



MINIMISE

Coming together to improve MIS AVR

Haemodynamic benefits of rapid deployment aortic valve replacement via a minimally invasive approach: 1-year results of a prospective multicentre randomized controlled trial

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Edwards

Minimally invasive aortic valve replacement (MIAVR) with the EDWARDS INTUITY Valve System

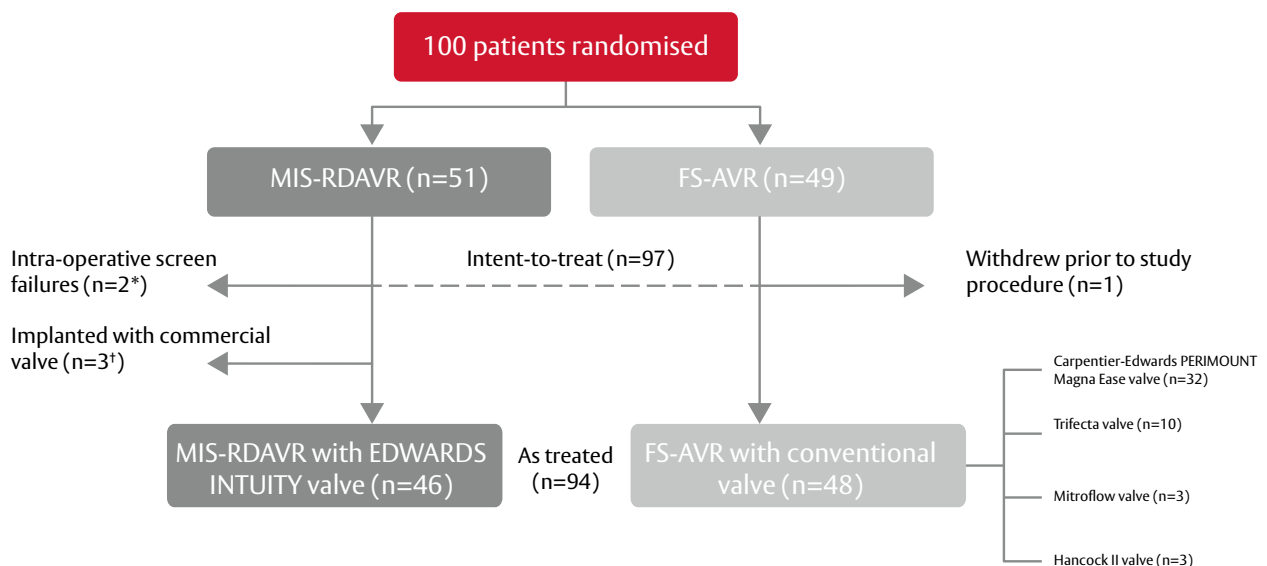
Overview

Aortic valve replacement (AVR) through minimally invasive surgery (MIS) may provide benefits to patients over conventional full sternotomy (FS). A novel class of bioprosthetic rapid deployment valves for aortic valve replacement (RDAVR)* have been developed to help overcome the technical complexity associated with performing MIAVR.

The **CADENCE-MIS** trial was a prospective, randomised, multicentre trial that compared the outcomes of MIS-RDAVR with FS for AVR using a conventional stented aortic bioprosthesis.

Between May 2012 and February 2013, 100 patients with aortic stenosis were enrolled, and surgeries were performed at 5 centres in Germany.

Treatment Flow Chart



* Extensive calcification of the aortic root; appropriate size device was unavailable

