

Comparison of Emergency Resection, Self-Expanding Metallic Stents and Decompressing Stoma for Left-Sided Obstructive Colon Cancer: A Protocol for Systematic Review and Network Meta-Analysis

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Study protocol

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Abstract

Background: The optimal management strategy for patients with left-sided obstructive colon cancer remains unclear. The aim of this study is to compare the efficacy and safety of emergency resection (ER), self-expanding metallic stents (SEMS) and decompressing stoma (DS) for left-sided obstructive colon cancer.

Methods: Electronic searches by titles/abstracts of ER, SEMS and DS for left-sided obstructive colon cancer will be performed using the following electronic bibliographic databases: PubMed, Cochrane Library, Embase and clinical trials. The protocol of this network meta-analysis has been registered on PROSPERO (CRD42021243097). The primary outcomes are the oncological outcomes such as local recurrence rate and overall and disease-free survival. Secondary outcomes of this study include peri- and postoperative outcomes, successful primary anastomosis, temporal and permanent stoma. Included randomized controlled trials will be evaluated on their risk of bias with the Cochrane Collaboration's risk of bias tool. The quality of *observation studies* will be assessed using Risk Of Bias In Non-Randomized Studies of Interventions (ROBINS-I) tool. The overall quality of the evidence will be judged based on Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) criteria in the network meta-analysis. *Heterogeneity, publication bias, subgroup analysis and sensitivity analysis will be explored.*

Discussion: Considering the importance of acute intestinal obstruction in left-sided colon cancer, we hope that this network meta-analysis can aid and accelerate the consolidation of evidence, such that health-care professionals and patients are provided with high-quality evidence to facilitate decisions on how to manage patients with left-sided obstructive colon cancer. We will conduct subgroup and sensitive analysis to determine *the potentially appropriate population* for either ER or a bridge to surgery (SEMS or DS) and provide *a foundation for future* studies from our network meta-analysis.

Introduction

Colorectal cancer is an important contributor to cancer mortality and morbidity, ranking as the third most common diagnosed cancer and the third -leading cause of cancer death in the United States[1]. Left-sided obstructive colon cancer is a significant clinical event, which accounts for about 20% of colonic neoplasms[2]. Moreover, this cohort of patients are often elderly and frail with multiple co-morbidities[3]. One third of patients with left-sided obstructive colon cancer never undergo curative resection [4] and many patients still require systemic cytotoxic chemotherapy, molecular targeted therapy and immunotherapy[5].

Most patients with left-sided obstructive colon cancer have been managed with several ways such as emergency primary resection, stent placement as bridge to surgery or diverting colostomy construction as a bridge to surgery[6, 7]. Several emergency surgical resection options are available for left-sided obstructing colonic cancer, including Hartmann's procedure and primary resection with either primary

anastomosis and/or stoma[8, 9], but permanent stoma, high surgical morbidity and mortality rates are serious socio-psychoeconomic problems[3]. A bridge to elective surgery approach was recommended to these patients. Self-expanding metal stent (SEMS) placement and decompressing stoma (DS) are two bridge to elective surgery techniques currently used clinically. SEMS, as a least invasive technique, are an effective method with no increase in mortality for left-sided obstructive colon cancer[10, 11]. However, many questions on the SEMS remain unanswered, most notably its stent related perforation, unsuccessful decompression, an increasing risk of tumor cell spreading due to tumor compression and long-term survival[10, 12–14]. DS, as another bridge to surgery, leads to decreased surgical mortality and morbidity and no potential procedure-related oncologic risks, but confers a prolonged length of hospital stay, increased number of surgical interventions and decreased quality of life[15–18]. Although several options exist in current practice, the optimal management of left-sided obstructive colon cancer is less clear[9].

