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EDITORIAL COMMENT

Optimizing Outcome of Transcatheter Aortic Valve Replacement

It Is All About Geometry*

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Aortic valve stenosis and its treatment is not a "black box." It is not like a genetic disorder resulting in a complex syndrome that requires a very profound understanding and a sophisticated therapeutic approach; it is not like arterial hypertension, with a broad set of competing treatment alternatives and yet a somewhat unpredictable interindividual response to a chosen regimen, with a need for constant monitoring and adjustments. Aortic valve stenosis is a simple mechanical problem that requires a mechanical solution. That is the reason why surgical aortic valve replacement has been the successful gold standard treatment for decades in patients with symptomatic and severe aortic valve disease. This also explains why transcatheter aortic valve replacement (TAVR) could emerge as a suitable therapeutic alternative in the past decade and is now established for inoperable and high-risk surgical candidates (1).

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Among various major technical and logistic differences as well as still-open questions on comparability, particularly with regard to durability and performance in moderate and lower-risk patients, a rather significant difference between surgical aortic valve replacement and TAVR lies in the valve accessibility. In surgery, the direct open access allows for a straightforward visual assessment of the relative aortic root geometry (even absolute for the annulus dimensions) and a highly controlled implantation of the prosthetic heart valve, which virtually excludes malpositioning and suboptimal hemodynamic outcomes, at least in the vast majority of patients.

In contrast, TAVR lacks this direct open access, which makes this approach highly dependent on "accessory" tools, namely imaging techniques such as echocardiography, computed tomography, and fluoroscopy, to precisely display and assess the aortic root geometry for optimal device selection and procedural guidance. In other words, imaging is mandatory to pick and place the proper device. In addition, in case of suboptimal procedural results, which in fact are always related to mechanical issues, imaging techniques are the only tools to detect and evaluate the cause of failure.

The recent advent of advanced 3-dimensional imaging techniques such as 3-dimensional computed tomography reconstruction and 3-dimensional echocardiography has markedly improved our understanding of the aortic root geometry. Based on this new understanding as well as the capabilities of modern imaging techniques, our TAVR device selection policy is currently moving from a diameter-based decision strategy toward a perimeter- and area-based approach, which better reflects the 3-dimensional characteristics of the annulus structure. Although there is currently only scarce evidence on this topic, this little evidence is rapidly growing, and the application of these innovations translates into improved outcomes as it enhances our appreciation for geometric requirements, issues, and limitations of TAVR.

In this context, Binder et al. (2) report in this issue of *JACC: Cardiovascular Interventions* the results of an interesting study evaluating the impact of post-implant device geometry and position on conduction disturbances, hemodynamic performance, and paravalvular regurgitation in patients with symptomatic aortic valve stenosis undergoing TAVR using the balloon-expandable Edwards Sapien XT prosthesis (Edwards Lifesciences, Irvine, California). A total of 89 patients were enrolled and underwent pre- and post-procedural multidetector computed tomography (MDCT) and 2-dimensional echocardiography. The investigators looked at various geometric parameters such as device expansion at the inflow level, mid-portion and outflow level, device circularity, device-to-annulus relationships, and implant height. Particularly the use of MDCT before and after the procedure yielded interesting data, which makes this paper a relevant contribution.

Geometry and Conduction Disturbances

The main conclusion presented by Binder et al. (2) is actually not new: a low device placement (implant height) (Fig. 1) with a relevant segment extending into the left ventricular outflow tract predicts the occurrence of severe atrioventricular conduction disturbances and need for permanent pacing.

It is well known that any intervention within the aortic annulus carries a risk for conduction disturbances due to the close proximity of the relevant anatomic structures, and this

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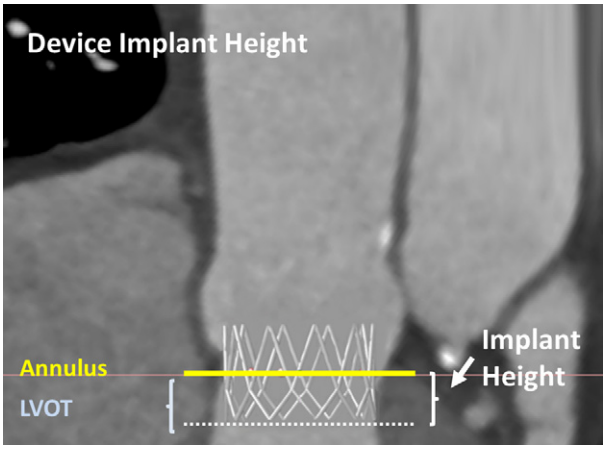

