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Commentary: Does this model reality?

Nadeen N. Faza, MD,[a] and Michael J. Reardon, MD[b]

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CENTRAL MESSAGE

Ex vivo studies must adequately approximate physiologic conditions and clinical criteria to reach useful conclusions.

In this issue of the *Journal*, Samaee and coauthors[1] present a study on the effect of ascending aortic (AA) size on the hemodynamics and pressure recovery (PR) in self-expanding transcatheter aortic valves (SEVs). They placed a 26-mm Evolut R valve in a heart simulator flow loop with 3 different aortic sizes, 23 mm, 28 mm, and 34 mm. The flow solution was at room temperature (25° C). They then measured center line pressures below the valve, at the valve level, and 5 mm downstream from the valve. This allowed them to measure the PR between the valve and the AA. The concluded that the 26-mm Evolut valve has greater peak and mean pressure gradients when deployed in small AA due to constraints from the AA.

In the retrospective clinical part of the study, the authors demonstrate the phenomenon of PR, which has been well-established in patients with prosthetic valves and AA <30 mm and accounts for the discrepancy between the pressure gradients measured noninvasively by Doppler and those measured invasively by catheterization.[2] It is therefore not surprising that the $PG_{Doppler}$–PG_{cath} was greater in patients with small AA, as this can be explained by the PR phenomenon rather than any valvular dysfunction. Clinically, however, the net pressure gradient calculated between the left ventricle and the AA is more relevant and takes into account the PR.

The central message of the study that AA size is important in valve choice is true and is a part of procedural planning. Nonetheless, there are several issues to highlight with the study design. The SEV's nitinol frame is temperature-sensitive and designed to fully expand at body temperature (37° C). However, the study was conducted at a lower temperature of 25° C, which is not reflective of physiological conditions and will not allow for full valve expansion where not in contact with the model (valve cage section). In addition, given their design, flow loops do not take into account the tissue–device bidirectional interaction, which would ultimately influence valve hemodynamics. The SEV landmark clinical trials, based on core laboratory–read computed tomography angiography scans of the CTA, did not include patients with small AA dimensions measuring 23 mm or less. A 26-mm Evolut valve would be considered inappropriate for use and oversized in this scenario. This inappropriate use would account for the greater gradients and high pinwheeling index resulting from distal frame constraint.

The conclusions drawn need to be taken in the context of nonphysiological testing conditions and AA sizes not included or studied in SEV clinical trials. Results from the CHOICE (Randomized Comparison of Transcatheter Heart Valves in High Risk Patients With Severe Aortic Stenosis: Medtronic CoreValve vs Edwards SAPIEN XT) randomized clinical trial demonstrate no significant difference in clinical outcomes between SEV and balloon-expandable valves but favored flow hemodynamics in SEV, similar to previously published studies.[3,4] In vivo evaluation of different transcatheter heart valve gradients in patients

From the Departments of [a]Cardiology and [b]Cardiovascular Surgery, Houston Methodist Hospital, Houston, Tex.

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Address for reprints: Michael J. Reardon, MD, Houston Methodist DeBakey Heart & Vascular Center, Cardiothoracic Surgery, 6550 Fannin, Suite 1401 Houston, TX 77030 (E-mail: mreardon@houstonmethodist.org).

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with small AA, such as the current SMART trial (Small Annuli Randomized to Evolut or SAPIEN Trial; NCT04722250), will shed light on the interaction between different transcatheter heart valves and AA under physiologic settings and better model reality.

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