

## Routine Predeployment Balloon Aortic Valvuloplasty During Transcatheter Aortic Valve Replacement: Time to Move On?

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Routine predeployment balloon aortic valvuloplasty (BAV) has historically been considered an essential part of the transcatheter aortic valve replacement (TAVR) procedure, ensuring unimpeded delivery of the prosthetic valve across the stenotic aortic valve, optimal valve expansion, and hemodynamic stability during valve deployment. This was particularly pertinent for first-generation valves with very large profiles (22-F and 24-F Edwards Sapien valve [Edwards Lifesciences, Irvine, CA]<sup>1</sup> and 24-F Medtronic CoreValve [Medtronic, Dublin, Ireland]<sup>2</sup>), for which valve crossing was often challenging. However, its continued role as a routine adjunct given more advanced delivery systems with lower profiles (14-F to 16-F for the Edwards S3 and Medtronic Evolut R valves) and improved trackability remains uncertain. Routine predeployment BAV for every TAVR might not be necessary, especially as operators strive to minimize TAVR-related risks. A tailored approach to predeployment BAV for specific patient subsets who will benefit the most is desired.

Risks associated with BAV are significant. Stroke remains a significant complication, with a reported rate of 1.8%.<sup>3</sup> Other major risks associated with BAV include major vascular complication (4%), procedural death (1.5%), severe aortic valve insufficiency (1.1%), cardiac tamponade (0.9%), and annulus rupture (0.3%).<sup>4</sup> Conduction disturbance is more likely when BAV is performed during TAVR.<sup>5</sup> In addition, standard BAV is not always well tolerated, especially in patients with low left ventricular ejection fraction.

In this issue of the *Journal of the American Heart Association*, Martin et al<sup>6</sup> retrospectively report on the use of BAV during TAVR in the United Kingdom between 2007 and 2014.

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After propensity score matching, outcomes of procedural complications including stroke, valve dysfunction, paravalvular leak, permanent pacemaker implantation, and 30-day mortality were similar between standard predeployment BAV and direct TAVR. There was also no difference in outcome by type of valve used. Hence, at 30 days, direct TAVR was as good as routine predeployment BAV during TAVR.

These results add to the existing data supporting that TAVR can be performed successfully without routine BAV. Omitting this additional step has been shown to be safe, results in successful valve deployment, and yields similar clinical and hemodynamic outcome at up to 1 year.<sup>5,7-16</sup> Additional benefits of direct TAVR are lower contrast use and shorter fluoroscopy and procedural time.<sup>8-10,12,14</sup> Nonetheless, other uses for nonroutine predeployment BAV, such as balloon sizing for confirmation of annulus dimension and evaluation of the interaction of the native leaflets with the coronary ostia when coronary artery takeoffs are low, continue to have a role in the contemporary TAVR era.

When tailoring BAV use during TAVR, the following considerations should be made. In this current study, patients who received BAV were significantly older, had higher mean transvalvular gradients, smaller aortic valve area, and more extensive ascending aortic calcification. Similar criteria were reported as a reason for a bailout BAV in a study where direct TAVR was attempted in every case.<sup>17</sup> This strategy of doing BAV only in patients with severe or asymmetric aortic valve calcification and small aortic valve area ( $\leq 0.5$  cm<sup>2</sup>) has been successfully implemented and identifies good basic criteria to follow when assessing the need for predeployment BAV during TAVR.<sup>18</sup> These features can be obtained from routine transthoracic echocardiography and computed tomography imaging. In addition, transesophageal echocardiographic evaluation of the aortic valve and root, although more invasive, can be helpful to determine which patients are best suited for direct TAVR and can potentially decrease the rate of permanent pacemaker implant and procedure-related mortality.<sup>19</sup>

Stroke remains one of the most feared complications of TAVR. New cerebral infarcts can be detected in up to 77% of cases following TAVR on magnetic resonance imaging.<sup>20</sup> Cerebral embolization of debris during TAVR happens in nearly

every case, and lesion volume correlates with neurocognitive decline.<sup>21</sup> Although emboli are generated during every step of the TAVR procedure, the majority occurs during valve positioning and implantation, suggesting that anatomical and procedural factors are responsible for cerebral embolization.<sup>17</sup> This correlates with findings that embolized material during TAVR is mostly from thrombus and arterial wall, possibly when the valve is advanced in the arch. The remaining material is from calcification, aortic valve tissue, myocardium, and foreign material.<sup>21</sup> Hence, to decrease cerebral emboli during TAVR, emphasis should be made on careful manipulation of catheters in the aortic arch, conscientious anticoagulation, and possibly prophylactic use of an embolic protection device. The present study<sup>6</sup> indicates that BAV during TAVR does not increase the incidence of procedure-related stroke, which correlates with the bulk of previous evidence.<sup>5,7–14</sup> This finding particularly applies to TAVR performed at experienced centers and when third-generation valves are used. Conversely, first- and second-generation valves were more likely to cause embolization when predeployment BAV was omitted.<sup>17</sup>