Figure 1. Concept of Device Implant Height in Relation to Annulus and LVOT

The device implant height is defined as the distance between the inflow stent frame edge to the aortic annulus. The height can amount to different values depending on the projection in case of device-to-annulus misalignment with a tilted device implant. Any implant height >0 mm means extension of the device into the left ventricular outflow tract (LVOT).

holds particularly true for TAVR. In 2009, Guiterrez et al. (3) already described this association in a series of patients undergoing transapical implantation of the balloon-expandable Edwards prosthesis, but in fact the majority of previous publications on this topic is based on patient populations treated with the self-expanding Medtronic CoreValve prosthesis (Medtronic, Minneapolis, Minnesota), suggesting an implant height of <6 mm to avoid relevant conduction disturbances (4). Therefore, the current paper provides another piece of evidence that this complication is obviously not device-specific, but it is related to procedural characteristics. Contemporary implantation strategies aiming for higher implant levels are actually the consequence of this known finding, with marked reduction in permanent pacemaker implantation rates in more recent publications. However, this modern implantation strategy is obviously conflicted by the risk of coronary occlusions in case of high straight stent frame designs, which certainly can pose a conceptual dilemma.

Another finding described in this paper is the fact that annular oversizing was not associated with conduction disturbances and the need for permanent pacing. Virtual area oversizing, defined as the relationship between nominal device area to annulus area, as well as effective area oversizing, defined as device area of the actual implant compared with the baseline annulus area (Fig. 2), are surrogate markers of applied radial forces onto the surrounding tissue. The higher the oversizing, the greater the potential stress to the native anatomy. One might expect that significant stress within the annulus area may provoke conduction disturbances. However, this is not exactly the case for the simple reason that what matters most is the stress applied to the conduction system itself and not to a more or less remote structure. As the bundle of His and the left bundle branches penetrate and run on the superior edge of the muscular septal portion with a superficial subendocardial course in the left ventricular outflow tract (LVOT), it is relevant to look at the radial impact of a TAVR device at the LVOT level rather than at the annulus level. The above-mentioned effect of implant height supports this concept and is actually its consequence. Unfortunately, in the past, we focused very exclusively on the annulus and somewhat ignored the LVOT device geometry, although LVOT trauma by oversizing and overexpansion is probably the key issue when conduction disturbances are observed. The present paper does not concentrate on this topic, but several studies are ongoing and will shortly provide further insights. Particularly, the capabilities and precision of 3-dimensional aortic root reconstruction by MDCT generate a new level of imaging that boosts our geometric understanding and helps to focus on these new aspects.

Geometry and Hemodynamic Performance

Geometry and hemodynamics are interdependent, as expressed by the Bernoulli principle or the continuity equation. Having said this, another finding described by Binder et al. is somewhat surprising. The investigators analyzed the impact of device expansion, device eccentricity, and labeled prosthesis size on post-procedural valve gradients and measured effective orifice areas. Only the labeled prosthesis size was found to affect gradient and orifice area; expansion and eccentricity did not. Whereas the former association is explainable, given the larger dimensions of larger device sizes, the latter is not. Reporting this finding is probably correct from the statistical point of view in the small cohort enrolled, but it is not likely to hold up in larger series as it speaks against physical laws. Optimal device expansion, meaning the best expansion for a given anatomy, is still the goal for a successful TAVR procedure.

