

# The influence of native aortic valve calcium and transcatheter valve oversize on the need for pacemaker implantation after transcatheter aortic valve insertion

Fu'ad Al-Azzam, MB, BCh,<sup>a</sup> Kevin L. Greason, MD,<sup>a</sup> Chayakrit Krittanawong, MD,<sup>b</sup> Eric E. Williamson, MD,<sup>c</sup> Christopher J. McLeod, MB, ChB, PhD,<sup>b</sup> Katherine S. King, MS,<sup>d</sup> and Verghese Mathew, MD<sup>b,c</sup>

## ABSTRACT

**Objective:** Native aortic valve calcium and transcatheter aortic valve oversize have been reported to predict pacemaker implantation after transcatheter aortic valve insertion. We reviewed our experience to better understand the association.

**Methods:** We retrospectively reviewed the records of 300 patients with no prior permanent pacemaker implantation who underwent transcatheter aortic valve insertion from November 2008 to February 2015. Valve oversize was calculated using area. The end point of the study was 30-day postoperative pacemaker implantation.

**Results:** Patient data included age of  $81.1 \pm 8.4$  years, female sex in 135 patients (45%), atrial fibrillation in 74 patients (24.7%), Society of Thoracic Surgeons predicted risk of mortality of 7.6% (interquartile range [IQR], 5.3-10.6), aortic valve calcium score of 2568 (IQR, 1775-3526) Agatston units, and annulus area of  $471 \pm 82$  mm<sup>2</sup>. Balloon-expandable valves were inserted in 244 patients (81.3%). Transcatheter aortic valve oversize was 12.8% (IQR, 3.9-23.3). Pacemaker implantation was performed in 59 patients (19.7%). Aortic valve calcium score (adjusted  $P = .275$ ) and transcatheter valve oversize (adjusted  $P = .833$ ) were not independent risk factors for pacemaker implantation when controlling for preoperative right bundle branch block (adjusted odds ratio, 3.49; 95% confidence interval, 1.61-8.55;  $P = .002$ ), implantation of self-expanding valve (adjusted odds ratio, 4.09; 95% confidence interval, 1.53-10.96;  $P = .005$ ), left bundle branch block (adjusted  $P = .331$ ), previous percutaneous coronary intervention (adjusted  $P = .053$ ), or valve surgery (adjusted  $P = .111$ ), and PR interval (adjusted  $P = .350$ ).

**Conclusions:** Right bundle branch block and implantation of a self-expanding prosthesis were predictive of pacemaker implantation, but not native aortic valve score or transcatheter valve oversize. (J Thorac Cardiovasc Surg 2016; ■:1-7)

Permanent pacemaker implantation occurs in approximately 30% of patients as a complication of transcatheter aortic valve insertion (TAVI).<sup>1-4</sup> Because some degree of transcatheter valve oversize is needed to securely seat the

prosthesis, it is not surprising some studies support that the amount of transcatheter valve oversize and aortic valve calcium are directly associated with postoperative pacemaker implantation.<sup>5-9</sup> It was our hypothesis that transcatheter valve oversize and aortic valve calcium score would influence the need for pacemaker implantation. We reviewed our single-center experience to

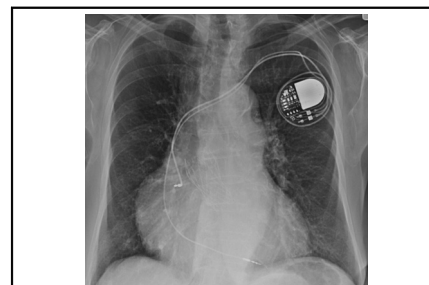
From the Divisions of <sup>a</sup>Cardiovascular Surgery, <sup>b</sup>Cardiovascular Diseases, and <sup>d</sup>Biomedical Statistics and Informatics, and <sup>c</sup>Department of Radiology, Mayo Clinic, Rochester, Minn.

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Address for reprints: Kevin L. Greason, MD, Division of Cardiovascular Surgery, Mayo Clinic, Rochester, MN 55905 (E-mail: [greason.kevin@mayo.edu](mailto:greason.kevin@mayo.edu)). 0022-5223/\$36.00

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Chest x-ray in a patient who received a self-expanding valve followed by permanent pacemaker insertion.

### Central Message

The calcium score of the aortic valve leaflets and annulus was not associated with high incidence of heart block post-TAVI.

### Perspective

Patients who are consulted for TAVI should be consulted for pacemaker insertion during the same admission specially if self-expanding devices are used.

Scanning this QR code will take you to supplemental tables for this article.

**Abbreviations and Acronyms**

CI	= confidence interval
CT	= computed tomography
IQR	= interquartile range
OR	= odds ratio
STS	= Society of Thoracic Surgeons
TAVI	= transcatheter aortic valve insertion

better characterize the effect these factors had on postoperative pacemaker implantation.

