Pacemaker Requirements following Self-Expanding Transcatheter Aortic Valve Replacement

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Despite improvements in transcatheter aortic valve replacement (TAVR), outcomes with advancing technology and experience, the need for permanent pacemaker (PPM) implantation remains a frequent problem. Prosthetic valves may interact with the bundle of His and the left bundle branch, resulting in conduction abnormalities that require a PPM. The requirement for new PPM implantation within 30 days of TAVR increases patients' length of stay, cost of care, and likelihood of readmission, although thankfully not the risk of mortality [1]. While PPM implantation following TAVR has been studied extensively, data specifically regarding self-expanding valves (SEVs) are scarce. For 1,973 patients receiving balloon-expandable valves (BEVs; Sapien, Edwards Lifesciences, Irvine, CA, USA) in the PARTNER trials through 2014, the new PPM rate was 8.8%, with increasing implantation depth being the most important risk factor [2]. By contrast, the 2014 CoreValve (Medtronic, Dublin, Ireland), US Pivotal Trial reported a new PPM rate of 19.8% at 30 days in 795 SEV patients [3].

Retrospective multicenter registry data are similarly skewed. A landmark study of 9,875 patients in the National Cardiovascular Data Registry (NCDR) Society of Thoracic Surgeons (STS)/American College of Cardiol-

ogy (ACC) Transcatheter Valve Therapy (TVT) Registry reported an overall PPM rate of 6.7% within 30 days of TAVR from 2011 through 2014, corresponding to a rate of 4.3% for 8,265 BEVs and 25.1% for 821 SEVs [4]. Similarly, a 41-study meta-analysis published in 2014 reported an aggregate PPM rate of 17%, composed of 6% with BEVs and 28% with SEVs [5]. Male gender, right bundle branch block (RBBB), left anterior fascicular block, underlying atrioventricular block, and intraprocedural atrioventricular block emerged among other predictors of PPM implantation (Table 1), which should be considered during procedural planning to individualize the discussion of each patient's PPM risk.

However, these data all predate current devices and deployment techniques, which include shallower implantation for both BEVs and SEVs, reducing the likelihood of interaction with the conduction system. While initial studies with first-generation TAVR devices and deployment techniques showed significantly higher PPM rates with SEVs, contemporary data show a reduction in PPM rates with SEVs, though still higher than with BEVs. In the 2 trials of TAVR for patients at a low surgical risk, PPM rates were 6.5% for BEV [6] and 17.4% for SEV [7]. In addition, a recent small study of a newer SEV, ACU-

Table 1. Demographic, anatomical, baseline electrocardiographic, and procedural predictors of PPM following TAVR [12]

Demographic and anatomic factors	Baseline electrocardiographic factors	Procedural factors
Increasing age	RBBB	SEV (vs. BEV)
Male gender	Left anterior fascicular block	Implantation depth
Decreasing LVOT diameter	First- or second-degree AV block	Prosthesis oversizing
Shorter membranous septum	Increasing QRS duration	Balloon pre- and postdilation
Aortic valve calcium burden (especially left cusp)	Atrial fibrillation	Intraprocedural AV block
Mitral annular calcification		

PPM, permanent pacemaker; TAVR, transcatheter aortic valve replacement; LVOT, left ventricular outflow tract; RBBB, right bundle branch block; AV, atrioventricular; SEV, self-expanding valve; BEV, balloon-expandable valve.

RATE neo (Boston Scientific, Marlborough, MA, USA), implanted with the current technique, reported a PPM rate of only 10.3% in 212 patients, with predictors of PPM including calcification of the aortic valve cusps, pre-existing RBBB, and age >82.7 years [8].

Data are virtually absent regarding PPM rates with 3 new Chinese SEVs. In the sole published paper, a series of 27 Venus A-Valves (MedTech, Hangzhou, China) and 27 CoreValves, the PPM rates were 7.4 and 37.0%, respectively ($p = 0.03$) [9]. No reports in English have been published to date on PPM rates associated with the VitaFlow (MicroPort Medical, Shanghai, China) or Taurus One (Peijia Medical, Suzhou, China) BEVs.

In the present issue of *Cardiology*, Du et al. [10] present a retrospective analysis of 256 Chinese patients undergoing TAVR with CoreValve, Venus A-Valve, VitaFlow, and Taurus One SEVs from 2013 through 2018. In this population, the incidence of post-TAVR PPM implantation was 14.8%. In a multivariable logistic regression model, predictors of PPM implantation included antecedent RBBB, implantation depth >6 mm below the aortic annulus, and trileaflet native aortic valve. PPM implantation was not associated with the mortality rate at 30 days or 1 year. Although this study entailed a retrospective, single-center analysis without comprehensive details on the indications for PPM implantation, the study's findings may be hypothesis generating.

First, this study confirms the established principles that pre-existing conduction abnormalities, especially RBBB, and deeper implantation are associated with an increased risk of conduction disturbances requiring PPM. Furthermore, the authors raise an exciting novel idea, that bicuspid-aortic-valve patients could have a lower PPM rate than trileaflet-aortic-valve patients. In their population, 43% of the patients had bicuspid valves, and their PPM rate was only 6.4% in contrast to the rate of 21.7% for trileaflet native valves ($p < 0.05$). This finding contrasts with a recent analysis from the NCDR STS/ACC TVT Registry reporting PPM rates of 9.1 versus 7.5% for bicuspid and trileaflet native valves, respectively (hazard ratio 1.23, 95% confidence interval 1.02–1.49), for 92,236 patients treated exclusively with Sapien 3 BEVs from 2015 through 2018 [11]. No randomized trial of TAVR in bicuspid-valve-patients is currently planned, but this discrepancy argues for the importance of such a trial.

In conclusion, the role of SEVs in TAVR continues to evolve, as does the associated PPM rate. Improvements in the procedural technique have reduced PPM rates over the last 5 years. Bicuspid-valve patients present a potential niche where SEVs may out-perform BEVs in terms of pacemaker. Most importantly, a steady stream of novel devices, including 3 new Chinese SEVs, will continue to advance the field of TAVR worldwide.

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