New bioprosthetic valve for TAVR fails to demonstrate non-inferiority

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In a randomized clinical trial, SCOPE II, a new self-expanding bioprosthetic valve used in transcatheter aortic valve replacement (TAVR) failed to demonstrate non-inferiority compared to an existing self-expanding valve.

Findings were reported today at TCT Connect, the 32nd annual scientific symposium of the Cardiovascular Research Foundation (CRF). TCT is the world's premier educational meeting specializing in interventional cardiovascular medicine. The study was also published simultaneously in *Circulation*.

The SCOPE II trial was designed to compare the clinical outcomes of the ACURATE neo and CoreValve Evolut valves. A total of 796 patients aged 75 years or older with symptomatic severe aortic stenosis and an indication for transfemoral TAVR as agreed by the Heart Team were recruited at 23 tertiary heart valves centers in Denmark, France, Germany, Italy, Spain and the United Kingdom. Participants were randomly assigned (1:1) to receive treatment with the ACURATE neo (n=398) or the CoreValve Evolut devices (n=398).

The primary safety endpoint, powered for non-inferiority of the ACURATE neo valve using a noninferiority margin of 6%, was the composite of all-cause mortality or stroke at 12 months. The primary efficacy endpoint, powered for superiority, was new permanent pacemaker implantation at 30 days. Secondary endpoints included clinical efficacy and safety endpoints at 30 days and 12 months.

In the intention-to-treat analysis, death or stroke at one year was 15.8% in the ACURATE neo group compared to 13.9% in the CoreValve Evolut group, while in the per-protocol analysis it was 15.3% vs. 14.3%. Noninferiority of the ACURATE neo was not met for the primary endpoint in the intent-to-treat analysis, while it was met in the per-protocol analysis. Based on the prespecified statistical plan, due to these inconsistent results, non-inferiority was not established for the primary endpoint.

New pacemaker implantation at 30 days was 10.5% with ACURATE neo compared to 18.0% with CoreValve Evolut (Risk Difference -7.5%, 95% CI -12.4—2.60, P= 0.0027). Cardiac death at 30 days (2.8% vs 0.8%, p=0.03) and one year (8.4% vs 3.9%, p=0.01) was greater in the ACURATE neo group. The rate of moderate-severe aortic regurgitation was 9.6% vs 2.9% (P