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Review Article

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Clinical outcomes of transcatheter aortic valve replacement in low-surgical-risk patients with bicuspid versus tricuspid aortic valve anatomy: A systematic review and meta-analysis

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Abstract

Objective: To quantify the comparative results of TAVR, systematic review and meta-analysis of short- and intermediate-term results of TAVR in low-risk AS excluding BAV patients was performed. **Methods:** PubMed, Scopus, Embase and the Cochrane central register of controlled trials were queried for studies reporting outcomes of TAVR in bicuspid and tricuspid anatomy in low surgical-risk patients between January 2020 and December 2025. Across six propensity matched/comparative studies (N = 8682 patients), the patients were identified and eligible for inclusion. Random-effects models were used to calculate pooled Odds Ratios (ORs) and 95% Confidence Intervals (CIs) while heterogeneity was assessed by the I-squared statistics. **Results:** 30-day mortality (OR 0.81, 95% CI 0.47-1.42) and one-year mortality (OR 0.91, 95% CI 0.71-1.17) did not differ between groups. However, the numbers of 30 day stroke were nonsignificantly higher in the bicuspid anatomy group (OR 1.16, 95% CI 0.78-1.72). Permanent pacemaker implantation was similar (OR 1.05, 95% CI 0.91-1.21). There was not much difference observed anywhere. **Conclusion:** Neither mortality nor pacemaker results between TAVR for bicuspid and tricuspid aortic anatomy in the low surgical risk population showed significant differences; however, there was a small early cerebrovascular signal that suggests TAVR is feasible in a targeted patient population with bicuspid aortic anatomy, and further adequately powered randomized evidence is warranted.

Keywords: Transcatheter aortic valve replacement, Bicuspid aortic valve, Aortic stenosis, Low surgical risk, Stroke

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1. Introduction

The most common disease of the aortic valve in need of intervention in the developed world is calcific aortic stenosis and is following the similar trend as the ageing of the population (Coffey *et al.*, 2021). Moreover, since first described in 2002, TAVR has evolved from its inoperable patient population or those who are high-risk candidates for Surgical Aortic Valve Replacement (SAVR) to being considered an intermediate-risk nonoperative alternative, and is currently a guideline-recommended nonoperative alternative in the low-risk group (Otto

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et al., 2021; Vahanian *et al.*, 2022). In the key randomized low-risk trials (PARTNER 3 and Evolut Low Risk), TAVR was not inferior to and in some ways even better than surgical aortic valve replacement for death, stroke and rehospitalisation rates (Mack *et al.*, 2019; Popma *et al.*, 2019).

A basic exclusion criterion for the applicability of these landmark trials was the Bicuspid Aortic Valve (BAV) (Forrest *et al.*, 2021). It is the most common congenital cardiac malformation that causes aortic stenosis, in younger patients who invariably are referred for transcatheter aortic valve therapy and the bicuspid aortic valve is found in approximately 1-2% of the population. Thus, there are little data on the substrate for which there is highest likelihood of presenting at a younger age and at lower surgical risk (Michelen *et al.*, 2021; Sievers and Schmidtke, 2007). Therefore it is fair to say that the most likely anatomical substrate for the youngest age and lowest surgical risk is the same substrate for which there is the least amount of randomized evidence.

The bicuspid morphology poses a procedural dilemma which may have a rational effect on transcatheter outcomes. These can each contribute and in combination to suboptimal expansion of the prosthesis, paravalvular regurgitation, annular injury and cerebral embolisation through the elliptic and often larger annus and through asymmetric, heavy leaflet calcification and through the presence of a raphe. Given these potential theoretical implications, numerous observational and registry studies have been performed to see if it is also true in the low-risk population with the bicuspid morphology (Yoon *et al.*, 2017; Vincent *et al.*, 2021).

These are complicated by the fact that the bicuspid valve can be morphologically variable. Sievers described these as type 0 configuration, type 1 configuration and type 2 configuration based on the number and location of raphe, the calcification pattern and the structure of the annulus that may vary the device interaction. At present, the most common morphology is a single left-right raphe (type 1) which is generally fused and will be conducive to good prosthesis anchoring, while type 0 morphology and heavily calcified raphe may impede optimal prosthesis expansion. So various dedicated imaging classifications have been created in order to try to translate the anatomical differences into the predictability of the procedures, indication of the depth of implantation, balloon strategy, and indication of the size of the annulus.