Some crucial procedural details that could have impacted the incidence of stroke in this study<sup>6</sup> are not reported, some of which are acknowledged as a limitation of this registry-based study. More specifically, the number of times the aortic valve was crossed, the procedural activated clotting time, the implantation duration, the number of inflations, the duration of the pacing run, and the need for postdilation could have impacted the incidence of TAVR-related stroke. It has been suggested that direct TAVR can require more frequent postdilation,<sup>13</sup> which is associated with increased cerebral embolic events.<sup>22</sup> However, most trials have not found a difference in the rate of postdilation between direct TAVR and predeployment BAV.<sup>7–12,14,17</sup> Again, BAV does not appear to significantly impact outcomes in TAVR, but its safety and association with stroke using third-generation valves need to be validated in large randomized trials.

The ideal balloon size for BAV remains unclear. The concept of moderate BAV, or partial valvuloplasty with a smaller balloon size (average of 15 mm) to allow valve delivery, has been suggested and shown to yield similar procedural success and clinical outcome compared to direct TAVR at 30 days with the Sapien S3 valve.<sup>18</sup> It currently remains unclear whether moderate BAV confers an advantage over standard/larger BAV, but upcoming trials should help answer this question. Another advancement in the field of BAV is the introduction of BAV catheter technology with a central orifice that allows for improved hemodynamic, uninterrupted left ventricular ejection, and balloon stability when inflated, without the need for rapid-burst right ventricular pacing.

As centers continue to gain experience, physicians are likely to become more comfortable with direct TAVR. This

trend has already transpired in the design of recent trials,<sup>14,18</sup> in the UK registry from 2007 to 2014 as presented in this study, and in the Italian registry where routine predeployment BAV rates have dropped from 91.7% in 2013 to 80.7% in 2015.<sup>23</sup>

Direct TAVR, when performed in the right subset of patients, is safe and yields comparable clinical and hemodynamic outcomes compared to routine predeployment BAV during TAVR. As percutaneous valves get implanted in lower surgical risk patients, the focus of attention will be on outcomes. Operators have the responsibility to carefully review every part of the procedure and ensure that the risks of any additional step are justified. Omitting the BAV, when appropriate, can contribute to minimizing TAVR-related complications. The use of BAV during TAVR continues to be supported in cases of critical aortic valve area, severe valve calcification, balloon sizing of the annulus, and assessment of coronary artery flow prior to valve deployment in case of low coronary takeoff. Future large randomized trials and results of the ongoing multicenter registry of transfemoral direct TAVR versus predeployment BAV (EASE-IT TF [Transfemoral Transcatheter Aortic Valve Implantation With or Without Predilation of the Aortic Valve]) will provide additional data regarding safety and outcome of direct TAVR (NCT02760771).<sup>24</sup>

## Disclosures

None.

