Incidence, predictors and clinical impact of permanent pacemaker insertion in women following transcatheter aortic valve implantation: Insights from a prospective multinational registry

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Period of study Women's International Transcatheter Aortic Valve Implantation (WIN-TAVI) registry compilation January 2013 – December 2015

Objectives

To describe the incidence, predictors and clinical impact of permanent pacemaker insertion (PPI) following transcatheter aortic valve replacement (TAVR) in women

Study design

Prospective

Materials and methods

- The WIN-TAVI registry was comprised of women undergoing TAVR with a commercially available device for symptomatic aortic stenosis in 19 centres in Europe and the US between January 2013 and December 2105
- Patients with a prior pacemaker or implantable cardiac defibrillator were excluded from the analysis
- All patients were deemed suitable for TAVR by the local heart team, procedural decisions were at the discretion of the treating physicians and indications for PPI were based on local practices and international guidelines
- The primary outcomes were the one-year rates of the valve academic research consortium criteria 2 (VARC-2) efficacy and safety endpoints

Key results

- 922 patients were included in the study, mean age 82.4 years
- Post-TAVR PPI occurred in 132 (14.3%) patients, including 120 (11.8%) patients within the first 30 days following TAVR
- Clinical and procedural characteristics were similar for all women receiving TAVI, the only differences being the prosthetic valve type and baseline conduction abnormalities
- Pre-existing right bundle branch block (RBBB) was associated with a high risk of post-TAVR PPI (OR 3.62, 95% CI 1.85 – 7.06, p<0.001)
- Implantation of balloon-expandable valves was associated with a lower risk (OR 0.47, 95% CI 0.30 – 0.74, p<0.001)
- Only 18.8% of patients with balloon-expandable valves received a pacemaker, compared to 31.2% receiving a self-expandable valve
- Post-TAVR PPI prolonged in-hospital stay by a median of 2 days (11 days in PPI vs. 9 days in no-PPI
- Risks of VARC-2 efficacy and safety endpoints at 1 year were similar in both groups

Limitations of study

- No conclusion regarding sex differences can be drawn from this analysis as the WIN-TAVI registry is by design limited to female patients
- Several variables that have been shown to be strongly associated with post-TAVR PPI, e.g. depth of prosthesis implantation, were not collected in this registry
- Data collection for the WIN-TAVI registry was up until the end of 2015, and advances in the field over the past 5 years must be considered when interpreting the results

Conclusions

- PPI frequently occurred within the first 30 days of females undergoing TAVI
- Pre-existing RBBB was a strong predictor of post-TAVI PPI
- Balloon-expandable devices were associated with a lower risk of PPI than self-expanding valves
- Although post-TAVI PPI prolonged in-hospital stay, it did not significantly impact adverse clinical outcomes at 1 year.