






The RHEIA Trial: TAVI and surgery in women

Eltchaninoff H *et al.* RHEIA – Transcatheter versus surgical aortic valve replacement in women with severe aortic stenosis. Presented at ESC 30 August–2 September 2024, London, UK.

Randomized research in women all comers with Aortic stenosis



Study design	Device(s) used	Distribution	Locations	Key patient demographics
 Randomised, controlled vs sAVR (1:1) N = 443	 SAPIEN 3 valve SAPIEN 3 Ultra valve	 20 mm: 4.7% 23 mm: 63.7% 26 mm: 27.0% 29 mm: 4.7%	 12 European countries 48 sites	 Mean age: TAVI: 73.1 years sAVR: 73.3 years

The world's first women-only randomised clinical trial comparing TAVI with sAVR¹


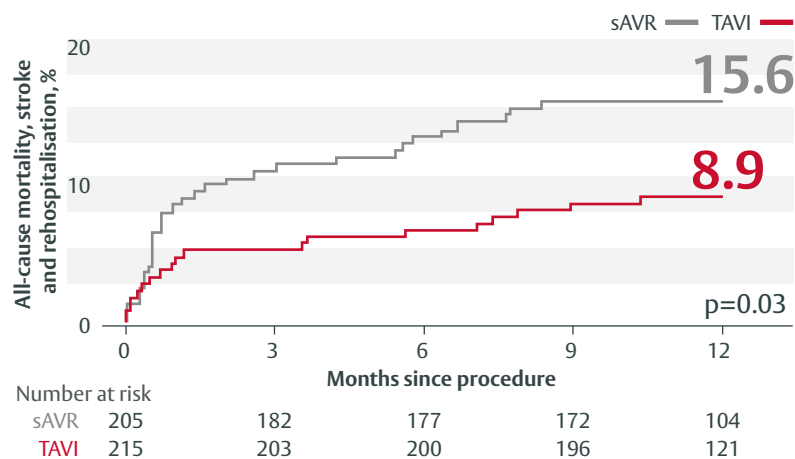
The Edwards SAPIEN 3 platform:
Outperforming for women*



*TAVI with the SAPIEN 3 and SAPIEN 3 Ultra valves was proven superior to surgery on the composite primary endpoint of death, stroke or rehospitalisation at 1 year in female patients

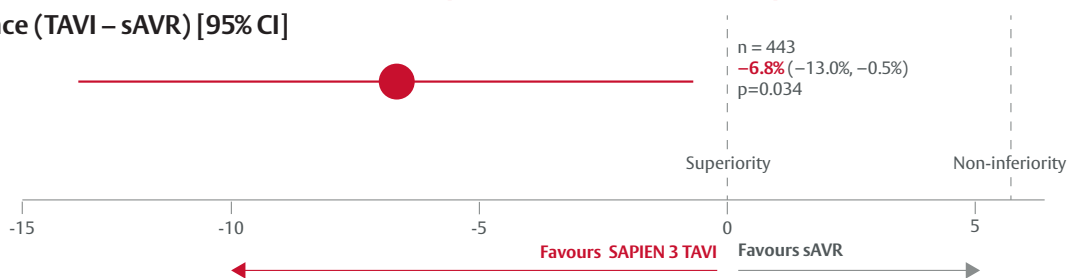
The SAPIEN 3 platform: Consistently excellent outcomes in female patients^{2,3}

Key patient outcomes included: **all-cause mortality, stroke and rehospitalisation**

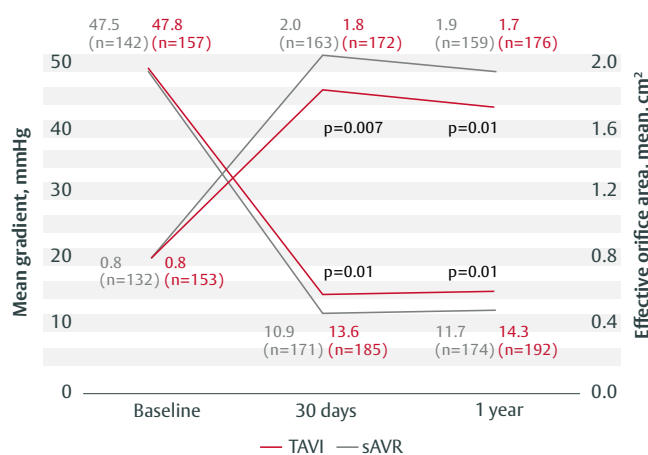
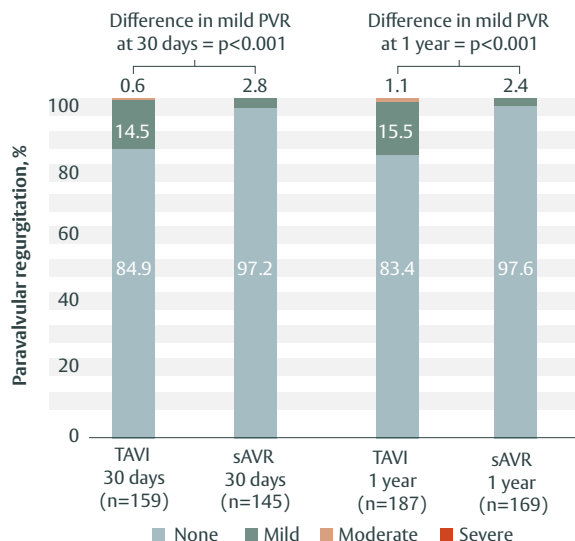



Excellent performance of the SAPIEN 3 platform in female patients

Event rate difference (TAVI – sAVR) [95% CI]



Excellent haemodynamic performance at 1 year for the SAPIEN 3 platform, with very low rates of paravalvular leak



Valve dysfunction (VARC-2) at 1 year:

p=1.00

0.5%

TAVI

(n=215)

0.0%

sAVR

(n=205)

Valve reintervention at 1 year:

p=0.5

0.9%

TAVI

(n=215)

0.0%

sAVR

(n=205)

Improved patient experience with the SAPIEN 3 platform



Index hospital stay, median:

4.0 days

TAVI

9.0 days

sAVR



Discharged to home or self-care facility:

90.2%

TAVI

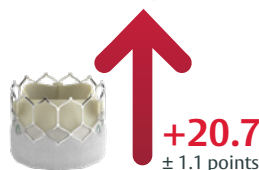
49.8%

sAVR

Change from baseline in KCCQ-OS at 1 year (mean ± SD):

TAVI

sAVR



References

1. Eltchaninoff H, Bonaros N, Prendergast B *et al.* Rationale and design of a prospective, randomized, controlled, multicenter study to evaluate the safety and efficacy of transcatheter heart valve replacement in female patients with severe symptomatic aortic stenosis requiring aortic valve intervention (Randomized research in womEn all comers with Aortic stenosis [RHEIA] trial). *Am Heart J.* 2020; **228**: 27–35.
2. Mack MJ, Leon MB, Thourani VH *et al.* Transcatheter aortic valve replacement with a balloon-expandable valve in low-risk patients. *N Engl J Med.* 2019; **380**: 1695–705.
3. Popma JJ, Deeb GM, Yakubov SJ *et al.* Transcatheter aortic-valve replacement with a self-expanding valve in low-risk patients. *N Engl J Med.* 2019; **380**: 1706–715.

Medical device for professional use. For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use (consult eifu.edwards.com where applicable).

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