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Clinical outcomes of Myval versus Edwards Sapien valve for transcatheter aortic valve implantation in patients with severe aortic stenosis: a systematic review and meta-analysis

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ADMINISTRATIVE INFORMATION

Support - Nil.

Review Stage at time of this submission - Piloting of the study selection process.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202560110

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 27 June 2025 and was last updated on 27 June 2025.

INTRODUCTION

Review question / Objective The objective of this review is to compare procedural and clinical outcomes after transcatheter aortic valve implantation with Myval versus Edwards Sapien valves.

The systematic review will address the following question: What are the procedural and clinical outcomes with Myval as compared to Edwards Sapien valve in patients with severe aortic stenosis undergoing transcatheter aortic valve implantation?

Rationale Aortic stenosis (AS) is a pathological condition of the aortic valve that results in narrowing of the valve. It is typically a degenerative condition that occurs with ageing, predominantly affecting the elderly population. Traditionally, aortic stenosis has been treated with surgical aortic valve replacement. Of late, transcatheter therapy in the form of transcatheter aortic valve implantation (TAVI) has been established as a reasonable alternative in elderly patients with severe AS across the entire spectrum of surgical risk, that is, low risk to high risk. Transcatheter valves can either be balloon-expanding or self-expanding. Edwards Sapien is the most commonly used balloon expandable valve with well validated clinical outcome data. Myval is a relatively new balloon expandable transcatheter heart valve but comparative outcome data with the established transcatheter heart valves is scarce. This systematic review and meta-analysis aim to synthesize evidence comparing clinical outcomes after TAVI between Myval and Edwards Sapien valves.

Condition being studied Aortic stenosis is a progressive, degenerative condition of the aortic valve characterised by narrowing of the valve orifice that impedes blood flow. In patients with severe aortic stenosis who are symptomatic, valve replacement is indicated to improve outcomes. This has traditionally been achieved by surgical aortic valve replacement. Transcatheter aortic valve implantation is a minimally invasive

alternative in which a catheter mounted bioprosthetic valve is delivered to the heart and implanted within the native aortic valve. Clinical trials have established TAVI as a comparable strategy to surgical aortic valve replacement in elderly patients with symptomatic severe aortic stenosis.

METHODS

Search strategy The search was conducted on 21st June, 2025 on Pubmed, Embase and CENTRAL through Cochrane library . The basic concepts for the search strategy were 'TAVI', 'Myval' and 'aortic stenosis'. The search string was combined using controlled vocabulary, keywords and synonyms. The search was adapted based on the database being searched to include the specific indexing terms. No search restrictions were used.

Only studies published in English and where full text is available will be included for the systematic review and meta-analysis. Study investigators will be contacted if necessary to obtain information.

Participant or population Patients with severe aortic stenosis undergoing transcatheter aortic valve implantation.

Intervention Myval (either first-generation Myval or Myval Octacor).

Comparator Edwards Sapien valve (either Sapien 3 or Sapien 3 Ultra).

Study designs to be included The review will include observational studies (prospective as well as retrospective studies) and interventional trials, including randomised control trials comparing Myval with the Edwards Sapien valves.

Eligibility criteria Studies will be included only if they fulfil the following criteria:
1) Studies comparing Myval and Edwards Sapien valves in patients with severe aortic stenosis undergoing TAVI
2) Studies reporting at least one of the predefined outcomes
3) Full-text available in English
Review articles, case reports, case series, scientific abstracts and non-journal publications will be excluded.

Information sources The search was conducted on PubMed, Embase and CENTRAL through the Cochrane Library. We also performed grey literature search for trials at clinicaltrial.gov.

Main outcome(s)
All-cause mortality at 30 days
Permanent pacemaker implantation at 30 days
Major vascular complications at 30 days
VARC criteria will be followed for the outcomes.

Additional outcome(s) Technical success post-procedure
Device success at 30 days
Clinically significant paravalvular regurgitation (moderate or severe) at 30 days
All stroke at 30 days
Major bleeding at 30 days
Minor vascular complications at 30 days
New-onset atrial fibrillation at 30 days
Significant acute kidney injury at 30 days
Early safety at 30 days
Hemodynamic parameters (mean gradient, effective orifice area, significant aortic regurgitation)
All stroke at 1 year
All-cause mortality at 1 year

VARC criteria will be followed for outcomes.

Data management Titles and abstracts of the studies yielded by the search strategy will be screened independently by two reviewers to shortlist studies for full-text review. Any disagreements noted after screening between the two reviewers will be resolved through discussion and a third reviewer if required.
Full text of studies shortlisted after screening will be independently examined by the two reviewers to identify eligible studies for the systematic review as per the eligibility criteria. Any disagreements between reviewers will be resolved through discussion and a third reviewer if required.

Data will be extracted independently by two reviewers in a predefined data collection form. Any discrepancy in data will be resolved through discussion and a third reviewer if required. Data extracted will include baseline characteristics of the participants reported in the studies and primary and secondary outcomes for planned meta-analysis.
Standard softwares such as EndNote, Zotero, Review Manager (RevMan), R, Rayyan and other web-based systems will be used for various steps of the meta-analysis.

Quality assessment / Risk of bias analysis Risk of bias assessment will be performed independently by the two reviewers using standardised tools that is, Cochrane Collaboration's Risk of Bias 2 tool for randomised

studies and Newcastle-Ottawa Scale for observational studies.

Strategy of data synthesis A quantitative synthesis will be performed if feasible. Dichotomous variables will be summarized in form of odds ratio or risk ratio while continuous variables will be summarized in form of mean difference. The results will be pooled using the random effects model for each outcome. Data synthesis will be performed using standard sofwares used for the meta-analysis. Heterogeneity will be evaluated using the I2 statistic and a value greater than 50% will be considered as significant heterogeneity.

Subgroup analysis Subgroup analysis will be done based on the type of studies with separate analysis for observational studies and randomised trials.

Sensitivity analysis Sensitivity analysis will be performed by removing low-quality studies with high risk of bias.

Language restriction Only studies in English will be included.

Country(ies) involved India.

Keywords aortic stenosis, TAVI, TAVR, Myval, Meril, Edwards Sapien.

Contributions of each author

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