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TAVR in Patients With a Small Aortic Annulus

The choice of transcatheter heart valve affects hemodynamics in patients with a small aortic annulus.

BY TOBY ROGERS, MD, PhD

As the field of transcatheter aortic valve replacement (TAVR) has evolved over the last 15 years, many of the early challenges to procedural success have been effectively addressed through advances in newer device generations/iterations and procedural technique. For example, many of the challenges of vascular access and vascular complications have been mitigated by device miniaturization, wholly percutaneous technique, and use of expandable and in-line sheath technology. Another example is the challenge of paravalvular leak, which has been mitigated by systematic use of CT sizing and device engineering to achieve better sealing between the transcatheter heart valve (THV) and the aortic annulus through the use of sealing skirts and wraps.

As a consequence, as TAVR has become safer and increasingly offered to younger patients with fewer comorbidities and longer life expectancies, our focus has shifted to different challenges: optimizing THV hemodynamics and durability.

SURGICAL APPROACH TO PATIENTS WITH A SMALL ANNULUS

Cardiothoracic surgeons aim to implant the largest possible aortic bioprosthesis to achieve optimal hemodynamics. In a patient with a small annulus, the surgeon has a number of available options to maximize the size of the implanted bioprosthesis. These options include root enlargement surgery or implantation of a stentless or sutureless valve. However, the reality is that many patients still receive a small bioprosthesis. The most recently published data of more than 78,000 surgical aortic valve replacement patients from the Society of Thoracic Surgeons database between 2007 and 2010 demonstrated that 38% of patients received a 19- or 21-mm valve.[1] The same pattern was observed in the surgical arms of the SURTAVI and PARTNER 2 trials in intermediate-risk patients, 34% and 44% of whom, respectively, received a 21-mm (or smaller) bioprosthesis.[2,3]

Many of these patients will have prosthesis-patient mismatch (PPM) with high gradients that may predispose to early bioprosthetic valve failure from increased leaflet shear stress. PPM after surgical aortic valve replacement is also associated with more frequent hospital readmissions and higher mortality.[4] Furthermore, the implantation of a small surgical bioprosthesis constrains the patient's options for valve-in-valve TAVR in the future. Even if the bioprosthetic valve ring is fractured with high-pressure balloon inflation before TAVR,[5] it may be difficult to achieve optimal valve-in-valve hemodynamics. The experience with surgical bioprosthesis fracture is still limited and the long-term impact on THV leaflet durability—if performed after TAVR—remains unknown. Data from the VIVID (Valve-in-Valve International Data) registry confirmed that 32% of patients have severe PPM immediately after valve-in-valve TAVR.[6] Furthermore, patients with a small surgical valve (≤ 21 mm) undergoing valve-in-valve TAVR had worse 1-year survival, with a hazard ratio of 2.04 (95% confidence interval, 1.14–3.67; $P = .02$).

IS TAVR THE SOLUTION FOR PATIENTS WITH A SMALL ANNULUS?

Through necessity, THVs have very low-profile metallic frames (compared to surgical bioprostheses with bulky sewing rings), which have the added benefit of maximizing effective orifice area (EOA) compared to an equivalently sized surgical bioprosthesis. This has the potential to be of particular benefit in patients with a small aortic annulus or in patients undergoing valve-in-valve TAVR for a failing surgical (or transcatheter) bioprosthesis with a small true internal diameter.

An early study of TAVR in patients with a small annulus (mean, 19 ± 1 mm by transesophageal echocardiography) using the 23-mm Sapien valve (Edwards Lifesciences), reported excellent procedural success but moderate or severe PPM (defined as indexed EOA ≤ 0.85 cm^2/m^2)

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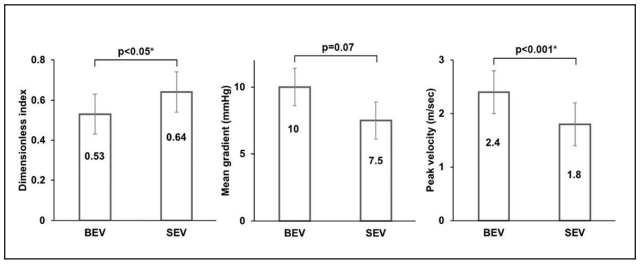

Figure 1. Valve hemodynamics according to valve type (balloon-expandable vs self-expanding) in patients with a small aortic annulus. BEV, balloon-expandable valve; SEV, self-expanding valve. * indicates statistical significance. Adapted from The American Journal of Cardiology, 119, Rogers T, Steinvil A, Gai J, et al, Choice of balloon-expandable versus self-expanding transcatheter aortic valve impacts hemodynamics differently according to aortic annular size, 900–904, Copyright 2017, with permission from Elsevier.

