

Five-Year Outcomes after Randomization to Transcatheter or Surgical Aortic Valve Replacement: Final Results of the PARTNER 1 Trial

Purpose: Five-year outcomes of the PARTNER 1 trial for the Edwards SAPIEN transcatheter valve (either transfemoral and transapical) in high surgical risk, severe aortic stenosis (AS) patients.

Trial Design: Randomized, open label, parallel, randomized, safety and efficacy trial comparing the Edwards SAPIEN transcatheter valve vs. either another surgical valve or medical therapy (and/or balloon angioplasty). N=699 high surgical risk patients with severe AS randomized to either transcatheter aortic valve replacement (TAVR) or surgical aortic valve replacement (SAVR). Approach was either transfemoral or transapical.

Primary Endpoint: 5-year results comparing TAVR to SAVR.

Trial Results @ 5 years	TAVR	SAVR	P value
Risk of Death	67.8%	62.4%	0.76
Moderate or severe aortic regurgitation (AR)	14%	1%	<0.0001
Increased 5 year mortality because of AR seen in TAVR	72.4% (mod-severe AR) 56.6% (mild AR or less)		0.003

Conclusions: This 5-year f/u found similar results in this patient population for either SAVR or TAVR. The TAVR approach had more aortic regurgitation. There was no deterioration of the valves for either approach that required surgical replacement.