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A mechanistic investigation of the EDWARDS INTUITY Elite valve's hemodynamic performance

Sadri V, Bloodworth IV CH, Madukauwa-David ID, Midha PA, Raghav V and Yoganathan AP

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Key points

- This *in vitro* analysis shows that the EDWARDS INTUITY Elite valve features a larger maximum diameter at the LVOT and valve inflow compared to the Carpentier-Edwards PERIMOUNT Magna Ease aortic valve.
- The EOA is increased and gradients reduced with the EDWARDS INTUITY Elite valve compared with the Magna Ease valve.
- The absence of pledgets and the inflow frame design of the EDWARDS INTUITY Elite valve improves valve haemodynamics.

Background information

- Previous clinical studies have demonstrated that rapid deployment aortic valve replacement (RD-AVR) results in different transvalvular pressure gradients than conventional aortic valve replacement (AVR).
- The mechanism underlying the differences in haemodynamics between conventional sutured aortic valves and rapid deployment aortic valves is unknown.
- Analysis of these two types of valves may explain how RD-AVR improves haemodynamic performance compared with conventional AVR.

Aim

- To understand the mechanism behind different transvalvular pressure gradients and haemodynamic outcomes of rapid deployment surgical aortic valve replacement (SAVR) versus conventional SAVR.

Type of study

- *In vitro* study.

Methods

- A 23 mm Magna Ease valve and a 23 mm EDWARDS INTUITY Elite valve were implanted into an explanted cadaver heart:
  - The explanted heart was donated by a 77-year old male with no heart disease history
  - Sequential implantation of both valves was performed by a trained surgeon, in a 23 mm aortic annulus
  - The Magna Ease valve was implanted in the supra-annular position
  - The EDWARDS INTUITY Elite valve was implanted in the aortic annulus
  - After pressurising the aorta and left ventricle in order to mimic early systole, segmented images of the aorta and left ventricular outflow tract (LVOT) were captured using micro-computed tomography (μCT). The images were then used to calculate the fluid volume of these heart structures.

Edwards

- The fluid volumes obtained through µCT were used to print 3D models of the aorta and LVOT sections.
  - The model of the EDWARDS INTUITY Elite valve included sub-annular LVOT inflow
  - The Magna Ease valve model included suture pledgets.
- The Magna Ease valve model was used during *in-vitro* tests to quantify hydrodynamics in both models.
  - A validated left heart simulator was used to obtain pressure and flow-field characteristics for both valve models and to understand flow visualisation through both valves
  - Pulsatile simulators were set up as per ISO 5840-2 guidelines to obtain haemodynamic parameters of transvalvular pressure gradients and EOA.

Results

- Table 1 compares the *in-vitro* properties of the 3D models of the EDWARDS INTUITY Elite valve and the Magna Ease valve.
- The design of the EDWARDS INTUITY Elite valve maintains the diameter across the LVOT more consistently than the Magna Ease valve.
- The use of pledgets in the Magna Ease valve reduced the diameter in the annulus of the valve.
- The EOA of the EDWARDS INTUITY Elite valve was 10.2% larger than that of the Magna Ease valve.
- The measurements of EOA and mean and peak gradients obtained in this study are comparable with other clinical trials, such as the TRITON and FOUNDATION trials (Europe) and the TRANSFORM trial (US), supporting the reliability of this *in-vitro* model.

Limitations

- The representation of the 3D flows around the valve were incomplete because velocity was calculated in a single plane.
- As the models were generated using a heart from a single donor, patient-specific anatomical differences are not accounted for in this study.

Conclusion

The absence of pledgets and the inflow frame design of the EDWARDS INTUITY Elite valve widen the LVOT resulting in reduced velocity, and mean and peak pressure gradients, with a more consistent diameter across the LVOT. This may lead to reduced patient–prosthesis mismatch due to improved flow characteristics, pressure gradients and EOA, resulting in better outcomes.

This document is a summary of the Sadri V et al. *paper and covers key information including aim, type of study, methods, results, limitations and conclusions.*

The full publication is available at:
https://bit.ly/3bq6Jg8

Table 1: Comparison of the *in-vitro* models of EDWARDS INTUITY Elite and Magna Ease valves

Variable	EDWARDS INTUITY Elite valve	Magna Ease valve
LV internal diameter (cm)*	5.50	5.33
Mean transvalvular pressure gradients (mmHg ± SD)*	7.92 ± 0.37	10.13 ± 0.48
Peak gradients (mmHg ± SD)*	16.55 ± 0.81	21.16 ± 0.98
EOA (cm² ± SD)*	1.94 ± 0.095	1.76 ± 0.088
Peak velocity (m/s)	1.45	1.61

Adapted from Sadri *et al.*

*EOA: effective orifice area; LV: left ventricle; SD: standard deviation

Abbreviations

AVR: aortic valve replacement
EOA: effective orifice area
LVOT: left ventricular outflow tract
LV: left ventricle
RD-AVR: rapid deployment aortic valve replacement
SD: standard deviation
SAVR: surgical aortic valve replacement
µCT: micro-computed tomography

Important safety information:

Use of the EDWARDS INTUITY Elite valve system may be associated with new or worsened conduction disturbances, which may require a permanent cardiac pacemaker implant (PPI). The rate of PPI for the EDWARDS INTUITY Elite valve is within the range reported in the literature for various rapid deployment valves, but higher than that reported for surgical aortic valves. Physicians should assess the benefits and risks of the EDWARDS INTUITY Elite valve prior to implantation. See instructions for use for additional information.

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