INPLASY PROTOCOL

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None declared.

The role of drug-eluting bead bronchial arterial chemoembolization in the treatment of non-small cell lung cancer: A protocol of meta-analysis

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Review question / Objective: **The objective of this study is to conduct a meta-analysis to comprehensively assess the effectiveness and safety of DEB-BACE in treating NSCLC and to investigate a novel therapeutic pathway for NSCLC.**
Eligibility criteria: **Reports in Chinese or English comparing the efficacy of DEB-BACE to other NSCLC treatment options will be included. Case reports, single-arm studies, conference papers, abstracts without full text, and reports published in languages other than English were not considered.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 25 March 2023 and was last updated on 25 March 2023 (registration number INPLASY202330096).

INTRODUCTION

Review question / Objective: **The objective of this study is to conduct a meta-analysis to comprehensively assess the effectiveness and safety of DEB-BACE in treating NSCLC and to investigate a novel therapeutic pathway for NSCLC.**

Rationale: **Non-small cell lung cancer (NSCLC) has a bad prognosis. Transvascular intervention is an important option in the treatment of NSCLC. Drug eluting bead bronchial artery chemoembolization (DEB-BACE) is the term for the technique of using DEBs loaded with chemotherapeutic drugs for BACE. The objective of this study is to**

conduct a meta-analysis to comprehensively assess the effectiveness and safety of DEB-BACE in treating NSCLC and to investigate a novel therapeutic pathway for NSCLC.

Condition being studied: Lung cancer is a common malignancy that has a bad prognosis and poses a serious risk to the health of the general public. Approximately 85% of all cases of lung cancer are non-small cell lung cancer (NSCLC), making it the most prevalent kind. Early-stage NSCLC is primarily treated with surgery, however, most patients are intermediate to advanced at the time of initial diagnosis and miss out on the chance to have surgery. Intravenous chemotherapy alone has limited efficacy and numerous side effects, and is poorly tolerated by patients. Targeted treatments and immunotherapy are generally beneficial but still have limitations in terms of application, and effective treatment alternatives for NSCLC are still urgently needed.

Angiogenesis is a key factor in the growth and proliferation of solid tumours. Transvascular intervention is an important option in the treatment of solid tumours, and it is equally applicable in the treatment of lung cancer. Through the first-pass effect of drugs and the embolization of blood vessels, the effect of drugs is enhanced and the blood supply to the tumor is reduced in order to inhibit tumor growth. New embolic materials have emerged as a result of recent developments in materials science, with drug eluting beads (DEBs) being one of the most brilliant. DEB bronchial artery chemoembolization (DEB-BACE) is the term for the technique of using DEBs loaded with chemotherapeutic drugs for bronchial artery chemoembolization (BACE). DEB-BACE has been successfully employed in a variety of advanced lung cancer, and has demonstrated very good therapeutic efficacy and safety. However, the sample sizes of studies on the use of DEB-BACE are currently small and there is still no evidence-based evidence on the benefit of DEB-BACE compared to other treatment modalities.

METHODS

Search strategy: #1 "Carcinoma, Non-Small-Cell Lung"[Mesh] OR “Carcinoma, Non Small Cell Lung” OR “Carcinomas, Non-Small-Cell Lung” OR “Lung Carcinoma, Non-Small-Cell” OR “Lung Carcinomas, Non-Small-Cell” OR “Non-Small-Cell Lung Carcinomas” OR “Nonsmall Cell Lung Cancer” OR “Non-Small-Cell Lung Carcinoma” OR “Non Small Cell Lung Carcinoma” OR “Carcinoma, Non-Small Cell Lung” OR “Non-Small Cell Lung Cancer” OR NSCLC
#2 DEB-TACE OR DEB-BACE OR “Drug-Eluting Bead Bronchial Arterial Chemoembolization” OR “Bronchial artery chemoembolization with drug-eluting beads” OR Microsphere OR embosphere OR hepasphere OR callisphere OR drug-eluting beads OR DEB OR “drug-eluting”
#3 #1 AND #2.

Participant or population: Patients with pathologically confirmed NSCLC who are being treated with DEB-BACE without regard for the combined chemotherapy regimen. We also do not restrict patients based on their age, gender, or ethnicity.

Intervention: DEB-BACE is the intervention.

