

# Rapid-deployment aortic valves for patients with a small aortic root: A single center experience

Coti L, Haberl T, Scherzer S, Mag SS, Binder T, Kocher A, Laufer G and Andreas M

*The Annals of Thoracic Surgery*. 2020; doi:10.1016/j.athoracsur.2020.02.030.

### Key points

- Due to higher transvalvular gradients, the risk of PPM may be higher in patients undergoing SAVR than those undergoing TAVR. Patients with a small aortic root are particularly affected by this phenomenon.
- The EDWARDS INTUITY valve showed excellent haemodynamic performance, survival rates, functional class improvements and a reduced PPM incidence.
- Overall survival was not significantly influenced by degree of PPM, even in cases of severe PPM.

### Background information

- Patients who undergo SAVR are potentially at risk of PPM due to higher transvalvular gradients.
  - This trend is often seen in patients with a small aortic root.
- Rapid deployment bioprostheses may help reduce PPM due to improved haemodynamic performance and shorter procedural times.

### Aim

- To assess PPM incidence and haemodynamic performance in patients with a small aortic root, and the impact on early- and intermediate-term mortality, following implantation with the EDWARDS INTUITY valve (19- and 21-mm).

### Type of study

- Cohort analysis.

### Endpoints

- Primary:
  - Early- and intermediate-term mortality rates

- Haemodynamic performance (transvalvular aortic gradients)
- Incidence of PPM (iEOA).
- Secondary:
  - Incidence of valve-related events
  - NYHA functional class.

### Methods

- Isolated or combined SAVR with the EDWARDS INTUITY valve was carried out in 659 patients with severe AS between May 2010 to November 2018.
- These patients were included in an ongoing, prospective, longitudinal end-point assessment database.
- From this sample, 32.9% received a 19- or 21-mm bioprostheses.
- This subgroup, who were implanted with the 19- or 21-mm bioprostheses, had their baseline characteristics (preoperative), operative parameters and postoperative outcomes analysed.



Edwards

## Results

### Patient and procedural characteristics

- A total of 217 patients received the 19- or 21-mm EDWARDS INTUITY valve (Table 1).
- All patients suffered from severe AS; dyslipidaemia was the most common comorbidity (59%).
- Most patients had a preoperative NYHA functional class of III or IV (Table 1).
- Mean follow-up was  $24 \pm 23$  months.

### Procedural characteristics

- A total of 40.6% patients underwent concomitant procedures, with CABG being the most common (23%).
- Mean CPB time for isolated AVR was  $101.1 \pm 31.9$  minutes.
- Mean cross-clamp time for isolated AVR was  $67.2 \pm 23.2$  minutes.
- Mean overall CPB and cross-clamp times were  $117.8 \pm 49.4$  minutes and  $79.8 \pm 36.3$  minutes.

### Clinical and haemodynamic outcomes

- During the final follow-up, mean NYHA functional scores were  $1.5 \pm 0.7$  versus a mean preoperative score of  $2.8 \pm 0.6$  ( $p < 0.001$ ).
  - A total of 8.5% of patients had an NYHA functional score of III and IV (compared to 73.5% at baseline [ $p < 0.001$ ]).
- Overall, PPM occurred in 35.5% of patients (25.8% moderate and 9.7% severe):
  - 19 mm valve: 33% (moderate) and 10% (severe)
  - 21 mm valve: 23% (moderate) and 9% (severe).
- Mean gradients reduced between discharge and 5-year follow-up (Table 2):
  - 19 mm valve:  $17.8 \pm 6.3$  mmHg (mean) and  $32.7 \pm 11.8$  mmHg (peak)
  - 21 mm valve:  $13.5 \pm 4.7$  mmHg (mean) and  $23.9 \pm 7.2$  mmHg (peak).
- Pacemaker implantation was required in 11.5% patients:
  - Early pacemaker implantation in 8.8% patients
  - Late pacemaker implantation in 2.7% patients.