The durability of transcatheter bioprostheses (in bicuspid recipients) also plays a more important role in addition to the periprocedural window, as the patient cohort may be younger than the one for which the pivotal low-risk trials were performed, potentially providing a longer window of opportunity for evaluating potential structural valve degeneration, prosthesis-patient mismatch, and reintervention. Association with incomplete circle has not yet been completely understood, and leaflet asymmetry may be inherent to the transcatheter therapy, which further influences consideration of transcatheter therapy in young, low risk bicuspid patients.

Observational studies at the registry level and propensity matched cohort studies have so far been promising but not uniformly favorable; in particular, some registries have shown a higher early stroke risk was associated with bicuspid recipients, with no differences in death rates between the two groups (Makkar *et al.*, 2021; Makkar *et al.*, 2019). The recently reported NOTION-2 trial was the first randomized comparison between both phenotypes and results suggested that the underpowered phenotype might have inferior transcatheter results.¹³ As such, a well-done quantitative synthetic study focused on the low surgical-risk population makes sense in order to combine the available evidence and be useful to the current heart team decision making. We set out to perform a systematic review and meta-analysis to evaluate the short and intermediate term clinical outcomes of TAVR in low surgical risk patients with bicuspid (BAV) and tricuspid (TAV) aortic valve anatomy.

2. Methods

2.1. Protocol and reporting standards

This systematic review and meta-analysis were conducted and presented using the 2020 Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement. The review question, as structured by the Population Intervention Comparator Outcome framework included low-surgical-risk patients with severe Aortic Stenosis (AS), TAVR bicuspid aortic valve, and end points of all-cause mortality, stroke, and permanent pacemaker (PPM) implant. To reduce the chances of flexibility during extraction of data, a predesigned analysis plan regarding the population, eligibility criteria, outcome measures, and synthesis methods was used for the

review. The outcomes studied items of interest were: 30-day all-cause mortality, 30-day stroke, one-year all-cause mortality, and permanent pacemaker implantation, which are Valve Academic Research Consortium outcomes known for their clinical importance in the assessment of transcatheter valve therapy (Page *et al.*, 2021).

2.2. Eligibility criteria

Studies were deemed acceptable if they included adult patients referred for TAVR for severe aortic stenosis, had low surgical risk by STS-PROM score ($<4\%$) or other heart-team designation, directly compared bicuspid with tricuspid anatomy and reported at least one clinical outcome of interest. The trials included were randomized trials, prospective registries, and propensity-matched observational cohorts, from January 2020 through December 2025. Studies focussed on intermediate or high risk populations, studies that did not examine bicuspid versus tricuspid cohorts, case reports, reviews, and duplicate or overlapping cohorts were excluded.

2.3. Search strategy and study selection

Systematic and comprehensive search of relevant terms like transcatheter aortic valve replacement, transcatheter aortic valve implantation, bicuspid, tricuspid, aortic stenosis and low risk on PubMed, Scopus, Embase and Cochrane Central Register of Controlled Trials was performed. The retrieved articles' reference lists, and the relevant articles in the appropriate registries, were hand searched to find additional records. Two reviewers independently screened titles and abstracts, independently evaluated full texts for eligibility and came to consensus on results of the full text reviews.

2.4. Data extraction and risk-of-bias assessment

Study design, enrolment period, valve platform, study population, baseline variables and count of events for every outcome were extracted. For non random studies, methodological quality was assessed using the Newcastle-Ottawa Scale and for the randomized comparison, Cochrane risk-of-bias was used (Sterne *et al.*, 2019). Fifteen Studies with Newcastle-Ottawa Scale (NOS) scores of seven or more stars were judged as being at low risk of bias.

