

EDITORIAL COMMENT

Balloon Valvuloplasty Before Transcatheter Aortic Valve Replacement

Is It Now Optional?*

Shikhar Agarwal, MD, MPH



Trascatheter aortic valve replacement (TAVR) has now become an important therapeutic option for patients with severe symptomatic aortic stenosis, especially in the intermediate-risk and the high-risk categories. Over the course of the last decade, this technology has seen significant development including new iterations of the valves, as well as refinement of the technique used to implant these valves. One of these alterations has been elimination of balloon aortic valvuloplasty (BAV) before valve implantation—generally referred to as “Direct TAVR.” Pre-dilation is generally intended to help with the delivery of the prosthesis across the valve, ensure optimal prosthetic expansion in the aortic annulus, and potentially reduce or eliminate the need for post-dilation, which in turn may result in adverse consequences. In addition, BAV has been used to evaluate possible coronary occlusion in patient with low coronary height. However, BAV has been associated with complications, including conduction abnormalities, stroke, and severe aortic regurgitation (1).

The feasibility of Direct TAVR has been demonstrated in several small studies, using both self-expandable and balloon-expandable valve platforms (2). In a meta-analysis of 16 studies involving 1,395 patients, TAVR with or without BAV was associated with similar clinical endpoints, including mortality, stroke, moderate/severe paravalvular leak (PVL), need for post-dilation, and permanent pacemaker

implantation (2). It is interesting to note that there is some heterogeneity in the results of meta-analyses that are available on this topic. Banerjee et al. (3) have demonstrated a significant reduction in PVL among patients that undergo Direct TAVR as compared with those that undergo BAV before TAVR. In this issue of *JACC: Cardiovascular Interventions*, Deharo et al. (4) have presented insights from the FRANCE TAVI (Registry of Aortic Valve Bioprostheses Established by Catheter) registry regarding impact of Direct TAVR upon procedural and clinical outcomes. The data from 5,784 patients represents one of the largest experiences available despite the fact that the authors had to exclude over 6,000 patients for lack of data on pre-dilation (4). Intuitively, the authors demonstrated a procedural simplification and a reduction in use of fluoroscopy and contrast with avoidance of BAV (4). There was no difference in short-term mortality or stroke rates between the 2 groups. Interestingly, the authors also noted a reduction in the rate of significant PVL in the Direct TAVR cohort, which remained significant after statistical adjustment (4). On stratified analysis, this difference was evident only in the balloon-expandable valves (BEV).

SEE PAGE 1956

The paper provides real-world data regarding an important question that faces the current structural operators performing TAVR. Certainly, it suffers from the traditional biases of observational studies, most importantly, “confounding by indication.” When posed with the question of pre-dilation, most operators use clinical, anatomic, as well as functional, information from the echocardiogram and multi-detector computed tomography to decide whether they would perform BAV before valve implantation. Clearly, the ones that require pre-dilation represent

*Editorials published in *JACC: Cardiovascular Interventions* reflect the views of the authors and do not necessarily represent the views of *JACC: Cardiovascular Interventions* or the American College of Cardiology.

From the Department of Cardiology, Section of Interventional Cardiology, Geisinger Medical Center, Geisinger Commonwealth School of Medicine, Danville, Pennsylvania. Dr. Agarwal has reported that he has no relationships relevant to the contents of this paper to disclose.

the valves with heavy leaflet/outflow tract calcification, which portends a higher grade of PVL post-valve implantation. Post-implantation PVL may very well be a function of underlying valvular anatomy rather than pre-dilation per se. It would be insightful to understand the predictors that led to pre-dilation in this cohort of patients.

