Results of the COREVALVE EXTREME RISK trial presented

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In a clinical trial, a self-expanding transcatheter aortic valve met the key performance objective of reducing death and stroke in patients with severe aortic stenosis at "extreme risk" for surgery.Results of the COREVALVE EXTREME RISK trial were presented today at the 25th 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.

Degenerative aortic stenosis is a progressive disease with a poor prognosis in the absence of surgical aortic valve replacement. For patients at extreme risk for surgical complications, transcatheter aortic valve technologies offer a less invasive option of therapy for aortic stenosis.

The COREVALVE EXTREME RISK trial was a prospective, multicenter, controlled, non-randomized, single-arm investigation evaluating the safety and efficacy of the transfemorally implanted CoreValve self-expanding transcatheter heart valve. The trial was conducted in 487 patients with symptomatic, severe aortic stenosis.

All patients were deemed to be at extreme risk for surgical aortic valve replacement, and were thus treated with the Corevalve device. The primary endpoint was a composite of all-cause mortality or major stroke rate at 12 months; the Kaplan-Meier determined event rate was compared with a pre-specified objective performance goal (OPG).

Of the 487 patients enrolled in the study, 471 had an attempted implantation and were designated as the primary "as treated" analysis population. Patients were elderly (83.1 years), and were severely symptomatic (NYHA class III or IV, 91.9 percent). The Society for Thoracic Surgery Predicted Risk of Mortality was 10.3 percent ± 5.6 percent and was > 15 percent in 17.6 percent of patients.

At 12 months, the composite rate of death or major stroke was 25.5 percent, significantly below the 95 percent confidence interval of the performance goal, which was set at 43 percent. While moderate paravalvular leak was observed in 11 percent of patients at one month, 80 percent of patients with moderate paravalvular leak (PVL) at one month who survived to one year experienced a reduction in PVL over time.

"The COREVALVE EXTREME RISK study achieved its primary endpoint of a reduction in all cause mortality or major stroke at one year compared to a rigorously defined OPG," said lead investigator Jeffrey J. Popma, MD. Dr. Popma is Director, Interventional Cardiology at Beth Israel Deaconess Medical Center.

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