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EDITORIAL COMMENT

Increased Pacemaker Implantation Rate After New-Generation Balloon-Expandable SAPIEN 3 Valve

Who Was to Blame, the Valve or the Doctor?*

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The occurrence of conduction disturbances and the need for permanent pacemaker implantation remain a significant issue associated with transcatheter aortic valve replacement (TAVR) (1). Indeed, the contiguity of the conduction system to the aortic annulus (landing zone of transcatheter valve prostheses) makes this procedure likely to develop this complication (2). To date, several predictors of pacemaker implantation after TAVR have been identified, including pre-existent right bundle branch block, prolonged baseline QRS duration, and age (3). These factors are strictly patient related, irrespective of the type of transcatheter prosthesis used. Historically, the self-expanding CoreValve (Medtronic, Galway, Ireland) has been associated with a higher rate of conduction disturbances compared with the balloon-expandable Edwards SAPIEN devices caused by the longer stent frame and a deeper implantation of the prosthesis in the left ventricular outflow tract (1). Having said that, some early reports of the new-generation balloon-expandable SAPIEN 3 valve (Edwards Lifesciences, Irvine, California) have demonstrated a rate of pacemaker implantation higher than generally reported with balloon-expandable devices, although still remaining lower than that seen with self-expanding valves (4,5). However, this was not confirmed in a more recent study by Nijhoff et al. (6), in which no difference in pacemaker implantation rate between the SAPIEN XT and SAPIEN 3 was reported.

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In this issue of *JACC: Cardiovascular Interventions*, De Torres-Alba et al. (7) aimed to look carefully into this important aspect of the SAPIEN 3 valve, which seemed to partially dampen the enthusiasm generated by the excellent results obtained with this new TAVR device in terms of clinical outcomes and valve performance (4,5). In this well-conducted, single-center study comparing 162 patients treated with the SAPIEN 3 valve with 287 patients treated with the SAPIEN XT valve, the investigators found a significantly higher pacemaker implantation rate with the SAPIEN 3 valve (7). More importantly, they demonstrated that a change in the valve deployment technique toward a higher valve implantation resulted in a significant reduction in the pacemaker implantation rate (25.9% vs. 12.3%). This concept is extremely interesting and confirms a practice-based perception of many operators regarding the effectiveness of this implantation strategy (8). However, the relatively small, nonrandomized, single-center, observational nature of the study by De Torres-Alba et al. and the lack of systematic pacemaker interrogation at follow-up preclude a definite conclusion and therefore warrant further investigation. Nevertheless, it cannot be denied that this study seems to identify the main culprit for the increased pacemaker implantation rate after the SAPIEN 3 as the implantation technique rather than the prosthesis itself.

The SAPIEN 3 valve incorporates a completely new frame design with a substantial basal foreshortening

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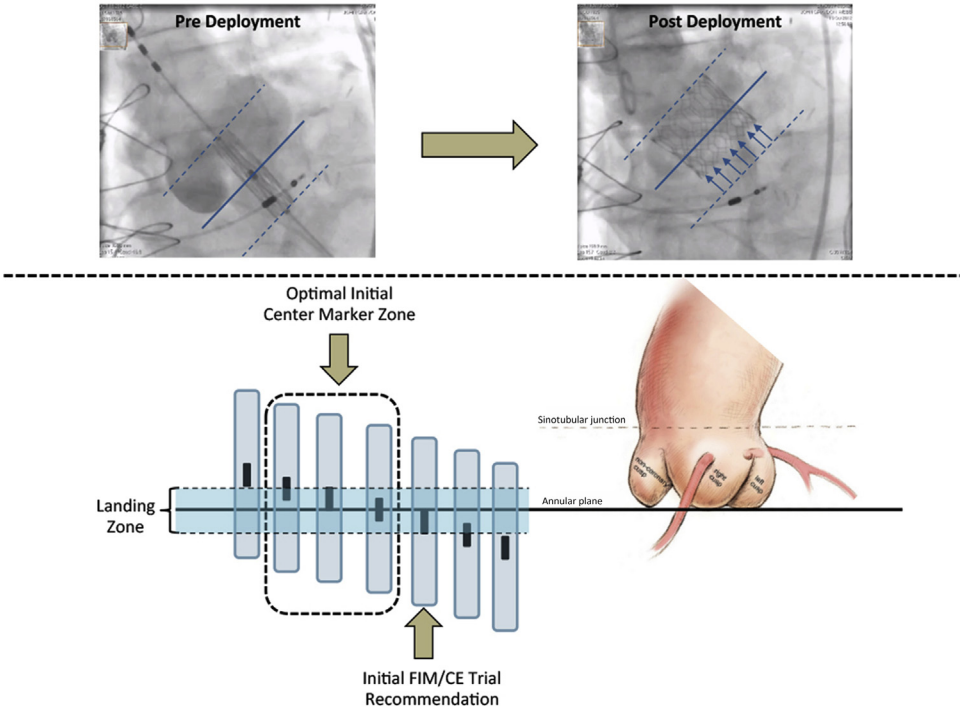
FIGURE 1 Edwards SAPIEN 3 Valve Foreshortening and Recommended Pre-Deployment Valve Positioning



(Top) The basal foreshortening of the SAPIEN 3 prosthesis (Edwards Lifesciences, Irvine, California) after complete deployment **(blue arrows)**. **(Bottom)** The initial positioning guidance used in First-in-Man (FIM) & Conformité Européenne (CE) trial, based on SAPIEN XT experience and the current indication with the bottom of the center marker position 1 to 3 mm higher than the base of the cusps.

at the end of the deployment (~5 mm), in contrast to minimal foreshortening of the "aortic" side of the prosthesis (Figure 1). This asymmetrical frame expansion, together with the company's first recommendation to place the central valve marker at the same level or a few millimeters below the insertion points of the aortic cusps (Figure 1), had led implanters to deploy the prosthesis too deeply in the left ventricular outflow tract (~60%/40% aortic/ventricular). This is notoriously associated with increased rates of conduction disturbances and pacemaker implantation after TAVR (1). Once this fact had been recognized, a revised pre-deployment marker position (the bottom of the center marker 1 to 3 mm higher than the base of the cusps) for the target setting (Figure 1) was proposed, which led to a final result of at least a 70%/30% aortic/ventricular implantation depth ratio. So far, the effectiveness of this new approach in reducing the pacemaker implantation rate similar to the one reported with the SAPIEN XT has mostly been a rumor spread by the bench laboratories and a few expert centers (8). The De Torres-Alba et al. study is therefore of critical importance as it provides clinical evidence legitimizing the adoption of such a deployment strategy. So should we give the "all-clear" signal? Should we consider the conduction disturbances after SAPIEN 3 implantation a resolved issue? I believe that the current pacemaker rates with TAVR still provide a great opportunity for improvement. We are no longer living in the era of first TAVR pioneers, in which many procedural complications were reasonably accepted and tolerated. Our target population is changing rapidly; TAVR has been increasingly offered to lower risk populations in whom mistakes are not allowed and avoidance of a single event can really make the difference. Continuous device improvements and procedure optimization are the paths to follow; clinical evidence will tell us whether we are walking in the right direction. The beginning looks encouraging.

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