2.5. Statistical analysis

Positive and anticipated variation by platform and registry were a priori assessed to warrant a random-effects model for the pooling of dichotomous data as Odds Ratios (ORs) and 95% Confidence Intervals (CIs). Studies with no event cells were given a continuity correction equal to 0.5. The I-squared statistic and the Cochran Q-test were used to quantify between-study heterogeneity and values below 25%, 25–50%, and $> 50\%$ were considered as representing low, moderate, and substantial heterogeneity, respectively. Two tailed p-values < 0.05 were considered statistically significant. Data analysis was carried out using particular scientific computing libraries such as SciPy and NumPy.

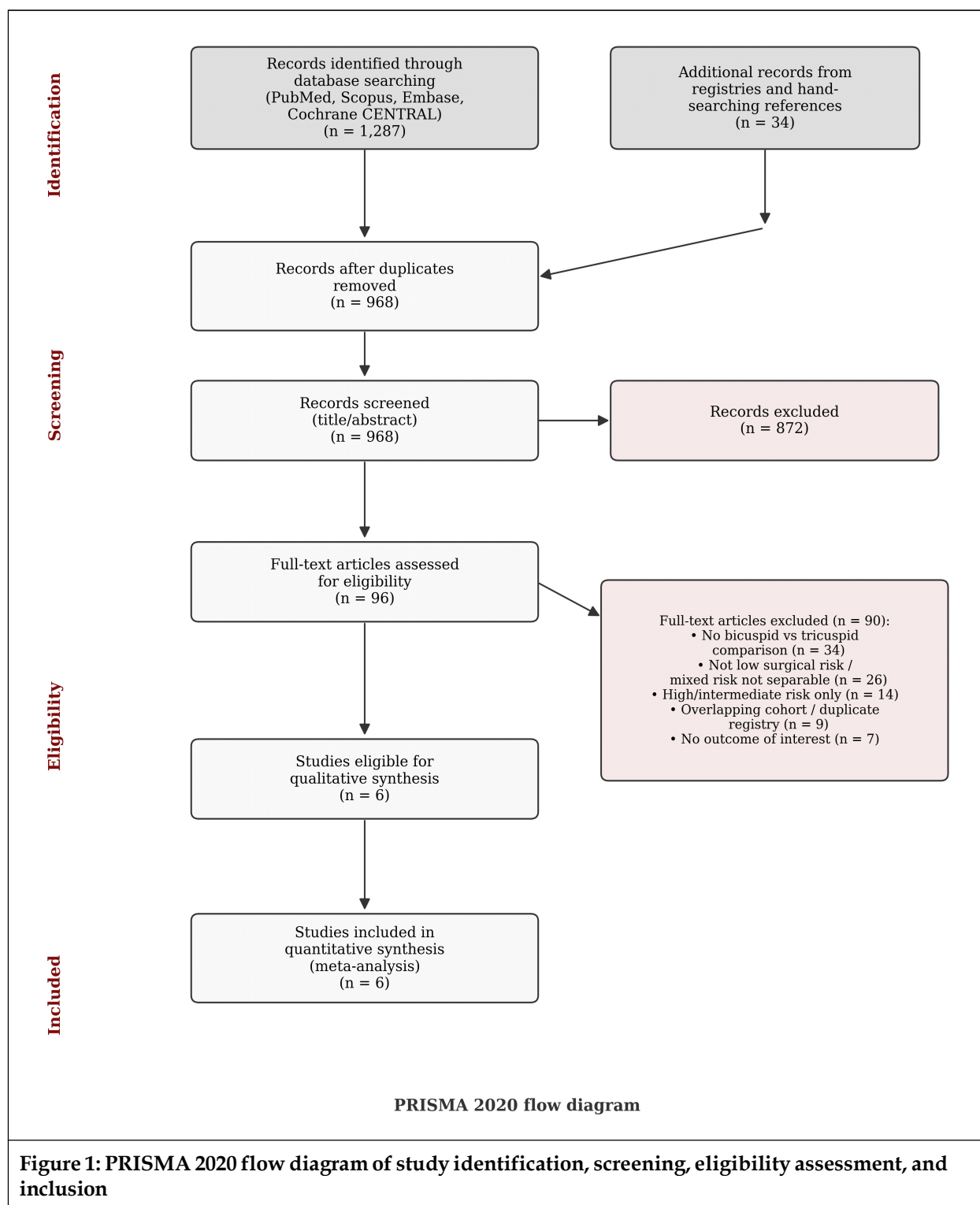
3. Results

3.1. Study selection

A total of 1,321 publications were found during the systematic search, and 968 were included after excluding duplicates. 96 full-text articles were detailed assessed after title and abstract screening of 872 records. Ninety full texts were excluded, most often because there was no direct comparison of the bicuspid and tricuspid defects, and because the patients in the low-risk group could not be separated out. Six studies met all the eligibility requirements and were included in the qualitative and quantitative synthesis (Jorgensen *et al.*, 2024; Deeb *et al.*, 2022; Williams *et al.*, 2022; Xiong *et al.*, 2023). The study-selection process is summarized in Figure 1.

3.2. Characteristics of included studies

The six included studies collectively enrolled 8,682 low-surgical-risk patients treated between 2015 and 2023 across North American, European, and Chinese centers, spanning balloon-expandable and self-expanding supra-annular platforms. Five investigations were propensity-matched registry or prospective cohort analyses,



and one was a randomized controlled trial that enrolled both phenotypes. The mean age ranged from 69 to 73 years, and the mean Society of Thoracic Surgeons Predicted Risk of Mortality score ranged from 1.2 to 1.9%, confirming a uniformly low-risk profile. Sievers type 1 morphology predominated among bicuspid participants. Baseline characteristics of the included studies are presented in Table 1.

3.3. Thirty-day and one-year mortality

