

EDITORIAL COMMENT

Optimizing Valve Sizing in Balloon-Expandable Transcatheter Aortic Valve Replacement*



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Trascatheter aortic valve replacement (TAVR) is a mature technology for the treatment of patients with severe aortic stenosis. However, despite excellent trial and “real-world” results, operators and investigators continue to find ways to improve. One such opportunity is to more precisely size the limited selection of valves specifically for each patient. On the basis of the clinical data and experience thus far, it is clear that some degree of valve “oversizing” in comparison to the measured annulus size is necessary for an optimal valve result with little or no paravalvular aortic regurgitation (PAR) (1). On the other hand, too generous a degree of oversizing increases the risk of complications, including pacemaker implantation, coronary obstruction, annular trauma/rupture, and leaflet thrombosis (2–4). To further minimize these complications, operators must take in to consideration, not only the degree of oversizing, but also the specific characteristics of the aortic root, including quantity and distribution of left ventricular outflow tract calcification, size of the sinuses and sinotubular junction, and depth of valve implantation. However, undersizing too aggressively may promote leaflet degeneration and failure (5). In routine practice, interventional cardiologists and cardiac surgeons have taken to underexpanding a larger valve or overexpanding a smaller valve as they see fit to walk the line between annular trauma and paravalvular regurgitation.

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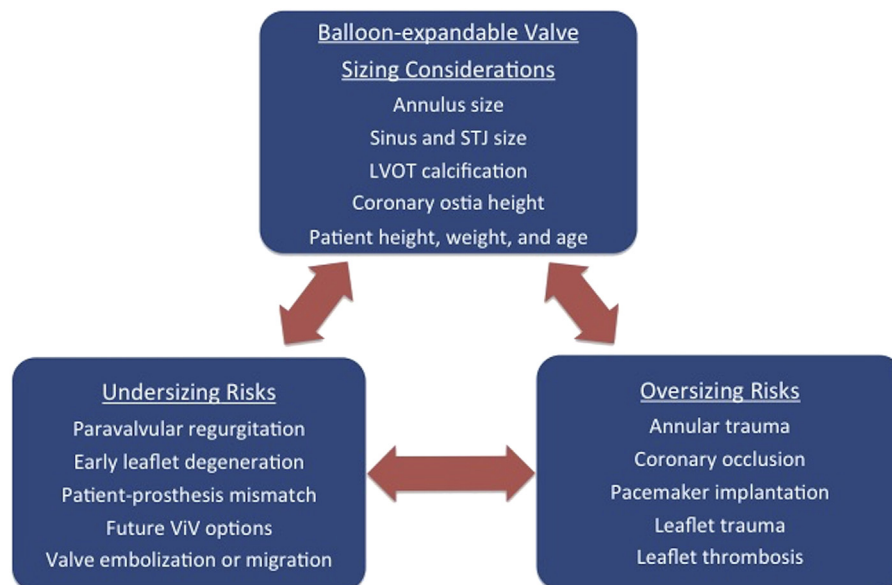
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It is in this arena that the papers in this issue of *JACC: Cardiovascular Interventions*, by Sathananthan et al. (6) and Huchet et al. (7) seek to introduce some objective data. Using systematic overexpansion of the SAPIEN-3 (S3) series of valves (Edwards Lifesciences, Irvine, California), Sathananthan et al. (6) analyzed gross valve morphology and hydrodynamic function. After overexpansion, they found that all valves had restricted leaflets; there was worse hydrodynamic function, with regurgitation noted for the over-expanded 23- and 26-mm valves, but not for the 29-mm valves; and the 26-mm valves demonstrated leaflet disruption. Further, compliant balloon post-dilation (as used for the 29-mm valves) resulted in asymmetric valve frame expansion (inflow and outflow > mid-valve), whereas non-compliant balloon dilation (for the 23- and 26-mm valves) resulted in symmetrical dilation. Huchet et al. (7) studied 6 valves, which they expanded and found that although nominally deployed valves demonstrated only mild stretching lesions, those dilated modestly (+1.5 ml) and significantly (+3.0 ml) demonstrated more leaflet stretching and some leaflet tearing. How can we place the benchtop findings of these 2 studies together and in clinical context?

The limited published case series of SAPIEN-3 valve overexpansion are for implantation of the 29-mm valve in patients with an annulus larger than what is recommended by the manufacturer. Tang et al. (8) recently demonstrated the feasibility of implanting the 29-mm valve in 69 patients with an average annulus area of 7.23 cm². Although 30% of the patients required only nominal fill volume, 70% were overfilled or post-dilated with between an additional 1 and 5 ml. The results were reasonable, with moderate aortic regurgitation (AR) seen in 4% of patients and none with severe AR, and no cases of annular trauma. Similarly, Mathur et al. (9) provided

FIGURE 1 Considerations for Balloon-Expandable Valve Sizing



LVOT = left ventricular outflow tract; STJ = sinotubular junction; ViV = valve-in-valve.

their experience of 3 patients with an average annulus of 7.76 cm². Although no patients had moderate AR, they dilated more aggressively with 2 patients treated with nominal volume + 4 ml and 1 treated with nominal volume + 5 ml. Although the short-term results of these trials are encouraging with regard to procedural success and safety, the series are limited to 30-day outcomes. Whether the bench testing demonstrated by the current papers would imply a longer-term clinical valve deterioration and dysfunction is therefore unclear. Further, as prior series have suggested, a higher risk of leaflet thrombosis for the 29-mm valve than the others, whether an even greater risk exists for an oversized 29-mm valve is also a theoretic consideration (4).

In the Sathananthan et al. study (6), hydrodynamic function was adversely affected by overexpansion in the 23- and 26-mm valves, but not in the 29-mm valves. This may be encouraging from a clinical perspective because the most common reported situation for overexpansion is for those patients with a larger than 29-mm S3 annulus as in the clinical series in the preceding text. On the other hand, the limited evaluation by Huchet et al. (7) does also suggest a risk of leaflet damage of overexpansion. Taken together, in patients with a smaller annulus that is “in-between” sizes, these findings raise the question

whether underexpansion is a better option to avoid leaflet trauma/overstretching or whether this also causes disordered leaflet function (i.e., better to implant an underfilled/underexpanded 26-mm valve instead of an overfilled/overexpanded 23-mm valve). In this regard, Barbanti et al. (10) analyzed a series of 47 patients who underwent balloon-expandable TAVR implantation (94% with the SAPIEN-XT device) that was purposely underfilled by ~10% volume (due to expected oversizing >20%) in comparison to 87 patients with nominal deployment. More than mild AR was seen in only 1 underfilled patient (vs. 6 patients in the control group; *p* = NS), and only 10.6% of patients in the underfilled group required post-dilation (3 with nominal volume and 2 with still underfilled balloons). Importantly, there was no difference in valve gradients between the 2 groups, though the underfilled group did demonstrate greater eccentricity of the valve stent on subsequent computed tomography scan at the inflow and mid-valve segments. Interestingly in this regard, modeling experiments have suggested that stent eccentricity and leaflet redundancy (as seen in underexpanded valves) result in greater leaflet stress and could portend reduced valve durability (5).

The applicability of the oversized/underexpanded SAPIEN XT valve choice (in the era when ~10%

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