EFFECT OF TRANSCATHETER AORTIC VALVE SIZE AND POSITION ON VALVE-IN-VALVE HEMODYNAMICS: AN IN VITRO STUDY

To the Editor:

I read with great interest article on use of CoreValve Evolut R (Medtronic, Minneapolis, Minn) by Azadani and colleagues,¹ and I congratulate them on addressing the complex issue of valve-in-valve (VIV) sizing and positioning. They tested the hypothesis that, unlike the native valve, for which the size 23 Evolut R is used with an annulus size of 18 to 20 mm and the size 26 Evolut R is used with an annulus size of 20 to 23 mm, a different sizing algorithm could be used for VIV implantation, and upsizing would be beneficial. Three sizes (21, 23, and 25, with true inner diameters of 16.5, 18.5, and 20.5 mm, respectively) of the Hancock II valve (Medtronic) were tested with the Evolut R in sizes 23 and 26 under similar conditions. Azadani and colleagues¹ also tested various implantation depths of the Evolut R to assess the effect on

gradients, effective orifice area, and leaflet morphology. They concluded that for the size 21 Hancock II, the size 23 Evolut R could be used safely. For the Hancock II in sizes 23 and 26, the size 26 Evolut R was better for mean gradients and geometric effective orifice area of the leaflet opening, but this performance came at the cost of significant leaflet distortion. They observed that higher implantation depth resulted in lower gradient and greater effective orifice area but could not eliminate the leaflet distortion completely. On the basis of these observations, Azadani and colleagues¹ recommended the use of the size 23 Evolut R for surgical valves with true inner diameters less than 17.5 and the use of the size 26 Evolut R for those with true inner diameters greater than 17.5 mm.

I congratulate Azadani and colleagues¹ for challenging the boundary set by the instructions for use (IFU) and welcome the observation that the size 23 Evolut R has acceptable results in true inner diameters of 16.5 mm. I believe, however, that we should debate the issue of upsizing beyond the IFU recommendation because of the following:

1. The gradients with the size 23 Evolut R for all combinations were always within the Valve Academic Research Consortium 2 (VARC-2) definition of successful implantation (<20 mm Hg).² Reduction in the gradient with use of a larger Evolut R for true inner diameters of 18.5 and 20.5 mm was 2 to 5 mm Hg at various depths, but at the cost of leaflet distortion and with great dependence on high positioning. Durability should be an important consideration, even in VIV implantation.
2. Azadani and colleagues¹ demonstrated how difficult it is to implant the Evolut R at predictable depths even during

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FIGURE 1. CoreValve Evolut R (Medtronic, Minneapolis, Minn). A, Image of a size 26 Evolut R highlighting the frame geometry. The best function is obtained after full expansion and with maintenance of the geometry of the frame. B, A size 26 Evolut R in a size 23 Hancock II (Medtronic) valve (true inner diameter of 18.5). This image demonstrates the inability of the Evolut R frame to deflect the Hancock II stent post outwardly. C, A postimplantation balloon dilatation was performed because of unsatisfactory gradients. Although the intervention resulted in acceptable gradients, it also resulted in unsubtle stent frame deformations at the inflow (white arrow) and the mid portion (black arrow).

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the bench testing. This issue is compounded in a clinical scenario. It would have been of value if an “ideal implantation depth,” yielding a balance among least leaflet distortion, least aortic regurgitation, and secure implantation, had been provided, rather than a generic “high implantation” recommendation, because the latter may increase the incidence of embolization or repeated repositioning, for marginal gains. This issue was reported earlier³ by a group including one of the authors of the Azadani and colleagues¹ study.

3. Use of a larger Evolut R does not deflect the stent posts of any surgical valve, as stated by Azadani and colleagues¹ (Figure 1, A and B), because it lacks the radial strength necessary unless a postimplantation balloon dilatation is performed (Figure 1, C). A postimplantation balloon dilatation may result in uneven expansion of the Evolut R frame, especially when a large size is used (Figure 1, C), and although balloon dilatation may lower the gradients on the table it will also affect durability.

Guidance in the VIV application, which I have developed, takes in to consideration IFU by the manufacturers, bench testing, and clinical experience.⁴ The aim is to provide a reliable source for ideal VIV positioning and sizing for all levels of clinical expertise. The next update will reflect growing clinical experience. The application will continue to warn the users when a particular VIV combination falls outside the IFU range, in the interest of clinical safety, and this should not be viewed as an inaccurate guidance until further evidence claims otherwise.

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RESPONSE TO MR BAPAT: DOES SIZE MATTER? IT DOES IN TEXAS

Reply to the Editor:

I thank Mr Bapat for his letter discussing our bench study of Core-Valve Evolut R valve-in-valve procedures. I will begin with a full disclosure: I use his valve-in-valve app, and I like it. I have great professional admiration for Mr Bapat's work, and we are personal friends. I value and understand his comments, but I nonetheless have trended toward the use of the size 26 Evolut R valve (Medtronic, Minneapolis, Minn) in size 23 surgical valves in my practice. I think, however, that this area is still open to debate, and we of course do not know how such upsizing will affect durability—nor are we even certain of the durability of valve-in-valve procedures in general. I do think that one takeaway from this work is that a high implantation is crucial unless you are implanting a size 25 or larger surgical valve, and even then a high implantation would be beneficial. There are several reasons that I have moved to the use of the size 26 Evolut R valve for a size 23 surgical valve, and these reasons center on having consistently better flow dynamics when the valve is implanted high. I also do not hesitate to use postimplantation balloon valvuloplasty if it appears to be needed. Although balloon annuloplasty may exert a long-term effect on durability, we have no evidence at this point to support such a possibility, and it is also hard to envision why the effect of balloon annuloplasty would be worse than that of constraining the valve in the sheath in the first place. The central valve cage does not have as much radial force as a balloon-expandable valve, but it does have a high hoop strength, and if the posts are expanded with a balloon, this hoop strength can maintain its expansion. We have also found that certain valves, and the Hancock II (Medtronic) is one of these, will actually fracture and expand their frame with aggressive balloon valvuloplasty, decreasing the gradient even further. I would also challenge the conclusions drawn from the valve pictures, because the valve in these images is implanted much lower than we would accept. If it had been implanted higher, the valve itself would have expanded fully, and this has been our clinical experience.

I thank Mr Bapat for his thoughtful comments, and I salute him for the many contributions that he has made to the valve-in-valve procedure, as well as to the entire field of transcatheter aortic valve replacement. Our work was