The Bern TAVI Registry 5-Year Small-Annuli Analysis¹

Okuno T, Tomii D, Lanz J, et al. 5-year outcomes with self-expanding vs balloon-expandable transcatheter aortic valve replacement in patients with small annuli. *JACC Cardiovasc Interv*. 2023;16(4):429-440.

Key patient Study design Device(s) used Distribution Locations demographics Propensity-matched SAPIEN XT*, CoreValve, Arm 1 (BEV): Bern University Female: registry comparing SAPIEN 3. Evolut R. 100% < 430 mm² Hospital BEV: 85.4% SAPIEN TAVI and and **Evolut PRO,** aortic annular area (Bern, Switzerland) SEV: 84.2% CoreValve/Evolut **SAPIEN 3 Ultra** and Arm 2 (SEV): Mean age: **Evolut PRO+** TAVI (1:1) for patients valves 100% < 430 mm² BEV 82.7 years with small annuli valves aortic annular area SEV 82.2 years (<430 mm² aortic Mean STS score: annular area) BEV **5.34** N = 342**SEV 5.15** (total matched cohort)

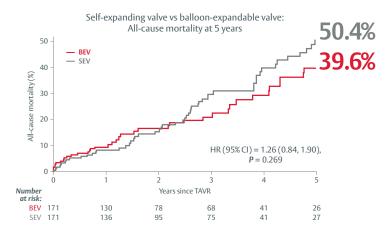
* The SAPIEN XT valve has been discontinued not commercially available anymore

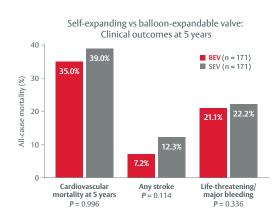
In a predominantly female, small annuli–only study:

- ✓ SAPIEN TAVI demonstrated significantly lower rates of disabling stroke than CoreValve/Evolut TAVI
- ✓ No improvement in mortality or reintervention associated with lower echo-derived gradients with self-expanding TAVI



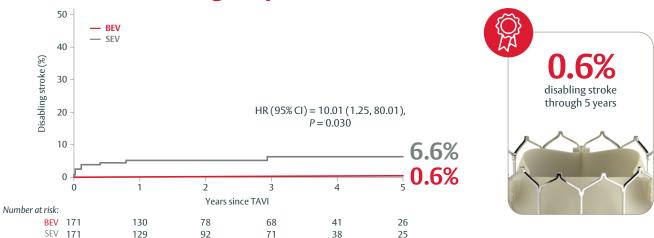
SAPIEN TAVI delivers on critical outcomes for smallannuli patients



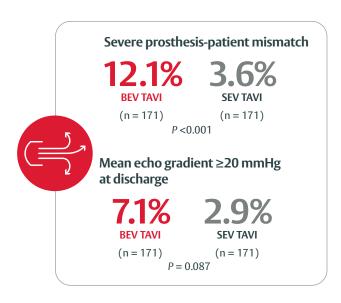


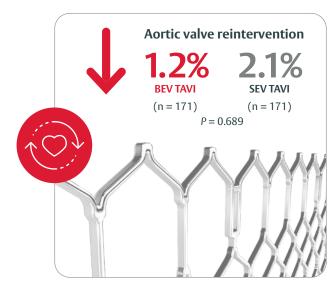
 $BEV = ballon-expandable\ valve;\ SEV = self-expanding\ valve;\ STS = Society\ of\ Thoracic\ Surgeons.$

Rates of disabling stroke were significantly lower for SAPIEN TAVI through 5 years



SAPIEN TAVI delivers low rates of reintervention, despite higher PPM and echo-derived gradients ≥20 mmHg







"...it is noteworthy that the echocardiographic hemodynamic advantage of self-expanding THVs did not translate into a higher VARC-3 device success rate or improved clinical outcomes up to 5 years." –Okuno et al, 2023

PPM=patient-prosthesis mismatch; VARC-3=Valve Academic Research Consortium-3.

TAVI: Transcatheter Aortic Valve Implantation

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