

Incidence and causes of pacemaker implantation during postoperative period of aortic valve replacement with rapid deployment prosthesis

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Key points

- The PPI rate after AVR with the EDWARDS INTUITY valve was within previously described limits for sutured aortic bioprostheses.
- Pacemaker was not required in 66% of patients at follow-up.
- Previous acute MI and preoperative amiodarone treatment were identified as independent predictors of postoperative PPI.

Background information

- Aortic stenosis is common among elderly people and has a poor prognosis if left untreated.
- In recent years, TAVR has emerged as an option for patients at high operative risk, while rapid deployment aortic bioprostheses have made SAVR simpler and less invasive.
- However, both transcatheter and rapid deployment prostheses have been associated with conduction disturbances, which may require postoperative PPI.

Aim

- To establish the incidence of, reasons for and factors associated with PPI after implantation of the EDWARDS INTUITY valve.

Type of study

- A single-centre, observational study.

Endpoints

- Incidence of postoperative PPI.
- Reasons for PPI.
- Impact of PPI on midterm follow-up.

Methods

- The study included patients with aortic stenosis or double aortic lesion who received an EDWARDS INTUITY valve or EDWARDS INTUITY Elite valve between October 2012 and December 2016.
- Patients were followed up at 3, 6 and every 12 months after discharge.
- Univariate predictors of postoperative PPI were obtained using logistic regression models.

Results

Patient characteristics

- Seventy-one patients (mean age 75.3 ± 5 years, 68% male) with aortic stenosis (60%) or double aortic valve lesion (40%) were included.
- A total of 48 patients received the EDWARDS INTUITY Elite valve and the remaining 23 received the EDWARDS INTUITY valve.



Permanent pacemaker implantation

- Mean follow-up was 33 ± 18 months.
- Six patients (8%) underwent postoperative PPI (83% ventricular pacemaker vs 17% atrioventricular pacemaker) for:
 - AV block (n=3)
 - Left bundle branch block (n=2)
 - Atrial flutter with slow conduction (n=1).
- Mean waiting period for PPI was 11 ± 6 days.
- Patients who underwent PPI had higher incidences of previous acute MI (33.3% vs 6.6%, $p=0.028$) and preoperative amiodarone administration (33.3% vs 1.6%, $p<0.001$) than patients who did not undergo PPI.
- The incidence of hypertension was lower in patients who underwent PPI (50% vs 84%, $p=0.047$).
- Patients who underwent PPI had a higher preoperative LVEF than those who did not undergo PPI (67% vs 62%, $p=0.034$).
- Patients who underwent PPI had longer hospital stays (15.5 days vs 8 days, $p=0.016$) and higher readmission rates (50% vs 9.2%, $p=0.014$) than those who did not undergo PPI.
- Predictors of PPI were:
 - Preoperative amiodarone ($p=0.009$)
 - Preoperative acute MI ($p=0.046$)
 - Prolonged QRS interval ($p=0.012$)
 - Higher rate of postoperative readmittance ($p=0.030$)
 - Higher rate of postoperative atrial flutter ($p=0.027$).

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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Follow-up events

- Rates of LVEF, atrial fibrillation, stroke and death at midterm follow-up were unaffected by PPI.

Limitations

- This was a small, single-centre study.
- Mean follow-up was relatively short.

Conclusion

The PPI rate (6 patients [8%]) after AVR with the EDWARDS INTUITY valve or the EDWARDS INTUITY Elite valve was within previously described limits for sutured aortic bioprostheses. At follow-up, the pacemakers were found to be stimulating, rather than sensing, in only two of these patients (3%). Previous acute MI and preoperative amiodarone treatment were associated with an increased incidence of PPI.

This document is a summary of the Arribas JM 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/arribasavr>

Abbreviations

AV: atrioventricular
AVR: aortic valve replacement
LVEF: left ventricular ejection fraction
MI: myocardial infarction
PPI: permanent pacemaker implantation
SAVR: surgical aortic valve replacement
TAVR: transcatheter aortic valve replacement



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