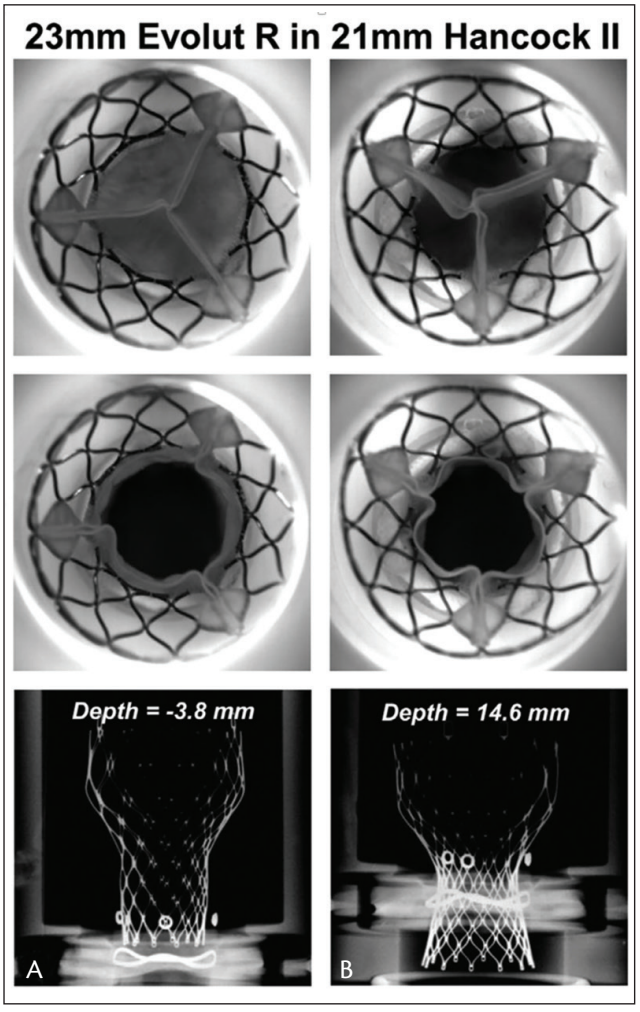

Figure 2. High (A) versus low (B) implantation of a 23-mm CoreValve Evolut R inside a 21-mm Hancock II bioprosthesis (Medtronic). Reprinted from The Journal of Thoracic and Cardiovascular Surgery, 153, Azadani AN, Reardon M, Simonato M, et al, Effect of transcatheter aortic valve size and position on valve-in-valve hemodynamics: an in vitro study, 1303–1315, Copyright 2017, with permission from Elsevier.

was observed in 38% of patients.[7] A substudy of patients with a small annulus from the Japanese TAVR registry (OCEAN-TAVI) compared hemodynamics in those who received a 20-mm versus a 23-mm Sapien XT THV (Edwards Lifesciences). Mean annulus area was 289 ± 28 mm^2 and 356 ± 38 mm^2 and mean annulus perimeter was 61 ± 3 mm versus 69 ± 4 mm in each group, respectively. Postprocedure mean gradients were 15 ± 4 mm Hg versus 11 ± 4 mm Hg, and the rate of moderate or severe PPM after TAVR was 32% versus 8% with the 20-mm versus the 23-mm THV, respectively. Neither of these studies included long-term follow-up data on valve hemodynamics or clinical outcomes.

A key feature of the self-expanding CoreValve Evolut R/PRO THV (Medtronic) is the supra-annular location of the leaflets. This offers a theoretical advantage over balloon-expandable valves in the setting of a small annulus because the supra-annular leaflets afford a larger EOA. In the PARTNER trial, 39.4% of patients with a small annulus had moderate or severe PPM after implantation of a balloon-expandable valve.[8] My colleagues and I published a comparison of valve hemodynamics and clinical outcomes according to annulus size and type of THV (balloon-expandable vs self-expanding).[9] In our study, a small annulus was defined as a < 73-mm perimeter (or approximately 23-mm diameter). Although there was no difference in valve hemodynamics in patients with a medium or large native aortic annulus, there were statistically significant differences in hemodynamics in patients with a small annulus (Figure 1). Notably, peak velocity was lower and dimensionless index was higher with self-expanding THVs.

We prefer to report the dimensionless index rather than the EOA. The dimensionless index is the ratio of the subvalvular velocity obtained by pulsed-wave Doppler and the maximum velocity obtained by continuous-wave Doppler across the aortic valve, and thus is not subject to transthoracic echocardiographic measurement error of the left ventricular outflow tract area, which typically overestimates the prevalence of PPM.[10] PPM is considered severe when the dimensionless index is < 0.25 and moderate when it is ≥ 0.25 and < 0.5. Although the hemodynamic differences observed between THV type were significant, the number of patients was too small and the follow-up duration too short to evaluate for a correlation between THV hemodynamics and long-term THV durability.

