INPLASY

INPLASY202480054

doi: 10.37766/inplasy2024.8.0054

Received: 10 August 2024

Published: 10 August 2024

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Prophylactic cranial irradiation in patients with resected small-cell lung cancer: a protocol of systematic review and meta-analysis

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ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - The review has not yet started.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202480054

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 10 August 2024 and was last updated on 10 August 2024.

INTRODUCTION

Review question / Objective This metaanalysis will evaluate the efficacy of PCI in SCLC patients who have undergone surgical resection. The overall survival (primary outcome) and incidence of brain metastasis (secondary outcome) of resected SCLC patients with postoperative PCI treatment will be compared to those without PCI.

Condition being studied The majority of SCLC patients at diagnosis have distant metastases, and about half develop brain metastases as the disease progresses. Prior studies have shown that prophylactic cranial irradiation reduced brain metastasis and improved survival for patients with both limited and extensive stage SCLC. However, PCI is still controversial for T1-T2N0 patients since brain metastases are relatively uncommon in these patients. There is an increasing number of SCLC patients undergoing surgery in real-world settings, but the role of PCI for resected SCLC patients remains unclear. Herein, we plan to conduct a

comprehensive meta-analysis of survival outcomes of SCLC patients with or without postoperative PCI.

METHODS

Search strategy Two independent reviewers will conduct literature searches in PubMed, EMBASE, Cochrane (CENTRAL), Web of Science, and ClinicalTrial. The terms "small cell lung cancer", "cranial irradiation", and "surgery" will be searched using Medical Subject Headings (MeSH) terms.

Participant or population 1). Patients with pathological diagnosis of stage I-III SCLC. 2). Patients with radical resection for their lung tumor.

Intervention Postoperative prophylactic cranial irradiation(PCI).

Comparator No prophylactic cranial irradiation(PCI) for postoperative SCLC patients.

Study designs to be included Randomized controlled trials (RCT) and cohort studies.

Eligibility criteria We will exclude letters, editorials, commentaries, case reports, conference abstracts, meta-analyses, and reviews in literature screening. Literatures written in languages other than English will be excluded. Patients who only received chemoradiotherapy will be excluded.

Information sources Database: PubMed, EMBASE, Cochrane library (CENTRAL), Web of Science and ClinicalTrial. Others: scanning the reference lists of identified review articles.

Main outcome(s) Hazard Ratio (HR) and 95% confidence interval (CI) for overall survival (OS) between SCLC patients with or without postoperative PCI.

Additional outcome(s) Risk Ratio (RR) and 95% confidence interval (CI) for Brain metastasis rate (BMR) between SCLC patients with or without postoperative PCI.

Data management Endnote and Zotero will be used to manage records.

Quality assessment / Risk of bias analysis The eligible studies will be evaluated by the Newcastle-Ottawa Scale (NOS). Based on the NOS rating scale, a study that receives a score of >6 will be considered high quality.

Egger's tests and funnel plots will be used to assess publication bias, and trim-and-fill method will be used to evaluate pooled HR after potential bias was adjusted.

Strategy of data synthesis Forest plot will be used to analyze pooled HR and RR of OS and BMR for patients with postoperative PCI vs. those without postoperative PCI. Statistical heterogeneity across studies will be assessed using Q statistics and I2 test. An analysis of data will be conducted using a fixed effect model if the I2 value is less than 50%, indicating a relatively low degree of heterogeneity. Otherwise, random effect model will be used. All statistical analyses will be conducted in STATA 15.0.

Subgroup analysis A subgroup analysis for patients with resected, N0 SCLC will be conducted using pooled HR of OS for PCI vs. non-PCI group. RR of BMR for resected, N0 SCLC between two groups will also be analyzed if there're more than two studies reporting BMR in N0 subgroup.

Sensitivity analysis Sensitivity analysis will be performed to validate the stability of the pooled results. Each eligible study included in the meta-analysis will be omitted one at a time, and the pooled HR will be reevaluated in order to find out if there are any individual studies that contributed to heterogeneity. Studies that may cause significant change of the HR or RR will be discussed among several reviewers and we'll carefully assess the quality of these studies and exclude some of them if necessary.

Language restriction Only literatures written in English will be included in our study.

Country(ies) involved China.

Other relevant information Any conflict during literature screening and selection will be resolved by discussion or consensus with a third reviewer.

Keywords PCI; postoperative; SCLC; overall survival; brain metastasis rate; stage N0.

Contributions of each author

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