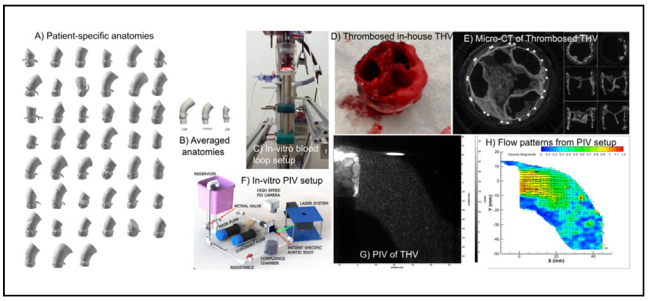

CONCLUSION Preliminary results suggest tilt and expansion influence thrombus deposition, with specific flow patterns leading to variability in deposition. Further parametric variations are expected to refine our understanding and guide preprocedural planning to minimize post-TAV thrombosis risk.

CATEGORIES **STRUCTURAL:** Valvular Disease: Aortic.

TCT-931

Outcomes of Self-Expanding vs Balloon-Expandable Transcatheter Aortic Valves in Patients With Small Aortic Annuli: A Meta-analysis

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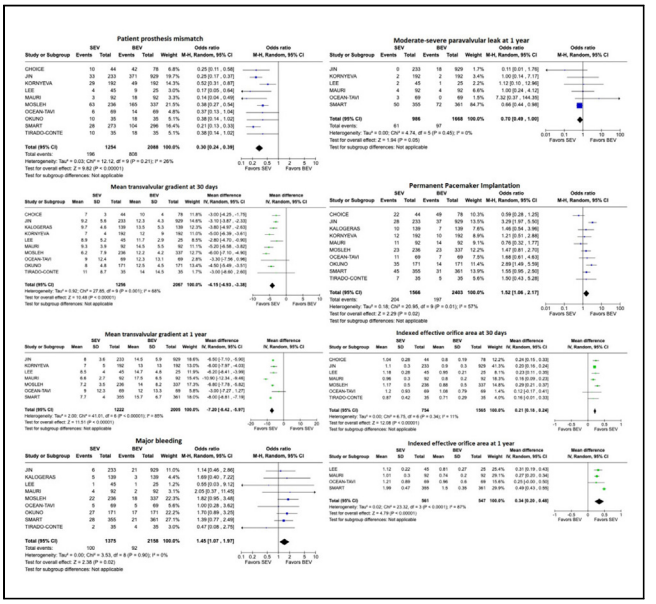
BACKGROUND Despite the benefits of TAVR, there is a lack of head-to-head comparison between different types of transcatheter aortic valves in patients with small aortic annulus essential to guide clinical decisions and improve patient outcomes in this high-risk group.

METHODS An electronic search of Medline, Embase, and Cochrane databases was performed until June 2024 for studies comparing self- vs balloon-expanding transcatheter aortic valves in patients with severe aortic stenosis and small aortic annulus.

RESULTS The final analysis included 11 studies (2 RCTs and 9 observational studies) with 4,039 patients: 1,611 in the SEV group and 2,428 in the BEV group. The mean age of the patients was 82 years, with women making up 80% of the study population. In patients with a small aortic annulus, those in the SEV group had significantly lower odds of patient-prosthesis mismatch (OR: 0.30; 95% CI: = 0.24-0.39; $P < 0.00001$), better mean transvalvular gradients at both 30 days (MD: −4.15; 95% CI: −4.93 to −3.98; $P = 0.00001$) and 1 year (MD: −7.20; 95% CI: −8.42 to −5.97; $P = 0.00001$), a lower incidence of moderate to severe PVL at 1 year (OR: 0.70; 95% CI: 0.49-1; $P = 0.05$), and a better iEOA at 30 days and 1 year compared with the BEV group. On the other hand, the BEV group had lower odds of pacemaker implantation, major bleeding, and mild PVL at 30 days. Subgroup analysis for RCTs validated these results.



CONCLUSIONS In patients with severe aortic stenosis and small aortic annulus, Self-expanding valves are associated with lower PPM, better mean transvalvular gradients, less long-term PVL, and better iEOA at 30 days and 1 year.

CATEGORIES **STRUCTURAL:** Valvular Disease: Aortic.

TCT-932

The Current Generation of THV: A Single-Center Propensity-Score Match Analysis

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BACKGROUND The Myval transcatheter heart valve (THV) series is a next-generation balloon-expandable transcatheter aortic valve replacement (TAVR) system that has shown consistent encouraging outcomes in terms of safety and efficacy.

METHODS We collected data from 1,053 patients between September 2019 and September 2023 through a TAVR registry at our study center. A propensity-score match analysis was used to compare the Myval THV Series, the Evolut Series, and the Sapien 3 devices. A total of 228 patients were enrolled in the propensity-score matching analysis, n = 76 for each device. The study endpoints included hemodynamic outcomes compared with baseline, in-hospital safety outcomes, and all-cause mortality at 30 days and 1 year. Echocardiographic follow-up was performed at 30 days.