Complete avoidance of pre-dilation before TAVR has been controversial in some aspects. Although hypothetically plausible, it has not been definitively proven if pre-dilation reduces or eliminates the need for post-dilation after valve implantation (2). Deharo et al. (4) were unable to analyze this aspect due to lack of post-dilation data in the FRANCE TAVI registry. In a propensity-matched Italian study of 517 patients, the use of pre-dilation was associated with reduced need for post-dilation after valve implantation (5). In addition, this study demonstrated a higher risk of stroke among patients in the Direct TAVR cohort, compared with the pre-dilation cohort (5). Interestingly, Bijuklic et al. (6) have demonstrated an increased risk of cerebral embolization after implantation of BEV without pre-dilation as compared with those that had BAV before valve implantation, using diffusion-weighted magnetic resonance imaging. Although these lesions are generally not associated with clinical strokes, there is increasing evidence linking these silent embolic lesions to accelerated neurocognitive decline and dementia (7). Even though the reasons for the findings of this small study were speculative, they are concerning. In an era of increasing use of embolic protection devices, one could surmise a greater role of these devices in preventing cerebral embolization among individuals undergoing Direct TAVR. This obviously needs to be confirmed in largescale studies. An important speculative concern is whether there would be any difference in stroke/cerebral embolization between the BEV versus self-expandable valves (SEV). In the case of SEV, the entire procedure can potentially be performed without the use of a balloon. The modern Evolut-R system (Medtronic, Minneapolis, Minnesota) takes advantage of this fact and uses a reduced diameter deployment catheter. By contrast, for the BEV, even if pre-dilation is avoided, balloon inflation is an integral part of valve deployment, and cannot be deferred, which might create the difference in cerebral embolization between the 2 valve types. Regardless of these speculations, the current study, as well as available meta-analyses, has failed to demonstrate differences in clinical strokes in the Direct TAVR and pre-dilation cohorts for both BEV and SEV (3,4).

An important consideration in the paper revolves around the impact of the type of valve prosthesis upon outcomes in either cohort (4). The authors observed a higher rate of significant PVL in the SEV subgroup as compared with the BEV subgroup. When stratified into Direct TAVR versus pre-dilation cohorts, the difference in significant PVL between these 2 cohorts was apparent only in the BEV subgroup (Direct TAVR 5.1%; pre-dilation 9.6%). There was no difference noted in the incidence of significant PVL in the SEV subgroup (Direct TAVR 15.9%; pre-dilation 17.9%). One potential mechanism that might explain this difference is that 1-time inflation during Direct TAVR with BEV cracks the valve and subsequently seals these cracks with 1 inflation. BAV before TAVR might crack the valve in different locations, which might not be sealed with the second balloon inflation for valve deployment, resulting in more PVL. This difference might not be appreciated with SEV, potentially due to greater degree of PVL seen with these valves (3). There is marked heterogeneity in the published reports with respect to the impact of valve type upon PVL incidence between the 2 cohorts (8). A few studies have demonstrated differences in PVL between the Direct TAVR and pre-dilation cohorts for SEV (9,10). On the contrary, some studies have demonstrated equivalence in the incidence of significant PVL between the Direct TAVR and pre-dilation cohorts for BEV (8). Whether the choice of valve truly matters in the context of pre-dilation still remains to be understood. In addition, most of the data available are using the older generations of the valves, and whether these differences persist with the modern iterations of current devices also remains to be seen.

Regardless of the inherent biases in the study (4), there are some important takeaways from the data available thus far. The data are markedly heterogeneous at this point. The omission of BAV before valve implantation seems to simplify the procedure with potential reduction in post-implantation PVL. However, it has been speculated based on few observational studies that there might be a higher need for post-dilation and possibly increased cerebral embolization with its antecedent consequences (5,6). There are several trials underway that seek to answer this important question in a systematic manner (DIRECT [preDilatation in tRanscatheter aortic Valve implantation Trial]; DIRECTAVI [Implantation of the Transcatheter Aortic Prosthesis SAPIEN 3 With or Without Prior Balloon Predilatation]; and SIMPLIFY TAVI [Transcatheter Aortic Valve Implantation Without Pre-dilatation]).