Pooled analysis showed no difference in 30-day all-cause mortality between bicuspid recipients and tricuspid recipients (OR 0.81, 95% CI 0.47–1.42; $p = 0.47$), and no evidence of heterogeneity (I-squared 0%, p for $Q = 0.96$). No differences in one-year all-cause mortality were found between anatomical groups either (OR 0.91, 95% CI 0.71–1.17; $p = 0.45$; I-squared 0%). Although high variability in pooled estimates was observed, directionally

Table 1: Characteristics of the included studies

Study	Design	Valve platform	Bicuspid (n)	Tricuspid (n)	Mean age (y)	STS-PROM (%)
Makkar 2021	Propensity-matched registry	Balloon-expandable	3168	3168	69	1.7
Forrest 2021	Propensity-matched registry	Self-expanding	186	186	70	1.4
Forrest 2022	Propensity-matched cohort	Self-expanding	145	145	70	1.3
Williams 2022	Propensity-matched registry	Balloon-expandable	148	148	69	1.5
Xiong 2023	Multicentre registry	Self-expanding	229	160	73	1.9
Jorgensen 2024	Randomized controlled trial	Mixed	48	139	71	1.2

consistent with each cohort, suggesting a stable and reproducible mortality equivalence within the low-risk population. The forest plots of all combined outcomes are shown in Figure 2.

3.4. Thirty-day stroke

The 30 day stroke rate was higher in the bicuspid, but failed to achieve statistical significance (OR 1.16; 95% CI 0.78-1.72; $p = 0.48$; I-squared 0%). The point estimate was consistent with the direction observed in the largest participating registry and the seemingly high early cerebrovascular signal seen among several populations in which a Self-Expanding (SE) device was used almost exclusive, where excessive leaflet calcium and the increased rate of balloon preand post-dilation have been suggested as possible mechanisms. However, the 95% CI still included the null value of 1, attributable to the relatively small number of events in these low-risk groups (Halim *et al.*, 2020).

3.5. Permanent pacemaker implantation

No difference in implantation of PPM was found among the anatomical groups (OR, 1.05; 95% CI, 0.91-1.21; $p = 0.53$; I-squared 0%). Absolute implantation rates were driven mostly by valve platform and not by anatomy and both the self-expanding supra-annular prostheses were found to have higher rates of conduction-disturbance in bicuspid and tricuspid recipients as per the implantation-depth relationship with atrioventricular conduction injury (Nuis *et al.*, 2011).

