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# Conduction disturbances following surgical aortic valve replacement with a rapid-deployment bioprosthesis

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## Key points

- Baseline RBBB and concomitant procedures, in particular CABG, are independent predictors of pacemaker need.
- Postoperative conduction disturbances and PPI do not affect early- and intermediate-term survival of patients undergoing RD-AVR.

## Background information

- Rapid deployment bioprostheses require a subannular frame that may interfere with the conduction system.
- Similar frames used in transcatheter valves have resulted in higher rates of permanent pacemaker implantation (PPI) than seen in conventional aortic valve replacement.

## Aim

- To assess postoperative conduction disturbances in patients who have undergone rapid deployment aortic valve replacement (RD-AVR) with the EDWARDS INTUITY valve system, and to determine underlying risk factors that lead to PPI.

## Type of study

- Prospective, single-centre, real-world experience.

## Endpoints

- Primary endpoint:
  - Early PPI after RD-AVR
- Secondary endpoints:
  - Overall occurrence of PPI
  - New-onset conduction disturbances (atrioventricular or intraventricular).
- Mortality.

## Methods

- Patients undergoing RD-AVR with the EDWARDS INTUITY valve between May 2010 and April 2019 were included in a prospective database.
- After exclusion of patients with a pre-existing pacemaker, data from 663 patients were included in this analysis.
- Assessment of conduction disturbances by electrocardiography (ECG) was performed during the procedure and at postoperative follow-ups at 3 months and 1, 3 and 5 years, postoperatively.
- Telephone follow-ups were conducted between clinic follow-ups at 2, 4 and 7 years, postoperatively.
- Median follow-up was 20 months (IQR 11–41 months), with a total duration of up to 9 years.

Edwards

- Univariate and multivariable logistic regression analyses were used to identify baseline PPI predictive factors in the first 14 days following surgery, including the following variables:
  - Age, valve size, concomitant procedures, concomitant coronary artery bypass grafting (CABG) and conduction anomalies at baseline.

## Results

### Patient and procedural characteristics

- Average age was 73.4 ± 7.8 years. 45.2% patients were female.
- Mean EuroSCORE II was 2.3%.
- Preoperative conduction disturbances were recorded in 126 patients (19.0%) (Table 1).

**Table 1. Patient characteristics**

| Conduction anomaly | Patients n (%) |
|---|---|
| Preoperative conduction anomalies (%): | |
| RBBB | 38 (5.7) |
| First degree AVB* | 37 (5.6) |
| LBBB* | 35 (5.3) |
| LAHB* | 33 (5.0) |
| Bifascicular block | 12 (1.8) |

Adapted from Coti *et al*.

*AVB: atrioventricular block; LAHB: left anterior hemiblock; LBBB: left bundle branch block; RBBB: right bundle branch block

### Postoperative bundle branch block

- Left bundle branch block (LBBB) before discharge occurred in 206 (31.1%) patients.
  - LBBB was transient in 36 (5.4%) of these patients.
- Right bundle branch block (RBBB) before discharge occurred in 11 (1.7%) patients.

### Permanent pacemaker implantation analysis

- A total of 61 patients required PPI in the first 14 days after RD-AVR.
  - Of these patients, 34 (5.1%) had no baseline conduction disturbance.
- In the first 30 days after RD-AVR, 68 patients (10%) required PPI.
- Overall, 80 patients required PPI during the complete follow-up period.
- Cumulative incidence of postoperative PPI was 9.4%, 10.3%, 11.7% and 15.3% at 14 days, 30 days, 1 year and 5 years.
- Multivariate analysis revealed several predictors for PPI (Table 2).

**Table 2. Independent predictors for PPI**

| Factor | HR (95% CI)* | p-value |
|---|---|---|
| Baseline RBBB* | 4.86 (2.74–8.63) | <0.001 |
| Baseline AVB* | 2.52 (1.28–4.96) | 0.007 |
| Baseline LAHB* | 2.06 (1.05–4.02) | 0.035 |
| Concomitant procedure | 3.49 (2.01–6.07) | <0.001 |
| Concomitant CABG* | 0.34 (0.19–0.60) | <0.001 |

Adapted from Coti *et al*.

*AVB: atrioventricular block; CABG: coronary artery bypass graft; CI: confidence interval; HR: hazard ratio; LAHB: left anterior hemiblock; RBBB: right bundle branch bock

### Survival analysis

- PPI did not significantly affect survival.
- Survival was found to be similar in patients who required PPI in the first 14 days after RD-AVR and in those patients who did not require it (p=0.60).
  - After early PPI, postoperative survival rates were 98%, 86% and 82% at 1 year, 3 years and 5 years.

## Limitations

- This study combines both pre-market clinical trial and post-market registry data.
- Due to variance in inclusion criteria over the course of the study, the patient population may not have been homogeneous.
- The rate of PPI was consistent with previously reported data and may be reduced by exclusion of patients with baseline conduction anomalies.

## Conclusion

Compared with conventional valves, the EDWARDS INTUITY valve has been historically associated with higher conduction disturbance after RD-AVR. This study provides evidence that nearly half of all patients who required PPI in the first 14 days after RD-AVR presented with various baseline conductions disturbances. In these patients, RBBB was found to be an independent predictor for increased PPI incidence. At early and intermediate follow-ups, PPI or new-onset LBBB did not significantly affect survival rates.

In conclusion, Coti *et al*. recommend improvements in patient selection, such as excluding patients with baseline conduction anomalies and surgical methods to achieve better outcomes after RD-AVR.

*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/2Kr2pRZ***

## Abbreviations

| | |
|---|---|
| AVB: | atrioventricular block |
| CABG: | coronary artery bypass grafting |
| CI: | confidence interval |
| ECG: | electrocardiography |
| EuroSCORE II: | European System for Cardiac Operative Risk Evaluation II score |
| HR: | hazard ratio |
| IQR: | interquartile range |
| LAHB: | left anterior hemiblock |
| LBBB: | left bundle branch block |
| PPI: | permanent pacemaker implantation |
| RBBB: | right bundle branch block |
| RD-AVR: | rapid deployment aortic valve replacement |
| SD: | standard deviation |

**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 where applicable).**

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