Comparator: Treatment modalities that do not include DEB-BACE are control measures.

Study designs to be included: Comparative study.

Eligibility criteria: Reports in Chinese or English comparing the efficacy of DEB-BACE to other NSCLC treatment options will be included. Case reports, single-arm studies, conference papers, abstracts without full text, and reports published in languages other than English were not considered.

Information sources: Guocan Yu created search strategies for the relevant databases based on the research objectives, and Wuchen Zhao reviewed the search strategies and collaborated with Guocan Yu to improve them. We will not

impose constraints on language and date when searching the relevant databases. The search strategies for the rest of the databases are similar to those in Pubmed.

Main outcome(s): The primary outcomes evaluated in this study will be overall survival (OS) and progression-free survival (PFS).

Additional outcome(s): Secondary outcomes of objective response rate (ORR), disease control rate (DCR), and adverse events (AEs).

Data management: Study selection - Endnote X9.2 will import the literature found through searches in pertinent databases for additional review. First, duplicates were eliminated, next those that were plainly unrelated to the subject of the study were eliminated via the title and abstract, and finally, those that satisfied the inclusion requirements were kept by reading the entire text. Two researchers (Guocan Yu and Bo Ye) separately chose the literature, and where their results did not match, a debate was held to reach a consensus.
Data extraction - The two researchers previously mentioned will also carry out the data extraction with the literature that passes the requirements after screening. Discussions will be used to settle conflicts as well. The first author of the included literature, the year of publication, the nation where the study was conducted, the study type, sample size, patient gender, age, tumor classification, tumor stage, the number of treatment lines, the chemotherapy regimen, times of DEB-BACE, the median OS and PFS with the corresponding hazard ratios (HRs), ORR, DCR, and AEs will all be taken from the included literature.

Quality assessment / Risk of bias analysis: Risk of bias - The Cochrane Handbook for Systematic Reviews of Interventions [19] will be used by the same two researchers to independently assess the risk of bias for each included study. Selection bias, performance bias, detection bias, attrition bias, reporting bias, and other biases are the four criteria we'll use to assess the risk of bias.
Publication bias - We will utilize the funnel plots and Egger test to evaluate publication bias when there are more than 10 eligible papers included. We will get in touch with the study's corresponding author if we suspect publication bias for that particular study in order to find out more. If a study's publication bias is proven, the fill-and-trim procedure will be used to conduct a more thorough analysis.

Strategy of data synthesis: For the statistical analysis of the data, we will utilize RevMan 5.3 software (Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014). If only Kaplan-Meier curves are displayed in original research but median PFS and/or OS with HRs are not directly presented, survival statistics data will be extracted from the Kaplan-Meier curves using the Engauge Digitizer 4.1 software. We will estimate pooled odds ratios (ORs) for various AEs, risk ratios (RRs) for ORRs and DCRs, and HRs for OS and PFS. To assess the heterogeneity between studies, the Q-statistic will be utilized (22). When $I2 > 50\%$ or the $P < 0.1$ for the Q-statistic, heterogeneity between studies will be deemed statistically significant (23). When there is significant heterogeneity between studies, a random-effects model will be used to examine the data; otherwise, a fixed-effects model will be used. A statistical difference was defined as a P value < 0.05. A pooled HR > 1 denoted a higher risk of disease progression or mortality after DEB-BACE treatment, a pooled RR > 1 denoted a higher overall response, and a pooled OR > 1 denoted a higher level of toxicity of DEB-BACE treatment.

Subgroup analysis: We will perform subgroup analyses to further investigate the origins of heterogeneity where inter-study heterogeneity is significantly substantial and adequate data are available for the pertinent parameters. The study type, patient gender, age, tumor classification, tumor stage, number of treatment lines, chemotherapeutic

regimen, and times of DEB-BACE will be used to separate the pertinent subgroups.

Sensitivity analysis: By excluding studies with a high risk of bias, a sensitivity analysis will be performed to assess the dependability and robustness of the results of the aggregation. Doing a sensitivity analysis to evaluate whether the study is a high-risk study involves deleting one study and providing the analysis results with and without this study.

Language restriction: No.

Country(ies) involved: China.

Keywords: DEB, BACE, non small cell lung cancer, efficacy, safety, meta-analysis.

Contributions of each author:

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