

INPLASY PROTOCOL

To cite: Zhang et al. Stenting with high-intensity focused ultrasound ablation for distal biliary obstruction caused by pancreatic carcinoma: a meta-analysis. Inplasy protocol 202130047. doi: 10.37766/inplasy2021.3.0047

Received: 15 March 2021

Published: 15 March 2021

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Support: None.

Review Stage at time of this submission: Preliminary searches.

Conflicts of interest:
None declared.

Stenting with high-intensity focused ultrasound ablation for distal biliary obstruction caused by pancreatic carcinoma: a meta-analysis

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Review question / Objective: To evaluate the clinical efficacy of stenting with high-intensity focused ultrasound (HIFU) ablation for patients with distal malignant biliary obstruction (MBO) caused by pancreatic carcinoma (PC).

Condition being studied: Distal malignant biliary obstruction (MBO) is usually caused by primary biliary and pancreatic tumors. Approximate 42%-77% of patients with distal MBO caused by pancreatic carcinoma (PC). PC itself is a highly malignant tumor, moreover, when it causes the distal MBO, only 10–20% of patients are eligible for surgical resection, and the 3- and 5-year survival rates of these patients are just 18–52% and 5–31%, respectively. When the patients are found with MBO caused by PC, only palliative treatment options can be used. At present, endoscopic or percutaneous metal stenting is the first choice for patients with distal MBO caused by PC. However, stenting alone has no effectiveness on the PC. The long-term patency and survival are usually limited by the tumor progression. Therefore, anticancer treatments addition to stenting should be performed for patients with distal MBO caused by PC. A number of anticancer approaches has been used to extend stent patency and patient overall survival (OS), including chemotherapy, radiotherapy, and combination chemoradiotherapy. At present, advances in the use of high-intensity focused ultrasound (HIFU) ablation addition to stenting to treat PC have been made owing to the non-invasive and non-toxic nature of this.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 15 March 2021 and was last updated on 15 March 2021 (registration number INPLASY202130047).

INTRODUCTION

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METHODS

Search strategy: (((biliary [Title/Abstract]) AND (((stent [Title/Abstract]) OR (SEMS [Title/Abstract])) OR (drainage [Title/Abstract]))) AND (((obstruction [Title/Abstract]) OR (stenosis [Title/Abstract])) OR (stricture [Title/Abstract]))) AND ((high-intensity focused ultrasound [Title/Abstract]) OR (HIFU [Title/Abstract])).

Participant or population: Patients with distal MBO caused by PC.

Intervention: Stenting with HIFU ablation.

Comparator: Stenting alone.

Study designs to be included: Study inclusion criteria were: (a) Type of study:

comparative studies; (b) Disease: distal MBO caused by PC; (c) Types of intervention: biliary stenting versus biliary stenting with HIFU ablation; (d) Language: any.

Eligibility criteria: Study inclusion criteria were: (a) Type of study: comparative studies; (b) Disease: distal MBO caused by PC; (c) Types of intervention: biliary stenting versus biliary stenting with HIFU ablation; (d) Language: any. Studies were excluded if they were any of the following: (a) single-arm studies; (b) case reports; (c) animal studies; (d) review articles.

Information sources: Two investigators independently extracted publication year, study design, authors, baseline patient characteristics, and treatment information from relevant studies. Discrepancies were resolved through discussion with a third author.

Main outcome(s): Stent patency.

Additional outcome(s): Improvement of total bilirubin (TBIL), stent patency, overall survival (OS), clinical response rate of HIFU, and complications.

Data management: RevMan v5.3 and Stata v12.0 are utilized for all statistical analyses.

Quality assessment / Risk of bias analysis: The Cochrane risk of bias tool was utilized to gauge potential bias in included randomized controlled trials (RCTs), which were evaluated for their risk of bias associated with selection, detection, performance, reporting, attrition, and other biases. All studies which were not RCTs were evaluated with the 9-point Newcastle-Ottawa scale, with scores of ≥ 7 , 4-6, and < 4 corresponding to low, moderate, and high bias risk, respectively.

Strategy of data synthesis: Pooled odds ratios (ORs) and 95% confidence intervals (CIs) for dichotomous variables are calculated via the Mantel-Haenszel approach, whereas pooled estimates of mean difference (MD) with 95% CIs are calculated the continuous variables.

Hazard ratios (HRs) with 95% CIs are used to compare stent patency and OS between groups. Heterogeneity among included studies is gauged using X² tests and the I² statistic, with I² > 50% being indicative of significant heterogeneity. Fixed-effects models are utilized in the absence of any significant heterogeneity. Sources of potential heterogeneity were identified via sensitivity analysis. Pooled clinical response rates are calculated using Stata v12.0. The potential for publication bias was analyzed with funnel plots.

Subgroup analysis: None.

Sensitivity analysis: None.

Language: English.

Country(ies) involved: China.

Other relevant information: None.

Keywords: Stent; High-intensity focused ultrasound; Biliary; Pancreatic carcinoma.

Dissemination plans: Publish in a journal.

Contributions of each author:

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Author 3 - Ping-Chao Huang.

Author 4 - Feng-Fei Xia.

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