

# INPLASY PROTOCOL

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**Support:** None.

**Review Stage at time of this submission:** Data analysis.

**Conflicts of interest:**  
None declared.

## Radioactive versus normal stent insertion for malignant hilar obstruction: a meta-analysis

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**Review question / Objective:** This meta-analysis aimed to compare the clinical effectiveness and safety between radioactive versus normal stent insertion for patients with malignant hilar obstruction.

**Condition being studied:** Malignant hilar obstruction (MHO) is a common clinical condition that is caused by the hilar cholangiocarcinoma, gallbladder carcinoma, or hilar metastasis. Most of the patients with MHO underwent palliative biliary drainage or stenting by an endoscopic or percutaneous approach until end of life. The previous studies suggested that that bilateral stent placement and the use of metal stents are superior to unilateral and plastic stents in the items of stent patency. However, bilateral stenting did not improve the patients' overall survival (OS) because stent alone had no treatment effect on the tumors themselves. Although several treatment options, including chemotherapy, external radiation, intra-ductal brachytherapy, etc, has been used to prolong the stent patency and OS for patients with malignant biliary obstruction (MBO), intra-ductal brachytherapy using I-125 seeds has been widely used because of its persistent brachytherapeutic effect. To combine the I-125 seeds and metal stent together, many researchers have developed a radioactive stent (RS) for the patients with MBO. Many meta-analyses also confirmed that RS insertion was associated with significant longer stent patency and OS for patients with MBO when compared to normal stent (NS). However, whether RS can also provide a good effectiveness for patients with MHO is still unclear.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 10 April 2022 and was last updated on 10 April 2022 (registration number INPLASY202240057).

### INTRODUCTION

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effectiveness and safety between radioactive versus normal stent insertion for patients with malignant hilar obstruction.

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## METHODS

**Search strategy:** (((stent) OR (SEMS)) AND (((irradiation) OR (radioactive)) OR (125I)) OR (I125)) OR (seed))) AND (((biliary) OR (jaundice)) OR (cholangiocarcinoma)) OR (Klatskin))) AND (hilar).

**Participant or population:** Malignant hilar obstruction.

**Intervention:** Radioactive stent.

**Comparator:** Normal stent

**Study designs to be included:** Studies eligible for inclusion met the following criteria:(a) Types of studies: comparative

studies;(b) Diseases: patients with MHO;(c) Types of interventions: RS versus NS insertion;(d) Languages: not limited.Studies were excluded if they were: (a) single-arm studies; (b) no English titles and/or abstract;(c) meta-analyses and reviews.

**Eligibility criteria:** Studies eligible for inclusion met the following criteria:(a) Types of studies: comparative studies;(b) Diseases: patients with MHO;(c) Types of interventions: RS versus NS insertion;(d) Languages: not limited.Studies were excluded if they were: (a) single-arm studies; (b) no English titles and/or abstract;(c) meta-analyses and reviews.

**Information sources:** Medline, Embase, Wanfang, and CNKI databases.

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

**Quality assessment / Risk of bias analysis:** The Cochrane risk-of-bias tool was used to establish the quality of randomized controlled trials (RCTs), with each of the following being assigned a low, high, or unclear risk of bias: performance, attrition, detection, selection, reporting, and other bias. Quality of non-RCTs was assessed using the Newcastle-Ottawa scale, which assigns points to each study based on selection (4 scores), comparability (2 scores), and exposure (3 scores) criteria. The scores  $\geq 7$  was considered indicative of a high-quality study.

**Strategy of data synthesis:** The data of these endpoints were pooled using RevMan v5.3. For dichotomous variables, pooled odds ratios (ORs) with 95% confidence intervals (CIs) were calculated, while continuous variables were compared using mean differences (MD) values with 95% CIs. Pooled stent patency duration and OS were calculated by hazard ratios (HRs) with 95% CI. The I<sup>2</sup> statistic and Q test were used to assess heterogeneity, with an I<sup>2</sup> > 50% being considered indicative of significant heterogeneity. Random-effects or fixed-effect models were used when significant heterogeneity was found or not. Publication bias was analyzed using Egger's test by Stata v12.0.

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**P < 0.05** was considered as the significance threshold.

**Subgroup analysis:** Subgroup analyses were conducted based on the studies which only included patients with hilar cholangiocarcinoma.

**Sensitivity analysis:** Sensitivity analyses were conducted via a “leave one out” approach in an effort to detect sources of heterogeneity.

**Language:** English.

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

**Keywords:** Hilar obstruction.

**Contributions of each author:**

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Author 2 - Dong-Lu Li.

Author 3 - Jun-Jun Du.

Author 4 - Jia-Xiang She.

Author 5 - Jiao Meng.

Author 6 - Jing Fan.