INPLASY PROTOCOL

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None declared.

Efficacy and safety of New-generation devices for transcatheter aortic valve replacement in the treatment of Aortic Regurgitation: a systematic review and meta-analysis

Chen, Y[1]; Chen, H[2]; Song, B[3].

Review question / Objective: **TAVR is widely used to treat patients with AS, but its efficacy in patients with AR is uncertain. With the advent of the new generation of TAVR valves, more and more studies have reported the treatment of AR by TAVR . The purpose of this meta is to evaluate the Efficacy and safety of New-generation devices for TAVR in the treatment of AR through systematic evaluation and Meta-analysis to provide a basis for clinical decision stragety.**
Condition being studied: **Aortic regurgitation (AR) is mainly caused by various congenital and acquired anomalies that result in abnormalities of the aortic valve leaflets or their supporting structures (aortic root and aortic annulus) . The incidence of AR is as high as 13.0% in men and 8.5% in women in the United States, with 0.5% of the population presenting with moderate or severe aortic valve insufficiency.The primary outcome measures:device success rates, and Secondary indicators:all-cause mortality (in-hospital, and 30 days), Cardiovascular mortality (in-hospital, and 30 days), conversion to open surgery rate, new permanent pacemaker implantation rate, moderate or higher paravalvular aortic regurgitation (PAR) rate and acute kidney injury rate.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 17 October 2022 and was last updated on 17 October 2022 (registration number INPLASY2022100068).

INTRODUCTION

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METHODS

Participant or population: Patients with AR and and treated with New-generation devices for TAVR.

Intervention: Patients with AR and and treated with New-generation devices for TAVR.patients diagnosed with AR by transthoracic echocardiography.new generation valves include the J-Valve valve, Venus-A valve, Jenavalve valve, Lotus valve valve, ACURATE valve, Direct Flow Valve valve, Evolut R valve, and Engager valve.

Comparator: Since this study is single-arm meta, there are no exposure factors.

Study designs to be included: Single-arm studies, cohort studies and randomized controlled trial.

Eligibility criteria: The inclusion criteria(1)Population: patients diagnosed with AR by transthoracic echo-cardiography.(2) Intervention:patients with AR and and treated with New-generation devices for TAVR(3)Outcomes. The primary outcome measures was device success rates, Secondary indicators were all-cause mortality (in-hospital, and 30 days), Cardiovascular mortality (in-hospital, and 30 days), conversion to open surgery rate, new permanent pacemaker implantation rate, moderate or higher paravalvular aortic regurgitation (PAR) rate and acute kidney injury rate.(4). Study design: single-arm studies, cohort studies and randomized controlled trial (RCT) .The exclusion criteria(1)the meta-analysis were conference reports, reviews, case reports, summaries, editorials,(2) repeated publication or overlapping of patients; study sample≤10; non-English-language studies.

Information sources: We systematically retrieved literature published in the PubMed, Embase, Web of Science, and Cochrane databases from the date of the database's establishment to December 5, 2022. The strategy of combining subject words and free words was used to search. then combined with each of thefollowing keywords: "TAVI," "TAVR," "transcatheter aortic valve implantation," "transcatheter aortic valvereplacement,""Aortic Valve Insufficiency""Insufficiency, Aortic Valve" "Aortic ValveIncompetence" "Incompetence, Aortic Valve""Aortic Regurgitation""Regurgitation, Aortic" "Regurgitation, Aortic Valve""Aortic Incompetence" "Incompetence, Aortic".

Main outcome(s): The primary outcome measures:device success rates.

Additional outcome(s): Secondary indicators:all-cause mortality (in-hospital, and 30 days), Cardiovascular mortality (in-hospital, and 30 days), conversion to open surgery rate, new permanent pacemaker implantation rate, moderate or higher paravalvular aortic regurgitation (PAR) rate and acute kidney injury rate.

Quality assessment / Risk of bias analysis: The risk of bias in the included studies was independently evaluated by 2 investigators, and the results were cross-checked.Methodological Index for Non-randomized Studies (MINORS)were used to assess the risk of bias in cohort studies and single-arm clinical trials, respectively.

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Funnel plots were used to visually assess publication bias for all endpoints, followed by quantitative assessment using Egger's test. $p < 0.05$ indicates a statistically significant difference.

Strategy of data synthesis: Stata 16.0 software was used to perform single-arm Meta-analysis using the "metaprop" command. We tested for heterogeneity between studies using the x2 test and I 2 statistics, in which I 2 values of 25%, 50%, and 75% represented low, moderate, and high heterogeneity, respectively . The risk ratio and 95% confifidence interval of the results were performed using a meta-analysis for random effect models.

Subgroup analysis: To search the sources of heterogeneity and analyze the factors related to clinical signifificance, we also performed meta-regression based on region of study, study type, Approach of surgery , sample size.And subgroup analysis was performed according to different Approach of surgery.

Sensitivity analysis: Sensitivity analyses were subsequently performed to assess the stability of the pooled effects by omitting each study sequentially.

Country(ies) involved: China.

Keywords: aortic regurgitation, meta-analysis, transcatheter aortic valve replacement, new-generation devices.

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