INPLASY PROTOCOL

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None declared.

Comparing clinical outcomes on oncology patients with severe aortic stenosis undergoing transcatheter aortic valve implantation: A systematic review and meta-analysis

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Review question / Objective: **P: patients are undergoing transcatheter aortic valve implantation; I: cancer patients; C: no cancer patients; O: mortality, stroke, acute kidney injury, cardiovascular mortality, bleeding events, myocardial infarction, vascular complication, new permanent pacemaker implantation and device success rate; S: cohort studies.**
Condition being studied: **The morbidity of oncology and valvular heart disease are both increasing in the world. Aortic stenosis (AS) is a common disease in valvular heart disease, therefore, cancer patients with severe AS is special in these population. Transcatheter aortic valve implantation (TAVI) is a new treatment which has applied widely to AS patients, however, the safety and efficiency of cancer patients with severe AS underwent TAVI are still unclear. It is significant to evaluate the clinical outcomes on cancer patients with severe aortic stenosis undergoing transcatheter aortic valve implantation.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 06 February 2022 and was last updated on 06 February 2022 (registration number INPLASY202220009).

INTRODUCTION

Review question / Objective: **P: patients are undergoing transcatheter aortic valve implantation; I: cancer patients; C: no cancer patients; O: mortality, stroke, acute kidney injury, cardiovascular mortality, bleeding events, myocardial infarction, vascular complication, new permanent pacemaker implantation and device success rate; S: cohort studies.**

Condition being studied: **P: patients are undergoing transcatheter aortic valve implantation; I: cancer patients; C: no cancer patients; O: mortality, stroke, acute kidney injury, cardiovascular mortality,**

bleeding events, myocardial infarction, vascular complication, new permanent pacemaker implantation and device success rate; S: cohort studies.

METHODS

Participant or population: All studies were included based on the following inclusion criteria: (1) the study enrolling AS patients with cancer; (2) the study intervention was TAVI with no restrictions on the valve style (balloon- or self-expendable valve) or delivery route; (3) the study comparing clinical outcomes of cancer to no cancer patients undergoing TAVI; (4) the study design was randomized controlled trials (RCT) or cohort studies.Studies will be excluded if one of the following conditions is met: (1) The type of study was case control studies, case reports, conference abstracts, reviews, comments or editorials were excluded; (2) the research data was missing too much or not available.

Intervention: Patients with cancer undergoing TAVI.

Comparator: Patients without cancer undergoing TAVI.

Study designs to be included: Cohort studies.

Eligibility criteria: All studies were included based on the following inclusion criteria: (1) the study enrolling AS patients with cancer; (2) the study intervention was TAVI with no restrictions on the valve style (balloon- or self-expendable valve) or delivery route; (3) the study comparing clinical outcomes of cancer to no cancer patients undergoing TAVI; (4) the study design was randomized controlled trials (RCT) or cohort studies.Studies will be excluded if one of the following conditions is met: (1) The type of study was case control studies, case reports, conference abstracts, reviews, comments or editorials were excluded; (2) the research data was missing too much or not available.

Information sources: A comprehensive literature search was performed through the PubMed, EMbase, The Cochrane Library, CBM, CNKI and Wanfang databases from establishment to October 2021.

Main outcome(s): mortality, stroke, acute kidney injury.

Quality assessment / Risk of bias analysis: The Cochrane Collaboration's tool for assessing risk of bias was utilized to assess risk of bias of RCTs including: (1) sequence generation, (2) allocation concealment, (3) blinding of participants and personnel, (4) blinding of outcome assessment, (5) incomplete outcome data, (6) selective outcome reporting, (7)other bias. Moreover, the Newcastle-Ottawa Scale (NOS) was used to assess the quality of cohort studies consisted of three factors: patient selection; comparability of the study groups; and the assessment of outcomes.

Strategy of data synthesis: A comprehensive literature search was performed through the PubMed, EMbase, The Cochrane Library, CBM, CNKI and Wanfang databases from establishment to October 2021 using the following terms: "transcatheter aortic valve implantation", "transcatheter aortic valve replacement", "TAVI", "TAVR", "neoplasm", "malignancy", "cancer", "tumor" with no restrictions on language. Reference lists of reviewed articles were screened to identify further relevant studies. When outcomes reporting were incomplete, the study authors were contacted for further information.

Subgroup analysis: The results of meta-analysis showed that the statistical difference was found in the 30-day mortality, 1-year mortality, late mortality, stroke and the acute kidney injury.

Sensitivity analysis: Categorical variables were reported as odds ratios (ORs) with corresponding 95% confidence intervals (CIs) and continuous variables were presented as weighted mean differences (WMD) with 95% CIs. To calculate the summary estimate across all included studies, we used the random effects model

(DerSimonian and Laird) because of the different studies assessing different yet related intervention effects related to valve style and delivery route. Heterogeneity assessments were performed using χ2-based Q statistics and I2 tests. A P50% were considered as significant heterogeneity. Subgroup analysis were also performed to find more potential information based on pre-set criteria in different follow-up time and different type of event. The likelihood of publication bias was assessed graphically through the generation of funnel plots, evaluated using an Egger's test. Statistical significance was set at P<0.05. All analyses were performed using STATA software 15.0 (StataCorp, College Station, Texas).

Country(ies) involved: China.

Keywords: Aortic stenosis; oncology; transcatheter aortic valve implantation; meta-analysis.

Contributions of each author:

Author 1 - Yumeng Song - Author 1 proposed the research ideas, screened titles and abstracts of all identified records to exclude unrelated studies based on inclusion/exclusion criteria and drafted the manuscript.
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Author 3 - Zuoxiang Wang - The author contributed to the development of the selection criteria, and the risk of bias assessment strategy.
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