Three pairwise meta-analyses of randomized clinical trials demonstrated that SEMS intervention resulted in significantly higher successful primary anastomosis and lower overall stoma rates comparing with emergency resection (ER)[10, 19, 20]. In contrast, a pairwise meta-analysis of five randomized clinical trials and 16 observational studies showed that there was no statistically significant difference between SEMS and ER in terms of oncological outcomes and local recurrence rate. Interestingly, a further sensitivity analysis showed a positive trend, though not significant, of ER was associated with better three-year survival when only randomized clinical trials were taken into account[21]. Furthermore, a pairwise meta-analysis showed that, compared with ER, DS achieved significantly more favorable rates of permanent stoma and primary anastomosis, although there were no significant differences between two groups regarding 30-day mortality and morbidity[6]. Recently, the results of a meta-analysis comparing ER with SEMS or DS indicated that SEMS led to better short-term outcomes but conferred no long-term survival advantage over ER. Similarly, these results on long-term survival were further confirmed by a recent real-world population-based analysis[22]. However, it was unclear whether SEMS had better short-term outcomes compared to decompressing stoma, because there was a lack of randomized controlled trials with long-term outcomes for SEMS versus DS[7].

Previous traditional pairwise meta-analyses have compared efficacy and safety of ER, SEMS and DS using only the direct comparison model, with somewhat inconsistent results. To address this question, it is necessary to carry out a network meta-analysis to comprehensively compare the effects of different agents based on randomized controlled trials and observational studies. In this network meta-analysis, we aim to compare the efficacy and safety of ER, SEMS and DS for left-sided obstructive colon cancer.

Methods And Design

We will conduct and report this protocol of network meta-analysis in accordance with the recommendations of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocol (PRISMA-P)[23]. The protocol of this network meta-analysis has been registered on PROSPERO (CRD42021243097)

Search strategy

Electronic searches by titles/abstracts of ER, SEMS and DS for left-sided obstructive colon cancer will be performed using the following electronic bibliographic databases: PubMed, Cochrane Library, Embase and clinical trials (www.clinicaltrials.gov). The planned time frame of the electronic searches will be from the inceptions of the databases to March 31, 2021. Two authors (QC H and QF W) will independently conduct all the relevant studies screening to identify potentially eligible articles. Moreover, we will manually screen relevant references of prior meta-analyses and systematic reviews to identify additional potentially eligible studies. We will record the reasons for exclusion for records at the full text screening stage and illustrate the study selection process via a standard PRIMSA flow diagram[24].

The preliminary search strategies will include the following medical subject heading (MeSH) terms and their entry terms: 'left-sided obstructive colon cancer', 'surgery', 'decompressing stoma' and 'self expandable metallic stents', according to Population Intervention Comparison Outcomes Study Design (PICOS) statement. All searches will be performed with MeSH terms and text words combined using the Boolean operators "AND" or "OR" in Title/Abstract. The details of the search strategy for PubMed are provided in online supplementary file 1 (see the appendix 1).

Two reviewers will perform a pilot-test independently to evaluate the inter-rater reliability at each screening stage. Two trained reviewers will independently screen the titles and abstracts for potentially eligible studies based on inclusion criteria. Moreover, two reviewers will retrieve potentially eligible studies and independently re-evaluated by reading the full text. They resolved any disagreements in screening by discussion or, if needed, with the help of a third independent reviewer.

