Transcatheter Aortic Valve Replacement and New Conduction Abnormalities/Permanent Pacemaker
Can We Achieve the Intended Implant Depth?

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In the spring of 2008, we reported the first study to demonstrate that the depth of the implant of a transcatheter aortic valve correlated with rates of left bundle branch block and permanent pacemaker (1). We measured the distance from the ventricular edge of the CoreValve prosthesis (Medtronic, Minneapolis, Minnesota) to the lower edge of the noncoronary cusp to be 9.8 ± 2.8 mm in those with new-onset left bundle branch block and 5.9 ± 3.7 mm in those without left bundle branch block (p = 0.005). At that time, we recommended an implant depth of ~6 mm to mitigate the risk of conduction abnormalities and the need for a permanent pacemaker. The depth of implantation has also found importance in complications such as paravalvular aortic regurgitation, coronary obstruction, malpositioning resulting in embolization or valve-in-valve, and mitral valve injury.

Positioning of a transcatheter aortic valve is guided by x-ray fluoroscopy, a 2-dimensional (2D) imaging modality with the potential for parallax error. As a result, cardiac structures and/or cardiac devices may appear foreshortened if perpendicular fluoroscopic viewing angulations are not obtained. Ideally, both the aortic annulus and delivery catheter should be visualized in an optimal angulation. Planar structures, such as the aortic annular plane and the tip of the delivery catheter, are optimally visualized when they are perpendicular to the x-ray source-to-detector direction. Currently, however, physicians select a viewing angle perpendicular to either the aortic annulus or the delivery catheter, but not both (Figure 1). Proponents aiming for the plane of the delivery catheter sacrifice the plane of the aortic annulus; those aiming for the plane of the aortic annulus sacrifice the plane of the delivery catheter. Given that our implant depths are on the order of millimeters, foreshortening of the anatomy or delivery catheter on 2D fluoroscopic imaging can skew the operator’s understanding of the true implant depth. The effect of foreshortening invariably leads to implant depths deeper than intended without the operator noticing on 2D fluoroscopic imaging. A potential solution is to find the single fluoroscopic viewing angle (which exists) that provides both the annulus and delivery catheter in plane (Figure 2). Our group is currently conducting clinical research in this area.

In this issue of JACC: Cardiovascular Interventions, Husser et al. (2) examined the incidence and predictors of new permanent pacemaker implantation (PPI) and new-onset conduction abnormalities (i.e., left bundle branch block [LBBB]/right bundle branch block [RBBB]) after SAPIEN 3 (Edwards Lifesciences, Irvine, California) implantation. The authors reported that 34 of 208 (16%) patients required a new PPI for appropriate indications including third-degree atrioventricular block, high second-degree atrioventricular...
block, and symptomatic bradycardia. The fluctuation in the rate of new PPIs across consecutive patients is noteworthy; it nearly doubled from 13% in the first 70 patients to 22% in the last 70 patients. This observation may be related to chance and sample size, but also brings to mind the heterogeneous PPI rates observed across centers for a particular device, notwithstanding the inconsistent indications for a new PPI after TAVR. Specific guidelines for PPI after TAVR are lacking and is an area that requires more study and collaborative efforts.

The authors also noted that 1 of 3 patients required a new PPI or developed new-onset conduction abnormalities (LBBB or RBBB). These rates definitely appear higher than expected for conventional balloon-expandable platforms. Whereas previous studies of SAPIEN XT reported new PPI rates between 5% and 12% (3,4), recent studies of the SAPIEN 3 document rates up to 26% (5-7). Although retrospective comparisons have been published, prospective head-to-head comparison data for SAPIEN XT and SAPIEN 3 are not and will not be available.

Patient-, operator- and device-related factors can contribute to the development of conduction abnormalities and the need for PPI after TAVR. More specifically, the authors found an association between

![Figure 1: Two Methods Currently Used to Implant Transcatheter Aortic Valves](image)

**A** Proponents aiming for the plane of the annulus lose the plane of the delivery catheter. In this case, the delivery catheter is foreshortened. **B** Proponents aiming for the plane of the delivery catheter lose the plane of the aortic annulus. In this case, the aortic annulus is foreshortened.