## References

1. The Edwards SAPIEN THV transcatheter heart valve system for patients with severe aortic stenosis who are not candidates for conventional open-heart aortic valve replacement surgery. Briefing document for the FDA circulatory systems device panel advisory committee. 2011. <http://www.fda.gov/downloads/AdvisorySystemDevicesPanel/UCM262935.pdf>. Accessed January 24, 2017.
2. Grube E, Laborde JC, Gerckens U, Felderhoff T, Sauren B, Buellesfeld L, Mueller R, Menicelli M, Schmidt T, Zickmann B, Iversen S, Stone GW. Percutaneous implantation of the CoreValve self-expanding valve prosthesis in high-risk patients with aortic valve disease: the Siegburg First-in-Man Study. *Circulation*. 2006;114:1616–1624.
3. Eltchaninoff H, Durand E, Borz B, Furuta A, Bejar K, Canville A, Farhat A, Fraccaro C, Godin M, Tron C, Sakhuja R, Cribier A. Balloon aortic valvuloplasty in the era of transcatheter aortic valve replacement: acute and long-term outcomes. *Am Heart J*. 2014;167:235–240.
4. Kumar A, Paniagua D, Hira RS, Alam M, Denktas AE, Jneid H. Balloon aortic valvuloplasty in the transcatheter aortic valve replacement era. *J Invasive Cardiol*. 2016;28:341–348.
5. Bernardi FL, Ribeiro HB, Carvalho LA, Sarmiento-Leite R, Mangione JA, Lemos PA, Abizaid A, Grube E, Rodes-Cabau J, de Brito FS Jr. Direct transcatheter heart valve implantation versus implantation with balloon predilatation: insights from the Brazilian transcatheter aortic valve replacement registry. *Circ Cardiovasc Interv*. 2016;9:e003605. DOI: 10.1161/CIRCINTERVENTIONS.116.003605.
6. Martin GP, Sperrin M, Bagur R, de Belder MA, Buchan I, Gunning M, Ludman PF, Mamas MA. Pre-implantation balloon aortic valvuloplasty and clinical outcomes following transcatheter aortic valve implantation: a propensity score analysis of the UK registry. *J Am Heart Assoc*. 2017;6:e004695. DOI: 10.1161/JAHA.116.004695.
7. Bagur R, Kwok CS, Nombela-Franco L, Ludman PF, de Belder MA, Sponga S, Gunning M, Nolan J, Diamantouros P, Teeffy PJ, Kiaii B, Chu MW, Mamas MA. Transcatheter aortic valve implantation with or without preimplantation

