Early Clinical and Echocardiographic Outcomes with the SAPIEN 3 Transcatheter Aortic Valve Replacement System in Inoperable, High-Risk and Intermediate-Risk Aortic Stenosis Patients (PARTNER II S3)

Purpose: For severe aortic stenosis (AS) patients who qualify for aortic valve replacement, a safety and effectiveness study of the transcatheter heart valve (SAPIEN 3 THV).

Trial Design: Interventional, open label safety and efficacy study comparing the SAPIEN 3 THV to . N= 1661 (583 high-risk, inoperable; 1078 intermediate risk)

Primary Endpoint: Rate of all-cause mortality 30 days after the procedure; Paravalvular regurgitation (PVR).

Trial Results for Sapien 3 TVAR	High-risk patients	Intermediate-risk patients	P value
Death (all-cause)	2.2%	1.1%	
Cardiac-related death	1.4%	0.9%	
Stroke	1.5% (0.9% disabling)	2.1% (1% disabling)	
Paravalvular regurgitation	3.7% (0.1% severe) – both groups of patients		

Conclusions: The rates of death and stroke were low with SAPIEN 3 for both hi-risk and intermediate-risk patients. The rate of Paravalvular regurgitation was also very low. These results compare favorably with surgical outcomes.

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