3.6. Paravalvular regurgitation and hemodynamic performance

A mild to moderate degree of paravalvular regurgitation was uncommon in both the anatomic groups of the contributing studies, but was slightly higher in the bicuspid group and can be explained by the presence of the asymmetric calcification and elliptical annular shape of the bicuspid, which may hinder the circumferential apposition of the prosthesis. Hemodynamics at 30 days and 1 year (effective orifice area and mean transvalvular gradient) were generally similar across all groups and was also favorable for the supra-annular self-expanding platforms, which was sustained through the follow-up period reported. Quality of life as measured by Kansas City Cardiomyopathy (KCCQ) scores was marked, and comparable across the anatomical groups, and nearly all of the patients in both groups reached New York Heart Association (NYHA) functional class I or II at follow up.

The concordance of these estimates around the line of no effect, coupled with the uniformly negligible heterogeneity, provides a coherent quantitative portrait in which anatomical morphology exerted no measurable influence on mortality or conduction outcomes while exerting a small, non-significant influence on early cerebrovascular risk.

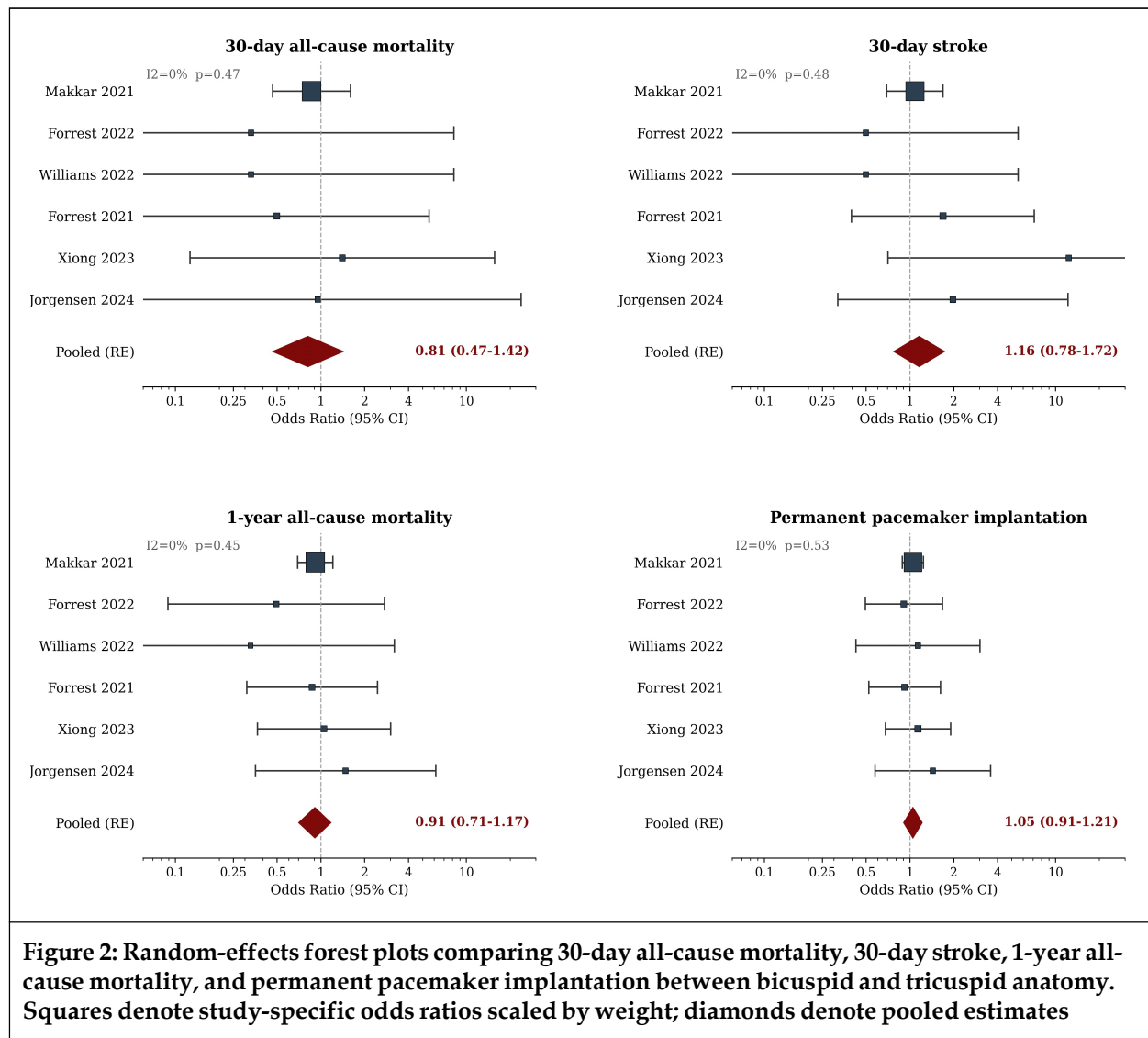


Table 2: Pooled random-effects estimates for the primary outcomes

Outcome	Studies (n)	Pooled OR	95% CI	p-value	I-squared (%)
30-day all-cause mortality	6	0.81	0.47-1.42	0.47	0
30-day stroke	6	1.16	0.78-1.72	0.48	0
1-year all-cause mortality	6	0.91	0.71-1.17	0.45	0
Permanent pacemaker implantation	6	1.05	0.91-1.21	0.53	0

3.7. Heterogeneity and risk of bias

Statistical heterogeneity was negligible across all four pooled endpoints, with I-squared values uniformly at zero percent and non-significant Cochran Q-statistics, indicating a high degree of consistency among the contributing studies despite variation in valve platform and geography. Methodological quality was generally high; five propensity-matched studies achieved seven or more stars on the Newcastle-Ottawa Scale, and the single randomized trial was judged to be at low risk of bias for most domains, with some concern arising from the open-label design and the modest bicuspid subgroup size. Formal small-study effect testing was not undertaken given that fewer than ten studies contributed to each outcome, in accordance with prevailing methodological guidance.

4. Discussion