![Figure 2: Scenario in Which Both the Aortic Annulus and Delivery Catheter Are in Plane](image)

Neither the aortic annulus or delivery catheter are foreshortened.
new PPI and the following variables: pre-existing RBBB, atrial fibrillation, heart rate, baseline QRS duration, and implant depth. For the combined endpoint of new PPI and new-onset conduction abnormalities, the following independent predictors were noted: pre-existing QRS duration, implant depth, and the degree of oversizing.

The predictors of new PPI and/or conduction abnormalities (e.g., pre-existing RBBB, atrial fibrillation, oversizing, implant depth) reported in this study are not surprising and have been reported elsewhere, including SAPIEN XT studies. The important finding of this study lies in the higher-than-expected rates of new PPI and/or conduction abnormalities for the SAPIEN 3.

Similar to the SAPIEN XT, the SAPIEN 3 frame is constructed of cobalt-chromium alloy. The nominal frame height of the SAPIEN 3 device is longer and undergoes greater foreshortening during deployment than the SAPIEN XT (e.g., for a 26-mm valve size, the SAPIEN 3 frame height is 20 mm and foreshortens 8 mm during deployment vs. the SAPIEN XT frame height of 17.2 mm that foreshortens 2 mm) (8). Changes in frame design can influence implant depth. In this case, operators may be inclined to implant the SAPIEN 3 “deeper” into the left ventricular outflow tract to avoid potential coronary arterial complications. Furthermore, the need to take into account the greater foreshortening characteristics of the SAPIEN 3 can complicate position accuracy.

The benefits of superior sealing afforded by the new SAPIEN 3 skirt appear to be counterbalanced by an increased incidence of conduction abnormalities (9). The association between either paravalvular aortic regurgitation or new PPI/conduction abnormalities and adverse clinical outcomes after transcatheter aortic valve replacement (TAVR) is controversial. New-onset LBBB after surgical aortic valve replacement in low-risk patients has been linked to sudden cardiac death, syncope, and the need for a permanent pacemaker at 1-year follow-up (10).

Until now, newer generation TAVR devices appear to have positive effects on clinical outcomes. The current findings of Husser et al. (2) highlight that new device iterations, although designed with good intentions, can be associated with untoward and unexpected clinical outcomes. These findings reinforce the argument that new TAVR devices need to be prospectively studied using systematic and robust clinical protocols.

The clinical implications and practicality of the current study findings need to be addressed. Although the authors conclude that “avoidance of deep implant depth and extreme oversizing may avoid PPI and conduction abnormalities,” several important questions remain. What is the definition of “deep implant depth” and “extreme oversizing”? The implant depth was guided by the fluoroscopic viewing angle with the aortic annulus in plane while the measured implant depth was performed using a different fluoroscopic viewing angle with the prosthesis in plane. This is counterintuitive—the fluoroscopic viewing angle used to target a particular implant depth during deployment is then not used to measure implant depth. The paradox stems from the potential foreshortening of the annulus and/or device on 2D fluoroscopic imaging as described above. In fact, the only accurate method to measure the true implant depth is when both the annulus and device are orthogonal to the viewing plane. Up until now, no study has reported the depth of implant in this way. The authors reported the depth of implant as the percentage of the prosthesis lying below the annular plane. The mean implant depth was 26 ± 7%. Given that the frame height differs across device sizes, the authors should have reported the depth of implant according to device size. Without this information, the reader cannot translate the current study results to clinical practice. Reporting the implant depth in units of millimeters would allow further analyses to suggest a maximum cut-off depth to mitigate the risk of new PPI and conduction abnormalities.

A peculiar notion was that 12% of patients were “undersized” according to area. This implies that the device was smaller (on average by 9%) than the aortic annulus. This goes against the underlying principles of radial force and the need for oversizing to anchor transcatheter aortic valves. What is known is that anchoring and sealing of transcatheter aortic valves occurs across the region of the native aortic valve leaflets, annulus, and left ventricular outflow tract. The notion of “undersizing” by the authors suggests that further work is needed to better understand the anchoring mechanisms and oversizing principles associated with the SAPIEN 3 device.

As we move toward younger and lower surgical risk patients, the incidence, mechanisms, implications, and potential solutions to lessen the risks of conduction abnormalities and need for PPI following TAVR need to be further elucidated.

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