



## Valvular Heart Disease

## EARLY OUTCOMES WITH THE EVOLUT R REPOSITIONABLE SELF-EXPANDING TRANSCATHETER AORTIC VALVE IN THE UNITED STATES

Moderated Poster Contributions Valvular Heart Disease Moderated Poster Theater, Poster Area, South Hall A1 Saturday, April 02, 2016, 4:00 p.m.-4:10 p.m.

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**Background:** An optimal TAVR platform would include a smaller caliber system and the ability to reposition the valve. This is the first report from the CoreValve Evolut R US IDE Study that evaluated the Evolut R self-expanding, fully recapturable TAV with an inline sheath.

**Methods:** Patients with severe AS deemed to be at high or extreme risk for surgery were eligible for this multicenter, non-randomized study. Primary safety endpoints were the rates of all-cause mortality and disabling stroke at 30 days. An independent Clinical Events Committee adjudicated all adverse events and an independent echocardiography core laboratory assessed valve hemodynamics. VARC-2 definitions were applied.

**Results:** 241 patients underwent attempted implant (23, 26, or 29 mm valve) at 23 US centers. Baseline age was 83.3±7.2 years, 68.5% women, STS 7.4±3.4%, 54.0% COPD, 34.9% PVD and 69.7% were considered frail. The most commonly used valve was the 29 mm (63.7%) and most common access was iliofemoral (89.5%). The resheath/ recapture feature was used 65 times in 54 patients. At 30 days, the mean effective orifice area and AV gradient were 1.9 ± 0.5 cm2 and 7.8 ± 3.1 mmHg. Paravalvular leak (PVL) at 30 days was none/trace in 62.6%, mild in 32.2%, moderate in 5.3% with no severe PVL. All-cause mortality was 2.5% and disabling stroke was 3.3%. The 30-day rate of major vascular complications was 7.5%, and life-threatening or disabling bleeding was 7.1%. Permanent pacemaker implantation (PPI) at 30 days was 16.4%.

**Conclusions:** At 30 days, the Evolut R valve was effective at safely relieving AS. The ability to reposition the valve was a frequently used feature that may have accounted for an excellent survival with lower rates of PPI, PVL and stroke compared to prior studies. Further long-term follow-up is necessary to better characterize the long-term benefits of this improved system.