Five-Year Comparison of Clinical and Echocardiographic Outcomes of Pure Aortic Stenosis with Pure Aortic Regurgitation or Mixed Aortic Valve Disease in the COMMENCE trial

Objective: Mixed aortic valve disease (MAVD) is associated with poorer outcomes compared to those with pure stenosis (AS). The present study will compare outcomes of surgical aortic valve replacement (SAVR) in patients with pure AS and those with pure aortic regurgitation (AR) or moderate to severe AR with stenosis (MAVD).

Methods: We analyzed 689 patients in the FDA IDE COMMENCE SAVR trial with RESILIA tissue to 5 years. The primary outcome was all-cause mortality at 5 years. Secondary outcomes included reoperation, bleeding, endocarditis, structural (SVD) and non-structural (NSVD) valve deterioration; and changes in left ventricle (LV) variables. Kaplan-Meier time-to-event curves and Cox proportional hazards regression models were used to compare safety outcomes between groups. Between group comparisons were performed with Wilcoxon Sum Tests. Clinical outcomes were adjudicated by an independent clinical events committee and echocardiographic outcomes by a core lab.

Results: 351 (51%) presented with pure AS (GROUP 1); GROUP 2 consisted of pure AR (n=44, 40%) and MAVD (n=67, 60%). At baseline, GROUP 2 was younger (median 64 yrs vs 70 yrs, $p<0.0001$), had fewer females (17% vs 33%, $p=0.0015$), more patients with endocarditis (4.5% vs 1.1%, $p=0.04$), and more patients with a LV ejection fraction (LVEF) <55% (36% vs. 12%, $p<0.0001$). 5 yr. freedom from all-cause mortality, reoperations, and major bleeding were not statistically different between GROUPS; no SVD or NSVD event occurred in either group (Figure). After adjusting for age and baseline LVEF, hazard ratio was numerically lower in GROUP 2 vs. GROUP 1 (HR: 0.8; 95% CI: 0.3-2.0). Compared to GROUP 1, GROUP 2 had a greater change in LV mass regression (-80 g vs -38 g, $p=0.0002$), LV end diastolic volume (-44 mL vs -3.5 mL, $p<0.0001$), and LV end diastolic dimension (-0.8 cm vs 0.1 cm, $p<0.0001$). There were no significant differences between GROUPS in improvement in LVEF ($p=0.32$) or in posterior wall thickness ($p=0.15$).

Conclusions: Patients with pure AR or MAVD demonstrated similar clinical safety and SVD at 5 years compared to those with pure AS. However, there was a significant difference in LV reverse remodeling and LV end diastolic volume in GROUP 2. These favorable outcomes in patients with AR reinforce the need for early treatment before irreversible changes occur.

Vinod Thourani (1), Joseph Bavaria (2), Bartley Griffith (3), Lars Svensson (4), Philippe Pibarot (5), Michael Borger (6), David Heimansohn (7), Thomas Beaver (8), Eugene Blackstone (4), John Puskas (9), (1) Piedmont Heart Institute, Atlanta, GA, (2) Hospital of the University of Pennsylvania, Philadelphia, PA, (3) University of Maryland Medical Center, Baltimore, MD, (4) Cleveland Clinic, Cleveland, OH, (5) Québec Heart & Lung Institute, Quebec, Canada, (6) Leipzig Heart Center, Leipzig, Germany, (7) St. Vincent Heart Hospital, Indianapolis, IN, (8) University of Florida Health, Gainesville, FL, (9) Mount SInai Morningside, New York, NY

Figure. 5-Year Survival Curves by group (A) Kaplan-Meier Plots (B) Survival curves based on a Cox proportional hazards model adjusting for age and baseline LVEF(%) with covariates at their median levels.