INPLASY

Immune checkpoint inhibitors therapies in patients with advanced non-small cell lung cancer and preexisting connective tissue disease: A systematic review and meta-analysis

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ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - Preliminary searches.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY2024120029

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 8 December 2024 and was last updated on 8 December 2024.

INTRODUCTION

Review question / Objective population: ICI-treated patients with advanced non-small cell lung cancer and preexisting connective tissue disease. Intervention/Exposure: inmmune checkpoints inhibitors. Comparison: patients without preexisting connective tissue disease. Outcome: immune-related adverse events. Study design: observational (retrospective or prospective) studies.

Condition being studied Immune checkpoints inhibitors (ICIs) are associated with frequent immune-related adverse events (irAEs), but patients with preexisting connective tissue disease (CTD) have been excluded from clinical trials, leaving serious gaps in knowledge.
To evaluate the safety and efficacy of ICIs in CTD patients and cancer and explore the impact of different CTD types and baseline receiving immunosuppressive therapy.

METHODS

Participant or population ICI-treated patients with advanced non-small cell lung cancer and preexisting connective tissue disease. Intervention/ Exposure: inmmune checkpoints inhibitors.

Intervention Inmmune checkpoints inhibitors.

Comparator Patients without preexisting connective tissue disease.

Study designs to be included Observational (retrospective or prospective) studies.

Eligibility criteria Patients were included if they were ≥18 years of age and had preexisting connective tissue disease confirmed by a treating oncologist or organ disease specialist prior to the initiation of ICI combination therapy.
Patients were excluded if they did not have established diagnosis of connective disease prior to ICI initiation or did not have sufficient data

available regarding their preexisting connective tissue disease and/or cancer treatments.

Information sources We conducted separate searches of PubMed, EMBASE and the Cochrane Library databases without language restrictions.

Main outcome(s) Preexisting connective tissue disease exacerbation, de novo irAEs or both and pooled response rates (complete or partial).

Quality assessment / Risk of bias analysis The assessment was based on six domains: sampling method, sample size, participation rate, criteria used to determine outcome measures and the eligibility criteria for participation. Articles were scored as follows: 0–3 = low quality; 4–6 = low to medium quality; 7–8 = medium to high quality; 9–10 = high quality.

Strategy of data synthesis Pooled incidence rates with their 95% CI for preexisting connective tissue disease exacerbation, de novo irAEs or both and pooled response rates (complete or partial) with their 95% CI among ICI-treated patients with preexisting connective tissue disease were calculated, stratifying by cancer, drug and preexisting connective tissue disease types.

Subgroup analysis In a secondary analysis, we explore the impact of baseline immunosuppressive therapy on safety and efficacy of ICI therapy.

Sensitivity analysis Meta-analysis was performed using a random- effects or fix-effects model according to heterogeneity between studies, assessed using the I2 statistic (low, I2 50%). Meta-regression was performed to identify sources of heterogeneity including publication year, country, center, number of participants and receiving immunosuppressive therapy at ICI start. Where significant effects were identified, stratified analysis was performed. Funnel plots were produced to explore the possibility of publication bias due to preferential publication of small studies report- ing high prevalence estimates; Begg's and Egger's tests of publication bias were also performed. For statistical significance, two-sided α was set at P = 0.05. All data were recorded in a Microsoft Excel spreadsheet and analyzed using STATA 13.

Country(ies) involved China.

Keywords connective tissue disease , Cancer, immune checkpoint inhibitors, Immune-related adverse events, Meta-analysis.

Contributions of each author

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