INPLASY PROTOCOL

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None declared.

The effect of gender on the clinical outcome of PD-1/PD-L1 inhibitor in solid cancer patients

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Review question / Objective: **We systematically reviewed the literature and conducted a meta-analysis to determine the impact of gender on the outcomes of PD-1/PD-L1 inhibitors in advanced cancer patients.**
Condition being studied: **Related database and conferences were searched. Studies that reported the relationship between gender and the overall survival (OS) or progression free survival (PFS) of PD-1/L1 inhibitor were included. Meta-analysis was conducted to obtain pooled HRs with 95% CI.**
Eligibility criteria: **We included randomized controlled trials and retrospective trials that met inclusion criteria. Inclusion criteria included: (1) Patients were definitely diagnosed with solid cancer and received PD-1/PD-L1 inhibitor treatment alone or in combination with other anti-cancer drugs; (2) Articles provided information concerning hazard ratios (HRs) for overall survival (OS) and/or progression-free survival (PFS) according to patients' sex subgroup. Two independent investigators separately screened the titles and abstracts of eligible studies by applying the inclusion criteria, and any discrepancies between them were resolved by consensus between all authors.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 12 February 2023 and was last updated on 12 February 2023 (registration number INPLASY202320048).

INTRODUCTION

Review question / Objective: **We systematically reviewed the literature and conducted a meta-analysis to determine the impact of gender on the outcomes of PD-1/PD-L1 inhibitors in advanced cancer patients.**

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METHODS

Search strategy: Two researchers independently searched databases such as PubMed, EMBASE, and the Cochrane Library for relevant publications. The conference proceedings of American Society of Clinical Oncology (ASCO), European Society for Medical Oncology (ESMO), and American Association for Cancer Research (AACR) were also screened to identify more potentially relevant studies. The cut-off date was set to December 31, 2022.
The keywords utilized were as follows: "PD-1 inhibitor", "PD-L1 inhibitor", "avelumab", "atezolizumab", "camrelizumab", "nivolumab", "pembrolizumab", "sintilimab", "durvalumab", "toripalimab", "sintilimab", "gender", "sex", "clinical outcomes", "overall survival", and "progression free survival". No language restrictions were applied.

Participant or population: Solid cancer patients treated with PD-1/PD-L1 inhibitors.

Intervention: Gender: male or female.

Comparator: Overall survival (OS) or progression free survival (PFS).

Study designs to be included: We included randomized controlled trials and retrospective trials that met inclusion criteria.

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Information sources: Two researchers independently searched databases such as PubMed, EMBASE, and the Cochrane Library for relevant publications. The conference proceedings of American Society of Clinical Oncology (ASCO), European Society for Medical Oncology (ESMO), and American Association for Cancer Research (AACR) were also screened to identify more potentially relevant studies. Following information were extracted from the eligible articles: authors, year of publication, region/country, number of centers, inclusion period, number of patients, gender, type of cancer, treatment line, treatment type, HR and 95%CI of PFS and OS. Missing data was handled by contacting the authors of the studies for unreported data or additional details. If there are duplicate reports of the same trial, we only included the most comprehensive publication to guarantee the reliability and quality of the data.

Main outcome(s): Literature Search. Results Quality of the Included Studies and Publication BiasCharacteristics of Identified Trials. Meta-analysis of the effect of gender on the clinical outcome of PD-1/PD-L1 inhibitor. Subgroup Analysis according to cancer type, therapy type, population size, and so on.

Quality assessment / Risk of bias analysis: Egger's test was used to determine the possibility of publication bias.

Strategy of data synthesis: Heterogeneity among the studies was evaluated by I2 statistics. When I2>50% and/or P<0.10, the heterogeneity was considered statistically significant. Under this circumstance, a random effects model was adopted to pool the HR. Otherwise, a fixed effects model was adopted.

Subgroup analysis: Subgroup Analysis according to cancer type, therapy type, population size, and so on.

Sensitivity analysis: To evaluate the degree to which each study affected the overall HRs with 95% CI, sensitivity analysis was performed using the "one-study removed" method.

Language restriction: No.

Country(ies) involved: China.

Keywords: "PD-1 inhibitor", "PD-L1 inhibitor", "avelumab", "atezolizumab", "camrelizumab", "nivolumab", "pembrolizumab", "sintilimab", "durvalumab", "toripalimab", "sintilimab", "gender", "sex", "clinical outcomes", "overall survival".

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