Summary 11

Minimally invasive aortic valve replacement with sutureless and rapid deployment valves: a report from an international registry (Sutureless and Rapid Deployment International Registry)

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European Journal of Cardio-Thoracic Surgery. 2019; doi: 10.1093/ejcts/ezz055.

Key points

- Minimally invasive sutureless and rapid deployment AVR (SURD-AVR) valves gave good outcomes, with low rates of in-hospital mortality and postoperative complications.
- The Perceval valve was used more often than the EDWARDS INTUITY valve in patients undergoing a right anterior thoracotomy, and was associated with shorter operative times.
- The EDWARDS INTUITY valve was associated with better postoperative haemodynamics and was more likely to be implanted in younger patients than the Perceval valve.
- Sutureless and rapid deployment valves can be considered a primary indication for minimally invasive AVR.

Background information

- Although minimally invasive AVR is associated with many benefits over AVR via a full sternotomy, its uptake by surgeons is low. This is probably because minimally invasive AVR is more complex, which can prolong operative times.
- Sutureless and rapid deployment valves are designed to facilitate implantation and shorten operative times, but their effect on clinical outcomes after minimally invasive surgery is unclear.
- The Sutureless and Rapid Deployment International Registry (SURD-IR) is the world's largest registry enrolling patients undergoing SURD-AVR. Its aim is to assess the management of valve diseases and the outcomes of valvular surgery.

Aim

- To assess clinical characteristics and in-hospital results of patients in the SURD-IR who had SURD-AVR through minimally invasive approaches.

Type of study

- An analysis of a multicentre, retrospective and prospective registry.

Endpoints

- Operative and in-hospital outcomes and postoperative haemodynamics.

Methods

- The study examined the data for 3,651 adults undergoing SURD-AVR with any sutureless or rapid deployment prosthesis, through a full sternotomy or a minimally invasive approach (April 2007–February 2018).
- Patients who had combined surgical procedures, reoperative AVR or implantation of the off-market 3F Enable valve (Medtronic) were excluded from the study.

Edwards

- Data on patient demographics, operative and in-hospital outcomes, and haemodynamics were analysed.

Results

Patient characteristics

- Of patients who had primary isolated SURD-AVR, 1,418 (73.3%; mean age 75.9 ± 7 years) had primary isolated SURD-AVR via a minimally invasive approach.
- The Perceval S valve (LivaNova) was implanted in 1,011 (71.3%) patients (mean age 76.7 ± 6.5 years; 32.6% male).
- The EDWARDS INTUITY or INTUITY Elite valves (Edwards Lifesciences) were implanted in 407 (28.7%) patients (mean age 73.8 ± 7.8 years; 46.9% male).
- Almost 13% of patients receiving the EDWARDS INTUITY valves were younger than 65 years, compared with 4.6% in the Perceval group (p<0.001).
- Patients who received the Perceval valve had a higher logistic EuroSCORE than those who received the EDWARDS INTUITY valves (9.4% *vs* 6.8%, p<0.001).