- balloon aortic valvuloplasty: a systematic review and meta-analysis. *J Am Heart Assoc*. 2016;5:e003191. DOI: 10.1161/JAHA.115.003191.
8. Ferrera C, Nombela-Franco L, Garcia E, Jimenez-Quevedo P, Biagioni C, Gonzalo N, Nunez-Gil I, Viana-Tejedor A, Salinas P, Alberto de Agustin J, Almeria C, Islas F, Perez de Isla L, Fernandez-Perez C, Escaned J, Fernandez-Ortiz A, Macaya C. Clinical and hemodynamic results after direct transcatheter aortic valve replacement versus pre-implantation balloon aortic valvuloplasty: a case-matched analysis. *Catheter Cardiovasc Interv*. August 12, 2016. DOI: 10.1002/ccd.26671. Available at: <http://onlinelibrary.wiley.com/doi/10.1002/ccd.26671/abstract>. Accessed January 31, 2017.
  9. Bijuklic K, Haselbach T, Witt J, Krause K, Hansen L, Gehrckens R, Riess FC, Schofer J. Increased risk of cerebral embolization after implantation of a balloon-expandable aortic valve without prior balloon valvuloplasty. *JACC Cardiovasc Interv*. 2015;8:1608–1613.
  10. Conradi L, Schaefer A, Seiffert M, Schirmer J, Schaefer U, Schon G, Blankenberg S, Reichenspurner H, Treede H, Diemert P. Transfemoral TAVI without pre-dilatation using balloon-expandable devices: a case-matched analysis. *Clin Res Cardiol*. 2015;104:735–742.
  11. Spaziano M, Sawaya F, Chevalier B, Roy A, Neylon A, Garot P, Hovasse T, Benamer H, Romano M, Untersee H, Bouvier E, Cormier B, Morice MC, Lefevre T. Comparison of systematic predilatation, selective predilatation, and direct transcatheter aortic valve implantation with the SAPIEN S3 valve. *Can J Cardiol*. 2017;33:260–268.
  12. Bandali A, Parry-Williams G, Kassam A, Palmer S, Williams PD, de Belder MA, Owens A, Goodwin A, Muir DF. Direct transfemoral transcatheter aortic valve implantation without balloon pre-dilatation using the Edwards Sapien XT valve. *Catheter Cardiovasc Interv*. 2016;88:978–985.
  13. Pagnesi M, Jabbour RJ, Latib A, Kawamoto H, Tanaka A, Regazzoli D, Mangieri A, Montalto C, Ancona MB, Giannini F, Chieffo A, Montorfano M, Monaco F, Castiglioni A, Alfieri O, Colombo A. Usefulness of predilatation before transcatheter aortic valve implantation. *Am J Cardiol*. 2016;118:107–112.
  14. Aggarwal SK, Delahunty N, Wong B, Tamimi AN, Reinthaler M, Cheang MH, Roberts N, Yap J, Ozkor M, Mullen MJ. Balloon-expandable transcatheter aortic valves can be successfully and safely implanted transfemorally without balloon valvuloplasty. *J Interv Cardiol*. 2016;29:319–324.
  15. Conradi L, Seiffert M, Schirmer J, Koschyk D, Blankenberg S, Reichenspurner H, Diemert P, Treede H. Transapical transcatheter aortic valve implantation without prior balloon aortic valvuloplasty: feasible and safe. *Eur J Cardiothorac Surg*. 2014;46:61–66.
  16. Fiorina C, Maffeo D, Curello S, Lipartiti F, Chizzola G, D'Aloia A, Adamo M, Mastropiero R, Gavazzi E, Ciccarese C, Chiari E, Etori F. Direct transcatheter aortic valve implantation with self-expandable bioprosthesis: feasibility and safety. *Cardiovasc Revasc Med*. 2014;15:200–203.
  17. Kim WK, Praz F, Blumenstein J, Liebetau C, Gaede L, Van Linden A, Hamm C, Walther T, Windecker S, Mollmann H. Transfemoral aortic valve implantation of Edwards SAPIEN 3 without predilatation. *Catheter Cardiovasc Interv*. 2017;89:E38–E43.
  18. Abramowitz Y, Jilaihawi H, Chakravarty T, Maeno Y, Kawamori H, Kazuno Y, Mangat G, Rami T, Allison Z, Anderson D, Chan L, Cheng W, Makkar RR. Sapien 3 transcatheter aortic valve implantation with moderate or without predilatation. *J Invasive Cardiol*. 2016;28:421–426.
  19. Islas F, Almeria C, Garcia-Fernandez E, Jimenez P, Nombela-Franco L, Olmos C, Marcos-Alberca P, Cuadrado A, Fernandez-Ortiz A, Macaya C, Perez de Isla L. Usefulness of echocardiographic criteria for transcatheter aortic valve implantation without balloon predilatation: a single-center experience. *J Am Soc Echocardiogr*. 2015;28:423–429.
  20. Fairbairn TA, Mather AN, Bijsterveld P, Worthy G, Currie S, Goddard AJ, Blackman DJ, Plein S, Greenwood JP. Diffusion-weighted MRI determined cerebral embolic infarction following transcatheter aortic valve implantation: assessment of predictive risk factors and the relationship to subsequent health status. *Heart*. 2012;98:18–23.
  21. Kapadia SR, Kodali S, Makkar R, Mehran R, Lazar RM, Zivadinov R, Dwyer MG, Jilaihawi H, Virmani R, Anwaruddin S, Thourani VH, Nazif T, Mangner N, Woitek F, Krishnaswamy A, Mick S, Chakravarty T, Nakamura M, McCabe JM, Sattler L, Zajarias A, Szeto WY, Svensson L, Alu MC, White RM, Kraemer C, Parhizgar A, Leon MB, Linke A. Cerebral embolic protection during transcatheter aortic valve replacement. *J Am Coll Cardiol*. 2017;69:367–377.
  22. Nombela-Franco L, Rodes-Cabau J, DeLarochelliere R, Larose E, Doyle D, Villeneuve J, Bergeron S, Bernier M, Amat-Santos IJ, Mok M, Urena M, Rheault M, Dumesnil J, Cote M, Pibarot P, Dumont E. Predictive factors, efficacy, and safety of balloon post-dilatation after transcatheter aortic valve implantation with a balloon-expandable valve. *JACC Cardiovasc Interv*. 2012;5:499–512.
  23. Giordano A, Corcione N, Biondi-Zoccai G, Berti S, Petronio AS, Pierli C, Presbitero P, Giudice P, Sardella G, Bartorelli AL, Bonmassari R, Indolfi C, Marchese A, Brscic E, Cremonesi A, Testa L, Brambilla N, Bedogni F. Patterns and trends of transcatheter aortic valve implantation in Italy: insights from RISPEVA. *J Cardiovasc Med*. 2017;18:96–102.
  24. Butter C, Bramlage P, Rudolph T, Jacobshagen C, Rothe J, Treede H, Kerber S, Frank D, Seilerova L, Schymik G. Balloon expandable transcatheter aortic valve implantation via the transfemoral route with or without pre-dilatation of the aortic valve—rationale and design of a multicentre registry (EASE-IT TF). *BMC Cardiovasc Disord*. 2016;16:223.

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