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EDITORIAL COMMENT

Swimming in the OCEAN-TAVI of Large Annulus

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Treating larger annuli with transcatheter aortic valve implantation (TAVI) might significantly affect valve performance and device success, namely, increased rates of paravalvular leak (PVL), pacemaker implantation, and 1-year mortality.[1-8] Following the manufacturer's instructions for use (IFU), both self-expanding (SEV) Evolut (Medtronic) and balloon-expandable (BEV) SAPIEN 3 (Edwards Lifesciences) bioprostheses are "on-label" restricted to a certain annulus size: annulus perimeter up to 94.2 mm for the former and an annulus area up to 683 mm^2 for the latter, respectively.[1-4] Nonetheless, patients with severe AS and an aortic annulus size exceeding the manufacturer's IFU might benefit from "off-label" TAVI with either of these bioprostheses. As a result, the annulus size for 1%-2% of patients deemed unsuitable for surgery falls outside the approved sizing range of most TAVI bioprostheses.[1] This lack of available treatments requires special attention from the interventional team for patients with a large annulus.[1-7]

In this issue of *JACC: Asia*, Onishi et al[9] have performed a subanalysis of the OCEAN-TAVI (Optimized CathEter vAlvular iNtervention -Transcatheter Aortic Valve Implantation) registry,[8] studying the Japanese population with large annuli defined as annular area ≥500 mm^2 and average diameter ≥25 mm in computed tomography. However, it is important to highlight that the study has some limitations. The first and the most important aspect is that these criteria used to define a large annulus differed from those used in previous studies.[1-4] The vast majority of the bioprostheses in this subanalysis were within the manufacturer's IFU, therefore, this should not have had impact in the procedural and in the clinical outcomes, limiting the originality for this substudy. In addition, not all large annuli are the same, ie, it is completely different to perform a comparison between a procedure in a patient with an annular area of 500 mm^2, which should be considered as an "on-label" procedure, vs a 690 mm^2 area, considered "off-label." A large retrospective trial using BEVs suggested that on-label device oversizing delivered better clinical outcomes than implantation with off-label device oversizing.[2]

Onishi et al[9] have performed a retrospective analysis for 773 patients, 671 for BEV. The primary endpoint was the 3-year all-cause mortality. They found that the SEV group showed a significantly higher incidence of above-moderate PVL and increased pacemaker implantation rate. The incidence of prosthesis-patient mismatch did not differ between the 2 groups.[9] It was a retrospective analysis with its inherent constraints, including different generations of Evolut and Sapien valves. The SEV cohort was much smaller (15%) than the BEV cohort, which could have led to inaccurate results. It is known that East Asians have smaller aortic valve annuli than individuals from Western countries, and few studies have reported TAVI outcomes in Asian patients with a large annulus. Therefore, the results of this trial may not be a surrogate for the entire population because large annuli for the Asian population may be considered normal size in Western countries. Finally, it is unknown if overexpansion of the BEV in patients with large annuli would compromise the long-term durability of the bioprostheses. Therefore, a dedicated comparison within a different spectrum of off-label sizes would be more rational, despite more challenging.

In the subanalysis, the Kaplan-Meier curve showed no significant differences in the 3-year all-cause mortality, heart failure hospitalization rates, or

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echocardiographic valve function at 2 years post-TAVI. To put this substudy into perspective, treatment of large annulus native aortic valves with third-generation TAVI prostheses is feasible and safe, providing similar device success and complication rates as in matched controls with regular-sized aortic annuli.[1-7] Postinterventional pacemaker implantation rates were low compared with the control group, yet the incidence of moderate PVL remains problematic in large annulus patients.[1,4,10]

It is known that SEVs provide better hemodynamic features compared with BEVs, including better clinical outcomes.[1,2,10] However, it is still unclear whether this hemodynamic superiority is significant for patients with larger annuli. With the increasing volume of TAVI for younger patients, it would be ideal that larger bioprostheses should be implanted to avoid prosthesis-patient mismatch for future TAV-in-TAV procedures. A recent meta-analysis revealed that the BEV provides better early outcomes in TAVI for large aortic annulus in terms of lower rates of stroke, valve embolization, need for a second valve, permanent pacemaker implantation, and aortic regurgitation ≥ moderate. Conversely, the SEV provides a better transvalvular gradient in the early period after TAVI.[10]

Onishi et al should be congratulated for concluding that the lack of differences in postoperative valve performance and long-term prognosis between SEV and BEV highlight the importance of selecting valves that can reduce the pacemaker implantation rate and PVL grade in the acute phase in patients with a large annulus.[9] There is indeed the need for future randomized trials to address the specific question of which valve should be used for each patient with a large aortic annulus. Meanwhile, a dedicated individualized treatment should be offered for each patient, taking into account the anatomy features and associated comorbidities.

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