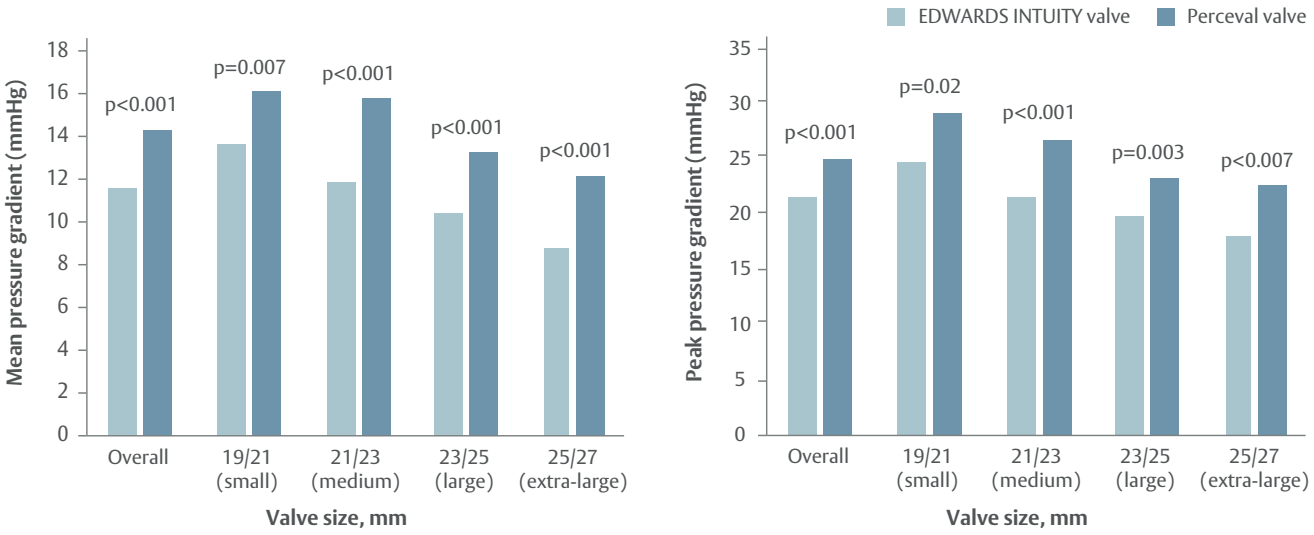
Operative outcomes

- Just over half of patients (56.4%) had an upper ministernotomy; the remainder (43.6%) had a right anterior thoracotomy.
- Overall, mean CPB time was 83.6 ± 30.4 minutes and mean cross-clamp time was 53.4 ± 21.3 minutes.
- Right anterior thoracotomy was associated with longer operative times than upper ministernotomy (CPB time 90.8 minutes *vs* 77.9 minutes; cross-clamp time 58.8 minutes *vs* 49.2 minutes, p<0.001).
- Right anterior thoracotomy was more common in patients receiving the Perceval valve than in those receiving the EDWARDS INTUITY valve (53.4% *vs* 19.2%, p<0.001). However, the Perceval valve was associated with shorter operative times (CPB time 81.2 minutes *vs* 89.4 minutes; cross-clamp time 51.2 minutes *vs* 59.0 minutes, p<0.001).
- Implantation success rate was 98.1%, regardless of surgical approach or type of prosthesis.

In-hospital outcomes and haemodynamics

- In-hospital mortality was 1.7%, with no significant difference between Perceval and EDWARDS INTUITY valves.
- The rates of postoperative complications were similar for both types of prosthesis. However, the Perceval group had higher incidences of atrial fibrillation (31.7% *vs* 23.3%, p=0.004) and sepsis (3.4% *vs* 0.4%, p=0.02).
- Overall, 9% of patients needed PPI, with no significant difference between Perceval (10%) and EDWARDS INTUITY valves (7.6%, p=0.3) or between different valve sizes.
- Overall, the PPI rate decreased over the study period, from 20.6% in 2009–2010 to 5.6% in 2017–2018 (p=0.02).
- The EDWARDS INTUITY valve was associated with significantly lower gradients overall (mean: 11.5 mmHg *vs* 14.3 mmHg; peak: 21.3 mmHg *vs* 24.8 mmHg, p<0.001) and for each valve size (Figure 1).

Figure 1. Postoperative mean (left) and peak (right) pressure gradients for the Perceval and EDWARDS INTUITY valves.



Valve size is reported as EDWARDS INTUITY valve size (Perceval valve size). Values are mean values; standard deviations not shown.

- Postoperatively, 7.1% of patients had aortic regurgitation. This was either mild or moderate, and the rate did not vary significantly between valves. This rate is higher than rates reported for conventional AVR, but it did not affect early results.
- Multivariate analysis found that the only independent predictor of in-hospital mortality was valve malpositioning (OR 16.2, 95% CI 2.55–10.8, p=0.03).

Limitations

- The study is based on an observational registry with no adjudication of patient inclusion or data collection, and no comparative arms.
- Selection bias may be present because the study did not use a propensity-matched analysis.
- Investigators were responsible for interpreting images and reporting data from their own centres.
- Many of the surgeons participated in first-in-man and CE mark studies, which may have introduced bias.

Conclusion

In the SURD-IR, 73.3% of patients who had primary isolated SURD-AVR underwent minimally invasive surgery. Minimally invasive SURD-AVR with the Perceval and EDWARDS INTUITY valves gave good outcomes, with low rates of in-hospital mortality and postoperative complications, and comparable operative times to conventional AVR. Sutureless and rapid deployment valves thus overcome the major limitation of minimally invasive AVR and can be considered a primary indication for this approach.

Although the overall PPI rate was 9%, the rate decreased over the course of the study to a low of 5.6%, which compares well with the rate reported for AVR with conventional bioprostheses, and is lower than rates reported after TAVR. The Perceval valve was used more often than the EDWARDS INTUITY valve in patients undergoing a right anterior thoracotomy. Despite this, it was associated with shorter operative times than the EDWARDS INTUITY valve.

The EDWARDS INTUITY valve was associated with superior postoperative haemodynamics compared with the Perceval valve and was more likely to be implanted in younger patients.

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

The full publication is available at:
http://bit.ly/berretta2019

Abbreviations

AVR: aortic valve replacement
CE: Conformité Européenne
CI: confidence interval
CPB: cardiopulmonary bypass time
EuroSCORE: European System for Cardiac Operative Risk Evaluation
OR: odds ratio
PPI: permanent pacemaker implantation
SURD-AVR: sutureless and rapid deployment aortic valve replacement
SURD-IR: Sutureless and Rapid Deployment International Registry
TAVR: transcatheter aortic valve replacement

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