The RHEIA Trial: Randomized researcH in womEn all comers wIth Aortic stenosis

Women tend to be under-represented in TAVI randomised controlled trials.[1–3] Recent studies have shown that they gain more benefit from TAVI with the SAPIEN 3 valve than men; in the PARTNER 3 trial, TAVI showed a stronger benefit in reducing composite adverse outcome in women compared with sAVR at 1 year and up to 5 years.[1,4]

RHEIA

In order to confirm whether TAVI with the SAPIEN 3 platform will benefit women, the RHEIA Trial was initiated.[5]

The RHEIA Trial

First randomised trial comparing TAVI *versus* sAVR in female patients.[5]

Study design[5]

European prospective, randomised, controlled, multicentre study to evaluate the safety and efficacy of TAVI, compared with sAVR, in female patients with severe symptomatic aortic stenosis (AS).

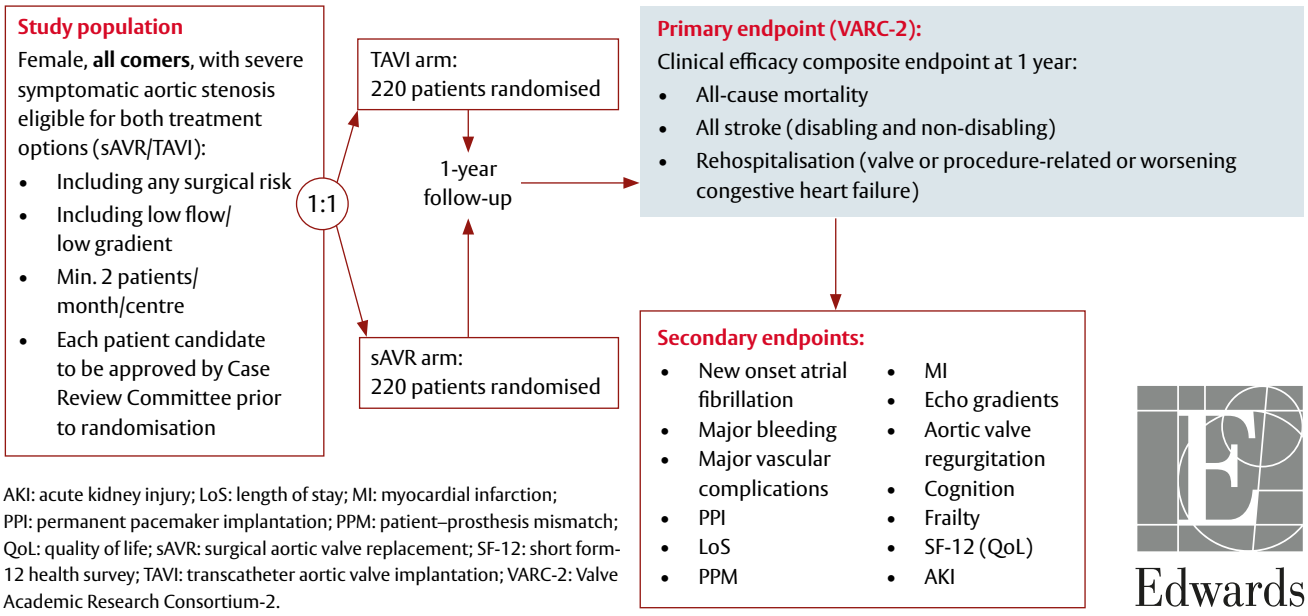
440 women | **35** sites | **10** countries

Edwards SAPIEN 3 or SAPIEN 3 Ultra valves *versus* sAVR with any commercially available bioprosthesis.

Randomised 1:1

Sample size was powered for non-inferiority (non-inferiority margin of 6%), then superiority. The primary endpoint at 1 year was a composite of all-cause mortality, stroke (disabling and non-disabling) and rehospitalisation for valve- or procedure-related symptoms or worsening congestive heart failure.

Figure 1. RHEIA study design[5,6]



AKI: acute kidney injury; LoS: length of stay; MI: myocardial infarction; PPI: permanent pacemaker implantation; PPM: patient–prosthesis mismatch; QoL: quality of life; sAVR: surgical aortic valve replacement; SF-12: short form-12 health survey; TAVI: transcatheter aortic valve implantation; VARC-2: Valve Academic Research Consortium-2.

Edwards

Assessments at: 30 days, 6 months and 1 year.

This trial is the first:[5]

- Women-only randomised controlled trial (RCT) in severe symptomatic AS
- RCT to include low flow/low gradient patients
- RCT to include all comers irrespective of risk

The RHEIA study aims to confirm the benefits of TAVI for female patients. The insights gained from this study will help inform your practice and might ensure women can benefit from the best outcomes.

References

1. Mack MJ *et al. N Engl J Med.* 2019; **380:** 1695–705.
2. Kodali S *et al. Ann Intern Med.* 2016; **123:** 377–84.
3. Burgess S *et al. Eur Cardiol.* 2022; **17:** e27
4. Mack MJ *et al.* N Engl J Med. 2023; **389:** 1949–60.
5. Eltchaninoff H *et al. Am Heart J.* 2020; **228:** 27–35.
6. ClinicalTrials.gov. 2023. Available at: https://clinicaltrials.gov/study/NCT04160130 [Accessed 26 June 2024].

Edwards Lifesciences Sàrl • Route de l'Etraz 70, 1260 Nyon, Switzerland • edwards.com

Edwards