Clinical Trial Supports Catheter-Based Valve Replacement

One-year data from the PARTNER clinical trial, published today in the *New England Journal of Medicine*, demonstrates that transcatheter aortic-valve implantation, compared with standard therapy, resulted in significantly lower rates of death among patients who cannot undergo surgery for aortic stenosis.

Transcatheter aortic-valve implantation (TAVI) is a new procedure in which a bioprosthetic valve is inserted through a catheter and implanted within the diseased native aortic valve. The Placement of AoRtic TraNscathetER valves (PARTNER) trial is a multi-center, randomized clinical trial comparing TAVI with standard therapy in high-risk patients with severe aortic stenosis. The co-principal investigators are Martin B. Leon, M.D., and Craig R. Smith, M.D., at NewYork-Presbyterian Hospital/Columbia University Medical Center. The data published today reflects a pre-specified cohort of patients who were considered to be unsuitable candidates for surgery.

The primary end point was the rate of death from any cause over the duration of the study. A total of 358 patients with aortic stenosis who were considered to be unsuitable candidates for surgery underwent randomization at 21 centers, including 17 in the United States. Patients randomized for standard therapy received a combination of watchful waiting, medications and balloon aortic valvuloplasty, which can provide transient clinical benefit but does not alter long-term outcomes.

At one year, based on the Hazard Ratio of 0.55, patients who underwent TAVI showed a reduction in mortality from 50.7 percent to 30.7 percent. In addition, there was a reduction in the combined endpoint of death from any cause or repeat hospitalization from 71.6 percent, with standard therapy to 42.5 percent with TAVI. Among survivors at one year, the rate of cardiac symptoms was significantly lower among patients who had undergone TAVI, as compared with those who had received standard therapy (25.2 percent vs. 58.0 percent).

"Based on the reduction in mortality during the first year of the study, balloon-expandable TAVI should be the new standard of care in patients who are not suitable candidates for surgery," said Martin B. Leon, M.D., professor of medicine and director of the Center for Interventional Vascular Therapy at NewYork-Presbyterian Hospital. Dr. Leon, founder and chairman emeritus of the Cardiovascular Research Foundation, is the co-principal investigator of the study.

At 30 days, TAVI, as compared with standard therapy, was associated with a higher incidence of major strokes (5.0 percent vs. 1.1 percent) and major vascular complications (16.2 percent vs. 1.1 percent). In the year after TAVI, patients had no deterioration in the functioning of the bioprosthetic valve, as assessed by evidence

of stenosis or regurgitation on an echocardiogram.

"This study shows that transcatheter valve replacement is a safe and effective option for this life-threatening illness in patients unsuitable for surgical valve replacement," said Dr. Smith, study co-principal investigator and surgeon-in-chief at NewYork-Presbyterian Hospital/Columbia University Medical Center. According to the study authors, research is already under way on the next generation of TAVI devices that researchers hope will address the vascular complications encountered in the trial.

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