Eligibility criteria

The eligibility criteria must include the followings: 1. Participants: left-sided obstructive colon cancer defined as a tumor originating from the distal transverse colon to the anus[9]; 2. Interventions and Comparators: ER, SEMS and DS. ER of any kind is considered, including intraoperative colonic lavage, subtotal colectomy, or temporary bowel stoma with or without primary anastomosis[20]; 3. Study design: Randomized controlled trials (RCTs), prospective studies and retrospective studies; 4. Outcomes: The primary outcomes are the oncological outcomes such as local recurrence rate, overall survival (OS) and disease-free survival (DFS). Secondary outcomes of this study include peri- and postoperative outcomes, successful primary anastomosis, temporal and permanent stoma. SEMS outcomes include rates of technical and clinical success and complications. Technical success is defined as successful stent deployment and placement across the stricture and clinical success was defined as adequate resolution of obstruction up to within 72h of stent insertion without reintervention[25]. Locoregional recurrence is defined as a recurrence at the level of the anastomosis, in a locoregional lymph node or a peritoneal metastasis. Successful primary anastomosis is defined as primary anastomosis with no related anastomotic adverse events; 5. Studies must be required to provide enough information to calculate hazard ratios (HRs) and 95% confidence intervals (CIs); 6. Publication date, language and status will be *not* considered; 7. No restriction will be applied regarding age, gender, nationality and ethnicity.

Data extraction and management

ENDNOTE X7 (Thomson Reuters, Canada) literature management software will be used to manage search records. A standardized spreadsheet will be created in Microsoft Excel 2010 (*Microsoft*, Redmond, Washington, USA) to collect relevant information of interest, such as the first author, year of publication, study design, enrolment period, number of patients included, mean age, gender distribution, indication for treatment, technical success of stent positioning, clinical success of stent positioning, adverse events related to stent positioning, overall adverse events rate, rate of surgery due to adverse events, hospital length of stay, temporary and permanent stoma, successful primary anastomosis, local recurrence rate, overall survival and disease-free survival.

Bias risk

Risk of bias for individual RCTs will be assessed by the Cochrane Collaborations risk of bias tool[26], including the following domains: random sequence generation, allocation concealment, blinding of participants and personnel, incomplete outcome data, selective outcome reporting, and other bias. Trials will be classified into three categories: low risk, high risk and unclear. High risk is defined as studies with high risk of bias for one or more domains. Low risk is defined as individual studies with low risk of bias for all domains. Two reviewers will independently assess and report the risk of bias of each trial as low risk of bias "+", high risk of bias "-", or unclear risk of bias "?". The quality of non-randomised comparative trials will be assessed using Risk Of Bias In Non-Randomized Studies of Interventions (ROBINS-I) tool[27]. Any disagreement regarding risk of bias will be resolved through discussion between the two reviewers, or an assessment by a senior author.

Quality of evidence

We will evaluate the quality of the evidence using the Grades of Recommendation, Assessment, Development, and Evaluation (GRADE). While taking into account the limitations of the risk of bias, inconsistency, indirectness, imprecision, and publication bias, the quality of the evidence is divided into four categories (high, moderate, low and very low)[28]. For RCTs, the starting confidence level for each network estimate is high, but will be rated down by one or more of five different domains of limitations. In the GRADE approach, observational studies receive an initial low evidence, which can upgrade according to one or more of the three domains (large effect, plausible confounding and dose-response gradient)[29]. *We will use the GRADEprofiler software (Version 3.6) to evaluate the quality of included studies in the network meta-analysis.*

Direct comparison and network meta-analyses

If an intervention no less than two clinical trials we will first conduct series of conventional pairwise meta-analyses for each direct comparison between two interventions with Stata V.13.0 (StataCorp, College Station, TX, USA). Moreover, we will draw network map, contribution graph, assessment of global heterogeneity and local heterogeneity, comparison-adjusted funnel plot, surface under the cumulative

