

INPLASY PROTOCOL

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None declared.

TAVR vs SAVR long-term mortality due to stroke and MI: A meta-analysis during COVID 19 pandemic

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Review question / Objective: If TAVR is a viable treatment option to prevent early stroke mortality in patients of low and intermediate risk compared to SAVR? It is not viable in the long-term at 5 or over years?

Condition being studied: Transcatheter aortic valve replacement (TAVR), surgical aortic valve replacement (SAVR), stroke, MI.

Eligibility criteria: Inclusion Criteria: The following eligibility criteria were used to select studies: (a) published randomized controlled trials or cohort studies; (b) Experimental and control population included in the studies had at least one neurological or cardiogenic outcome reported. Exclusion Criteria: a) Any study which was not a trial b) Studies over five years old c) studies which didn't contain any control or experimental data. d) Studies which did not report a neurological or cardiogenic cause of mortality.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 22 November 2022 and was last updated on 22 November 2022 (registration number INPLASY2022110110).

INTRODUCTION

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METHODS

Search strategy: An electronic search of MEDLINE, Google Scholar, and Cochrane

Central was carried out from their inception to 28th September 2022 without any language restrictions, using the search strategy: ("TAVR"[All Fields] AND (("surgical instruments"[MeSH Terms] OR ("surgical"[All Fields] AND "instruments"[All Fields]) OR "surgical instruments"[All Fields] OR ("sur-gical"[All Fields] AND "valve"[All Fields]) OR "surgical valve"[All Fields]) AND ("re-place"[All Fields] OR "replaceable"[All Fields] OR "replaced"[All Fields] OR "replac-es"[All Fields] OR "replacing"[All Fields] OR "replacement"[All Fields] OR "replanta-tion"[MeSH Terms] OR "replantation"[All Fields] OR "replacement"[All Fields] OR "re-placements"[All Fields])) AND ("adult"[MeSH Terms] OR "adult"[All Fields] OR "adults"[All Fields] OR "adult s"[All Fields] OR ("aged"[MeSH Terms] OR "aged"[All Fields] OR "elderly"[All Fields] OR "elderlies"[All Fields] OR "elderly s"[All Fields] OR "elderlys"[All Fields])) AND ("mortality"[MeSH Terms] OR "mortality"[All Fields] OR "mortalities"[All Fields] OR "mortality"[MeSH Subheading])) AND (clinicaltrial[Filter] OR randomizedcontrolledtrial[Filter]).

Participant or population: Patients who suffered TAVR or SAVR interventions.

Intervention: TAVR, SAVR.

Comparator: TAVR vs SAVR.

Study designs to be included: The following eligibility criteria were used to select studies: (a) published randomized controlled trials or cohort studies; (b) Experimental and control population included in the studies had at least one neurological or cardiogenic outcome reported.

Eligibility criteria: Inclusion Criteria: The following eligibility criteria were used to select studies: (a) published randomized controlled trials or cohort studies; (b) Experimental and control population included in the studies had at least one neurological or cardiogenic outcome reported. Exclusion Criteria: a) Any study

which was not a trial b) Studies over five years old c) studies which didn't contain any control or experimental data. d) Studies which did not report a neurological or cardiogenic cause of mortality.

Information sources: An electronic search of MEDLINE, Google Scholar, and Cochrane Central was carried out from their inception to 28th September 2022 without any language restrictions, using the search strategy.

Main outcome(s): Eight trials evaluating the effectiveness of TAVR vs SAVR were included. According to the analysis, on long-term, TAVR didn't significantly reduce the incidence of stroke in experimental population as compared to the control population, treated by SAVR intervention. The findings showed that all the research studies carried equal weights in the pooling of studies (12.5%) in the stroke outcome along with a 95% CI of -14.24 [-62.81, 34.33] whereas in the forest plot of the cardiogenic cause, Ito 2020's research study had the lowest weight (10.3%) and the largest spread among the pooled studies, and a 95% CI of 15.00 [1.38, 28.62] The studies' heterogeneity turned out to be 99 percent for cardi-ogenic cause such as MI, and the findings were significant with a P value of P = 0.02. This demonstrates that the SAVR intervention procedures used in the six distinct studies were effective in lowering the cardiogenic causes in the long-term. SAVR was associated with a significant lower rate of mortality due to cardiogenic causes. Moreover, when TAVR and SAVR were analyzed for the mortality due to stroke, the results turned out to be non-significant with a P value of P = 0.57 which indicated that the TAVR and SAVR could not assist in preventing the stroke in the long-term duration.

