

INPLASY PROTOCOL

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The authors have no conflicts of interest to disclose.

INTRODUCTION

Review question / Objective: We will conduct a systematic review and meta-analysis to estimate the efficacy and safety of the application of neck anastomotic muscle flap embedded in three-incision

Application of neck anastomotic muscle flap embedded in three-incision radical resection of oesophageal carcinoma: a systematic review and meta-analysis protocol

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Review question / Objective: We will conduct a systematic review and meta-analysis to estimate the efficacy and safety of the application of neck anastomotic muscle flap embedded in three-incision radical resection of oesophageal carcinoma. **Condition being studied:** Oesophageal cancer is one of the most common malignant tumours and has been identified as one of the leading causes of cancer death worldwide. Surgery is considered to be the optimal treatment for patients with resectable oesophageal cancer. Oesophagectomy for oesophageal cancer can significantly extend the survival period of patients and provide a potential opportunity for a cure. However, there is still controversy regarding application of neck anastomotic muscle flap embedded. This systematic review and meta-analysis will be performed to determine whether the application of neck anastomotic muscle flap embedded would benefit patients more.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 14 August 2020 and was last updated on 14 August 2020 (registration number INPLASY202080059).

radical resection of oesophageal carcinoma.

Rationale: Oesophageal cancer is one of the most common malignant tumours and has been identified as one of the leading causes of cancer death worldwide. Surgery is considered to be the optimal treatment for patients with resectable oesophageal

cancer. Oesophagectomy for oesophageal cancer can significantly extend the survival period of patients and provide a potential opportunity for a cure. However, there is still controversy regarding application of neck anastomotic muscle flap.

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METHODS

Participant or population: The participants will be patients diagnosed with resectable, pathologically confirmed oesophageal cancer who were treated with video-assisted thoracoscopic oesophagectomy, and there will be no restrictions on sex, ethnicity, economic status, or education.

Intervention: All types of video-assisted thoracoscopic oesophagectomy with application of neck anastomotic muscle flap embedded or not for patients diagnosed with resectable oesophageal cancer will be studied.

Comparator: Application of neck anastomotic muscle flap embedded or not for patients diagnosed with resectable oesophageal cancer will be studied.

Study designs to be included: Randomized controlled trials (RCTs), quasi-RCTs, propensity score matched comparative studies and prospective cohort studies of interest.

Eligibility criteria: The participants will be patients diagnosed with resectable, pathologically confirmed oesophageal cancer who were treated with video-assisted thoracoscopic oesophagectomy, and there will be no restrictions on sex, ethnicity, economic status, or education.

Information sources: Two reviewers (ZWT and XJY) will search PubMed, Web of Science, Cancerlit, Embase, Cochrane Central Register of Controlled Trials, and Google Scholar databases for relevant trials published before October 1, 2020, without any language restrictions.

Main outcome(s): The primary outcome will be overall survival of patients with resectable oesophageal cancer after surgery.

Additional outcome(s): We will evaluate the 5-year survival, esophageal stomal leak, recurrence-free survival, and median survival rates as well as the quality of life and complication rate of patients with resectable oesophageal cancer after surgery.

Data management: We will extract the following data from the included trials. • Study characteristics: author, publication date, country, study design, randomization, periods of data collection, follow-up duration, withdrawals, and overall duration of study. • Population characteristics: age, sex, pathology diagnosis, tumour stage, pathologic tumour size, performance status, ethnicity, history of smoking, and inclusion criteria. • Interventions: type of operation, number of lymph nodes retrieved, extent of resection, duration of operation, bleeding, and postoperative adjuvant therapy. • Outcomes: overall survival, 5-year survival, recurrence-free survival, median survival, length of stay, length of ICU stay, quality of life, complications, and adverse events. We will use the pre-designed table to record the data extracted from the included trials. If relevant data from the trials are lost or unclear, we will consult the author via email before determining whether the study is to be included.

Quality assessment / Risk of bias analysis:

The Cochrane Handbook for Systematic Reviews of Interventions will be used to assess the risk of bias of each trial included. The two authors (ZWT and XJY) will evaluate the risk of bias based on the following domains: random sequence generation (selection bias), allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias), selective outcome reporting (reporting bias), and other biases. The risk of bias in each domain will be assessed as high, low, or uncertain, and the results of the evaluation will be shown on the risk of bias graph. EPOC guidelines will be used to assess the risks of the non-randomized controlled trials included.

Strategy of data synthesis: We will use Review Manager and Stata software to synthesise the data extracted. If the data extracted from the included studies are evaluated as highly homogeneous, we will use them to conduct a meta-analysis for the purpose of obtaining a clinically meaningful result. To carry out a standard meta-analysis, we will use the Chi² and I² statistical tests to evaluate statistical heterogeneity among the studies. If there is high heterogeneity ($p > 50\%$), we will use the DerSimonian and Laird random effect model to analyse the extracted data. Because high heterogeneity may be caused by different types of tumours and different stages of tumours diagnosed by pathology and different means of adjuvant therapy may be used after the operation, we will perform a subgroup analysis of the types of tumours (oesophageal squamous cell carcinoma and oesophageal adenocarcinoma), the pathological stages of the tumours, and the means of adjuvant therapy after the operation (types of chemotherapeutic drugs and whether or not radiotherapy is accepted). Otherwise, we will adopt a fixed-effect model to analyse the data. We will adopt the Mantel-Haenszel method to pool the binary data, and the results will be reported in the form of relative risk (RR) with a 95% confidence interval (CI). An inverse variance analysis

method will be used to pool the continuous data, and the results will be reported in the form of a standardized mean difference (SMD) with a 95% confidence interval (CI).

Subgroup analysis: If there is substantial heterogeneity and if the available data are sufficient, we will perform subgroup analysis to search for potential origins of heterogeneity. If the extracted data are enough, we will conduct subgroup analysis of the type of operation, type of tumour, tumour stage, age, and postoperative adjuvant treatment.

Sensitivity analysis: We will conduct a sensitivity analysis to evaluate the robustness and reliability of the aggregation results by eliminating trials with a high bias risk. If a reporting bias exists, we will use the methods of fill and trim to analyse for publication bias.

Language: Without any language restrictions.

Country(ies) involved: China.

Keywords: Oesophageal cancer, three-incision, radical resection, muscle flap of embedding, esophageal stomal leak.

Contributions of each author:

Author 1 - Zhangwei Tong - drafted the manuscript.

Author 2 - Xiaojie Yang - The author provided statistical expertise.

Author 3 - Fei Luo - The author contributed to the development of the selection criteria, and the risk of bias assessment strategy.

Author 4 - Jiafu Zhu - The author read, provided feedback and approved the final manuscript.

Author 5 - Jiangbo Lin - The author read, provided feedback and approved the final manuscript.