## A Highly Predictive Risk Model for Pacemaker Implantation After TAVR



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## ABSTRACT

**OBJECTIVES** This study sought to develop a robust and definitive risk model for new permanent pacemaker implantation (PPMI) after SAPIEN 3 (third generation balloon expandable valve) (Edwards Lifesciences, Irvine, California) transcatheter aortic valve replacement (third generation balloon expandable valve TAVR), including calcification in the aortic-valvular complex (AVC).

**BACKGROUND** The association between calcium in the AVC and need for PPMI is poorly delineated after third generation balloon expandable valve TAVR.

**METHODS** At Cedars-Sinai Heart Institute in Los Angeles, California, a total of 240 patients with severe aortic stenosis underwent third generation balloon expandable valve TAVR and had contrast computed tomography. AVC was characterized precisely by leaflet sector and region.

**RESULTS** The total new PPMI rate was 14.6%. On multivariate analysis for predictors of PPMI, pre-procedure third generation balloon expandable valve TAVR, right bundle branch block (RBBB), shorter membranous septum (MS) length, and noncoronary cusp device-landing zone calcium volume (NCC-DLZ CA) were included. Predictive probabilities were generated using this logistic regression model. If 3 pre-procedural risk factors were present, the c-statistic of the model for PPMI was area under the curve of 0.88, sensitivity of 77.1%, and specificity of 87.1%; this risk model had high negative predictive value (95.7%). The addition of the procedural factor of device depth to the model, with the parameter of difference between implantation depth and MS length, combined with RBBB and NCC-DLZ CA increased the c-statistic to 0.92, sensitivity to 94.3%, specificity to 83.8%, and negative predictive value to 98.8%

**CONCLUSIONS** By using a precise characterization of distribution of calcification in the AVC in a single-center, retrospective study, NCC-DLZ CA was found to be an independent predictor of new PPMI post-third generation balloon expandable valve TAVR. The findings also reinforce the importance of short MS length, pre-existing RBBB, and ventricular implantation depth as important synergistic PPMI risk factors. This risk model will need validation by future prospective multicenter studies. (J Am Coll Cardiol Img 2017;10:1139–47) © 2017 Published by Elsevier on behalf of the American College of Cardiology Foundation.

ranscatheter aortic valve replacement (TAVR) is a well-established alternative to surgical aortic valve replacement for intermediate and high-risk patients with severe aortic valve stenosis (1). Cardiac conduction disturbance requiring new permanent pacemaker implantation (PPMI) is an important complication of TAVR that has been associated in some studies with increased mortality and rehospitalization rates (2). The exact frequency of new PPMI varies according to the valve design used and was previously noted to be significantly lower with balloon-expandable (BE) TAVR

Manuscript received May 24, 2016; revised manuscript received October 28, 2016, accepted November 10, 2016.

From the Cedars-Sinai Heart Institute, Los Angeles, California. Dr. Jilaihawi is a consultant for Edwards Lifesciences, St. Jude Medical, and Venus MedTech. Dr. Makkar has received grant support from Edwards Lifesciences and St. Jude Medical; is a consultant for Abbott Vascular, Cordis, and Medtronic; and holds equity in Entourage Medical. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.