ranking (SUCRA) graphs and forest plot. The weight of nodes and edges in the network map will be proportional to the corresponding number of patients. A contribution plot will also be constructed to measure the percent contribution of direct and indirect comparisons in the entire network. A comparison-adjusted-funnel plot will be conducted to assess the potential publication bias of network meta-analysis. To compare three interventions for left-sided obstructive colon cancer through integrating all direct and indirect evidence, network meta-analysis for all outcomes is planned using GeMTC version 1.4.3 (MRC Biostatistics Unit, Cambridge, UK). Results regarding the technical success of stent positioning, clinical success of stent positioning, adverse events related to stent positioning, overall adverse events rate, rate of surgery due to adverse events, hospital length of stay, temporary and permanent stoma, successful primary anastomosis, local recurrence rate are expressed as odds ratios (ORs) for dichotomous outcomes with 95% confidence intervals (CIs)/ credible intervals (CrIs). In addition, HRs with 95% (95% CIs/ CrIs) for DFS and OS will be calculated by pooling the arms of identified studies. Both fixed and random effects models will be run for outcomes of interest in the *conventional* pairwise meta-analysis[30]. The I^2 statistic for heterogeneity will be employed to estimate fixed or random effects models. Fixed effects models will be used in case of minor *heterogeneity* ($I^2 < 50\%$), otherwise the random effects models will be generated[31]. The inconsistency of Bayesian network meta-analysis will be compared using the deviance information criterion (DIC), of which a change of five points or more is considered significant[32, 33]. The node-splitting method and loop-specific approach will be employed to evaluate inconsistency between direct and indirect comparisons if a triangular loop exists in network meta-analysis[34, 35]. If there is no inconsistency on both overall and local tests, we will use a consistency model to draw conclusions about the relative effect of three interventions for left obstructive colon cancer[34]. The group with SUCRA of being the most effective in term of efficacy and safety will be evaluated based on the network meta-analysis results. The efficacy and safety of *the* three interventions would be certain to be better with a higher SUCRA, on the contrary, they would be certain to be worse with a lower SUCRA. The cluster analysis will be performed to assess comprehensively the efficacy and safety of *the* three interventions based on SUCRA value. A two-sided P-value < 0.05 will be considered statistically significant.

Transitivity, homogeneity and consistency assumption

In order to obtain valid and reliable results, we will assess the transitivity assumption, homogeneity assumption and consistency assumption before performing the network meta-analysis[36]. We will conduct a thorough comparison of the baseline characteristics of patient, study design information, interventions and controls[37]. If substantial heterogeneity is found, meta-regression will be used to explore possible sources of heterogeneity[38]. The possible reasons of high heterogeneity will be explored through subgroup analysis described below[39]. To detect consistency between direct and indirect comparisons, we will apply both local and global methods[35, 40].

Subgroup and sensitivity analyses

We will conduct post hoc subgroup analyses for primary outcomes and secondary outcomes according to age (≥ 70 years and < 70 years). In addition, the following subgroup analyses will be as follows: *tumor location* (splenic flexure vs descending colon vs sigmoid), prior abdominal surgery, metastatic stage at presentation [no metastasis (*M0*) vs metastasis (*M1*)] and length of stenosis (> 4 cm vs ≤ 4 cm).

To assess the robustness of our findings, a number of sensitivity analyses will be conducted to determine the impact of Bayesian model (fixed-effect model vs random-effect model), study design (RCTs vs observation studies) and studies at high risk of bias. To determine whether any one study explains the observed heterogeneity, additional sensitivity analyses will be performed by sequentially excluding the included studies, one at a time[41].

Discussion

In the complex clinical condition and tumor-related hallmarks, there is no clear consensus regarding the optimal treatment of left-sided obstructive colon cancer. Current guidelines suggest that either ER or a bridge to surgery with either SEMS or DS could be taken into account *when deciding on implementing interventions*[42, 43]. In fact, it is difficult to perform multicenter RCTs because of practical difficulties such as insufficient patient numbers and surgical techniques. Furthermore, it is not possible to blind patients in RCTs, comparing surgery with SEMS in patients undergoing *implementing interventions*. Thus, *good quality evidence is lacking* to determine the best long-term strategy for the management of left-sided obstructive colon cancer in terms of efficacy, safety, cost and utility[44]. It is necessary to carry out a network meta-analysis to comprehensively compare the efficacy and safety of ER, SEMS and DS for left-sided obstructive colon cancer based on RCTs and *observational studies*. In addition, we will conduct subgroup analysis to determine *the potentially appropriate population for* either ER or a bridge to surgery and provide *a foundation for future* studies from our network meta-analysis.

