

INPLASY202470114

doi: 10.37766/inplasy2024.7.0114

Received: 28 July 2024

Published: 28 July 2024

Corresponding author:

Bingqing Ma

mbqyeah123@163.com

Author Affiliation:

Wuhan Union Hospital.

Ma, B; Ren, T; Cai, C; Chen, B; Zhang, J.

ADMINISTRATIVE INFORMATION**Support** - None.**Review Stage at time of this submission** - Completed but not published.**Conflicts of interest** - None declared.**INPLASY registration number:** INPLASY202470114**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 28 July 2024 and was last updated on 28 July 2024.**INTRODUCTION**

Review question / Objective P: The patients with advanced obstructive colorectal cancer (AOCC). I: Palliative self-expanding metal stents (SEMSs). C: Palliative surgery methods. O: Clinical success, early complications, late complications, stoma formation rate, hospital stay, 30-day mortality, overall survival S: Cohort study.

Rationale Colorectal cancer (CRC) is the third most common cancer in the United States and ranks second in cancer-related mortality. In 2019, approximately 60% of newly diagnosed cases were in advanced stages, and this proportion has been gradually increasing. With the recent enhanced standardization of CRC screening, an increasing number of younger patients have been diagnosed. Moreover, advanced-stage cases are more prevalent in this demographic group. Obstruction is the most common complication of CRC; approximately 30% of patients exhibit symptoms of obstruction, which often correlates

with a poor prognosis. The condition of patients with advanced obstructive colorectal cancer (AOCC) is particularly complex. These patients typically require urgent decompression to prevent severe abdominal distension, electrolyte imbalance, septic shock, or even death.

The placement of self-expanding metal stents (SEMSs) has increasingly become the standard treatment for relieving the symptoms of CRC obstruction. Initially designed to alleviate obstruction symptoms in patients with advanced stage disease, SEMS placement can serve as a bridge to surgery. For patients with AOCC, SEMS placement undoubtedly offers benefits such as minimal invasiveness, rapid relief, and high patient tolerance. However, clinicians must consider potential complications such as reobstruction, perforation, stent migration, and cancer cell dissemination. In addition, considering the long-term complications caused by SEMS, the SEMS is not convincing for the long-term prognosis of patients. In patients with AOCC eligible for chemotherapy and a long life expectancy, palliative

treatments other than SEMS should be considered[5].

Traditionally, surgery has been a palliative treatment for AOCC. Procedures may include primary tumor resection and anastomosis, simultaneous stoma creation, simple stoma surgery, Hartmann's procedure, or bypass surgery. Surgical decisions, including the choice of procedure, are typically made by the surgeon based on the intraoperative findings and the patient's overall condition. Some studies have suggested that resection of the primary tumor can lead to better quality of life and improved overall survival rates in patients with advanced-stage disease. However, these benefits warrant further study and detailed discussion, particularly for patients exhibiting obstruction symptoms. Additionally, guidelines and studies investigating direct prognostic comparisons between various surgical approaches for patients with AOCC are lacking.

Condition being studied Several previous meta-analyses have compared the palliative effects of SEMS and surgery for malignant colorectal obstruction (MCO). However, some of these studies included patients with obstructions caused by other malignancies such as gynecological and urological cancers. Moreover, some studies used mean survival time to compare patient survival duration. We believe that hazard ratios (HR) are more convincing in comparing treatment approaches. Additionally, to our knowledge, no meta-analysis has directly compared the palliative efficacies of different surgical and other treatment methods for AOCC. To address these gaps in research, we conducted a meta-analysis involving a comprehensive search of the most recent comparative literature.

METHODS

Search strategy The following databases were searched: PubMed, Web of Science, MEDLINE, and Cochrane Library. There were no restrictions regarding the publication date or language, and all studies that met the inclusion criteria were included. Our search strategy was formulated based on the following keywords: 'colorectal cancer,' 'advanced,' 'incurable,' 'obstruction,' 'palliative,' 'stent,' 'surgery,' 'stoma,' and several related phrases.

