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The Mirage of the Optimal Implantation Depth With Transcatheter Bioprosthesis*

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Navigating the "Optimal Implantation Depth" With a Self-Expandable TAVR Device in Daily Clinical Practice

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Key Words

self-expandable valve
transcatheter aortic valve replacement
transcatheter heart valve

For both self-expanding (SE) and balloon-expanding (BE) transcatheter heart valve (THV) designs, the holy grail is to obtain the most precise implantation of the valve, with the hope that this will reduce the most common complications of the procedures such as permanent pacemaker implantation (PPI) or paravalvular regurgitation (PVR) (1,2).
It has been demonstrated for both designs that the protrusion of the bioprosthesis frame below the valve annulus should be minimized to decrease the interaction with the atrioventricular conduction axis (3) and reduce the risk of conduction abnormalities (4,5). Similarly, a too low or too high implantation has been shown to increase the risk of PVR (6). The last iteration of the SE-THV (Evolut-R/Pro; Medtronic, Dublin, Ireland) is providing resheathing features that are theoretically increasing the chance to deliver the valve to the appropriate location (7).
The "optimal" depth of implantation (OID) of this SE-THV has been determined by the manufacturer's bench tests as being between 3 to 5 mm to offer an optimal native annulus sealing and a good anchoring of the bioprosthesis. However, whether this OID is providing the best clinical outcomes is currently unknown because implantation depth (ID) is usually not reported in the large trials and cohorts. Moreover, no consensus exists on the method of measurements of the ID.

In this issue of *JACC: Cardiovascular Interventions,* Piayda et al. (8) should be commended for addressing this very important and practical issue. Their study sought to compare the impact of the ID according to 3 definitions of measurements of numerous clinical and hemodynamic outcomes (PPI rate, PVR, aortic regurgitation index [ARI], and mean pressure gradient reduction).
They retrospectively studied a cohort of 258 consecutive patients only implanted with Evolut-R SE-THV in a high-volume center. They conducted a thorough analysis of ID according to the 3 main methods of fluoroscopic measures:

- •Arithmetic mean: the arithmetic mean of the measured distances from the noncoronary cusp (NCC) and the left coronary cusp (LCC) to the distal THV end.
- •NCC distance: the distance from the distal THV end to the NCC.

- •Deepest edge (DE): the distance between the DE of the THV end to the annulus regardless of the anatomic orientation.
  They reported that an OID was rarely reached by the operators (<30%) and that a corrective maneuver was barely attempted because resheathing was hardly used in 7% of the cases.

  This intriguing and counterintuitive combined observation could be interpreted in 3 different ways. 1) The operators did not identify, in real time, that ID was “nonoptimal”. 2) They were not convinced that achieving an OID would make a difference in clinical outcomes. 3) They considered that resheathing and redeploying the THV would not achieve a more adequate delivery.

  These 3 interpretations are plausible and nonmutually exclusive. 1) Recognition of “nonoptimal” ID in real time with current imaging tools is not easy, which is indirectly confirmed by the need of a thorough off-line analysis in this study to allow such identification. 2) The impact of OID as recommended by the manufacturer on clinical outcomes has been rarely investigated before the present study. It is its merit to suggest that there is some clinical benefit to reach an OID, in particular a lower PPI rate (3.7% vs. 14.6%; p = 0.033) and a higher ARI OID 20.8 ± 6.5 vs. no OID 25.1 ± 8.1. 3) Finally, we have to concede that it is somewhat challenging to achieve a millimetric accuracy in THV deployment. Generally (depending on the aortic root anatomy), the delivery catheter of SE-THV is naturally running along the outer curve of the aorta and reach the annulus area below the NCC. At the beginning of the deployment, the ID of THV is adjusted based on the distance between the distal edge of the prosthesis and the NCC containing a pigtail as a landmark. The THV is progressively unsheathed from this pivot point toward the LCC. The depth of contact below the LCC with the distal edge of the stent frame is assessed by aortogram after removing the parallax and before full deployment of the THV to allow recapturing. This whole deployment process including the pivotal movement of the bioprosthesis frame during the final deployment contains a significant degree of uncertainty while depending on numerous technical, anatomic, and hemodynamic parameters (Figure 1). Because the coaxiality between THV and annulus is rarely achieved, the NCC and the DE distances are usually different, and the DE seems the less predictable. Overall, the landing zone of the THV still remains difficult to predict until full deployment is completed (Figure 1), and the experience of the operator is of paramount importance to control the protrusion of the THV frame below the annulus. Recently, an elegant individualized strategy of SE-THV implantation based on the membranous septum length of each patient achieved an excellent low rate of PPI through a low ID of 2.3 ± 1.2 mm (9). It is important to note that the ID was assessed on the pre-release angiogram as the distance from the base of the NCC to the prosthesis inflow, which may be different than the final ID obtained after full deployment.

