

# INPLASY

## Efficacy and adverse event outcomes after surgical treatment and argon helium knife cryoablation for early stage non-small cell lung cancer: a systematic evaluation and meta-analysis

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### ADMINISTRATIVE INFORMATION

**Support** - None.

**Review Stage at time of this submission** - Data analysis.

**Conflicts of interest** - None declared.

**INPLASY registration number:** INPLASY202470080

**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 21 July 2024 and was last updated on 21 July 2024.

### INTRODUCTION

**Review question / Objective** Efficacy and adverse event outcomes after surgical treatment and argon helium knife cryoablation for early stage non-small cell lung cancer: a systematic evaluation and meta-analysis.

**Rationale** The latest statistics from the International Agency for Research on Cancer (IARC) 2022 show that lung cancer is the malignant tumor with the highest morbidity and mortality rate in China. Eighty-five percent of its histologic typing is categorized as non-small cell lung cancer (NSCLC), and because of its insidious early symptoms, the majority of patients are already in advanced stages when diagnosed. Studies have reported that the 5-year survival rate after surgery for stage I-II NSCLC is 77%-92%, while the survival rate after surgery for stage III-IV NSCLC is only 10%-36%, with a significant difference between the two. Early diagnosis and early treatment is the best strategy to improve the prognosis of NSCLC patients.

However, only about 30% of NSCLC patients are potential candidates for surgery. For patients who cannot tolerate surgery due to old age or high risk of severe perioperative complications, or for some patients who refuse surgical treatment due to low acceptance of surgical treatment, it is not only difficult to gain benefit or even risk of lung cancer progression if simple conservative treatment is used. Based on the advantages of cryoablation therapy combined with the pathological characteristics of early NSCLC tumor diameter range and no lymph node metastasis, it is reasonable to think that cryoablation therapy can be an alternative therapeutic intervention for early NSCLC. However, there is not yet sufficient theoretical basis to support clinical decision-making. To date, there is a lack of large-sample clinical RCT studies on the interventional efficacy and safety of PCT therapy for early-stage NSCLC compared with the gold standard of surgical treatment, and the results are unclear. The aim of this study is to compare the prognostic efficacy and safety of PCT for early-stage NSCLC through reticulated Meta-analysis, using RFA, which has

been commonly used in NSCLC clinical treatment for a relatively long period of time, as an intermediate control group, so as to provide a more intuitive theoretical basis for the scientific decision-making of clinical therapeutic interventions.

**Condition being studied** The latest statistics from the International Agency for Research on Cancer (IARC) 2022 show that lung cancer is the malignant tumor with the highest morbidity and mortality rate in China. Eighty-five percent of its histologic typing is categorized as non-small cell lung cancer (NSCLC), and because of its insidious early symptoms, the majority of patients are already in advanced stages when diagnosed. Studies have reported that the 5-year survival rate after surgery for stage I-II NSCLC is 77%-92%, while the survival rate after surgery for stage III-IV NSCLC is only 10%-36%, with a significant difference between the two. Early diagnosis and early treatment is the best strategy to improve the prognosis of NSCLC patients.

## METHODS

**Search strategy** PubMed, Web of Science, EMBASE, CNKI, Wanfang Data, China Science and Technology Journal Database, China Biomedical Literature Service, Chinese Clinical Trial Registry.

**Participant or population** Inclusion criteria: ① The study type was randomized controlled trial (RCT) and non-randomized clinical controlled trial (including cohort study or case-control study, prospective and retrospective) in the research literature; ② The study subjects were patients with early-stage non-small cell lung cancer diagnosed. For patients with complete tumor and lymph node pathology available, pathological staging was used as the criterion. If complete tumor tissue or lymph node specimens could not be obtained due to the limitation of diagnostic and treatment modalities, clinical staging was based on CT, PET/CT, bronchoscopic needle aspiration biopsy, or ultrasonic bronchoscopy; (3) the study interventions included surgical treatment, RFA treatment, and cryoablation, and involved the comparison of any two or more treatment modalities; (4) the study outcome index: Overall Survival rate, Progression Free Survival rate, and adverse events;

Exclusion criteria: (1) duplicate publications; (2) mixed data from patients with multiple stages (non-early), repeated reports from the same patient, and studies with additional interventions such as targeted therapy and radiotherapy; (3) studies in which the surgical intervention was a

traditional open pneumonectomy; and (4) studies in which the number of lost visits was too large and the data quality was poor.

