INPLASY

Prophylactic Pancreatic External or Internal Duct Stent Versus No Stent in Patients Undergoing Pancreaticoduodenectomy: A Systematic Review and Meta-Analysis

INPLASY2024120010
doi: 10.37766/inplasy2024.12.0010
Received: 2 December 2024
Published: 2 December 2024

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ADMINISTRATIVE INFORMATION

Support - None..

Review Stage at time of this submission - Preliminary searches.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY2024120010

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 2 December 2024 and was last updated on 2 December 2024.

INTRODUCTION

Review question / Objective In patients undergoing pancreaticoduodenectomy with pancreatico-jejunostomy, does the prophylactic use of internal or external pancreatic duct stent compared to no stent result in differences in outcomes, specifically postoperative pancreatic fistulas, length of hospital stay after surgery and major complications? Additionally, what impact does duct stent use have on secondary outcomes such as biochemical leak and length of stay?

Rationale Postoperative pancreatic fistulas are common (20%) after resection of the pancreatic head. This complication increases postoperative mortality and lead to delay in oncological treatment after surgery. Several RCTs have been published with results vary between studies. A meta analysis would compile these results and give a definite answer.

Condition being studied The systematic review focuses on patients undergoing proximal pancreatectomy or pancreaticoduodenectomy with pantreaticojejunal anastomosis. These surgeries are commonly performed in the context of different pathologies such as pancreatic cancer or pancreatic tumors. The review specifically investigates the prophylactic use of pancreatic duct stent during these procedures, aiming to assess its impact on outcomes related to postoperative pancreatic fistula, biochemical leak and any serious complications (defined as Clavien Dindo 3 or above)Patients undergoing pancreatectomy with pancreaticojejunostomy for various medical conditions, including but not limited to pancreatic cancer or other conditions requiring pancreaticojejunostomy.

METHODS

Search strategy ((("Pancreatectomy"[Mesh] OR pancreatectomy[tiab] OR "pancreatic surgery"[tiab]) AND ("Pancreatic Fistula"[Mesh] OR "postoperative pancreatic fistula"[tiab] OR

"POPF"[tiab])) AND (("Internal stent"[tiab] OR "internal pancreatic duct stent"[tiab]) OR ("External stent"[tiab] OR "external pancreatic duct stent"[tiab]) OR ("No stent"[tiab] OR "without stenting"[tiab]))) AND ("Randomized Controlled Trial"[pt] OR "randomized controlled trial"[tiab] OR RCT[tiab]).

Participant or population Patients undergoing pancreatectomy with pancreaticojejunostomy for various medical conditions, including but not limited to pancreatic cancer or other conditions requiring pancreaticojejunostomy.

Intervention Prophylactic use of pancreatic duct stent: The application of a pancreatic duct material during the surgical procedures of pancreaticoduodenectomy with pancreatico-jejunostomy with the primary aim of preventing postoperative pancreatic fistula.

Comparator No stent (control or standard care): Definition: Surgical procedures of pancreatico-jejunostomy without pancreatic duct stent.

Study designs to be included Only randomized controlled trials will be included.

Eligibility criteria Patients undergoing pancreaticoduodenectomy by any approach; Patients that undergo a pancretico jejunal anastomosis; Intervention group is either internal or external pancreatic duct stent.

Information sources Pubmed, Google Scholar, Scopus.

Main outcome(s) Postoperative Pancreatic Leak:
- Definition: Drain amylase >3x upper limit of normal serum vale AND drain needed for >3 weeks, change in normal management because of the fistula, infection with or without organ failure, interventional drainage needed because of the fistula, o**.**

Additional outcome(s) Length of stay, major complications (Clavien Dindo >2).

Data management Study Selection:
- Two reviewers will independently evaluate studies and select applicable ones with inclusion criteria in mind. A third reviewer will evaluate discrepancies.
- Ryann software will be employed to record decisions

Data extraction:
- Patient baseline demographics including but not limited to age, sex, diagnosis, comorbidities will be extracted by reviewers from each study.
- Two reviewers will indepdendently extract the data with a third reviewer evaluating for discrepencies.
- Numerical missing data will be handled by median imputation while missing categorical variables will be excluded from analysis.
- Recording of data will be done in an Excel spreadsheet on a secure OneDrive server.

Quality assessment / Risk of bias analysis Risk of bias of RCTs included will be assesed with RoB 2 Tool from Cochrane.

Strategy of data synthesis Data will be used to estimate mean difference and odds ratios between groups using review manager. Fixed effects models will be used for studies with higgins I^2% values under 50, otherwise a random effects model will be used.

Subgroup analysis Studies will be stratified by known high-risk factors for postoperative pancreatic fistula such as soft gland texture and a pancreatic duct caliber <3mm.

Sensitivity analysis N/A.

Language restriction Only English studies will be included.

Country(ies) involved United States of America.

Keywords postoperative pancreatic fistula; pancreatic cancer; pancreatic resection; systematic review; meta-analysis.

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