Quality assessment / Risk of bias analysis: The articles discovered via the systematic search were imported into EndNote Reference Library, where duplicates were recognised and removed. Only studies that met the previously defined criteria were selected from the remaining papers, which were extensively evaluated. All trials were

first shortlisted based on the title and abstract, and the whole article was then reviewed to ensure relevancy. Furthermore, any inconsistencies were excluded. The completed trials yielded the following results: stroke and cardiovascular causes such as MI It was retrieved using an Excel spreadsheet, and all data and values were preserved in the spreadsheet for subsequent study. In addition, the Cochrane Collaboration's risk of bias tool for randomised controlled trials was used to assess the quality of the studies and provide a plot and risk of bias summary for each.

Strategy of data synthesis: RevMan (version 5.3; Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014) was used for all statistical analyses. The results from studies were presented as means and standard deviations with 95% confidence intervals (CIs), and were pooled using a random effects model. Forest plots were created to assess visually the results of pooling. Furthermore, funnel plot was also constructed to evaluate the publication bias in studies in addition to the risk of bias graph and risk of bias summary chart.

Subgroup analysis: 6290 stroke patients were randomly assigned to the experimental arm of the research, while 8311 patients were randomly assigned to the control arm. While for the cardio-genic reason, 3024 patients were randomly assigned to the experimental arm and 2949 patients to the control arm throughout the six investigations.

Sensitivity analysis: Furthermore, when the publication bias of the pooled studies was examined, there was publication bias seen in the funnel plot for the TAVR and SAVR in stroke as well as MI outcome, which was created using RevMan (version 5.3; Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014).

Language restriction: None.

Country(ies) involved: Romania.

Other relevant information: Translations
Surgical valve: "surgical instruments"[MeSH Terms] OR ("surgical"[All Fields] AND "instruments"[All Fields]) OR "surgical instruments"[All Fields] OR ("surgical"[All Fields] AND "valve"[All Fields]) OR "surgical valve"[All Fields] replacement: "replace"[All Fields] OR "replaceable"[All Fields] OR "replaced"[All Fields] OR "replaces"[All Fields] OR "replacing"[All Fields] OR "replacment"[All Fields] OR "replantation"[MeSH Terms] OR "replantation"[All Fields] OR "replacement"[All Fields] OR "replacements"[All Fields] Adults: "adult"[MeSH Terms] OR "adult"[All Fields] OR "adults"[All Fields] OR "adult's"[All Fields] elderly: "aged"[MeSH Terms] OR "aged"[All Fields] OR "elderly"[All Fields] OR "elder-lies"[All Fields] OR "elderly's"[All Fields] OR "elderlys"[All Fields] Mortality: "mortality"[MeSH Terms] OR "mortality"[All Fields] OR "mortalities"[All Fields] OR "mortality"[Subheading] 7822:32:26 In addition to that we also manually screened the reference list of retrieved trials, re-view articles and previous meta-analyses to identify any relevant studies. However, only the randomized trial studies and cohort studies were included in our meta-analysis.

Keywords: transcatheter aortic valve replacement (TAVR), surgical aortic valve replacement (SAVR), stroke, stroke mortality, COVID 19 pandemic.

Contributions of each author:

Conceptualization, L.I.S., E.P., A.C.I. ; methodology, L.I.S.; software, L.I.S., E.P.; validation, A.C.I., S.S.B. and C.L.A.; formal analysis, L.I.S., A.C.I.; investigation, L.I.S., A.C.I., E.P.; resources, A.C.I.; data curation, L.I.S.; writ-ing—original draft preparation, L.I.S.; writing—review and editing, A.C.I.; visualiza-tion, S.S.B.; supervision, C.L.A.; project administration, A.C.I.; All authors have read and

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