

# INPLASY PROTOCOL

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**Support:** None.

**Review Stage at time of this submission:** Preliminary searches.

**Conflicts of interest:**  
None.

## Stent insertion for hilar cholangiocarcinoma: a meta-analysis of comparison between unilateral and bilateral stenting

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**Review question / Objective:** To compare the clinical efficacy of unilateral and bilateral metal stent insertion for patients affected by hilar cholangiocarcinoma (HCCA).

**Condition being studied:** Malignant hilar biliary obstruction (MHBO) always arise as a consequence of either malignant growths in the hilar hepatobiliary area. At time of diagnosis, MHBO patients are generally unable to undergo definite resection as the disease is often detected at an advanced stage when only palliative treatment is viable. Metal stenting can be inserted as a primary treatment option for alleviating MHBO symptoms. At present, although many studies focused on the topic of unilateral or bilateral stenting for MHBO, it remains unclear as to which technique is preferable for treating MHBO. Although some meta-analyses indicated that bilateral metal stenting yielded lower rate of stent dysfunction than did unilateral metal stenting in MHBO patients, many bias, such as type of stents, stenting approaches, disease types, did exist. To overcome these potential causes of bias, there is a clear need for a study comparing these two stenting types in patients with a single type of cancer.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 15 January 2021 and was last updated on 15 January 2021 (registration number INPLASY202110051).

### INTRODUCTION

**Review question / Objective:** To compare the clinical efficacy of unilateral and bilateral metal stent insertion for patients affected by hilar cholangiocarcinoma (HCCA).

**Rationale:** Analyzed endpoints included rates of technical success, clinical success, complications, stent dysfunction, and overall survival. These endpoints were compared to assess the clinical effectiveness of unilateral and bilateral metal stenting for HCCA.

**Condition being studied:** Malignant hilar biliary obstruction (MHBO) always arise as a consequence of either malignant growths in the hilar hepatobiliary area. At time of diagnosis, MHBO patients are generally unable to undergo definite resection as the disease is often detected at an advanced stage when only palliative treatment is viable. Metal stenting can be inserted as a primary treatment option for alleviating MHBO symptoms. At present, although many studies focused on the topic of unilateral or bilateral stenting for MHBO, it remains unclear as to which technique is preferable for treating MHBO. Although some meta-analyses indicated that bilateral metal stenting yielded lower rate of stent dysfunction than did unilateral metal stenting in MHBO patients, many bias, such as type of stents, stenting approaches, disease types, did exist. To overcome these potential causes of bias, there is a clear need for a study comparing these two stenting types in patients with a single type of cancer.

## METHODS

**Search strategy:** (((unilateral[Title/Abstract]) AND bilateral[Title/Abstract]) AND stent[Title/Abstract]) AND ((biliary obstruction[Title/Abstract]) OR cholangiocarcinoma[Title/Abstract]).

**Participant or population:** HCCA patients.

**Intervention:** Patients who underwent bilateral stenting.

**Comparator:** Patients who underwent unilateral stenting.

**Study designs to be included:** Included studies met the following criteria: (a) studies comparing outcomes for unilateral vs. bilateral stenting for the treatment of HCCA; and (b) English studies. Studies were excluded if they met any of the following criteria: (a) non-comparative studies; (b) case reports; (c) animal studies; and (d) reviews.

**Eligibility criteria:** Included studies met the following criteria: (a) studies comparing

outcomes for unilateral vs. bilateral stenting for the treatment of HCCA; and (b) English studies. Studies were excluded if they met any of the following criteria: (a) non-comparative studies; (b) case reports; (c) animal studies; and (d) reviews.

**Information sources:** Relevant studies published in the Pubmed, Embase, and the Cochrane Library databases through June 2020 were identified.

**Main outcome(s):** Stent dysfunction.

**Additional outcome(s):** Technical success, clinical success, complications, and overall survival.

**Data management:** Two investigators independently extracted data (authors, publication year, baseline patient characteristics, study design, and treatment information) from all studies. Any discrepancies found in the extracted data were resolved by the corresponding author.

**Quality assessment / Risk of bias analysis:** The 8-point Jadad composite scale was utilized to evaluate randomized controlled trial (RCT) quality. All non-RCTs were evaluated with the 9-point Newcastle-Ottawa scale.

**Strategy of data synthesis:** RevMan v5.3 was used for all data analyses. The Mantel-Haenszel approach was used for calculating pooled odds ratios (ORs) and 95% confidence intervals (CIs) for dichotomous variables. Overall survival was assessed using hazard ratios (HRs) with 95% CIs. Heterogeneity was measured using the  $X^2$  and  $I^2$  tests, with  $I^2 > 50\%$  indicating significant heterogeneity. When significant heterogeneity was not present, analysis proceeded using a fixed-effects model. Potential heterogeneity sources were evaluated using sensitivity and subgroup analyses, while funnel plots were utilized to assess potential publication bias.

**Subgroup analysis:** None.

**Sensibility analysis:** None.

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**Language:** English.

**Country(ies) involved:** China.

**Other relevant information:** None.

**Keywords:** Stent; Unilateral; Bilateral; Hilar cholangiocarcinoma.

**Dissemination plans:** We want to publish the meta-analysis.

**Contributions of each author:**

**Author 1 - Xin-Qiang Liu.**

**Author 2 - Sha-Sha Cui.**

**Author 3 - Yu-Ling Kan.**

**Author 4 - Lu-Lu Yang.**

**Author 5 - Jia-Fen Wang.**