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Results of the PARTNER Trial Cohort B 2-year follow up presented at TCT 2011

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A two-year study of patients in the landmark PARTNER trial, which compared transcatheter aortic valve replacement (TAVR) in patients who have severe aortic stenosis and are not candidates for open heart surgery, confirm the one-year findings and support the role of TAVR as the standard of care.

Trial results were presented today at the 23rd annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium, sponsored by the Cardiovascular Research Foundation.

Cohort B of the PARTNER trial – those patients with severe aortic stenosis who were not candidates for surgery - randomized 358 patients to transfemoral TAVR with an early generation balloon-expandable bovine pericardial valve or standard therapy (ST, including balloon valvuloplasty) at 21 centers, emphasizing a multi-disciplinary heart team approach.

The primary end point was death from any cause at one year and secondary endpoints included symptom status, serial echo assessments (core lab) and early/late adverse events (e.g. strokes).

After two years, the rate of all cause mortality was 18.2% in the TAVR group and 35.1% in the standard therapy group. The rate of cardiovascular mortality was 13.2% in the TAVR group and 32.1% in the standard therapy group.

The rate of repeat hospitalization was 35.0% in the TAVR group and 72.5% in the standard therapy group.

The rate of stroke at two years was higher – 13.8% in the TAVR group and 5.5% in the standard therapy group.

"At two years, in patients with symptomatic severe aortic stenosis who are not suitable candidates for surgery, TAVR remained superior to standard therapy with incremental benefit from one to two years markedly reducing the rates of all cause mortality, cardiovascular mortality and repeat hospitalization," said Raj R. Makkar, MD, the principal site investigator for the PARTNER trial. Dr. Makkar is Director of Interventional Cardiology and the Cardiac Catheterization Laboratory at Cedars-Sinai Medical Center and Associate Director of the Cedars- Sinai Heart Institute

"There were more neurologic events in TAVR patients compared to standard therapy (16.2% vs. 5.5%; p = 0.003) with five new events (three strokes and two TIAs) between 1-2 years in TAVR patients. After 30 days, differences in stroke frequency were largely due to increased hemorrhagic strokes in TAVR patients." Dr. Makkar said.

"Two year data continues to support the role of TAVR as the standard-of-care for symptomatic patients with aortic stenosis who are not surgical candidates," said Dr. Makkar.

"The ultimate value of TAVR in 'inoperable' patients will depend on careful selection of patients who are not surgical candidates, and yet do not have extreme co-morbidities that overwhelm the benefits of TAVR."

Provided by Cardiovascular Research Foundation