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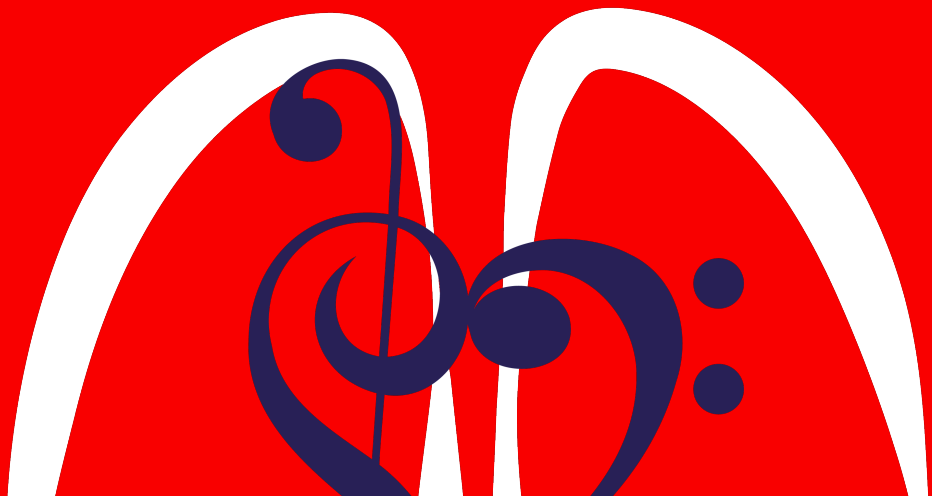
5-year results from a prospective, single-arm European trial on decellularized allografts for aortic valve replacement

– The ARISE Study



THE 37TH EACTS ANNUAL MEETING | 4 – 7 OCTOBER 2023

Background / Study Objective

- Aortic valve replacement (AVR) in young adult patients still constitutes a major problem as these young individuals face a difficult choice between a complex, dual-valve procedure such as the Ross-procedure and the life-long medication with blood thinners and their inherent risks once a mechanical prosthesis is chosen.
- Cell-free allografts may constitute an additional AVR option in such patients as they hold the potential to overcome the high early failure rate of conventional allogenic and xenogenic aortic valve prostheses.

Methods

- Prospective, EU-funded, single-arm, multi-centre trial in 8 centres evaluating non-cryopreserved, decellularised aortic homografts (DAH) for aortic valve replacement, the ARISE Study.
- Primary endpoints were peri-procedural complications, heart valve dysfunction and repeat procedure for valve-related dysfunction (surgical or interventional therapy).
- DAH results were compared with long-term data available from a contemporary Ross-operation cohort (Tirone E. David et al., J Thorac Cardiovasc Surg 2019).
- The study was registered under ClinicalTrials.gov - NCT02527629, and received the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP®) seal as a Post Authorization Safety Study, EU PAS 10201. The study was also registered at the German Federal Institute for Vaccines and Biomedicines (www.pei.de) under Ref. Number NIS322.

Patients

- Indication for aortic valve replacement according current clinical guidelines was the key inclusion criterion.
- Patients with active endocarditis were not included.

