INPLASY PROTOCOL

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Corresponding author: Chenming Liu

22118065@zju.edu.cn

Author Affiliation:

Shaoxing People's Hospital(Shaoxing Hospital, Zhejiang University School of Medicine).

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Conflicts of interest: None declared.

INTRODUCTION

Review question / Objective: Is efficacy of endoscopic radiofrequency ablation plus stent superior to stent-alone for malignant

Is efficacy of endoscopic radiofrequency ablation plus stent superior to stent-alone for malignant biliary obstruction? A systematic review and meta-analysis

Liu,CM¹; Chen, RC²; Deng, SQ³; Lu, BC⁴.

Review question / Objective: We will conduct a systematic review and meta analysis on the comparison of the efficacy of endoscopic radiofrequency ablation combined with stent implantation and stent implantation alone for patients with malignant biliary obstruction.

Condition being studied: In recent years, most meta-analyses have confirmed that the efficacy of radiofrequency ablation combined with stenting in the treatment of malignant biliary obstruction is significantly better than that of stenting alone, and the complication rate is lower. However, those metaanalyses did not distinguish which kind of way of the curative effect of radiofrequency ablation of malignant biliary obstruction.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 27 April 2023 and was last updated on 27 April 2023 (registration number INPLASY202340096).

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METHODS

Participant or population: Patients with malignant biliary obstruction such as cholangiocarcinoma, pancreatic cancer, ampulla cancer, and gallbladder cancer.

Intervention: Endoscopic radiofrequency ablation with stent implantation.

Comparator: Overall survival and stent patency rate; Median survival time and stent patency time; Incidence of adverse events.

Study designs to be included: Randomized controlled trials, Observational studies.

Eligibility criteria: 1) Patients with malignant biliary obstruction, including cholangiocarcinoma (intrahepatic cholangiocarcinoma, hilar cholangiocarcinoma, distal cholangiocarcinoma), pancreatic cancer, ampulla cancer, and gallbladder cancer. (2) The patient was unable to undergo radical surgery at the time of treatment. (3) The literature types were randomized controlled trials and observational studies (prospective studies and case-control studies) comparing radiofrequency ablation combined with stent implantation and stent implantation alone. (4) The language of the paper was English, and the research scope was human. (5) The radiofrequency ablation method was endoscopic.

Information sources: We will search relevant literature on Medline(Pubmed), Embase, Cochrane Library and Web of science.

Main outcome(s): Overall survival and stent patency rate; Mean overall survival and mean stent patency time; Incidence of adverse events (bleeding, pancreatitis, cholangitis, perforation, etc.)

Quality assessment / Risk of bias analysis: For risk of bias assessment, we will apply the tool developed by the Cochrane Collaboration. The quality of the evidence will be assessed by GRADE principles (Grading of Recommendations Assessment, Development, and Evaluation).

Strategy of data synthesis: The dichotomous variables will be assessed by risk ratio (RR) and their 95% confidence interval (CI), continuous variables by standardized mean difference (SMD), and overall survival and stent patency rate by HR. All pooled results will be calculated using the random-effect model.

Subgroup analysis: Subgroup analysis will be performed for survival and stent patency and biliary stenosis and diameter of different tumor types such as cholangiocarcinoma and hilar cholangiocarcinoma.

Sensitivity analysis: We will assessed the each outcome by funnel plots and each study effect will be judged by removing each study one by one and see its effect on the final outcome.

Language restriction: English.

Country(ies) involved: China.

Keywords: Radiofreqency ablation, ERCP, stent implantation.

Contributions of each author:

Author 1 - Chenming Liu - Author 1 will draft the manuscript. Email: 22118065@zju.edu.cn Author 2 - Ruanchang Chen - The author will search the relevant literature and

statistical expertise. Email: 1020306234@gg.com

Author 0 Chining Dong

Author 3 - Shiqing Deng - The author will contribute to the development of the selection criteria, and the risk of bias assessment strategy.

Email: 294523189@qq.com

Author 4 - Baochun Lu - The author will read, provide feedback and approve the final manuscript.

Email: lubaochun@zju.e