peripancreatic fluid collections (PFCs).According to the 2012 Revised Atlanta

Classification, the PPFCs may develop into pseudocysts or walled-off necrosis (WON) 4 weeks after pancreatitis. In acute pancreatitis, the incidence of pseudocysts ranges from 5% to 16%, and the incidence of necrosis is about 20% 1. These PFCs could potentially cause severe complications.

Intervention methods are chosen according to the patient's condition, the location of the necrosis, and the facility capability. Initially open surgery was the only choice, but with the advancement of endoscopy, interventions for necrotizing pancreatitis have evolved significantly over the two decades years, from step-down approach to step-up approach, and from surgery to minimally invasive techniques, which provides better life quality and reduces adverse events such as pancreatic-cutaneous fistula4. Minimally invasive techniques include endoscopic (by gastroenterologist/endoscopist) or percutaneous (by radiologist) techniques, among which the endoscopic approach is the most preferred one. The endoscopic drainage of PFCs is a clinically effective and safe technique that was first reported in the late 1980s5. The evolution of endoscopic ultrasound (EUS) devices and techniques has expanded the indications for PFC drainage to pancreatic abscesses, organized liquefied necrosis, and non-bulging PFCs. Endoscopists typically use EUS-assisted transmural approach to drain the necrosis, and different kinds of stent have been invented to provide drainage. There are three major types of stents: double pigtail plastic stent (DPPS), fully covered self-expanding stent (FCSEMS), and lumen apposing metallic stent (LAMS). Among the current evidence, the recommended type of stent is still under debate and research. To our knowledge, there are many RCT studies comparing the safety and efficacy among different stent, but none of which compared FCSEMS and LAM head-to-head in an RTC study.

METHODS

Search strategy pubmed

((("pancreatitis, acute necrotizing"[MeSH Terms] OR ("pancreatitis"[All Fields] AND "acute"[All Fields] AND "necrotizing"[All Fields]) OR "acute necrotizing pancreatitis"[All Fields] OR "pancreatitis acute necrotizing"[All Fields] OR "pancreatitis, acute necrotizing"[MeSH Terms] OR "acute pancreatitis"[Title/Abstract] OR (("peripancreatic"[All Fields] AND ("fluid"[All Fields] OR "fluid s"[All Fields] OR "fluids"[All Fields]) AND ("collect"[All Fields] OR "collectable"[All Fields] OR "collected"[All Fields] OR "collecting"[All Fields] OR "collection"[All Fields] OR "collections"[All Fields] OR "collects"[All Fields])) OR (("necrosis"[MeSH Terms] OR "necrosis"[All Fields] OR "necrotic"[All Fields] OR "necrotising"[All Fields] OR "necrotization"[All Fields] OR "necrotize"[All Fields] OR "necrotized"[All Fields] OR "necrotizing"[All Fields]) AND ("collect"[All Fields] OR "collectable"[All Fields] OR "collected"[All Fields] OR "collecting"[All Fields] OR "collection"[All Fields] OR "collections"[All Fields] OR "collects"[All Fields])) OR "wall-off"[All Fields] OR ("pseudocyst"[All Fields] OR "pseudocystic"[All Fields] OR "pseudocysts"[All Fields]) OR ("walled-off"[All Fields] AND ("necrose"[All Fields] OR "necrosed"[All Fields] OR "necrosi"[All Fields] OR "necrosing"[All Fields] OR "necrosis"[MeSH Terms] OR "necrosis"[All Fields] OR "necroses"[All Fields]))))) AND ("stent s"[All Fields] OR "stentings"[All Fields] OR "stents"[MeSH Terms] OR "stents"[All Fields] OR "stent"[All Fields] OR "stented"[All Fields] OR "stenting"[All Fields])) AND (randomizedcontrolledtrial[Filter]).

Participant or population Adults with necrotizing pancreatitis with complication of pancreatic fluid collection.

Intervention Endoscopic approach trans-gastric stenting, such as FCSEMS, DPS, and LAMS.

Comparator Endoscopic approach trans-gastric stenting, such as FCSEMS, DPS, and LAMS.

Study designs to be included RCTs.

Eligibility criteria Inclusion criteria: Adults with necrotizing pancreatitis with complication of pancreatic fluid collection.

Information sources We searched PubMed, Embase and the Cochrane Library, and we also manually reviewed the relevant studies from the previous RCTs, meta-analysis, and published guidelines in this field.

Main outcome(s) Clinical improvement, including the improvement of organ systems, SIRS resolution, or PFC resolution detected by images.

Additional outcome(s) Clinical success rate a Adverse event.

Data management We used Review Manager Version 5.3 (Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014) to conduct a random-effects meta-analysis owing to the possibility of the clinical heterogeneity among the included RCTs. Considering the heterogeneity in the RCTs, we separately calculated the pooled

risk ratio (RR) and mean difference (MD) with a 95% confidence interval (CI) for categorical and continuous outcomes, respectively. Funnel plots were not constructed due to less than 10 included RCTs in the meta-analysis.

Quality assessment / Risk of bias analysis We used the Cochrane Collaboration's ROB tool 2.0, consists of the critical domains of randomization process, deviations from intended interventions, missing outcome data, measurement of the outcome, selection of the reported result and overall bias, to evaluate the methodological quality of the included RCTs.
The Certainty of evidence of study outcomes were evaluated by two independent reviewers (XWI and JS) based on the Grading of Recommendations Assessment, Development and Evaluation (GRADE) criteria. Any discrepancy between the review authors would be discussed and judged by another author (CHW).

Strategy of data synthesis We used Review Manager Version 5.3 (Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014) to conduct a random-effects meta-analysis owing to the possibility of the clinical heterogeneity among the included RCTs. Considering the heterogeneity in the RCTs, we separately calculated the pooled risk ratio (RR) and mean difference (MD) with a 95% confidence interval (CI) for categorical and continuous outcomes, respectively. Funnel plots were not constructed due to less than 10 included RCTs in the meta-analysis.

Subgroup analysis No subgroup analysis was done.

Sensitivity analysis No sensitivity analysis was conducted.

Language restriction There is no language limitation.

Country(ies) involved Taiwan.

Other relevant information Characteristics and included studies ; PRISMA Checklist.

Keywords necrotizing pancreatitis, double pigtail plastic stent (DPPS), fully covered self-expanding stent (FCSEMS), lumen apposing metallic stent(LAMS).

Dissemination plans Journals.

Contributions of each author

Author 1 - Chin-Lang Lin - study design.
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