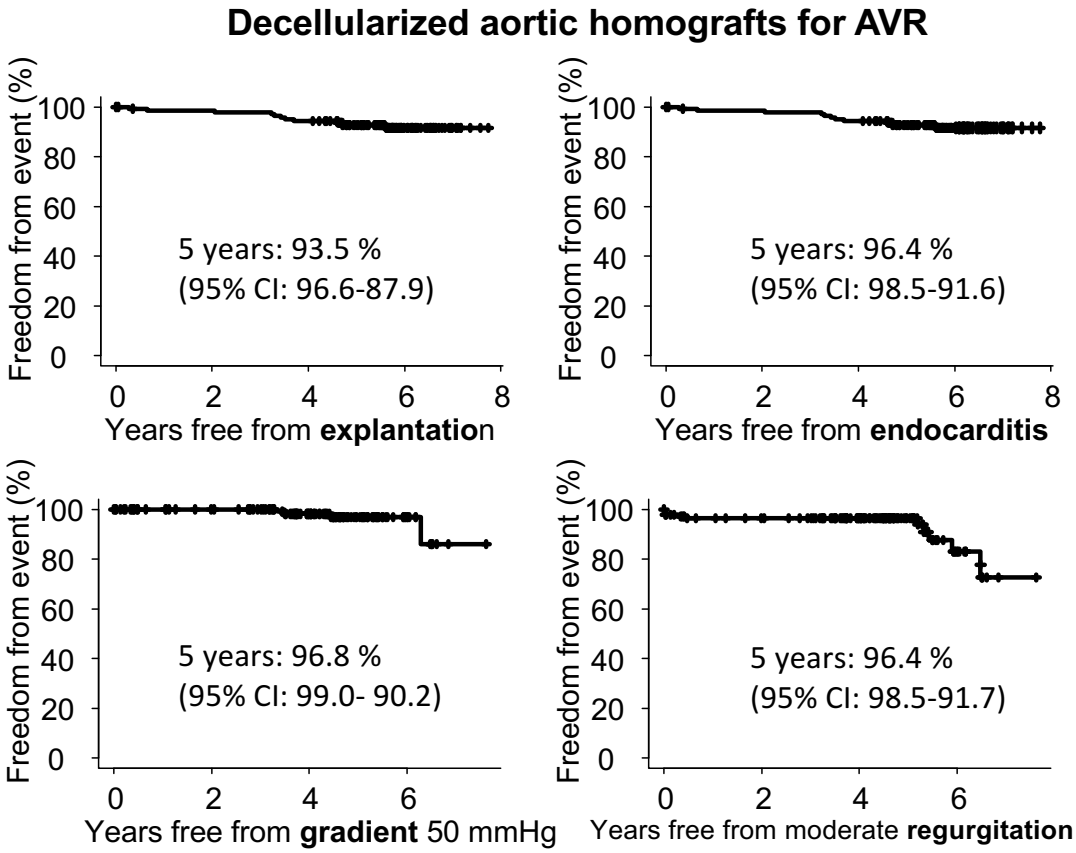
- **144 patients** (99 male) were prospectively enrolled within the ARISE Trial between 10/2015 and 10/2018, **mean age 33.6 ± 20.8** yrs.,
- 45 % of the patients underwent previous cardiac operations.

Results 1

- Mean implanted DAH diameter 22.6±2.4 mm, mean operation duration 341 ± 140 min, CPB 174 ± 80 min, cross-clamp 126 ± 43 min.
- **2 early deaths** (1 LCA thrombus on day 3 and 1 ventricular arrhythmia 5 h postop.)
- There were **3 late deaths**, 1 death due to endocarditis 4 months postoperatively and 2 unrelated deaths after 5 and 7 years due to cancer and Morbus Wegener resulting in a **total mortality of 3.47 %**.
- After a **mean follow-up of 5.5 ± 1.3** yrs. (max. 7.6 yrs.), the primary efficacy endpoints peak gradient (mean 13.8 ± 10.8 mmHg) and regurgitation (mean 0.49 ± 0.69, Grade 0-3) were excellent.

Results 2

- At 5 yrs. freedom from
- death/reoperation/endocarditis/ bleeding/ thrombembolism were: 97.8/93.5/96.4/99.2/99.3 % respectively,
- and comparable to the 5-year results of an age-matched Ross-operation cohort of 212 patients with a mean age of 34 yrs. (98.6/94.2/100/100/100 %) ,
- despite >2x more previous procedures in DAH patients.



Conclusion

- The 5-year results of the prospective multi-centre ARISE trial continue to demonstrate DAH as safe for AVR with excellent hemodynamics in the follow-up available.
- DAH results compared well with the midterm outcome of contemporary Ross-operation cohorts despite more >2x previous cardiac procedures in DAH patients.
- The planned follow-up period of at least 10-(20) years will help to further clarify whether DAH constitutes a good long-term biological AVR option for young patients.