

## Prognostic role of Iodine-125 seeds combined with esophageal stents for unresectable malignant esophageal obstruction? a Meta-Analysis of randomized controlled trials

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Yu, X<sup>1</sup>; Zhu, J<sup>2</sup>; Shen, TH<sup>3</sup>; Zhou, C<sup>4</sup>; Jiang, TH<sup>5</sup>; Liu, Y<sup>6</sup>.**ADMINISTRATIVE INFORMATION****Support** - Shanghai Health Commission Talent Project (2022YQ037).**Review Stage at time of this submission** - Data analysis.**Conflicts of interest** - None declared.**INPLASY registration number:** INPLASY2023110108**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 28 November 2023 and was last updated on 28 November 2023.**INTRODUCTION**

**Review question / Objective** Malignant esophageal obstruction is usually caused by unresectable malignant esophageal cancer, which requires the placement of esophageal stents to relieve the obstruction. In recent years, Iodine-125 seeds seed irradiated scaffolds have been used to improve stent patency and patient survival time. We conducted this meta-analysis to evaluate the efficacy and safety of Iodine-125 seeds placement in combination with esophageal stents versus stents alone in patients with malignant esophageal obstruction.

**Condition being studied** We selected Pubmed, Web of Science, Scopus, Cochrane Library, Embase and CNKI databases to search the randomized controlled trials of Iodine-125 seeds combined with esophageal stents in the treatment of malignant esophageal obstruction. The software RevMan (5.4) was used to evaluate the quality of

the literature, and meta-analysis and sensitivity analysis were performed on the clinical effective rate and related biochemical indicators.

**METHODS**

**Participant or population** The subjects of this study were patients with malignant esophageal stenosis who received iodine particle implantation combined with esophageal stent.

**Intervention** Iodine-125 seeds combined with esophageal stents.

**Comparator** Normal esophageal stent was used in the control group, and iodine particle esophageal stent was used in the treatment group.

**Study designs to be included** Randomized controlled trial.

**Eligibility criteria** Inclusion criteria included (1) it was a RCT for unresected malignant esophageal obstruction (2) stent combined with I-125 seeds therapy was compared to stent monotherapy (3) at least one of the following was reported: survival time or rate; stent patency or stent occlusion rate. (4) full text of studies are available. (5) patients in studies did not receive other radiotherapy. Studies were excluded when information about the survival or stent patency in the patient groups was not provided. Meanwhile, non-randomized controlled trials, animal experiments, narrative reviews were excluded too.

**Information sources** We selected Pubmed, Web of Science, Scopus, Cochrane Library, Embase and CNKI databases to search the randomized controlled trials of I-125 seeds combined with esophageal stents in the treatment of malignant esophageal obstruction.

**Main outcome(s)** I-125 seeds combined with stent demonstrated superior stent patency and improved survival time compared to stent alone with acceptable complications.

**Quality assessment / Risk of bias analysis** Since all studies were randomized controlled trials, we used the Cochrane Collaboration tool to determine the risk of bias, including six: (1) sequence generation (2) allocation hiding (3) blind method (4) incomplete result data (5) no selective result reporting (6) other sources of bias. For each project, the low risk score is 1, for a total of 6 points. Any differences that arose were discussed with the third author and a consensus was reached.

**Strategy of data synthesis** The primary end points were overall survival time. The odds ratios (OR) with 95% confidence intervals (CIs) were calculated. Also, survival was continuous variables, the means and standard deviations of observed patients were extracted from the included studies. Then, the pooled estimate of the mean difference (MD) with 95% confidence intervals (CIs) was calculated. Finally, the OR or MD of each study was pooled using either a fixed-effects or random-effects model.

**Subgroup analysis** The number of references that could be included in this study will not be analyzed by subgroups.

**Sensitivity analysis** Sensitivity analysis was used to check the stability of the results.

**Country(ies) involved** China/Putuo Hospital affiliated to Shanghai University of Traditional Chinese Medicine.

**Keywords** Iodine-125 seeds combined with stent demonstrated superior stent patency and improved survival time compared to stent alone with acceptable complications.

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

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