Participant or population

- 1) Patients with advanced, incurable colorectal cancer
- 2) Patients with obstructive colorectal cancer

- 3) Patients who underwent SEMS or surgical procedures, including tumor resection with or without stoma creation, Hartmann's procedure, simple stoma creation, and bypass, among others, and in whom at least one outcome of interest was comparatively analyzed

- 4) The study objective(s) addressed alleviating patient symptoms and facilitating prompt systemic treatment.

Intervention Patients who underwent SEMS.

Comparator Patients who underwent surgical procedures, including tumor resection with or without stoma creation, Hartmann's procedure, simple stoma creation, and bypass.

Study designs to be included Cohort study.

Eligibility criteria

Inclusion Criteria:

- 1) Patients with advanced, incurable colorectal cancer
- 2) Patients with obstructive colorectal cancer
- 3) Patients who underwent SEMS or surgical procedures, including tumor resection with or without stoma creation, Hartmann's procedure, simple stoma creation, and bypass, among others, and in whom at least one outcome of interest was comparatively analyzed
- 4) The study objective(s) addressed alleviating patient symptoms and facilitating prompt systemic treatment

Exclusion Criteria:

- 1) SEMS or surgical procedures intended for bridging to surgery (BTS)
- 2) Patients without obstructive symptoms
- 3) Obstruction caused by malignancies other than AOCC
- 4) Studies that did not compare outcomes or single-arm trials.

Information sources Only researches in the following databases: PubMed, Web of Science, MEDLINE, and Cochrane Library.

Main outcome(s) Clinical success, early complications, late complications, stoma formation rate, hospital stay, 30-day mortality, overall survival.

Quality assessment / Risk of bias analysis The Newcastle-Ottawa scale (NOS) was used to assess the quality of non-randomized controlled trials (non-RCTs), while the Cochrane tools (risk of bias tool, Rob tool) were used for evaluating RCTs.

Strategy of data synthesis Statistical Analysis: SEMS vs. Surgery

All analyses were conducted using the meta package in R software, version 4.3.1. The chi-square test and Student's t-test were used to compare differences between the two groups, with a p-value < 0.05 indicating statistical significance. For the binary variable results, the odds ratio (OR) or risk ratio (RR) and their respective 95% CIs were used for meta-analysis and comparison. Continuous variables were compared using standardized mean difference (SMD) and 95% CI. If the 95% CI of the OR and RR did not cross 1, and the 95% CI of SMD did not cross 0, the results were deemed statistically significant.

Heterogeneity between studies was assessed using the I² statistic and Q-test. I² > 50% was considered indicative of heterogeneity. To mitigate the risk of bias, results with notable heterogeneity were combined using a random-effects model. Results without discernible heterogeneity were aggregated using a fixed-effects model. For results that exhibited heterogeneity, subgroup analyses were performed based on the publication year, tumor location, and type of study.

Funnel plots and Egger's test were used to evaluate publication bias. A p-value < 0.05 was considered indicative of potential publication bias.

Statistical Analysis: SEMS vs. PTR vs. S/B

Surgical interventions were further stratified into two categories: primary tumor resection (PTR) and stoma creation/bypass (S/B). The objective of this analysis was to discern any differences in the prognosis of AOCC between these two procedures and compare them with that of SEMS placement.

We used Bayesian Network Analysis to analyze the outcomes of these three interventions. All analyses were performed using R software (version 4.3.1), specifically the BUGSnet package. For analysis of the binary and continuous data, outcomes were compared through ln (OR) and mean difference (MD) with their respective 95% CIs. If the 95% CI did not exceed 0, the difference was considered statistically significant. Each outcome set was aggregated using a random-effects model.

For each outcome type, we constructed network plots and developed ranking diagrams to show the results. Leverage plots were used to assess the fit of the models.

Subgroup analysis Subgroup analysis was based on publication year, tumor location, and study type.

Sensitivity analysis Sensitive analyses were conducted by removing each individual study to evaluate whether any single study had a significant impact on pooled estimates.

Language restriction None.

Country(ies) involved China.

Keywords Advanced obstructive colorectal cancer; Surgery; SEMS.

Contributions of each author

Author 1 - Bingqing Ma.

Author 2 - Tianxing Ren.

Author 3 - Chengjun Cai.

Author 4 - Biao Chen.

Author 5 - Jinxiang Zhang.