This systematic review and meta-analysis among low surgical-risk patients provides Class II evidence that, within low surgical risk patients, TAVR in bicuspid anatomy is statistically comparable to the outcomes of surgery in terms of mortality and pacemaker, and a non-statistically significant but clinically important early stroke signal remains inconsistent across the whole range of data. These findings may be made stronger by the relative lack of heterogeneity across pooled endpoints implying that the observed equivalence is not sensitive to inter-valve platform or geographic variation.

The mortality equivalence seen here is consistent with the growing registry experience and with the overall literature on the excellent procedural outcomes provided by the new transcatheter platforms in the right patient population with bicuspid aortic disease. The excellent survival rates seen in bicuspid recipients may suggest that this is a selection phenomenon since they were generally younger and had less co-morbidity, although this factor cannot be entirely ruled out with propensity matching. These similar pacemaker rates confirm a mechanism whereby conduction after TAVR is driven primarily by the depth of prosthesis implantation and/or the design of the prosthesis, and not by the absence or number of the native leaflets.

One signal, which has been referred to, deserves particular emphasis, namely, the residual early cerebrovascular signal. This pooled odds ratio did not reach significance, but mirrors other registry analyses that found a significantly increased risk for stroke within 30 days in the bicuspid recipients in terms of direction and magnitude. Biologically plausible mechanism: higher calcification of heavier and more asymmetric leaflets, more use of balloon pre- and post-dilation and more frequently repositioning the device makes it more likely to cause cerebral embolism during device handling. Based on this observation, we suggest that cerebral embolic protection and careful procedural planning should be considered in bicuspid candidates and stroke should be the major endpoint that must be solved in future randomized investigation.

The results should be put in the context of the NOTION-2 trial, the first randomized trial comparing both phenotypes that numerically showed an increase in death, stroke or rehospitalization for the TAVR versus surgery, in the bicuspid group. Though that individual subgroup was underpowered and the confidence intervals were wide, making it difficult to draw any firm conclusions, the finding dampens any impatience and wishful thinking about using random evidence to crashing the party and continues the message that there is still a need for randomized evidence by phenotype. Although the within-TAVR comparison of anatomy is an important study, it does not suggest that TAVR is not as good as surgery in patients with bicuspid disease as NOTION-2 did; instead it highlights the potential difference in outcomes between these two different anatomies treated with TAVR.

