

Results from the PARTNER I FIVE YEAR ECHO study presented

November 1 2016

A substudy of the PARTNER I Trial and Continued Access Registry found that hemodynamic trends in patients who received transcatheter aortic valve replacement (TAVR) showed excellent durability without significant structural valve deterioration at five years. The trial represents the largest to-date longitudinal analysis of echocardiographic hemodynamic parameters systematically assessed by a core laboratory.

Findings were reported today at the 28th annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium. Sponsored by the Cardiovascular Research Foundation (CRF), TCT is the world's premier educational meeting specializing in interventional cardiovascular medicine.

"TAVR is a safe and effective treatment for [severe aortic stenosis](#)," said lead investigator Pamela S. Douglas, MD. Dr. Douglas is the Ursula Geller Professor of Research in Cardiovascular Diseases at Duke University School of Medicine and Director of the Multimodality Imaging Program at the Duke Clinical Research Institute. "However, the long term durability of transcatheter heart valves and the potential implications for patient outcomes are not completely understood. Therefore, determining the midterm hemodynamic profiles is critical to patient and device selection."

The study's patient population included all successful TAVR procedures in PARTNER IA, IB and continued access trials using a first generation SAPIEN THV device. Echocardiograms were performed at intervals of

seven days, 30 days, six months, and one, two, three, four and five years post implant and then analyzed by a single core laboratory. All echoes on all successful TAVRs (n=2,482; 282 patients at five years) were centrally assessed for mean aortic (AV) gradient, valve area and Doppler velocity index. Severely abnormal echo hemodynamic findings were also tabulated and reviewed.

The results show that the modeled trend of mean AV gradient decreased in the first few months post implant, and then increased non-significantly over follow up (12.1 vs. 9.2 at three months vs. 10.3 mmHg at 5 years; $P=0.63$). Among the 2,230 patients with multiple post-op AV gradients, a large interval change between subsequent echoes was uncommon, with just 10 patients (0.45%) having an interval increase of ≥ 20 mmHg.

"The five-year data from the largest, core-lab based study of TAVR to date showed stable AV mean gradients over the mid-term, with no suggestion of late structural deterioration," added Dr. Douglas.

"Similarly, severely abnormal hemodynamics in individual patients which might be suggestive of valve thrombosis or stenosis were rare. Together, the results suggest that the low five-year survival observed in this cohort is not due to adverse hemodynamics."

The PARTNER I FIVE YEAR ECHO trial was funded by Edwards Lifesciences. Dr. Douglas disclosed a research grant from Edwards Lifesciences which supported the study.

The results of the PARTNER I FIVE YEAR ECHO trial will be presented on Tuesday, November 1 at 9:40 AM ET in the Main Arena (Ballroom, Level 3) in the Walter E. Washington Convention Center.

Provided by Cardiovascular Research Foundation

Citation: Results from the PARTNER I FIVE YEAR ECHO study presented (2016, November 1) retrieved 2 May 2024 from

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