CoreValve U.S. Pivotal High Risk Trial

Purpose: Safety and efficacy trial of the self-expanding transcatheter aortic valve (the Medtronic CoreValve® System); TAVR- in the Treatment of Symptomatic Severe Aortic Stenosis (AS) in High Risk and Very High Risk Subjects Who Need Aortic Valve Replacement

Trial Design: 2-year safety/efficacy outcomes; interventional, randomized, open label trial comparing self-expanding transcatheter and surgical aortic valve replacement in patients with severe aortic stenosis who are high surgical risks. N= 747. Parallel assignment of TAVR or surgical aortic valve replacement (SAVR) in patients with severe AS.

Primary Endpoint: All-cause mortality for those at high and extreme risk at 2 years.

Trial Results

1 year survival TAVR vs. SAVR	4.8%	2 year survival TAVR vs. SAVR	6.4%
Perivalvular leakage		1 year = 6%	2 year = 6.1%

Conclusions: Survival for patients treated with the self-expanding transcatheter aortic valve demonstrated better survival in this trial at 2 years compared to surgical aortic valve replacement. TAVR results were better for other endpoints, as well.

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