INPLASY PROTOCOL

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Comparison of cusp-overlap projection and standard three-cusp coplaner view during transcatheter aortic valve replacement: a systematic review and meta-analysis

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Review question / Objective: To evaluate whether cuspoverlap projection technique could reduce permanent pacemaker implantation when compared with standard threecusp coplaner projection in patients underwent transcatheter aortic valve replacement.

Condition being studied: More younger patients who have a low surgical risk would be candidate for transcatheter aortic valve replacement (TAVR). Permanent pacemaker implantation (PPI) is a common complication. The incidence of PPI is highly variable between different centers. It is known implantation depth is associated with conduction disturbances after TAVR. However, it is hard to precisely releasing prosthesis higher using the conventional device implantation technique. Recently, some studies suggested that using cusp-overlap projection (COP) technique can releasing prosthesis higher and reduce permanent pacemaker implantation. Nevertheless, as a new technique, it is uncertain whether COP is actually associated less PPI after procedure. The study was performed to make a systematic review and meta analysis to compare the COP and three-cusp coplaner projection.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 15 April 2022 and was last updated on 15 April 2022 (registration number INPLASY202240092).

INTRODUCTION

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METHODS

Search strategy: Databases: Pubmed and Embase Terms: (TAVR OR TAVI OR "transcatheter aortic valve") AND ("cusp overlap" OR "cusp overlapping").

Participant or population: Patients underwent self-expanding transcatheter aortic valve replacement.

Intervention: Cosp-overlap projection technique.

Comparator: Standard three cusp coplaner projection.

Study designs to be included: randomized controlled study, non-randomized study, cohort study.

Eligibility criteria: Inclusion criteria: 1) the study made comparison between cuspoverlap technique and standard technique; 2) self-expanding valve were used; 3) at least 10 patients were enrolled in the study; 4) writing in English; 5) conference presentation and abstract fulfilling the above criteria; Exclusion criteria: case reports, single-arm studies; If a same population was reported in different studies, only the largest and the most recent studies were included.

Information sources: Electronic databases, conference presentation and abstract.

Main outcome(s): post-operative permanent pacemaker implantation (inhospital PPI and 30-day PPI were both defined as post-operative PPI).

Additional outcome(s): Intra-procedural radiation doses, fluoroscopic time, prosthesis implantation depth, length of hospital stay, and post-operative left bundle branch block, mortality, stroke, mean aortic valve gradient, moderate or severe paravalvular leakage.

Quality assessment / Risk of bias analysis: RCTs will be evaluated by the revised Cochrane Risk of Bias tool (ROB) 2.0 For cohort sutdy, the quality of studies will be assessed using Newcastle-Ottawa Scale (NOS).

Strategy of data synthesis: We will use the Cochrane Q-statistic (χ 2) and Higgins' and Thompson's I2 statistics to test heterogeneity. Random-effect model will be used when significant heterogeneity exists, which is defined as I2 > 50% or p \leq 0.01. Otherwise, fixed-effect model will be used. We will use stata software version 14.0 (StataCorp LP, College Station, USA) and use metan command to conduct statistical analyses. Since the exported figure is different between stata software and Review Manager. If journal require, Review Manager 5.4 will be used for figure export and data analyses.

Subgroup analysis: The subgroup analysis will be performed for permanent pacemaker implantation: data based on original article or conference presentation.

Sensitivity analysis: A sensitive analysis will be performed for permanent pacemaker implantation by removing each study from the pooled analysis and examining whether the result have changed.

Language: English.

Country(ies) involved: China.

Keywords: transcatheter aortic valve replacement; cusp-overlap projection; three cusp coplaner projection; permanent pacemaker implantation; self-expanding valve.

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