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EDITORIAL COMMENT

Midterm Outcomes With the Self-Expanding ACURATE neo Aortic Bioprosthesis

The "Bumblebee Paradox" in Transcatheter Aortic Valve Replacement*

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"First prompted by what is done in aviation, I applied the laws of air resistance to insects, and I arrived, with Mr. Sainte-Laguë, at this conclusion that their flight is impossible"
—Antoine Magnan (1)

In the last 15 years, transcatheter aortic valve replacement (TAVR) technology has had a remarkable advancement, transforming a very challenging procedure in a standardized and streamlined therapy (2). The new-generation TAVR devices have deeply contributed to this evolution by overcoming some of the most important limitations of initial technologies (i.e., suboptimal positioning, paravalvular regurgitation, vascular injury, stroke, and conduction disturbances) (3).

Features such as an external sealing skirt, a reduced delivery catheter profile, a simplified deployment technique, and repositioning and retrieval capability have been closely coupled with the core of innovation in TAVR technology. That said, having to bet on what transcatheter heart valve (THV) will provide the better short- and long-term outcomes after TAVR, one would definitely go "all in" for a device that incorporates as many of the previously mentioned features as possible. Therefore, it is not surprising that almost all new-generation self-expanding TAVR devices are following this pipeline in terms of technological evolution; at the same time, investments made by the companies are indeed paying back, with remarkable improvements of clinical results compared with earlier generation THVs (3).

Among the entire spectrum of self-expanding THVs, the ACURATE neo aortic bioprosthesis (Symetis SA/Boston Scientific, Ecublens, Switzerland) is walking a different path. This prosthesis has a unique design: it includes a porcine pericardium valve sewed on a nitinol stent that comprises, from the top to the bottom, 3 stabilization arches for the axial alignment, an upper crown for capping aortic annulus, and a lower crown covered both externally and internally by a porcine pericardium layer.

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The ACURATE neo is not recapturable, has no external cuff or skirt, and is still implanted through a relatively large-profile (18-F compatible) delivery system. Looking at these characteristics, one may think that this device cannot even aim to compete with the latest self-expanding THVs currently available in clinical practice. Here lies the paradox! The 1-year results of the SAVI-TF (Symetis ACURATE neo Valve Implantation Using Trans-Femoral Access) registry (4), available in this issue of *JACC: Cardiovascular Interventions*, are the most classic testimony that medicine is not a perfect equation. Briefly, the SAVI-TF registry is a well-conducted prospective, multicenter registry that enrolled 1,000 "real-world" high- or intermediate-risk patients (patients' mean age 81.1 ± 5.2 years; mean Society of Thoracic Surgeons score 6.0 ± 5.6%) at 25 European centers. Thirty-day results already

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showed promising outcomes with very low mortality (1.4%), disabling stroke (1.2%), and pacemaker (8.3%) rates (5). Kim et al. (4) have reported the 1-year outcomes: all-cause mortality and disabling stroke rates remained very low (8.0% and 2.3%, respectively), and quite in line with those reported with other new-generation THVs in real-world registries. Reintervention (3 valve-in-valve and 2 surgical aortic valve replacements) was required in 5 patients (0.5%). It must be said that the authors provided the cause of THV failure for 2 of these cases (1 endocarditis and 1 THV migration), while the underling mechanisms of aortic regurgitation reported in the other 3 patients were not specified. However, valve performance was excellent, with very low residual aortic valve gradient and large effective orifice areas, likely reflecting the supra-annular design of the prosthesis. The incidence of more than mild paravalvular leak (PVL) at 1 year was also very low (3.6%) (4). Interestingly, the authors found that patients who underwent post-dilatation (clear indicator of more calcific native valve) had significantly higher rates of PVL (5.8% vs. 1.8%) (4). This finding seems to feed a practice-based perception of several operators, that in highly calcified aortic valves the ACURATE neo, while remaining extremely safe and quite effective, probably guarantees performances that are slightly inferior in terms of PVL. The low radial force exerted by the lower crown of the frame gives a technical background to this hypothesis (5). On the contrary, low calcified aortic valves look the perfect environment for the ACURATE neo, also demonstrated by the absence of moderate or severe PVL in patients with mild aortic valve calcifications included in the SAVI-TF registry.

Finally, permanent pacemaker implantation was required in only 9.9% of patients (4); this rate has been hardly reported with the previous and current generation self-expanding THVs (3), and it is also likely related to the low radial force of the frame (6).

What is, then, the main driver for such favorable results of the ACURATE neo? We believe that the high control and accuracy of the deployment, peculiarity of the balloon-expandable valve, plays a fundamental role: unlike other self-expanding devices, the ACURATE neo is initially released from the aorta (arches) rather than from the left ventricle outflow tract, with subsequent deployment of the subannular portion (lower crown). This enables stability during valve positioning as well as minimizes hemodynamic compromise during deployment. Indeed, the V-shape of the device with the upper crown and stabilizers opened avoids obstruction of antegrade blood flow during the positioning and self-deployment steps, thereby protecting against uncontrolled device movements and/or embolization.

It is undeniable that the SAVI-TF registry has several limitations: above all, echocardiographic outcomes and adverse events were based on site-reported data and were not independently adjudicated. However, we believe that the study by Kim et al. (4) is an important contribution to the current literature, as it starts to reduce the gap in evidence between the ACURATE neo and the 2 THV leaders in the market (SAPIEN [Edwards Lifesciences, Irvine, California] and CoreValve/Evolut [Medtronic, Minneapolis, Minnesota]).

The SCOPE-I (Safety and Efficacy Comparison Of Two TAVI Systems in a Prospective Randomized Evaluation) (NCT03011346) and SCOPE-II (NCT03192813) trials, randomizing the ACURATE neo versus the SAPIEN 3 and CoreValve Evolut R/Evolut PRO THV, respectively, are currently ongoing and will provide more rigorous and meaningful data on outcomes with ACURATE neo in comparison with other THVs.

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