**Table 1: Patient characteristics**

Variable	Results
Age (mean $\pm$ SD years)	$74.9 \pm 7.9$
Female (%)	85.3
Valve size: 19 mm (%) 21 mm (%)	30.4 69.6
NYHA functional class III or IV (%)	73.5
iEOA (mean $\pm$ SD $\text{cm}^2/\text{m}^2$ )	$0.32 \pm 0.19$
Transvalvular gradient (mean $\pm$ SD mmHg)	$56.9 \pm 20.2$
Predicted median operative risk: STS score EuroSCORE II	2.7 2.8

**Table 2: Mean gradients**

Follow-up	Gradients (mean $\pm$ SD mmHg)
Discharge	$15 \pm 6$
3 months	$13 \pm 5$
1 year	$14 \pm 5$
3 years	$13 \pm 5$
5 years	$12 \pm 4$

- The patients' EOA and iEOA were  $1.55 \pm 0.36 \text{ cm}^2$  and  $0.87 \pm 0.22 \text{ cm}^2/\text{m}^2$ :
  - 19 mm valve:  $1.44 \pm 0.37 \text{ cm}^2$  and  $0.83 \pm 0.26 \text{ cm}^2/\text{m}^2$
  - 21 mm valve:  $1.59 \pm 0.35 \text{ cm}^2$  and  $0.89 \pm 0.21 \text{ cm}^2/\text{m}^2$ .
- Patients with PPM had a significantly higher mean body surface area ( $1.83 \pm 0.19 \text{ m}^2$  versus  $1.74 \pm 0.15 \text{ m}^2$ ,  $p = 0.004$ ) and mean gradient ( $17 \pm 5 \text{ mmHg}$  versus  $12 \pm 5 \text{ mmHg}$ ,  $p < 0.001$ ) than those who did not.
- Following the index procedure, reoperation occurred in 2.3% of patients with 1.4% occurring due to:
  - Severe paravalvular regurgitation: n=2
  - Ventricular rupture: n=1 (due to myectomy).

- Reoperation and valve explantation, due to endocarditis at 112 and 390 days postoperatively, occurred in 0.46% of patients.
- There were no cases of valve thrombosis, non-structural dysfunction coronary ostia obstruction or valve-in-valve procedures/valve explantation for SVD.

### Mortality

- A total of 12.4% of patients died (0.5% during the first month and 1.8% perioperatively).
- Whilst there were only a few cases of PPM, overall survival was not significantly influenced by any PPM degree (HR: 0.95; 95% CI 0.75 to 1.19:  $p=0.638$ ).

### Limitations

- Potential lack of a homogeneous sample due to varied inclusion criteria.

### Conclusion

The EDWARDS INTUITY valve demonstrated excellent haemodynamic performance and early and intermediate term survival rates, functional class improvements and a reduced PPM incidence. Rapid deployment AVR might be a superior solution to be considered in patients with small aortic annulus.

*This document is a summary of the Coti L 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/coti\\_avr](https://bit.ly/coti_avr)

### Abbreviations

AS:	Aortic stenosis
AVR:	Aortic valve replacement
CABG:	Coronary artery bypass graft
CI:	Confidence interval
CPB:	Cardio pulmonary bypass
EOA:	Effective orifice area
EuroSCORE II:	European System for Cardiac Operative Risk Evaluation II score
HR:	Hazard ratio
iEOA:	Indexed effective orifice area
NYHA:	New York Heart Association
PPM:	Patient-prosthesis mismatch
SAVR:	Surgical aortic valve replacement
SD:	Standard deviation
STS:	Society of Thoracic Surgeons
SVD:	Structural valve deterioration
TAVR:	Transcatheter aortic valve replacement

#### 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.

For professional use. For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use (consult [eifu.edwards.com](http://eifu.edwards.com) where applicable).

Edwards devices placed on the European market meeting the essential requirements referred to in Article 3 of the Medical Device Directive 93/42/EEC bear the CE marking of conformity.

Edwards, Edwards Lifesciences, the stylized E logo, EDWARDS INTUITY, and EDWARDS INTUITY Elite are trademarks or service marks of Edwards Lifesciences Corporation or its affiliates. All other trademarks are the property of their respective owners.

© 2020 Edwards Lifesciences Corporation. All rights reserved. PP--EU-0098 v1.0

Edwards Lifesciences • Route de l'Etraz 70, 1260 Nyon, Switzerland • [edwards.com](http://edwards.com)



Edwards