In conclusion, the data available thus far call for an individualized approach towards deciding on pre-dilation before TAVR. Clinical risk profile, anatomic characteristics based on multidetector computed tomography, functional characteristics based on echocardiography, as well as procedural data, should all be used to make this decision. Patients with hemodynamic instability, severe left ventricular dysfunction, or severe pulmonary hypertension would likely benefit from omitting pre-dilation (clinical criteria). Similarly, patients with severe leaflet calcification (especially asymmetric), severe LVOT calcification, or horizontal aorta (aortic angulation $>50^\circ$) ought to undergo pre-dilation (anatomic criteria). Also, patients with valve area >0.5 cm², mean gradient <50 mm Hg, and those with severe aortic regurgitation might benefit from Direct TAVR rather than pre-dilation before valve implantation (functional criteria). Several operators

decide about BAV when they cross the aortic valve and observe how the catheter crosses into the left ventricle. It is generally believed that if the catheter falls in the commissures and easily enters the left ventricle, there may not be any need for pre-dilation before valve implantation (procedural criteria). Furthermore, several operators have adopted the use of undersized balloons in cases where BAV is considered essential. It is very likely that this strategy helps mitigate the risks of BAV, whenever deemed necessary.

ADDRESS FOR CORRESPONDENCE: Dr. Shikhar Agarwal, Department of Cardiology, Section of Interventional Cardiology, Geisinger Medical Center, Geisinger Commonwealth School of Medicine, Danville, Pennsylvania 17821. E-mail: dr.shikhar.agarwal@gmail.com.

REFERENCES

1. Ben-Dor I, Pichard AD, Satler LF, et al. Complications and outcome of balloon aortic valvuloplasty in high-risk or inoperable patients. *J Am Coll Cardiol Intv* 2010;3:1150-6.
2. Bagur R, Kwok CS, Nombela-Franco L, et al. Transcatheter aortic valve implantation with or without preimplantation balloon aortic valvuloplasty: a systematic review and meta-analysis. *J Am Heart Assoc* 2016;5:e003191.
3. Banerjee K, Kandregula K, Sankaramangalam K, et al. Meta-analysis of the impact of avoiding balloon predilation in transcatheter aortic valve implantation. *Am J Cardiol* 2018;122:477-82.
4. Deharo P, Jaussaud N, Grisoli D, et al. Impact of direct transcatheter aortic valve replacement without balloon aortic valvuloplasty on procedural and clinical outcomes: insights from the FRANCE TAVI registry. *J Am Coll Cardiol Intv* 2018;11:1956-65.
5. Pagnesi M, Jabbour RJ, Latib A, et al. Usefulness of predilation before transcatheter aortic valve implantation. *Am J Cardiol* 2016;118:107-12.
6. Bijuklic K, Haselbach T, Witt J, et al. Increased risk of cerebral embolization after implantation of a balloon-expandable aortic valve without prior balloon valvuloplasty. *J Am Coll Cardiol Intv* 2015;8:1608-13.
7. Barber PA, Hach S, Tippett LJ, Ross L, Merry AF, Milsom P. Cerebral ischemic lesions on diffusion-weighted imaging are associated with neurocognitive decline after cardiac surgery. *Stroke* 2008;39:1427-33.
8. Pagnesi M, Baldetti L, Del Sole P, et al. Predilatation prior to transcatheter aortic valve implantation: is it still a prerequisite? *Interv Cardiol* 2017;12:116-25.
9. Fiorina C, Maffeo D, Curello S, et al. Direct transcatheter aortic valve implantation with self-expandable bioprosthesis: feasibility and safety. *Cardiovasc Revasc Med* 2014;15:200-3.
10. Toutouzas K, Latsios G, Stathogiannis K, et al. One-year outcomes after direct transcatheter aortic valve implantation with a self-expanding bioprosthesis. A two-center international experience. *Int J Cardiol* 2016;202:631-5.

KEY WORDS balloon aortic valvuloplasty, paravalvular leak, transcatheter aortic valve replacement