

## Effectiveness and safety of myval versus self-expanding valves in patients undergoing transcatheter aortic valve implantation: a systematic review and meta-analysis

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**Background:** Transcatheter Aortic Valve Implantation (TAVI) is the preferred treatment for patients with severe aortic stenosis (AS) across various surgical risk categories. While self-expanding valves (SEV) are widely used due to their conformability and hemodynamic profile, the Myval transcatheter heart valve (THV), a newer-generation balloon-expandable valve (BEV), has been designed to improve annular sealing, reduce paravalvular aortic regurgitation (AR), and lower conduction disturbances. However, the comparative safety and efficacy of Myval versus SEV remain an area of active investigation.

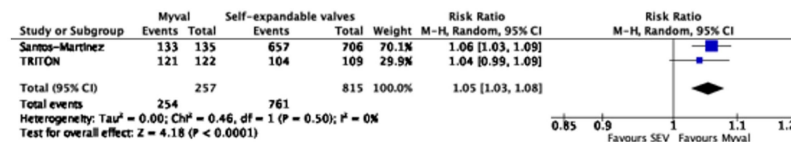
**Purpose:** This study aimed to evaluate the comparative effectiveness and safety of Myval versus SEV in patients undergoing TAVI.

**Methods:** Our systematic review and meta-analysis was conducted according to the latest PRISMA guidelines. A comprehensive electronic literature search was performed across the three major databases—Cochrane, Medline, and Scopus—to identify relevant studies published up to December 19, 2024. The primary endpoint was device success assessed periprocedurally and at 30-days. Secondary endpoints included periprocedural, 30-day and 1-year all-cause mortality, periprocedural device embolization, need for >1 THV, coronary arteries obstruction or occlusion and cardiac tamponade, 30-day and 1-year stroke, 30-day early safety, permanent pacemaker implantation (PPI), major and minor vascular complications, acute kidney injury (AKI), major bleeding and moderate or severe transvalvular AR.

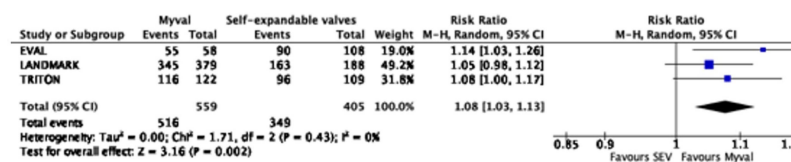
**Results:** A systematic review and meta-analysis were performed, incorporating data from 5 studies involving 1,996 patients undergoing TAVI. Among them, 790 patients received the Myval THV, while 1,206 were treated with SEV THVs. When compared to SEV, Myval was associated with a 5% higher rate of periprocedural (RR: 1.05, 95% CI: 1.03–1.08,  $I^2=0\%$ ) and an 8% higher rate of 30-day device success (RR: 1.08, 95% CI: 1.03–1.13,  $I^2=79\%$ ). Additionally, Myval exhibited a 16% improvement in 30-day early safety outcomes (RR: 1.16, 95% CI: 1.04–1.28,  $I^2=0\%$ ). Importantly, the risk of PPI was 40% lower in the Myval cohort compared to SEV (RR: 0.60, 95% CI: 0.38–0.95,  $I^2=44\%$ ), while Myval was associated with a 58% lower incidence of minor vascular complications (RR: 0.42, 95% CI: 0.18–0.98,  $I^2=0\%$ ) and a 81% reduction in the risk of at least moderate transvalvular AR (RR: 0.19, 95% CI: 0.05–0.81,  $I^2=76\%$ ), at 30-days. No statistically significant differences were observed between the two groups in the remaining clinical and procedural endpoints.

**Conclusion:** The Myval THV demonstrated superior periprocedural and 30-day device success, with significantly lower rates of PPI, minor vascular complications, and moderate or severe transvalvular AR, compared to the SEVs. Further randomized controlled trials with long-term follow-up are warranted to validate these findings.

**Figure 1:** Forest plot showing periprocedural device success with Myval and self-expanding valves (SEV) with risk ratio and 95% confidence intervals. CI; confidence interval, M-H; Mantel Haenszel.



**Figure 2:** Forest plot showing 30-day device success with Myval and self-expanding valves (SEV) with risk ratio and 95% confidence intervals. CI; confidence interval, M-H; Mantel Haenszel.



**Table:** Summary of Risk Ratios, Confidence Intervals and I<sup>2</sup>

MYVAL vs SEV				
Procedural Success		1.05	1.03-1.08	0
Periprocedural mortality		0.97	0.16-6.07	0
Device embolization		0.33	0.09-1.22	0
Need for >1 THV		0.36	0.10-1.31	0
Coronary arteries obstruction/occlusion		0.56	0.15-2.03	0
Cardiac Tamponade		0.27	0.03-2.13	0
Device success		1.08	1.03-1.13	79
30-day all-cause mortality		0.80	0.38-1.69	0
30-day stroke		0.99	0.46-2.11	0
30-day AKI		0.71	0.33-1.53	0
30-day major bleeding		1.03	0.44-2.41	60
30-day early safety		1.16	1.04-1.28	0
30-day PPI		0.60	0.38-0.95	44
30-day major vascular complications		1.42	0.20-10.22	60
30-day minor vascular complications		0.42	0.18-0.98	0
30-day moderate or severe transvalvular AR		0.19	0.05-0.81	76
1-year all-cause mortality		0.75	0.29-1.95	35
1-year stroke		0.56	0.18-1.76	0
AKI; Acute Kidney Injury, PPI; Permanent Pacemaker Implantation, THV; Transcatheter Heart Valve				
Low heterogeneity is marked with Green, Moderate with Yellow and High with Red.				