Geometry and Post-Procedural Aortic Regurgitation

Finally, the investigators also focused on geometric device characteristics and the incidence of post-procedural aortic regurgitation. Paravalvular regurgitation is probably the most obvious geometric issue in the context of TAVR. The device needs to fit into the native annulus in order to stay there and to function properly. Whereas oversized devices carry the risk of annulus or LVOT rupture, particularly when using a balloon-expandable device, undersizing may lead to incomplete anchoring with risk for device embolization, incomplete expansion with relevant gradients as

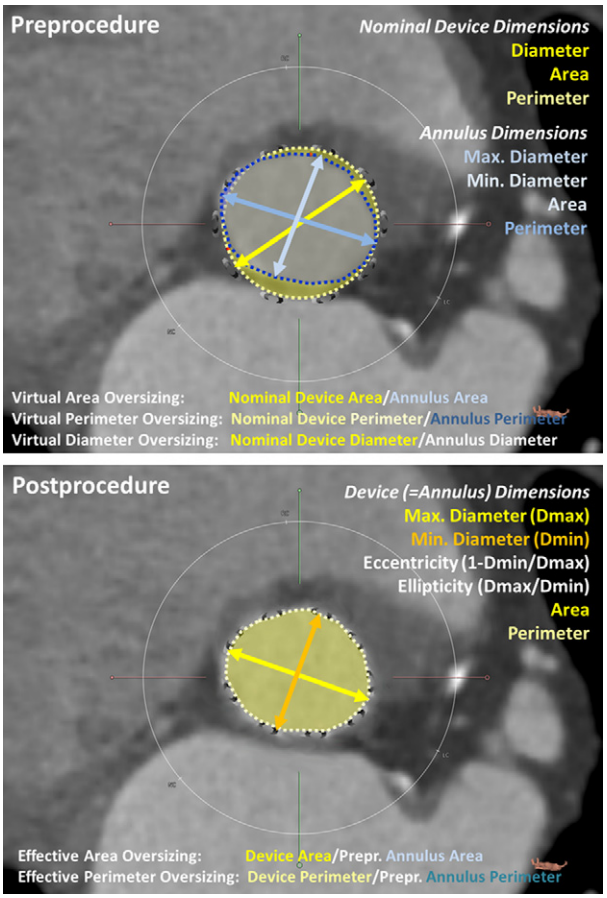

Figure 2. Pre-Procedural and Post-Procedural MDCT Parameters of Aortic Annulous and Device Geometry

Three-dimensional multidetector computed tomography (MDCT) reconstruction of the aortic annulus allows for a precise evaluation of the annulus geometry. In addition to diameters, annulus perimeter and area as well as virtual and actual device dimensions and relative and absolute relationships can be assessed.

detailed herein, and incomplete sealing resulting in paravalvular leaks. In addition, device underexpansion or leaflet destruction or immobility can cause valvular regurgitation, which must be differentiated from a paravalvular leak. Binder et al. did not state the number of valvular leaks, but they did report paravalvular leaks in 67 patients, ranging from mild in 67% of the population to moderate in 6% and severe in 2%. The identified predictive geometric parameter for occurrence of paravalvular regurgitation was the relation of inflow stent frame area and annulus area. This finding corroborates the underlying mechanical concept that the device must be adequately sized for complete sealing to avoid paravalvular gaps. However, the issue of paravalvular regurgitation is more complex, as it is not only the result of device and annulus dimensions, but also of calcification patterns, which we are just starting to acknowledge and to investigate in full extent with modern imaging capabilities. When doing so, it is important to match corresponding geometries, which is not exactly the case in the highlighted relationship of inflow stent frame area to annulus area, as the inflow stent frame usually acts in the LVOT level rather than the area level, unless the device has an implant height of 0 mm.

Conclusions

Geometry, dimensions, and spatial relationships are the cornerstones for a successful TAVR procedure. Particularly, the recent innovations in the field of imaging improved substantially our screening capabilities and device selection process along with our understanding of the human aortic root anatomy. These developments enable us to perform TAVR in a safer, more effective, and more predictable way than we did in the early years. And this progress is ongoing. Imaging tools are the reason why interventional treatment of aortic valve stenosis is not a black box, but a transparent one that reveals its contents. The surgeon uses a different way; he or she just opens that box. Yet, this direct access does not necessarily prevent a blurred view, as expressed in a recent noteworthy publication: "The everyday used nomenclature of the aortic root components: the tower of Babel?" (5). So what Goethe said centuries ago is still somewhat true: "This is the most difficult thing of all, though it would seem the easiest: to see that which is before one's eyes." However, we are making progress.

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Key Words: aortic annulus ■ multidetector computed tomography ■ transcatheter aortic valve replacement.