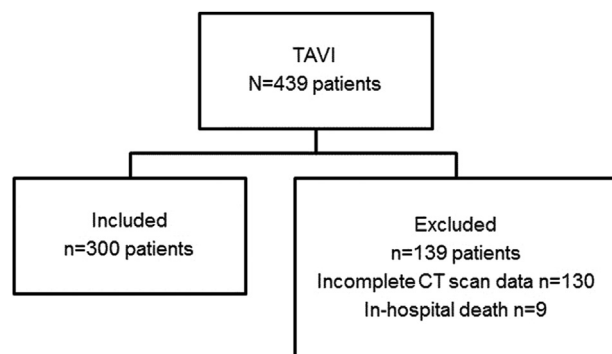
**MATERIALS AND METHODS**

The purpose of this study was to determine whether transcatheter aortic valve oversize and native aortic valve calcium were predictive of pacemaker implantation after TAVI. We proposed a multivariate model using the 2 variables and controlling for factors previously identified from the literature to be associated with pacemaker implantation. The Mayo Clinic Institutional Review Board approved this study.

We retrospectively reviewed the records of 435 patients without a previous permanent pacemaker who underwent TAVI between November 2008 and February 2015. There were 126 patients (29.6%) excluded from study because of inadequate computed tomography (CT) scan data, which included patients who were part of the PARTNER studies that did not initially require specific CT scan analysis of the aortic valve and left ventricular outflow tract.<sup>1,2,10</sup> An additional 9 patients (2.1%) were excluded from the study because of operation-related death. A total of 300 patients were entered into the study, and all patients received TAVI under general anesthesia (Figure 1).

Baseline patient, electrocardiography, and operative characteristics and 30-day outcome data were abstracted from the Division of Cardiovascular Surgery database and individual patient electronic medical records. Baseline patient characteristics were defined as outlined in the Society of Thoracic Surgeons Adult Cardiac Surgery Database (Society of Thoracic Surgeons, Chicago, Ill). Balloon-expandable valves were sized on the basis of CT-derived aortic valve annulus area, and self-expanding valves were sized on the basis of CT-derived aortic valve annulus perimeter.<sup>11,12</sup>

All patients received a preoperative electrocardiography-gated CT scan of the heart, first without contrast and then with contrast. Calcium quantification was performed using semiautomated software (Syngovia, Siemens Healthcare, Erlangen, Germany) and reported as Agatston units. Native aortic valve annulus area and perimeter were derived using the semiautomated polygon tool (Aquarius iNtuition, TeraRecon, Foster City, Calif)



**FIGURE 1.** Consort diagram of study population. TAVI, Transcatheter aortic valve insertion.

using hand placement of seed points oriented to the plane of the native aortic valve cusp tips.

Valve area oversize was determined on the basis of the equation  $([\text{prosthetic aortic valve area} \div \text{native aortic valve annulus area}] - 1) \times 100$ .<sup>13</sup> Perimeter oversize was determined on the basis of a similar equation:  $([\text{prosthetic aortic valve perimeter} \div \text{native aortic valve annulus perimeter}] - 1) \times 100$ . Transcatheter prosthetic aortic valve areas and perimeters are reported in Table 1.

Descriptive statistics for categorical variables are reported as count (percentage) and continuous variables as mean  $\pm$  standard deviation when normally distributed or median (interquartile range [IQR]) when not normally distributed. Chi-square test, Student *t* test, and Wilcoxon rank-sum test were used to test associations of baseline characteristics and valve type.

Native aortic valve calcium score and transcatheter valve oversize along with other electrocardiography and valve characteristics identified with pacemaker implantation in previous studies and any additional univariate significant variables were included in a multivariable logistic model. The cohort also was stratified by valve type (ie, self-expanding) to account for the difference in oversize calculation method (eg, area vs perimeter) while controlling for bundle branch block. Data were analyzed with SAS statistical software version 9.4 (SAS Institute, Inc, Cary, NC). An alpha level of 0.05 was used to determine statistical significance.

**RESULTS**

Baseline patient characteristics included an age of  $81.1 \pm 8.4$  years, female sex in 135 patients (45.0%), and a Society of Thoracic Surgeons predicted risk of mortality of 7.6% (IQR, 5.3-10.6). Additional baseline patient data are presented in Table 2. The aortic valve calcium score was 2568 (IQR, 1775-3528) Agatston units, and native aortic valve area was  $471 \pm 82$  mm<sup>2</sup>.

Atrial fibrillation was present in 74 patients (24.7%). In the 226 patients with sinus rhythm, the mean PR interval was 184 ms (IQR, 162-208), and 66 patients (29.2%) had a PR interval greater than 200 ms. For all patients, the QRS duration was 100 ms (IQR, 92-118), and 71 patients (23.7%) had a QRS duration greater than 120 ms. Right bundle branch block was present in 45 patients (15%), and left bundle branch block was present in 25 patients (8.3%).

TAVI access was transfemoral in 174 patients (58.0%), transapical in 113 patients (37.7%), transaortic in 12 patients (4.0%), and transaxillary in 1 patient (0.3%). Balloon-expandable valves were inserted in 244 patients (81.3%), and self-expanding valves were inserted in 56 patients (18.7%). Specific valve types included the SAPIEN valve (Edwards Lifesciences, Irvine, Calif) in 131 patients (43.7%), SAPIEN XT valve (Edwards Lifesciences) in 69 patients (23.0%), SAPIEN S3 valve (Edwards Lifesciences) in 44 patients (14.7%), and CoreValve (AccuTrak, Medtronic, Minneapolis, Minn) in 56 patients (18.7%).

Baseline characteristics were similar in patients who received balloon or self-expanding transcatheter prosthetic aortic valve insertion (Table 3). Baseline PR interval was less in the balloon-expandable group (184; IQR, 164-210) than in the self-expanding group (173; IQR, 154-199; *P* = .048), but there was no difference in the number of

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