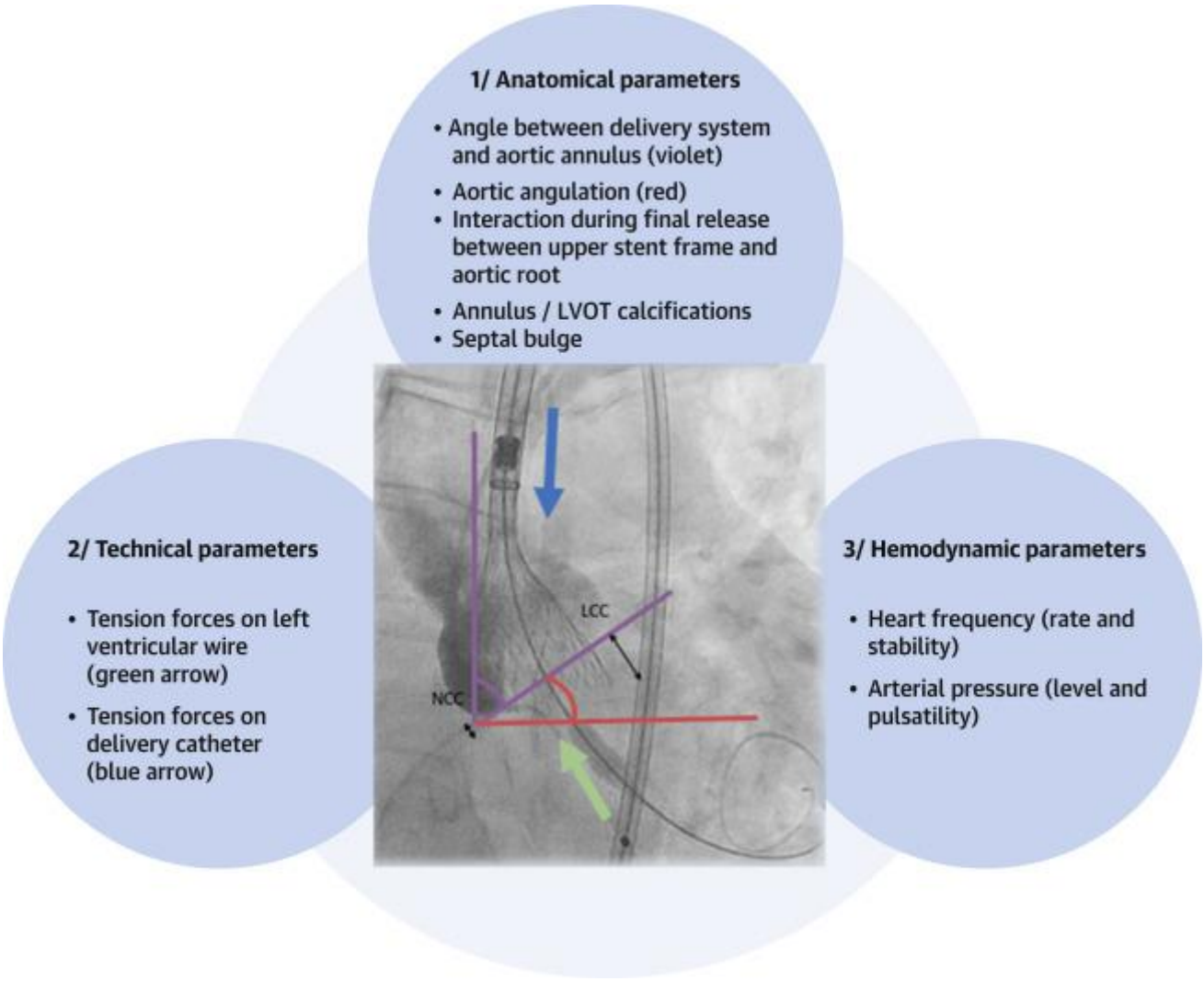

Figure 1. Anatomic, Technical, and Hemodynamic Parameters Involved in Deployment of SE-THV

Pre-release aortic angiogram showing a delivery catheter running toward the inner curvature of the aorta. Angle between delivery catheter and annulus **(angle in violet)** and angle between the horizontal plane and the aortic annulus **(angle in red)** are shown. Noncoaxiality between THV frame and annulus with optimal implantation depth of 1 mm achieved below the noncoronary cusp (NCC) **(short black arrow)** and deepest edge of stent frame exceeding optimal implantation depth below the left coronary cusp (LCC) **(long black arrow)**. LVOT = left ventricular outflow tract; SE-THV = self-expanding transcatheter heart valve.

Interestingly, Piayda et al. (8) reported that: 1) the rate of OID significantly differs according to the method of measurement; and 2) the DE method was the most clinically relevant because achieving OID (vs. not achieving OID) was associated with a lower PPI rate and a higher ARI. These results should, however, be seen as preliminary, and larger-scale studies are needed to confirm this observation.

They also report that the larger the valve that you implant, the more risk you have to end-up with a “low” and “nonoptimal” ID. This very interesting observation could explain in part why oversizing the prosthesis could fail to reach its primary objective of reducing the risk of PVR if counterbalanced by a less precise and lower implantation.

The most apparent limitation of the present work is the small sample size, which may have prevented the ability to analyze stronger clinical endpoints. Also, the single-center nature of the study and the use of a single THV device could prevent the generalizability of the observation to all centers, practices, and devices. Moreover, because no central core laboratory–based review of the quality of the angiograms was performed, measurement of ID could be partly inaccurate due to residual valve parallax and/or poor opacification quality of the aortic cusps.