Mechanistically, it makes sense that leaflet durability would be reduced by higher transvalvular gradients,

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increased leaflet shear stress, and eccentric geometry. Therefore, the approach to patients with a small annulus is not as simple as "small annulus = TAVR." In vitro studies, mostly focused on valve-in-valve TAVR, have demonstrated that type of THV (balloon-expandable vs self-expanding), suboptimal THV sizing, THV implantation depth, and annulus eccentricity contribute to leaflet pinwheeling and abnormal leaflet shear stress, which could affect hemodynamics and ultimately durability.[11-13] Many of the lessons from studies on valve-in-valve TAVR are applicable to patients with a small native aortic annulus. For the self-expanding CoreValve Evolut TAVR platform, optimal hemodynamics are achieved with a high implantation to maximize the benefit of the supra-annular leaflets (Figure 2).[14] Oversizing the THV is probably not advisable, as this leads to excessive leaflet redundancy, pinwheeling, and shear stress.

CONCLUSION

Patients with a small aortic annulus deserve careful consideration by a heart team. If the patient is operable but the surgeon is not prepared to perform root enlargement surgery or implant a stentless or sutureless valve, then TAVR should be the preferred treatment option. The data are clear: hemodynamics and clinical outcomes are worse in patients with small aortic bioprostheses. Available data in patients with a small native aortic annulus support the use of TAVR over surgical aortic valve replacement and favor the use of self-expanding THVs with supra-annular leaflets to achieve optimal hemodynamics. ■

1. Thourani VH, Suri RM, Gunter RL, et al. Contemporary real-world outcomes of surgical aortic valve replacement in 141,905 low-risk, intermediate-risk, and high-risk patients. Ann Thorac Surg. 2015;99:55-61.
2. Reardon MJ, Van Mieghem NM, Popma JJ, et al. Surgical or transcatheter aortic-valve replacement in intermediate-risk patients. N Engl J Med. 2017;376:1321-1331.
3. Thourani VH, Forcillo J, Szeto WY, et al. Outcomes in 937 intermediate-risk patients undergoing surgical aortic valve replacement in PARTNER-2A. Ann Thorac Surg. 2018;105:1322-1329.
4. Fallon JM, DeSimone JP, Brennan JM, et al. The incidence and consequence of prosthesis-patient mismatch after surgical aortic valve replacement. Ann Thorac Surg. 2018;106:14-22.
5. Chhatriwalla AK, Allen KB, Saxon JT, et al. Bioprosthetic valve fracture improves the hemodynamic results of valve-in-valve transcatheter aortic valve replacement. Circ Cardiovasc Interv. 2017;10.
6. Dvir D, Webb JG, Bleiziffer S, et al. Transcatheter aortic valve implantation in failed bioprosthetic surgical valves. JAMA. 2014;312:162-170.
7. Kalavrouziotis D, Rodes-Cabau J, Bagur R, et al. Transcatheter aortic valve implantation in patients with severe aortic stenosis and small aortic annulus. J Am Coll Cardiol. 2011;58:1016-1024.
8. Rodes-Cabau J, Pibarot P, Suri RM, et al. Impact of aortic annulus size on valve hemodynamics and clinical outcomes after transcatheter and surgical aortic valve replacement: insights from the PARTNER trial. Circ Cardiovasc Interv. 2014;7:701-711.
9. Rogers T, Steinvil A, Gai J, et al. Choice of balloon-expandable versus self-expanding transcatheter aortic valve impacts hemodynamics differently according to aortic annular size. Am J Cardiol. 2017;119:900-904.
10. Mooney J, Sellers SL, Blanke P, et al. CT-defined prosthesis-patient mismatch downgrades frequency and severity, and demonstrates no association with adverse outcomes after transcatheter aortic valve replacement. JACC Cardiovasc Interv. 2017;10:1578-1587.
11. Stearns G, Saikrishnan N, Siefert AW, Yoganathan AP. Transcatheter aortic valve implantation can potentially impact short-term and long-term functionality: an in vitro study. Int J Cardiol. 2014;172:e421-422.
12. Midha PA, Raghav V, Condado JF, et al. Valve type, size, and deployment location affect hemodynamics in an in vitro valve-in-valve model. JACC Cardiovasc Interv. 2016;9:1618-1628.
13. Gunning PS, Saikrishnan N, McNamara LM, Yoganathan AP. An in vitro evaluation of the impact of eccentric deployment on transcatheter aortic valve hemodynamics. Ann Biomed Eng. 2014;42:1195-1206.
14. Azadani AN, Reardon M, Simonato M, et al. Effect of transcatheter aortic valve size and position on valve-in-valve hemodynamics: an in vitro study. J Thorac Cardiovasc Surg. 2017;153:1303-1315.e1.

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