

# INPLASY

## Efficacy and safety of covered self-expandable metal stent for malignant hilar biliary obstruction: A systematic review and meta-analysis

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### ADMINISTRATIVE INFORMATION

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

**Conflicts of interest** - None declared.

**INPLASY registration number:** INPLASY202440072

**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 17 April 2024 and was last updated on 17 April 2024.

### INTRODUCTION

**Review question / Objective** To evaluate the efficacy and safety of covered self-expanding metal stent (SEMS) in malignant hilar biliary obstruction (MHBO) managementS in MHBO management.

**Condition being studied** Despite the increasing number of studies investigating covered SEMS in clinical practice for MHBO, the evidence regarding their efficacy and safety remains heterogenous and inconclusive. Existing observational studies and randomized controlled trials (RCTs) have yielded conflicting findings, owing to variations in study design, patient populations, and follow-up durations. Moreover, to date, there has been no comprehensive meta-analysis evaluating the efficacy and safety of covered SEMS as a primary treatment modality for MHBO.

### METHODS

**Search strategy** A comprehensive systematic literature search was conducted across PubMed, EMBASE, and the Cochrane Library, finishing on March 31, 2024. The principal search terms employed were “klatskin tumor,” “hilar cholangiocarcinoma,” “proximal biliary obstruction,” “covered SEMS.”

**Participant or population** Adult patients with MHBO.

**Intervention** Treated with endoscopic retrograde cholangiopancreatography and placement of a covered SEMS, either fully covered (FC) or partially covered (PC).

**Comparator** Not applicable.

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**Study designs to be included** All prospective or retrospective studies.

**Eligibility criteria** (1) adult patients with MHBO, (2) treated with endoscopic retrograde cholangiopancreatography and placement of a covered SEMS, either fully covered (FC) or partially covered (PC), and (3) reporting both clinical success rate and postprocedural adverse event rate.

**Information sources** A comprehensive systematic literature search was conducted across PubMed, EMBASE, and the Cochrane Library, finishing on March 31, 2024. Further relevant studies were identified through meticulous manual cross-referencing of the bibliographies of retrieved articles.

**Main outcome(s)** Clinical outcomes, covering technical and clinical success rates, occurrence of adverse events, stent migration, RBO, and success rates of reintervention.

**Additional outcome(s)** Stent patency.

**Quality assessment / Risk of bias analysis** The quality of the included studies was assessed using the Newcastle-Ottawa Scale, which ranges from 0 to 9. Studies scoring 7 or higher were categorized as high quality, those with scores between 4 and 6 were considered moderate quality, and studies scoring 3 or lower were classified as low quality.

**Strategy of data synthesis** The pooled results, along with their corresponding 95% confidence intervals (CIs), were computed using the random effects model, following the method recommended by DerSimonian and Laird.

**Subgroup analysis** Subgroup analyses and meta-regression were conducted to explore potential sources of heterogeneity, including variables such as study design (prospective vs. retrospective), setting (preoperative vs. unresectable), type of stent (FC-SEMS vs. PC-SEMS), stent diameter (6 mm vs. 8 mm), and the location of the distal tip (above papilla vs. across papilla).

**Sensitivity analysis** Not applicable.

**Language restriction** English only.

**Country(ies) involved** South Korean and USA.

**Keywords** Self-expandable metal stent; hilar obstruction; efficacy; safety; covered.

#### **Contributions of each author**

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