Dedicated trial in women demonstrates the superiority of transcatheter vs. surgical aortic valve replacement

September 3 2024

Credit: Pixabay/CC0 Public Domain

Transcatheter aortic valve implantation (TAVI) was superior to surgical aortic valve replacement for reducing death, stroke or rehospitalization in women with severe aortic stenosis, according to late-breaking research presented in a Hot Line session today at ESC Congress 2024.

"Limited data suggest that transcatheter, as compared with surgical, aortic valve replacement may be more effective in female than male patients. As most evidence is derived from subgroup analyses of large trials, we conducted a dedicated randomized trial to compare the safety and efficacy of TAVI vs. surgical replacement in women all-comers with severe symptomatic aortic stenosis. The RHEIA trial demonstrated not only the non-inferiority of TAVI but its superiority over surgery for improving outcomes, particularly reducing rehospitalizations," explained one of the Principal Investigators, Professor Helene Eltchaninoff of the University Hospital of Rouen, France.

The prospective RHEIA trial recruited women all-comers with severe symptomatic aortic stenosis, with any (except prohibitive) surgical risk status, from 48 sites in 12 countries across Europe. They were randomized 1:1 to undergo either TAVI with a third-generation balloon-expandable system using transfemoral access or surgical aortic valve replacement and were followed up for 1 year. The primary composite endpoint was all-cause mortality, stroke and rehospitalization for valve- or procedure-related symptoms or worsening heart failure at 1 year.

In total, 443 patients were randomized, with a mean age of 73 years. The mean Society of Thoracic Surgeons risk score was 2.1–2.2%.

The incidence of the primary composite endpoint was significantly lower in the TAVI group (8.9%) compared with the surgical group at 1 year (15.6%; hazard ratio [HR] 0.55; 95% confidence interval [CI] 0.34 to 0.88; p=0.03). The absolute event rate difference between the groups was −6.8% and the upper bound of the two-sided 95% CI met the criteria for both non-inferiority and superiority.

The significant reduction in the primary endpoint was predominantly driven by a reduction in rehospitalization for valve- or procedure-related symptoms or worsening heart failure, which occurred in 4.8% in the TAVI group and 11.4% in the surgical group (difference −6.6%; 95% CI −11.9% to −1.4%; p=0.02). There was no significant difference in all-cause mortality or stroke.

TAVI was associated with a lower incidence of new-onset atrial fibrillation than surgery at 1 year (3.3% vs. 28.8%; p