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Ten-year results display strong safety and efficacy profile for TPV device

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Ten-year follow-up results of the U.S. Investigational Device Exemption (IDE) Trial of the Melody transcatheter pulmonary valve (TPV) were presented today during the SCAI 2020 Scientific Sessions Virtual Conference. Findings showed favorable outcomes for long-term function, safety, and efficacy for congenital patients who underwent Melody valve implantation within an existing dysfunctional right ventricular outflow tract (RVOT) conduit or bioprosthetic pulmonary valve.

The study evaluated the safety and performance of the Melody TPV at 10-year follow-up in the IDE cohort (n=150). TPV dysfunction, defined as reoperation, catheter reintervention, or hemodynamic dysfunction (ie. moderate or greater pulmonary regurgitation [PR] and/or mean RVOT gradient >40 mmHg) was assessed. Safety outcomes included serious device-related adverse events, stent fracture, catheter reintervention, surgical conduit replacement, and death.

The investigators reported that the median age of patients in the study was 19 years old; 71 patients were younger than 18 years. Tetralogy of Fallot was the original diagnosis in 51% of the patient population. The primary indication for intervention was PR in 53%, RVOT obstruction in 26%, and both in 21% of patients. Discharge mean RVOT gradient was 17 mmHg (3-36).

At 10 years of follow-up:

- Freedom from all-cause mortality was 90%.
- Freedom from surgical reintervention was 79% and freedom from catheter intervention was 72%.
- Freedom from TPV dysfunction, the primary endpoint of the study and a composite outcome of freedom from reintervention and hemodynamic dysfunction was 54% at 10 years; results align with contemporary long term surgical series with similar patient populations.
- When freedom from TPV dysfunction was stratified by age, a significant difference was observed. While 65% of adults were free of TPV dysfunction, only 47% of pediatric age patients met the endpoint.
- 81% of patients were free from TPV-related endocarditis, while 76% were free from any endocarditis events. Annualized incidence rates, with over 1100 patient-years of follow-up, show rates of 2.96 for any endocarditis and 2.00 for TPV-related infection. These annualized rates have dropped somewhat compared with endocarditis incidence published several years ago when there was 7-years of follow-up in the three combined Melody regulatory trials.
- The Melody valve fulfills its intended design goal of prolonging the useful life of surgically implanted RVOT conduits and bioprosthetic valves and reducing the lifetime burden of repeat open-heart operations.

"Having long-term data now available is an important milestone especially for the pediatric patient population who are growing and changing so rapidly during a ten-year period," said Thomas K. Jones, M.D., director of cardiac catheterization at Seattle Children's in Seattle, Wash. "While the data reinforces the longevity, durability, and efficacy of the Melody TPV, it will also serve as a study model for future evaluations of novel pediatric congenital heart disease technologies."

The investigators conclude that this data set is a unique contribution to understanding the natural history of TPV replacement for patients with dysfunctional RVOT. The study also provides a model for future evaluations of novel technologies and overcoming challenges in study design and execution in populations with congenital heart disease.

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