

# Long term outcomes of contemporary balloon-expandable transcatheter valves: a single center observational study

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**Introduction:** Recently, a randomized head-to-head LANDMARK trial demonstrated that the balloon-expandable transcatheter valve (BEV) Myval was non-inferior to the BEV Sapien S3 in terms of the primary composite endpoint at 30 days.<sup>1</sup> *Aim:* To explore if there is difference in mean pressure gradient (MPG), paravalvular regurgitation (PVR), major bleeding and vascular complications, permanent pacemaker implantation (PPI) and long-term survival between Myval and Sapien S3 BEV.

**Patients and Methods:** In this single center, observational cohort study we included 347 patients who underwent transcatheter aortic valve implantation (TAVI) and were implanted with either Myval BEV (n=199) or Edwards Sapien S3 BEV (n=148). Mean follow-up (FU) was 12 months. We compared MPG after TAVI between two groups as well as the rate of conduction disturbances that require permanent pacemaker implantation (PPI), and the incidence of moderate to severe paravalvular regurgitation (PVR), major bleeding and vascular complications and survival rate in the FU.

**Results:** There was no significant difference in demographic and clinical parameters between two groups. Patients implanted with Myval BEV were statistically significant more likely to experience early adverse effects (68 vs 34 early adverse effect, p 0.02) driven mostly by higher incidence of moderate PVR (21 vs 7, p 0.049) and non-fatal stroke (11 vs 1, p 0.04) but there was no statistically significant difference in PPI (12.6% vs 9.46, p 0.49) and major bleeding and vascular complications. There was no statistically significant difference in survival during index hospitalization or during follow up. Mean pressure gradient (MPG) did not differ significantly between groups (11.49 (9.28 – 15) vs 12 (9.35 – 15.9), p 0.51).

**Conclusion:** Our all-comer observational real-world registry showed similar survival rates as well as early MPG after TAVI with both platforms.

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## LITERATURE

1. Baumbach A, van Royen N, Amat-Santos IJ, Hudec M, Bunc M, Ijsselmuiden A, et al. LANDMARK trial investigators. LANDMARK comparison of early outcomes of newer-generation Myval transcatheter heart valve series with contemporary valves (Sapien and Evolut) in real-world individuals with severe symptomatic native aortic stenosis: a randomised non-inferiority trial. *Lancet.* 2024 Jun 22;403(10445):2695-2708. [https://doi.org/10.1016/S0140-6736\(24\)00821-3](https://doi.org/10.1016/S0140-6736(24)00821-3)