# INPLASY PROTOCOL

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**Review Stage at time of this submission: Preliminary searches.** 

Conflicts of interest: None declared. Impact of chronic kidney disease on the prognosis of transcatheter aortic valve replacement in patients with aortic stenosis: protocol for a systematic review and meta-analysis

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**Review question / Objective:** The prognosis of patients with aortic stenosis (AS), in conjunction with chronic kidney disease (CKD), after transcatheter aortic valve replacement (TAVR) remains unclear. This study assessed the impact of CKD, and different stages of CKD, on prognosis of patients undergoing TAVR.

Condition being studied: In the last decade, transcatheter aortic valve replacement (TAVR) has gained popularity as an alternative to surgical aortic valve replacement (SAVR) for patients, who are either inoperable or are at high- to intermediate-risk for surgery. Chronic kidney disease (CKD) often coexists with aortic stenosis (AS), likely due to similar risk factors and pathophysiology. The prognostic effects of CKD on TAVR, however, remain unclear. Moreover, little is known about the difference of prognosis among different CKD stages.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 07 June 2021 and was last updated on 07 June 2021 (registration number INPLASY202160023).

## INTRODUCTION

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#### **METHODS**

Search strategy: Two researchers conducted an extensive and systematic computerized literature review, using the PubMed, Cochrane Library, EMBASE, and Web of Science databases, using various combinations of the following free text and key terms: "TAVI", "TAVR", "transcatheter aortic valve implantation", "transcatheter aortic valve replacement", "chronic kidney disease", "chronic kidney failure" and "CKD".

Participant or population: Patients diagnosed with AS and treated with TAVR.

**Intervention:** Patients with AS complicated CKD treated with TAVR.

**Comparator:** Patients with AS without CKD treated with TAVR.

**Study designs to be included: Randomized controlled trial (RCT) and cohort studies.** 

Eligibility criteria: The inclusion criteria for the meta-analysis were as follows: 1. population: Patients diagnosed with AS and treated with TAVR 2. intervention group: Patients with AS complicated CKD treated with TAVR 3. comparison group: Patients with AS without CKD treated with TAVR 4. outcome measures: The primary outcome of our study was all-cause mortality after TAVR at the short-(30-day), medium-(1year), and long-term(2-year) follow-ups. Secondary outcomes included stroke, bleeding, permanent pacemaker implantation (PPI), acute kidney injury (AKI), and major vascular complications at the short-term (30-day) follow up. 5. study

design: randomized controlled trial (RCT) and cohort studies.

Information sources: As of June 2021, we performed a comprehensive literature search on studies related to CKD and TAVR, using databases like PubMed, Embase, Cochrane Library, and Web of Science.

Main outcome(s): The main outcome of our study was all-cause mortality after TAVR at the short-(30-day), medium-(1-year), and long-term(2-year) follow-ups.

Additional outcome(s): Secondary outcomes included stroke, bleeding, permanent pacemaker implantation (PPI), acute kidney injury (AKI), and major vascular complications at the short-term (30-day) follow up.

Quality assessment / Risk of bias analysis: The risk of bias in the included studies was independently evaluated by two investigators, and the results were crosschecked. The RCT risk of bias was assessed using the RCT risk of bias assessment tool recommended in the Cochrane Handbook 5.1.0. The Newcastle-Ottawa Scale (NOS) was used for the bias risk assessment. In case of differences, they shall be resolved through discussion or with the assistance of a third party.

Strategy of data synthesis: Stata 15.0 software was used for Meta analysis. Risk ratio (RR) was used as the statistic for effect analysis, and 95%CI was provided for each effect size. We combined the given data across the studies using DerSimonian and Laird random effects models.

Subgroup analysis: We will conduct subgroup analysis to find more potential information based on three variables: (1) Different follow-up time, (2) Patients in different surgical risk score, (3) Different types of implanted valve in TAVI patients.

Sensitivity analysis: A sensitivity analysis was performed when the between- study heterogeneity was significant. A p value < 0.05 was considered statistically significant.

Country(ies) involved: China.

Keywords: Chronic kidney disease, Transcatheter aortic valve replacement, Meta-analysis, Prognosis.

## **Contributions of each author:**

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