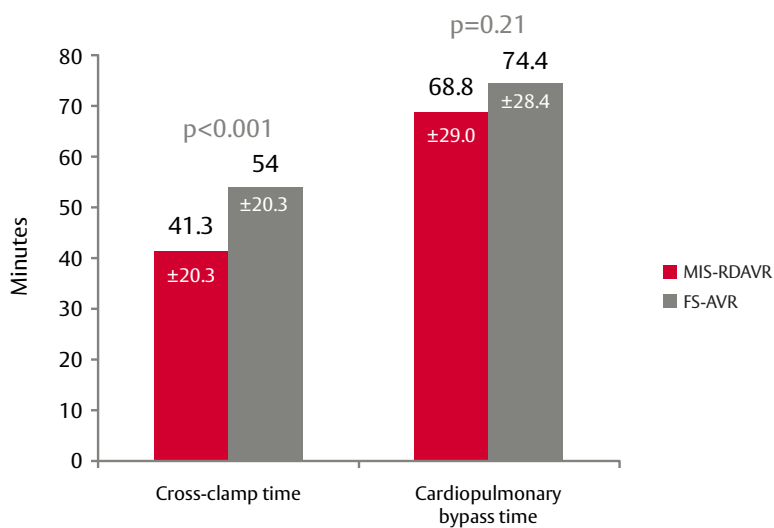
† Three patients converted to commercial valve due to valve positioning issues (two patients) and annular tear (one patient)
Results based on the first generation of the EDWARDS INTUITY valve system, Model 8300A

| Characteristic | MIS-RDAVR (n=46) | FS-AVR (n=48) | p-value |
|--------------------------|------------------|---------------|---------|
| Age (years) | 73.0 ± 5.3 | 74.2 ± 5.0 | 0.30 |
| Female (%) | 19 (41%) | 27 (56%) | 0.15 |
| BMI (kg/m ²) | 29.4 ± 5.1 | 28.8 ± 5.1 | 0.48 |
| STS Score (%) | 1.6 ± 0.7 | 1.7 ± 0.0 | 0.21 |
| NYHA Class ≥III (%) | 31 (67%) | 29 (60%) | 0.48 |

NYHA, New York Heart Association; BMI, Body Mass Index; STS, Society of Thoracic Surgeons

*Simplified implantation in the context of reduced suture steps.

Procedural outcomes: Cross-clamp and cardiopulmonary bypass time

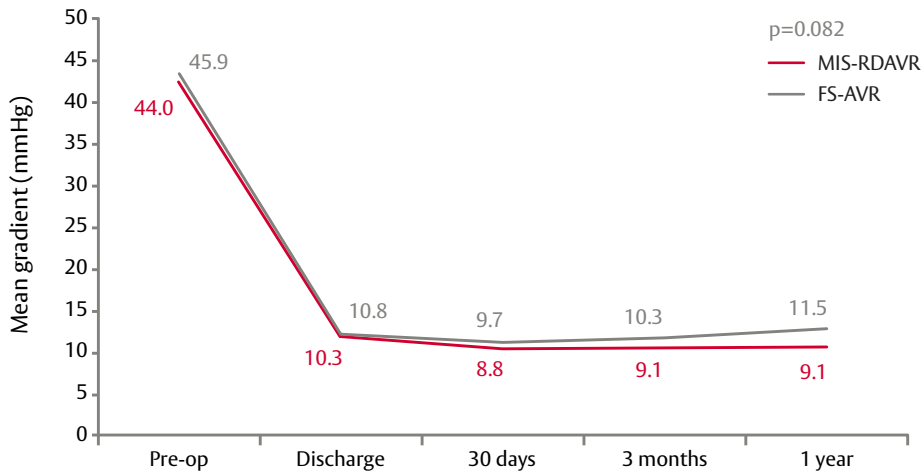


Significant, **12 MINUTE** reduction in cross-clamp time with MIS-RDAVR vs. FS-AVR

Numerical reduction in cardiopulmonary bypass time of **5 MINUTES** with MIS-RDAVR vs. FS-AVR

Haemodynamic outcomes at 1 year are comparable for MIS-RDAVR* and FS-AVR patients