RESULTS After propensity-score matching (tri-match) the rates of stroke (2.63% in all groups), life-threatening bleeding (1.32% in Myval THV series and Evolut groups, 2.63% in Sapien 3 group), myocardial infarction within 72 h after TAVR (2.63% vs 1.32% vs 1.32%; $P = 1.00$), and myocardial infarction more than 72 h after TAVR (0.00% in all groups) were comparable among the Myval THV Series, Evolut Series, and Sapien 3 groups, respectively. All-cause mortality rates were similar in Myval THV Series and Evolut Series, whereas they were higher in Sapien 3 group at 30 days (2.67% vs 2.63% vs 5.26%; $P = 0.7359$). One-year all-cause mortality rates were 6.67% vs 9.21% vs 7.89% ($P = 0.8459$) in the Myval THV Series, Evolut Series, and Sapien

3 groups, respectively. The rate of new permanent pacemaker implantation after TAVR was numerically higher in the Evolut Series and Sapien 3 groups (14.47% and 13.33%, respectively) than in the Myval THV Series group (10.67%), but the difference was not statistically significant ($P = 0.7732$). Only 4 cases of moderate paravalvular regurgitation (PVR) were reported: 1 in the Myval THV Series, 1 in the Evolut Series, and 2 in the Sapien 3 group. All other cases of PVR were mild or trace/absent.

CONCLUSION The tri-match analysis of the THV devices showed that the performance of the Myval THV Series is comparable to the other established contemporary valves in terms of safety and efficacy.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic.

TCT-933

Win Ratio Analysis of the LANDMARK Trial: Myval Transcatheter Heart Valve vs Contemporary Standard Valves (Sapien and Evolut) in Patients With Severe Aortic Stenosis

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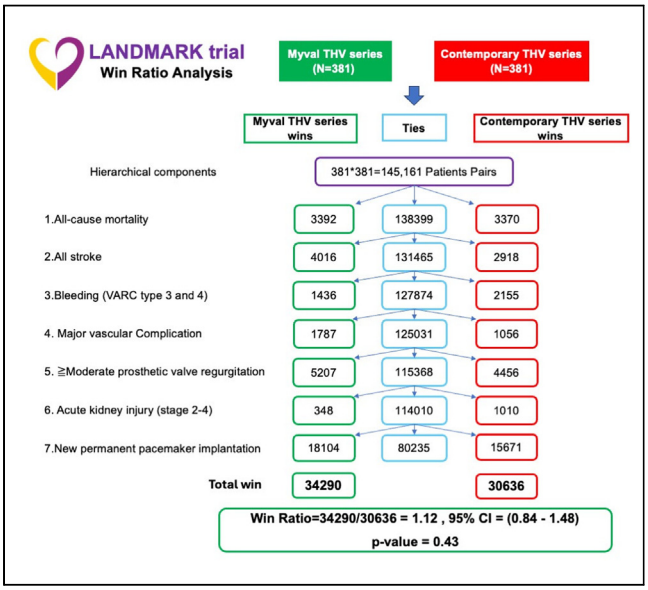
BACKGROUND The LANDMARK trial reported the noninferiority of the Myval transcatheter heart valve (THV) compared with the contemporary standard THVs (Sapien and Evolut) regarding a 30-day composite endpoint in patients with severe aortic stenosis.

METHODS The LANDMARK was a multicenter, randomized, noninferiority trial comparing the Myval series and the contemporary THV series. From January 2021 to December 2023, 768 patients were randomized 1:1 to Myval or contemporary THV group. This substudy aimed to compare the 2 groups using a win ratio analysis. A consensual ranking order of severity of the 7 items of the primary composite endpoint was obtained among 10 cardiologists by means of the Delphi method and became all-cause death, all stroke, VARC type 3 or 4 bleeding, major vascular complication, ≥ moderate prosthetic valve regurgitation (PVR), acute kidney injury (AKI) stage 2-4, and new permanent pacemaker implantation (PPI).

RESULTS In the win ratio analysis with 145,161 unmatched patient pairs, five events (death, stroke, vascular complications, ≥ moderate PVR, and PPI) numerically favored the Myval group, and 2 (bleeding and AKI) the contemporary group (Figure 1). Overall, there were 34,290 wins in the Myval and 30,636 in the contemporary group, such that the win ratio was not statistically significant (34,290/30,636 = 1.12; 95% CI: 0.84-1.48; $P = 0.43$).



CONCLUSIONS The win ratio of the primary composite endpoint was not statistically significant, and consistent with the primary analysis of noninferiority of the Myval series to the contemporary THV series at 30 days.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic.

Session: TAVR vs TAVR – 2

TCT-158

Comparative Efficacy and Safety of Self-Expanding Versus Balloon-Expandable TAVR in Patients With Aortic Stenosis: A Systematic Review and Meta-Analysis

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BACKGROUND Patients with aortic stenosis have a high mortality risk. New self-expanding valves (SEV) and balloon expandable valves (BEV) are used in transcatheter aortic valve replacement (TAVR). We performed a systematic review and meta-analysis to compare the clinical outcomes of efficacy and safety of these 2 valves in patients of aortic stenosis.

METHODS A systematic search of PubMed, Embase, and Cochrane was conducted from inception to June 2024. Randomized controlled trials that included adult human patients with aortic stenosis undergoing TAVR comparing clinical outcomes of efficacy and safety between SEV and BEV were eligible. Random effects meta-analysis using the inverse variance method was employed. Quality appraisal was done using Cochrane Risk of Bias 2 Tool. This review was registered with PROSPERO, CRD4202456362.

RESULTS We identified 8 RCTs and data from 2,779 patients was analyzed. Random effects analysis showed that SEV when compared with BEV significantly increased risk of all-cause mortality RR: 1.84 (95% CI: 1.11-3.04), cardiovascular mortality RR: 2.00 (95% CI: 1.05-3.83), and permanent pacemaker implantation RR: 1.67 (95% CI: 1.22-2.28) at 30 days. However, these outcomes were not statistically significant at 1 year. Other assessed outcomes like stroke, acute kidney injury, and myocardial infarction also did not have statically significant results