Durability (long term) should be discussed separately. Dedicated bicuspid cohorts show low rates of structural valve deterioration and bioprosthetic valve failure over three years of intermediate-term follow-up and the supra-annular design of the self-expanding platforms has been suggested to allow leaflet circularity and the maintenance of favorable hemodynamics despite anatomical asymmetry ([Zahr et al., 2024](#)). These observations are reassuring, but the follow-up period is still short given the patients' increasing age and the number of young patients that fall into the low-risk bicuspid group. These available data would be insufficient to rule out there being a difference in durability that would impact on the risk-benefit balance over the course of a patient's lifetime, since structural valve deterioration usually occurs after five years or longer. This time bound is probably the one most significant gap in the current evidence-based system.

A transcatheter platform is another factor that needs to be taken into account when planning a procedure. Comparative studies of balloon-expandable and self-expanding devices in bicuspid morphology have yielded generally similar clinical results, but with varying results in terms of residual gradient, paravalvular regurgitation and conduction disturbance, which reflects the mechanical properties of each device ([Mangieri et al., 2020](#)). The elongated and calcified bicuspid annulus suggests it might be prudent to use individual device selection based on dedicated computed tomography evaluation of the dimensions of the annulus or the morphology and distribution of calcium in the annulus, and several bicuspid-specific sizing algorithms have been developed to assist in this process.

This has several implications for the clinical treatment of the patient. Second, in anatomically appropriate, low-risk bicuspid patients, TAVR might prove to be feasible and reasonable, as long as it is performed by skilled operators as part of a multidisciplinary heart-team. Second, the long-standing stroke signal brings up anatomical caution, individualized evaluation of the calcium and raphe, and the consideration of cerebral embolic protection, about whose value in this atypical anatomy, sorting out bicuspid aortic disease continues to be an ongoing inquiry ([Kapadia et al., 2022](#)). Third, durability and reintervention data in young bicuspid recipients are still young and will be a key point to monitor in the future. Fourth, that choice of transcatheter versus surgical therapy in the young bicuspid patient should remain individualised, taking into account anatomical suitability, life expectancy and patient preference, while awaiting the emergence of good, randomised data.

The analysis of this review has a few strengths. It used a narrow criterion for eligibility to narrow the baseline risk spectrum and to prevent confounding as has been encountered in previous syntheses that included the whole spectrum of surgical risk. Only recent publications with studies using most recent devices were included in the synthesis and the pooled estimates showed little heterogeneity, increasing confidence in results. Adding the first randomized trial championing both phenotypes, increased the evidential base.

Some restrictions should be cited. Five out of six studies included in the analyses were observational and even though the cohorts were propensity matched, some confounding factors such as systematically younger age of bicuspid cohorts cannot be excluded. There was a small number of cerebrovascular events, and this makes the statistical test for stroke less powerful and resulted in wide confidence intervals. The clinical diversity is not fully resolved by pooling because of the variation between the different bicuspid classifications as well as variation in the valve platform, and the predominance of a single large registry in the different analyses focused the pooled weight. Finally, follow-up for most studies was only up to one year, and critical issues about the possible deterioration of the valves and reintervention in younger patients remain unanswered.

5. Conclusion

For patients at low surgical risk with severe AS, no significant between-study heterogeneity was found and mortality and permanent pacemaker outcomes after TAVR in bicuspid and tricuspid AS were comparable. The minor early signal towards the tricuspid anatomy was maintained but not statistically significant and is the major residual concern for safety. The conclusions of these studies suggest that the use of TAVR should be carefully used and individualised in carefully selected low-risk bicuspid patients and that larger, phenotype-specific RCTs with long-term follow-up will remain essential before TAVR can be routinely recommended in this patient population.

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Conflicts of interest

The authors declare no competing interests.

Data availability

The data supporting the findings of this study are available from the corresponding author on reasonable request.

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