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None declared.

Comparing Clinical Outcomes of Sutureless Aortic Valve Replacement Versus Transcatheter Aortic Valve Implantation: A Systematic Review and Meta-analysis of Propensity Score Matching

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Review question / Objective: **(1) the population treated with sutureless aortic valve or TAVR regardless of operative risk (2) the intervention was sutureless aortic valve replacement with no restrictions on the valve style (rapid-deployment or sutureless valve) (3) the comparison was TAVI with no restrictions on the valve style (balloon- or self-expandable valve) or delivery route (4) outcomes studied included any of the following: all-cause mortality, stroke, new permanent pacemaker implantation (PPI), moderate-to-severe paravalvular leak (PVL), more-than-mild residual aortic regurgitation (AR), new renal replacement therapy, myocardial infarction, new atrial fibrillation, major vascular complication, major or life-threatening bleeding event, length of stay, ICU length of stay, postoperative mean aortic gradient, cardiopulmonary bypass time and cross-clamp time (5) the study design was randomized controlled trials (RCT) or comparative cohort studies using propensity-matched analysis.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 13 November 2022 and was last updated on 13 November 2022 (registration number INPLASY2022110058).

INTRODUCTION

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Condition being studied: TAVI has revolutionized the treatment of aortic valve stenosis and has impacted on guidelines of valvular heart disease. TAVI has been recognized as established treatment option in AS patients at intermediate or high surgical risk and becomes increasingly suitable for patients at low surgical risk. As the gold standard and most frequent valve operation, SAVR with good clinical results due to low complication and mortality rates is challenged by less invasive TAVI procedure with excellent results even in AS patients.

With the development of transcatheter heart valves, sutureless valves have been recently introduced into surgical practice in the past few years. Sutureless valves are made of biological tissue mounted on an atypical stent frame and implanted surgically by anchoring mechanisms, which allow to maintain the advantage of surgical inspection and removal of diseased and calcified aortic valve tissue. Therefore, sutureless aortic valve replacement (SUAVR) shortens aortic cross-clamp, cardiopulmonary bypass and operation time compared with conventional SAVR, and facilitates less invasive approaches for SAVR through mini-sternotomy or mini-thoracotomy and is expected to reduce complication and mortality of AS patients.

The population currently treated with SUAVR may have potential similarities with the TAVI population. Therefore, we performed this systematic review and meta-analysis to assess clinical outcomes of SUAVR and TAVI.

METHODS

Search strategy: Using the following terms "Sutureless Surgical Procedures", "Sutureless technique", "Surgical Procedure, Sutureless", "Transcatheter Aortic Valve Replacement", "Transcatheter aortic valve implantation", "TAVR" and "TAVI" with no restrictions on language. Reference lists of the retrieved articles were reviewed for additional studies not identified from the initial database search.

Participant or population: The population treated with sutureless aortic valve or TAVR regardless of operative risk.

Intervention: the intervention was sutureless aortic valve replacement with no restrictions on the valve style (rapid-deployment or sutureless valve).

Comparator: The comparison was TAVI with no restrictions on the valve style (balloon- or self-expandable valve) or delivery route.

Study designs to be included: The study design was randomized controlled trials (RCT) or comparative cohort studies using propensity-matched analysis.

Eligibility criteria: Studies were excluded if one of the following conditions is met: (1) the type of study was comparative cohort studies without propensity-matched analysis, case-control studies, case reports, conference abstracts, reviews, comments, or editorials; and (2) a significant amount of research data was missing or not available.

Information sources: A systematic search of online databases including PubMed, EMBASE, MEDLINE, the Cochrane library and the Clinical Trials Registry (www.clinicaltrials.gov) was performed until the end of October 2022.

Main outcome(s): The primary endpoint of the study was all-cause mortality in follow-up time.

Additional outcome(s): Secondary endpoints included stroke, new permanent pacemaker implantation (PPI), moderate-to-severe paravalvular leak (PVL), more-than-mild residual aortic regurgitation (AR), new renal replacement therapy, myocardial infarction (MI), new atrial fibrillation (AF), major vascular complication, major or life-threatening bleeding event, postoperative mean aortic gradient, length of stay, ICU length of stay, cardiopulmonary bypass (CPB) time and cross-clamp time.

Quality assessment / Risk of bias analysis: The Cochrane Collaboration's tool for assessing the risk of bias was utilized to assess the risk of bias in 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; and (7) other bias. Besides, the Newcastle-Ottawa Scale (NOS) was used to assess the quality of cohort studies consisting of three factors: patient selection, comparability of the study groups, and the assessment of outcomes. We assigned a score of 0–9 to each study following the evaluation; higher scores represent higher study quality. A total score of ≥ 7was considered good quality.

Strategy of data synthesis: Continuous variables and categorical variables were presented as the mean ± SD and percentages respectively. For dichotomous outcomes, risk ratio (RR) with 95% confidence intervals (CIs) and p values for the endpoints were calculated using Mantel-Haenszel method. For continuous outcomes, mean differences (MD) with 95% CIs and p values were considered using inverse-variance method.

Subgroup analysis: The primary endpoint was performed subgroup analysis by different follow-time.

Sensitivity analysis: All the results were performed using the random effect model. Whenever heterogeneity was present, sensitivity analyses were performed to examine the robustness of the results and the effect of potential effect modifiers by excluding one study in each turn.

Country(ies) involved: China.

Keywords: SUAVR; TAVI: Meta-analysis: Propensity Score Matching.

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