INPLASY PROTOCOL

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Comparison of self-expandable metallic stent (SEMS) and preventative stoma (PS) as a bridge to surgery (BTS) for obstructive colorectal cancer. A protocol for systematic review and meta-analysis

Zhang, JH[1]; Yang, WM[2]; Liu, XT[3].

Review question / Objective: P: symptomatic large bowel obstruction induced by curable colorectal cancer; I: self-expandable metallic stent (SEMS); C: preventative stoma (PS); O: 3-year overall survival, complication and mortality; S: retrospective non-randomized controlled studies.

Condition being studied: Self-expandable metallic stent (SEMS) has been used as a "bridge to surgery"(BTS) to treat acute malignant large bowel obstruction (MLBO) for decades. Meanwhile, preventative stoma (PS) has also been served as another conventional BTS. However, the debate over the role of SEMS has never disappeared. The aim of this meta-analysis is to evaluate whether endoscopic stent is a safe and effective alternative to temporary colostomy in patients with acute malignant colonic obstruction. This will be the first systematic review to date, that compares both the long-term and short-term outcomes of SEMS and PS as a BTS followed by selective resection instead of palliative treatment.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 22 October 2020 and was last updated on 22 October 2020 (registration number INPLASY2020100079).

INTRODUCTION

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METHODS

Search strategy: Terms: "stent" or "stents" or "self-expanding metallic stents", "stoma" or "colostomy" or "decompression surgery", and "malignant obstruction" or "colorectal cancer". Electronic databases: PUBMED, MEDLINE, EMBASE, the Cochrane Library, International Clinical Trails Registry Platform and Google Scholar databases.

Participant or population: Patients with obstructive colorectal cancer.

Intervention: Self-expandable metallic stent.

Comparator: Preventative stoma.

Study designs to be included: RCTs or retrospective non-randomized controlled studies.

Eligibility criteria: (1) RCTs or retrospective non-randomized controlled studies on stent vs preventative stoma as a bridge to surgery in patients with malignant large bowel obstruction. (2) All patients should be planned to take selective resection surgery (3) Published in English (4) Newcastle-Ottawa Scale scores >6.

Information sources: We will systematically search the electronic databases, including PUBMED, MEDLINE, EMBASE, the Cochrane Library, International Clinical Trails Registry Platform and Google Scholar databases, for all literatures that may meet the predetermined inclusion criteria.

Main outcome(s): The primary outcomes will be 3-year overall survival, procedure-relative complication rate and short-term mortality.

Additional outcome(s): The secondary outcomes will be permanent stoma rate, additional intervention and time from SEMS or stoma to resection.

Data management: EndNote X9 software (Clarivate Analytics) will be employed to manage all citations, as well as for duplicates screening.

Quality assessment / Risk of bias analysis: To Assess the methodological quality of included studies, the Newcastle-Ottawa Scale (NOS) will be used to score them from 0 to 9. Each included study will be assessed from the following three aspects: case selection(0-4), comparability(0-2), and outcome(0-3). Articles marked 6 or higher will be considered as a qualified study.

Strategy of data synthesis: The RevMan 5.3 software (The Nordic Cochrane Centre, The Cochrane Collaboration, Copenhagen, Denmark) will be employed for statistical analysis. Since all the outcomes are dichotomous variances, fixed-effects models will be used in all meta-analyses. And the relative risks (RR) and 95% confidence intervals (CIs) will be estimated by using the Mantel-Haenszel method.

Subgroup analysis: We will conduct subgroup analysis on the basis of sex, age and so on, to explore possible sources of heterogeneity.

Sensibility analysis: We will conduct sensibility analysis by separately excluding the impact of each study on the overall combined results.

Language: English only.

Country(ies) involved: China.

Keywords: Large bowel obstruction, Colorectal cancer, Stent, SEMS, Stoma, Bridge to surgery.

Contributions of each author:
Author 1 - Jianhao Zhang - Research design, feasibility identify of the studies, manuscript draft and data analysis.
Author 2 - Wenming Yang - Retrieval of the literature and data extraction.
Author 3 - Xueting Liu - Author 3 contributed equally to this systematic review and meta-analysis with author 2.