

EDITORIAL COMMENT

The Oversizing Versus Post-Dilatation Trade-Off

Focus on the SAPIEN 3*

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Post-procedural paravalvular regurgitation (PVR) is a well-established adverse prognostic indicator of short- and long-term survival following transcatheter aortic valve replacement (TAVR) (1). Mismatch between the aortic annulus and the prosthesis sizes remains the principal cause of PVR after TAVR (1), particularly for balloon-expandable valves (2). Additional factors include aortic root calcification and suboptimal device positioning (1). Ad hoc balloon post-dilatation (BPD) following implantation of both balloon-expandable and self-expandable prostheses has been considered common practice to minimize residual PVR (2,3). Introduction of new designs of transcatheter heart valves (THVs) as well as computed tomography-based oversizing algorithms has lowered the prevalence and severity of PVR following TAVR (4). Nevertheless, both oversizing and BPD have been associated with adverse outcomes, such as annular rupture and cerebrovascular embolism (5,6).

The SAPIEN 3 valve (Edwards Lifesciences, Irvine, California), a relatively new version of balloon-expandable THV designed with an external sealing cuff and an improved delivery catheter, has been associated with a lower rate of PVR, compared with precedent valve generations (7). The PARTNER 2 (Placement of Aortic Transcatheter Valves) SAPIEN 3 multicenter trial demonstrated low rates of mortality, procedural complications, and paravalvular leak with

the SAPIEN 3, suggesting TAVR as the preferred treatment option for high-risk or inoperable patients and a reliable alternative to surgery in elderly intermediate-risk patients (8). In this issue of *JACC: Cardiovascular Interventions*, Hahn et al. (9) describe the predictors and prognostic impact of BPD in all patients included the PARTNER 2 SAPIEN 3 registry. By stratification of patients to BPD (n = 208, 12.5%) versus no BPD (n = 1,453, 87.5%), the authors report several key points; First, moderate or severe sub-annular calcification, low area oversizing, and high degree of ellipticity were all found to be independent predictors of BPD. Second, post-TAVR echocardiography showed that BPD patients had no difference in prosthesis-patient mismatch and higher rate of PVR despite larger effective orifice area. Third, BPD (adding up to 2 cc³) was not associated with a significant difference in procedural complications as well as in rehospitalization, stroke or mortality at 1-year follow-up.

SEE PAGE 1710

The SAPIEN 3 valve has been previously demonstrated to have an effective profile in term of balancing between the degree of oversizing from one hand and the need for BPD from the other (i.e., less PVR with relatively less oversizing) (7). Nonetheless, in the current study, Hahn et al. still bring-up the key trade-off between these 2 techniques. BPD patients had significantly lower THV sizes, leading to a higher rate of post-procedural PVR (p < 0.01) and aortic valve reinterventions at 1 year (p = 0.04). These findings reflect that less oversizing is still a “short blanket,” even with the latest generation of THVs, and BPD provides a limited backup for patients with residual PVR following valve deployment. Of note, quantitative evaluation of BPD’s effect on PVR degree following SAPIEN 3 implantation is lacking in the

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current report and is yet to be determined. Interestingly, despite the increased rate of PVR and a higher Society of Thoracic Surgeons score observed in BPD patients, no difference in 1-year survival was observed.

An additional highlight to be noted in Hahn et al. study is the tendency to “undersize” a certain subset of patients. The patients in the BPD group had significantly more left ventricular outflow tract (LVOT) calcification ($p = 0.005$) and severe annular calcification ($p = 0.006$). Moderate and severe subannular calcification arise as independent predictors of BPD. Without any surprise, an increase in minor strokes was noted in the BPD groups. However, it was no longer significant following multivariate adjustment for computed tomography calcium burden, previously described as a risk factor for cerebrovascular events in TAVR patients (4). Thus, though the tendency to minimize oversizing in patients with large calcium burden is reasonable, higher rate of BPD apparently exposes this population to higher risk of cerebral embolism by supplemental interventions in a calcific aortic valve. Another independent predictor of BPD noted in the current study was high annular ellipticity, in which the discordance between valve

area and perimeter might often lead to inadequately less oversizing, compared to more circular annulus (10). To this end, these findings reinforced the notion that “optimal oversizing” is multifaceted and should include a variety of anatomical properties, that combine variably between patients. New methods, such as computed tomography-based 3-dimensional printing (11), have been recently suggested to ameliorates sizing and PVR prediction, potentially paving the way for future individualized TAVR.

Finally, the main message derived from the Hahn et al. (9) study is that BPD with an oversized balloon was not associated with excess of mortality, strokes, annular rupture, valve embolization, central aortic regurgitation, or need for new pacemakers. Thus, while major improvements in THV design and imaging-based sizing have significantly reduced the occurrence of PVR, BPD should be considered a safe option to minimize PVR severity when present.

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