INPLASY PROTOCOL

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Conflicts of interest:
None.

I-125 seeds-loaded versus normal stent insertion for obstructive esophageal cancer: a meta-analysis

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Review question / Objective: **Whether I-125 seeds-loaded stent can significant prolong the stent patency and patients' survival when compared to normal stent.**
Condition being studied: **Malignant esophageal obstruction is usually caused esophageal and other chest cancers. More than 80% of cases with esophageal obstruction were caused by esophageal cancer. When patients are diagnosed with obstructive esophageal cancer (OEC), more than 80% of cases lost the chance of curative resection. In addition, patients with OEC also had a poor quality of life because of the dysphagia. Stent insertion is a first-line palliative approach used to treat incurable OEC. Like most malignant luminal obstruction, normal stent (NS) insertion, does not directly treat the causes of obstruction. To extend the stent patency and survival, several researchers have developed a novel I-125 seeds-loaded stent (ISS) for patients with inoperable OEC. The ISSs not only can effectively relieve the dysphagia, but also can provide the brachytherapy to the tumor. The results from a single study might be influenced by many factors, a meta-analysis should be carried out to decrease the bias and increase the statistical power of the small sample study.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 27 December 2020 and was last updated on 27 December 2020 (registration number INPLASY2020120138).

INTRODUCTION

Review question / Objective: **Whether I-125 seeds-loaded stent can significant prolong the stent patency and patients' survival when compared to normal stent.**

Rationale: **The pooled dysphagia score, stent re-stenosis rates, time-to-restenosis, complication rates, and overall survival duration are calculated to compare the**

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clinical effectiveness between I-125 seeds-loaded and normal stents.

Condition being studied: Malignant esophageal obstruction is usually caused esophageal and other chest cancers. More than 80% of cases with esophageal obstruction were caused by esophageal cancer. When patients are diagnosed with obstructive esophageal cancer (OEC), more than 80% of cases lost the chance of curative resection. In addition, patients with OEC also had a poor quality of life because of the dysphagia. Stent insertion is a first-line palliative approach used to treat incurable OEC. Like most malignant luminal obstruction, normal stent (NS) insertion, does not directly treat the causes of obstruction. To extend the stent patency and survival, several researchers have developed a novel I-125 seeds-loaded stent (ISS) for patients with inoperable OEC. The ISSs not only can effectively relieve the dysphagia, but also can provide the brachytherapy to the tumor. The results from a single study might be influenced by many factors, a meta-analysis should be carried out to decrease the bias and increase the statistical power of the small sample study.

METHODS

Search strategy: (((stent[Title/Abstract]) OR (SEMS[Title/Abstract])) AND ((((irradiation[Title/Abstract]) OR (seed[Title/Abstract])) OR (radioactive[Title/Abstract])) OR (iodine[Title/Abstract]))) AND ((esophageal[Title/Abstract]) OR (esophagus[Title/Abstract])).

Participant or population: Patients with obstructive esophageal cancer who underwent I-125 seeds-loaded or normal stent insertion.

Intervention: Patients who underwent I-125 seeds-loaded stent insertion.

Comparator: Patients who underwent normal stent insertion.

Study designs to be included: Study inclusion criteria included: (a) Type of study: comparative studies (randomized controlled trials [RCTs] and retrospective studies); (b) Disease: patients with OEC; (c) Types of intervention: ISS versus NS insertion; (d) Language: English. Studies were excluded if they were: (a) non-comparative studies; (b) case reports; (c) animal or other preclinical studies; (d) review articles.

Eligibility criteria: Study inclusion criteria included: (a) Type of study: comparative studies (randomized controlled trials [RCTs] and retrospective studies); (b) Disease: patients with OEC; (c) Types of intervention: ISS versus NS insertion; (d) Language: English.

Information sources: The Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement was used to guide the present meta-analysis. The Medline, Cochrane Library, and Embase databases were queried for relevant studies published through November 2020.

Main outcome(s): Survival time.

Additional outcome(s): Clinical effectiveness, stent patency, and complications.

Data management: Data from all included studies was independently extracted by two researchers, while discrepancies were resolved through discussion with a third author. Extracted items included: study baseline data, patient baseline data, and treatment-associated data. Clinical effectiveness was evaluated by comparing the dysphagia score before and after stent insertion. Stent patency included the items of stent restenosis, time-to-restenosis (TTR), and migration. Complications included severe chest pain, haemorrhage, aspiration pneumonia, and fistula formation.

Quality assessment / Risk of bias analysis: The Cochrane risk of bias tool was utilized to gauge potential bias in included RCTs, which were evaluated for their risk of bias associated with selection, detection, performance, reporting, attrition, and other

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biases. All studies which were not RCTs were assessed using 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: RevMan v5.3 was utilized to analyze data. The Mantel-Haenszel method was used to measure pooled odds ratios (ORs) and 95% confidence intervals (CIs) for dichotomous variables, and continuous variables were assessed through mean differences (MDs) and 95% CIs. Hazard ratios (HRs) with a 95% CI were used to measure pooled survival. Study heterogeneity was gauged via X2 and I2 tests, with I2 > 50% indicating significant heterogeneity. Fixed-effects models were used for analyses when significant heterogeneity was not detected, whereas random-effects models were otherwise used. Causes of heterogeneity were assessed through subgroup and sensitivity analyses, whereas risk of bias was examined using funnel plots.

Subgroup analysis: Subgroup analyses were performed based on the studies which focused on esophageal squamous cell carcinoma.

Sensibility analysis: Not intended to do the sensibility analysis.

Language: English.

Country(ies) involved: China.

Other relevant information: None.

Keywords: I-125; Seed; Stent; Esophageal cancer.

Dissemination plans: Publishing a meta-analysis will be the main dissemination plan.

Contributions of each author:
Author 1 - Chun-Lei Zhao drafted the manuscript.
Author 2 - Bing Gu provided statistical expertise.
Author 3 - Xiao-Bing Huo contributed to the development of the selection criteria, and the risk of bias assessment strategy.
Author 4 - Feng-Fei Xia read, provided feedback and approved the final manuscript.

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