Although this work brings more questions than answers, the investigators should be congratulated for this original exploratory study that paves the way for larger investigations.

“Recommended” OID should no longer be based on manufacturer recommendations but determined by clinical studies. The ID in patients enrolled in large clinical trials and cohorts that evaluated THV should be reported to determine for BE and SE-THV the ideal method of measurement and the OID that is associated with the best clinical outcomes. This study is also a call for defining a unified method of measurement of ID and suggests to the Valve Academic Consortium the need to tackle this issue in their forthcoming third opus. The DE method appears simple and stringent, but more data are needed before a broader adoption. It also highlights the lack of accuracy in the positioning of THV with current devices. If a “clinically based” OID can be defined for a given device, would not the next logical step be, rather than some re-sheathing capability, to integrate as part of the device or the delivery system, a feature allowing the ability to reach the pre-defined OID in a precise and reproducible manner? Other SE-THV technologies attempted to achieved this goal by adding “stabilization arches,” but did not demonstrate their superiority over BE-THV (10).
Whether new cusp-overlap techniques of implantation of SE-THV (11), or new technology such as imaging fusion of fluoroscopy and computed tomography scan, will increase our accuracy and improve outcomes is an open question.
Because transcatheter aortic valve replacement is becoming the gold standard for the treatment of aortic stenosis, it is more critical than ever to continue the quest for refinement and optimization to improve the outcome of our patients.

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