The use of SEMS as a bridge to surgery for left-sided obstructive colon cancer *has been increasingly used in* qualified medical centers[45]. A potential advantage of the bridge to surgery approach is the ability to decompress the colon, preserve perforation and sepsis, provide time for staging and *multidisciplinary* comprehensive treatments[46]. Another potential advantage of preoperative SEMS is the ability to cleanse the colon to enable a one-stage operation, by avoidance of two-stage operation to a risk of failure and improve quality of life without undertaking a further treatment to a stoma[46]. *The use of SEMS is increasing with continuous improvements in surgical technology*[43]. However, the local recurrence rate of cancer and disease-free survival rate were contradictory between SEMS and ER in several studies[47-51].

When the efficacy and complications are comparable between SEMS, ER and DS in patients with left-sided obstructive colon cancer, cost-effectiveness is another important aspect of antitumor treatment[52]. SEMS is a more cost-effective palliative intervention than ES in patients with metastatic colon cancer at the time of acute colonic obstruction[53]. However, ES might offer the best *survival* advantages compared with SEMS[53]. Although randomized prospective head-to-head comparisons between SEMS and DS for

left-sided obstructive colon cancer are lacking, we could conduct cost-effectiveness analysis between SEMS and DS with indirect comparisons through network meta-analysis. Future studies may explore how to effectively integrate cost-effectiveness analysis and network meta-analysis between ES, SEMS and DS in patients with *intestinal obstruction*, including both locally *advanced* and metastatic colon cancer.

As we known, there is little network meta-analysis which has evaluated efficacy and safety between ES, SEMS and DS in patients with left-sided obstructive colon cancer. A subgroup analysis will be also performed to explore whether one of three interventions is tailored to a *specific* group of patients that have not shown in other meta-analyses. Considering the importance of acute intestinal obstruction in left-sided colon cancer, we hope that this network meta-analysis can aid and accelerate the consolidation of evidence, such that health-care professionals and patients are provided with high-quality evidence to facilitate decisions on how to manage patients with left-sided obstructive colon cancer.

Review status

We have commenced searching relevant studies in the databases as *mentioned above* from 31 March, 2021 until 30 April, 2021. The protocol of this network meta-analysis has been registered on PROSPERO (CRD42021243097). The network meta-analysis is expected to be complete by December 2021.

Abbreviations

ER

emergency resection; SEMS:self-expanding metallic stents; DS:decompressing stoma; PRISMA-P:Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocol; PICOS:Population Intervention Comparison Outcomes Study Design; MeSH:medical subject heading; OS:overall survival; DFS:disease-free survival; RCTs:Randomized controlled trials; SUCRA:surface under the cumulative ranking; DIC:deviance information criterion; ORs:odds ratios; HRs:hazard ratios; CIs:confidence intervals; CrIs:credible intervals; ROBINS-I:Risk Of Bias In Non-Randomized Studies of Interventions; GRADE:Grades of Recommendation, Assessment, Development, and Evaluation; M0:no metastasis; M1:metastasis;

Declarations

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Not applicable.

Authors' contributions

HF G and QC H conceived and designed the network meta-analysis and wrote the paper. QC H and QF W developed the search *strategy* and participated in the literature search. QC H, SR T, QY H and X W will participate in data analysis and clinical interpretation of the findings and will conceive and write the final draft of the manuscript. HF G will provide critical revision of the manuscript and serve *as guarantor* for

the contents of this manuscript. All authors read, provided critical feedback and approved the final version of the protocol to be published.

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Availability of data and materials

Not applicable.

Ethics approval and consent to participate

Ethical approval was not required for this network meta-analysis.

Consent for publication

Not applicable. This article does not contain any individual participant data.

Competing interests

The authors declare that they have no actual or potential competing interests.

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