The RHEIA Trial: First women-only randomised controlled trial in severe symptomatic aortic stenosis

Aortic stenosis (AS) affects millions of people worldwide, but did you know that women are more likely to be mis- or underdiagnosed compared with men, despite similar disease severity?

Background

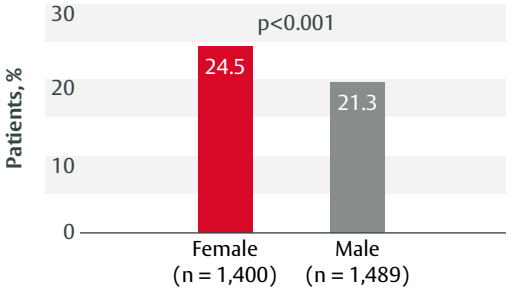
With their unique profile,[1] AS in women may be missed. Studies reveal a gender gap in their diagnosis and referral.[2]

Women are **20% less likely** to receive treatment for aortic valve disease than men.[2]

Studies suggest that TAVI benefits female patients

STS/ACC TVT Registry™

Improved survival rates in female patients with AS undergoing TAVI compared with males.[3]



THE PARTNER 3 TRIAL

In the PARTNER 3 trial, TAVI showed a stronger benefit in reducing composite adverse outcome versus SAVR at 1 year in female patients compared with males.[4]

These findings suggest women gain more benefits from TAVI than men. This emphasises the need for a dedicated trial to investigate TAVI's superiority over SAVR in women only.

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The RHEIA Trial

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

RHEIA

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 AS.

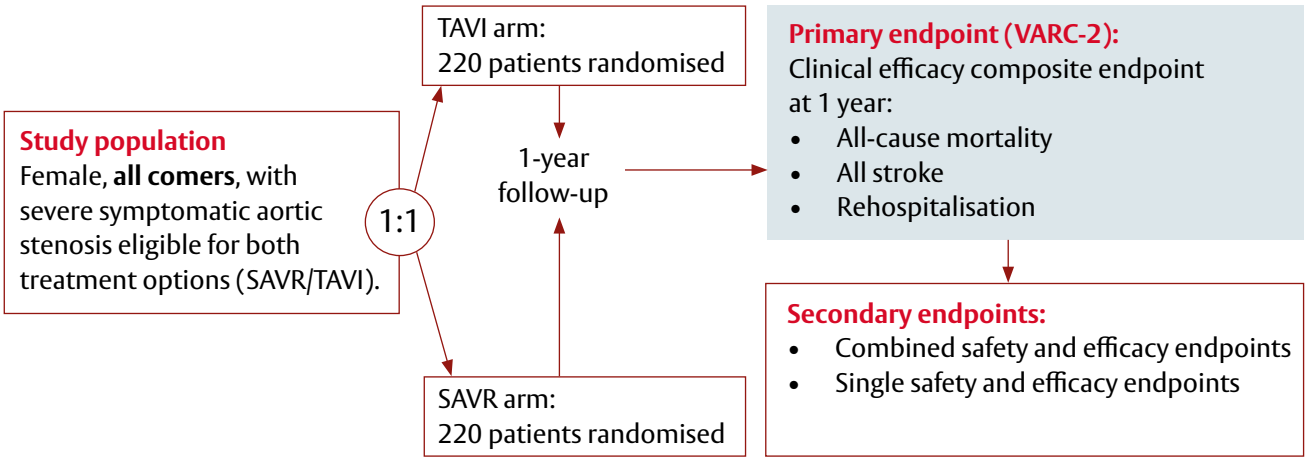
440 women | **35** sites | **10** countries

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, all stroke and rehospitalisation (valve- or procedure-related, or worsening congestive heart failure).

Figure 1. RHEIA study design[5,6]



SAVR: surgical aortic valve replacement; TAVI: transcatheter aortic valve implantation; VARC-2: Valve Academic Research Consortium-2.

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

The RHEIA Trial 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. Steeds RP *et al. Open Heart*. 2021; **8:** e001443.
2. Stehli J *et al. Front Cardiovasc Med*. 2023; **10:** 1256970.
3. Chandrasekhar J *et al. J Am Coll Cardiol*. 2016; **68:** 2733–44.
4. Mack MJ *et al. N Engl J Med*. 2019; **380:** 1695–705.
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].

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