INPLASY PROTOCOL

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None declared.

Comparison of results of transcatheter femoral aortic valve replacement under local and general anesthesia: a protocol for systematic review and meta analysis

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Review question / Objective: **Population: Patients with aortic stenosis receiving a transfemoral TAVR; Itervention: Local anaesthesia; Comparison: General anesthesia; Outcome: Any cause death, TIA, stoke, myocardial infarction, major vascular complication, acute kidney injury, new atrial fibrillation, new permanent pacemaker; Style: Randomized controlled trials and non-Randomized controlled trials.**
Condition being studied: **More and more evidences indicate that with the increase of clinical experience and advances in transcatheter technology, transfemoral TAVR is also feasible with Local anesthesia/conscious anesthesia (LA). Previous studies have shown that LA can avoid hemodynamic fluctuations caused by general anesthesia (GA) and lung damage caused by positive pressure ventilation, as well as reduce medical costs. However, in some studies comparing anesthesia selection in patients with transfemoral TAVR, the criteria for choosing LA versus GA remain vague and often depend on institutional and surgeon preferences.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 July 2021 and was last updated on 24 July 2021 (registration number INPLASY202170078).

INTRODUCTION

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METHODS

Participant or population: Patients with aortic stenosis receiving a transfemoral TAVR.

Intervention: Local anaesthesia.

Comparator: General anesthesia.

Study designs to be included: Randomized controlled trial and non-Randomized studies.

Eligibility criteria: Inclusion criteria included 1. Study type: Randomized controlled trials and non-Randomized controlled trials comparing the efficacy and safety of local and general anesthesia during femoral TAVR. The language is English only. 2. Study subjects: Patients with aortic stenosis who underwent transfemoral TAVR. 3. Intervention: When TFTAVR was treated in the experimental group, the anesthesia method was LA, while the control group was GA. There was no restriction on the type of valve (balloon dilatation or self-dilatation) and the specific method of LA (selection of anesthesia drugs and anesthesia approach). 4. Outcome measures: The primary outcome measures were all-cause mortality (in-hospital, 30 days, and 1 year), postoperative stroke (in-hospital, 30 days), Myocardial infarction (MI) (in-hospital, 30 days), cardiac arrest, length of ICU care, and total length of hospital stay. Secondary indicators were surgery duration, duration of anesthesia, major bleeding event (including fatal bleeding event), vascular vascular complications, new Permanent pacemaker implantation (PPM), new onset of atrial fibrillation, and Acute kidney injury. AKI).

Information sources: We searched PubMed, The Cochrane Library, Embase,and Web of Science databases from the beginning of the database to the end of September 2020.

Main outcome(s): The main outcomes were all-cause mortality (in-hospital, 30 days, and 1 year), postoperative stroke (in-hospital, 30 days), Myocardial infarction (MI) (in-hospital, 30 days), cardiac arrest, length of ICU care, and total length of hospital stay.

Additional outcome(s): The additional outcomes were surgery duration, duration of anesthesia, major bleeding event (including fatal bleeding event), vascular complications, new Permanent pacemaker implantation (PPM), new onset of atrial fibrillation, and Acute kidney injury. AKI).

Quality assessment / Risk of bias analysis: Two researchers independently read the titles and abstracts of the literature obtained. After excluding the studies that did not meet the inclusion criteria, they read through the full text of the remaining literatures to determine whether they truly met the inclusion criteria. When two researchers disagree on the included literature, the third researcher decides whether to include it or not. The risk of bias of the RCTs was assessed using the Cochrane Collabation Risk of Bias tool, and the quality of the cohort was assessed using the Newcastle-Ottawa Scale (NOS). The included studies were assessed by two researchers for the risk of bias, and cross-checked. If there was any disagreement, it would be discussed and resolved, and if necessary, it would be referred to the third researcher for decision.

Strategy of data synthesis: STATA16.0 was used for Meta-analysis, and the count data were presented as hazard ratio (RR) and its 95% confidence interval (95% CI). Mean Difference (MD) of 95% confidence interval was used as effect size for measurement

data. Heterogeneity was assessed by χ2 test and I-2 quantification. Pooled analysis was performed by random effects model. Sensitivity analysis was performed by excluding references one by one. P < 0.05 was considered statistically significant.

Subgroup analysis: In order to discover more potential information, we will use subgroup analysis when necessary.

Sensitivity analysis: If the heterogeneity of the indicators is significant, we will use a single study method to eliminate one by one for sensitivity analysis.

Country(ies) involved: China.

Keywords: Local anesthesia, General anesthesia, Transcatheter aortic valve replacement, Meta analysis.

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