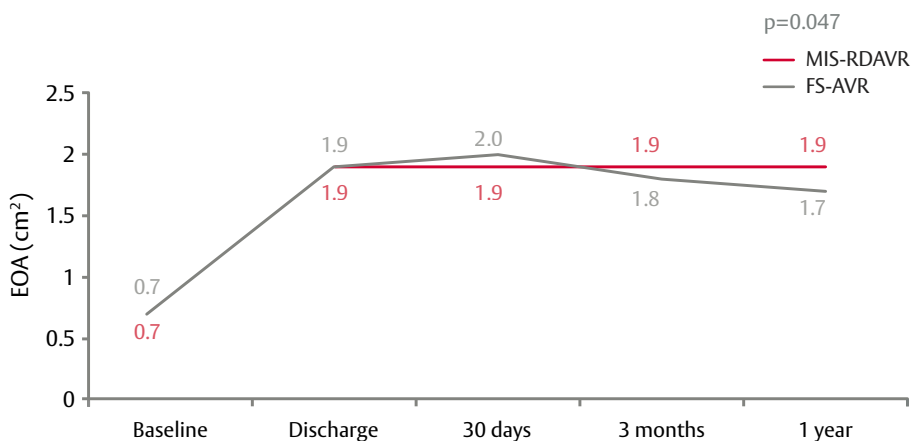
Transvalvular gradients



The **MIS-RDAVR** group experienced **stable** mean and **peak** gradients over time, whereas gradients **worsened** in the **FS-AVR**

At 1 year, the EDWARDS INTUITY valve demonstrated a numerically lower peak transvalvular gradient for MIAVR compared to conventional bioprosthesis for FS (16.9 ± 5.3 vs. 21.9 ± 8.6 mmHg; $p=0.033$).

Effective orifice area (EOA)



At 1 year, the EDWARDS INTUITY valve demonstrated significantly larger EOAs compared to conventional bioprosthesis for all valve sizes

Patient-prosthesis mismatch (PPM) at 1 year







| | | | |
|------------------|-------------|---------------|---------------|
| MIS-RDAVR | 3.7% | FS-AVR | 10.3% |
| | | | p=0.34 |

*Simplified implantation in the context of reduced suture steps.

Clinical outcomes at 1 year are comparable for MIS-RDAVR* and FS-AVR patients

Clinical outcomes at 30 days and 1 year

Clinical and functional outcomes were similar at 30 days and 1 year postoperatively for both groups.

| | | 30 days | | | 1 year | | |
|------------------------------|---|---------------|--------------|---------|---------------|---------------|---------|
| | | MIS-RDAVR | FS-AVR | p-value | MIS-RDAVR | FS-AVR | p-value |
| Mortality |  | 4% (2/46) | 2% (1/48) | 0.53 | 6% (3/46) | 6% (3/48) | 0.96 |
| Major bleeding event |  | 17% (8/46) | 8% (4/48) | 0.19 | 17% (8/46) | 10% (5/48) | 0.33 |
| CVA or permanent stroke |  | 4% (2/46) | 4% (2/48) | 0.97 | 4% (2/46) | 4% (2/48) | 0.97 |
| Deep sternal wound infection |  | 2% (1/46) | 2% (1/48) | 0.98 | 2% (1/46) | 2% (1/48) | 0.98 |
| Renal failure |  | 7% (3/46) | 0% (0/48) | 0.072 | 7% (3/46) | 2% (1/48) | 0.29 |
| New permanent pacemaker |  | 4% (2/46) | 2% (1/48) | 0.53 | 4% (2/46) | 2% (1/48) | 0.53 |

CVA; Cerebrovascular Accident

Paravalvular leak

| Discharge | One year |
|---|---|
| <ul style="list-style-type: none"> No difference between MIS-RDAVR and FS-AVR (p=0.81) | <ul style="list-style-type: none"> A significant increase in the proportion of people experiencing PVL (13/36) with MIS-RDAVR compared with FS-AVR (6/40; p=0.027) Only one patient has required explant for PVL in MIS-RDAVR Other cases of PVL have remained clinically non-significant thus far |

Conclusion

Haemodynamic outcomes such as EOA and transvalvular gradients in MIS-RDAVR* patients, were significantly better when compared to conventional valve patients after 1 year.

MIS-RDAVR* was also associated with statistically significant reduction in aortic cross-clamp times compared with FS-AVR.

*Simplified implantation in the context of reduced suture steps.

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