

# SMART trial reaffirms hemodynamic superiority of TAVR self-expanding valve

May 3 2024

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Additional analysis from the SMAll Annuli Randomized To Evolut or SAPIEN (SMART) study demonstrated clinical non-inferiority of self-expanding valves (SEV) versus balloon-expandable valves (BEV) in

aortic stenosis patients undergoing transcatheter aortic valve replacement (TAVR) and confirmed valve performance superiority over time based on hemodynamics.

Data also showed similar positive results in two age groups (Society for Cardiovascular Angiography & Interventions (SCAI) 2024 Scientific Sessions).

Patients with [aortic stenosis](#) (AS) and small aortic annuli (SAA), typically female and underrepresented in clinical trials, are at risk for impaired valvular hemodynamics, or [blood flow](#), and associated adverse cardiovascular outcomes following TAVR. The underrepresentation of women in research and the severity of the condition creates a call for more clinical data.

The SMART trial is an international, prospective, multi-center, randomized (1:1) post-market trial comparing the safety and performance of SEV versus BEV in TAVR patients with symptomatic severe AS and SAA.

Eligible patients had an aortic valve annulus area of less than or equal to 430 mm<sup>2</sup> by CT and suitable anatomy for transfemoral TAVR with an Evolut PRO/PRO+/FX or a SAPIEN 3/3 Ultra valve. The co-primary endpoints were: a clinical outcome composite of mortality, disabling stroke, or heart failure rehospitalization; and a valve function composite of bioprosthetic valve dysfunction (BVD) through 12 months.

A total of 716 patients (87% women, mean age 80 years) were treated at 83 sites. The SMART trial met both primary endpoints. Compared with BEV, the supra-annular SEV demonstrated non-inferior clinical outcomes and superior valve performance as measured by multiple definitions of bioprosthetic [valve](#) dysfunction (BVD) as well as by standard hemodynamics (doppler velocity index [DVI], effective orifice

area [EOA], severe prosthesis-patient mismatch [PPM], mean gradient >20 mmHg) at one year. As an additional analysis, the hemodynamics over time were evaluated and found to be similar between cohorts at baseline and favored SEV compared to BEV at all follow-up time points through 12 months (p

Citation: SMART trial reaffirms hemodynamic superiority of TAVR self-expanding valve (2024, May 3) retrieved 17 July 2024 from <https://medicalxpress.com/news/2024-05-smart-trial-reaffirms-hemodynamic-superiority.html>

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