**Intervention** Percutaneous Cryoablation Therapy, Pneumonectomy.

**Comparator** Radiofrequency Ablation.

**Study designs to be included** RCTs.

**Eligibility criteria** Only studies that were randomized controlled trials (RCTs) and non-randomized clinical trials (including cohort or case-control studies, prospective and retrospective) were included.

**Information sources** PubMed, Web of Science, EMBASE, CNKI, Wanfang Data, China Science and Technology Journal Database, China Biomedical Literature Service, Chinese Clinical Trial Registry.

**Main outcome(s)** For the 70% of early-stage NSCLC patients who cannot tolerate surgical treatment or do not want to receive surgical treatment, PCT is an excellent alternative treatment option, and has been promoted as the first choice of non-surgical ablative treatment for early-stage NSCLC.

**Additional outcome(s)** None.

**Data management** Two researchers used a data extraction form built in Excel to extract data from the seven RCTs study articles that were eventually included, which included basic characteristics (title, authors, publication date, literature source, contact information, study timeframe, etc.), patient characteristics (mode of diagnosis, tumor stage, sample size, age-race, and other characteristics, and basic status of the included population), interventions, duration of followup, the Follow-up content, outcome metrics (outcome definition, remission rate, survival rate, OS, PFS, postoperative complications, etc.), and Hazard Ratio (HR) and its 95% confidence interval (95% CI) were directly obtained or calculated. In case of disagreement, the decision was made after consulting a third investigator for discussion.

### Quality assessment / Risk of bias analysis

Relevant literature was identified by reading abstracts and full texts. The quality of relevant studies was evaluated using the Newcastle-Ottawa-Scale (NOS). The main evaluation indexes of this scale include three parts: study population selection, comparability and outcome. The selection of study subjects included the following:

whether the selection of the exposure cohort was representative, whether the non-exposure cohort was from the same population as the exposure cohort, whether the determination of the exposure was from rigorously accurate records, and whether any of the study subjects had already presented with the outcome of the study at the beginning of the study (i.e., whether the study was a prospective or retrospective study). Comparability of the exposed and non-exposed cohorts was evaluated primarily for whether or not corrections were made for important confounders. Outcomes were evaluated for accuracy of recording of results, whether follow-up was long enough to visualize sufficient outcomes, and whether follow-up was complete. The scale has a total of 9 points and is generally considered 0-4 as low quality literature, 5-7 as moderate quality literature, and 8-9 as high quality literature; literature with a score of >7, i.e., high quality, was included in the analysis for this study.

**Strategy of data synthesis** The data sources included covered a number of different groups and experimental cohorts, and in order to minimize the interference of potential confounders with the study conclusions and to visualize the degree of change in the risk of an event for the study subjects at a given time compared with the control group, and thus to make indirect comparisons between groups, the risk ratios were chosen as the main comparative to assess OS and PFS for the cohort Indicators. Some of the original literature did not directly provide the corresponding HR values and their 95% CIs, which were obtained as follows: (1) if individual participant data were available, multivariate Cox proportional risk regression models were used to obtain the HR values and their 95% CIs; (2) if individual participant data could not be obtained, Engauge Digitizer software was used to process the Kaplan-Meier (K-) curves and extract the data; and (3) if individual participant data could not be obtained, the data were extracted by using the Engauge Digitizer software. M) curve and extracted the data, and then refer to the literature of Jayne F Tierney et al to calculate HR,  $\ln(\text{HR})$ , and  $\text{se}(\ln(\text{HR}))$ ; if there were insufficient data in the original article and HR could not be obtained by the K-M curve method, Relative Risk (RR) was used instead.

**Subgroup analysis** None.

**Sensitivity analysis** After obtaining the HR values of each study, the consistency test of the data within the group was performed by means of the Q-test, and when  $P > 0.05$ , it proved that the data heterogeneity within the study was small, which

tended to be analyzed by the consistency model, and vice versa, which tended to be analyzed by the non-consistency model.

**Language restriction** English and Chinese.

**Country(ies) involved** China.

**Other relevant information** None.

**Keywords** Percutaneous Cryoablation Therapy, Pneumonectomy, Radiofrequency Ablation, Non-Small-Cell Lung.

**Dissemination plans** Publish.

**Contributions of each author**

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