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]1 and 24-F Medtronic CoreValve [Medtronic, Dublin, Ireland]2), 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%. Three 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%). Conduction disturbance is more likely when BAV is performed during TAVR.5 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 al6 retrospectively report on the use of BAV during TAVR in the United Kingdom between 2007 and 2014.

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.5,7–16 Additional benefits of direct TAVR are lower contrast use and shorter fluoroscopy and procedural time.8–10,12,14 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.17 This strategy of doing BAV only in patients with severe or asymmetric aortic valve calcification and small aortic valve area (≤0.5 cm²) has been successfully implemented and identifies good basic criteria to follow when assessing the need for predeployment BAV during TAVR.18 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.19

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.20 Cerebral embolization of debris during TAVR happens in nearly
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every case, and lesion volume correlates with neurocognitive
decline. 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.
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. Hence, to decrease
cerebral emboli during TAVR, emphasis should be made on
careful manipulation of catheters in the aortic arch, conscien-
tious anticoagulation, and possibly prophylactic use of an
embolic protection device. The present study indicates that
BAV during TAVR does not increase the incidence of
procedure-related stroke, which correlates with the bulk of
previous evidence. 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.

Some crucial procedural details that could have impacted
the incidence of stroke in this study 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, which is associated with increased cerebral
embolic events. However, most trials have not found a
difference in the rate of postdilation between direct TAVR and
predeployment BAV. 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. 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 hemodynamics, 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,
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.

Direct TAVR, when performed in the right subset of
patients, is safe and yields comparable clinical and hemody-
namic 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 com-
plications. 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 Tran-
catheter Aortic Valve Implantation With or Without Predila-
tion of the Aortic Valve]) will provide additional data regarding
safety and outcome of direct TAVR (NCT02760771).

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/AdvisorySystems DevicesPanel/UCM262935.pdf. Accessed
January 24, 2017.
2. Grube E, Laborde JC, Gerckens U, Felderhoff T, Sauren B, Buellesfeld L, Mueller
R, Menichelli 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, Borgez B, Buruta A, Bejar K, Carvillie A, Harhat A,
Fraccaro C, Godin M, Tron C, Sakhura 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, Panigada 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, Sarmento-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, Gunnung 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, Diamantopoulou P, Teefy PJ, Khai B, Chu MW, Mamas MA.
Transcatheter aortic valve implantation with or without preimplantation
implantation.
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, Biagini 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. Aug 12, 2016. DOI: 10.1002/ccd.26671. Available at: http://onlinelibrary.wiley.com/doi/10.1002/ccd.26671/abstract. Accessed January 31, 2017.

9. Bjuklic K, Haselbach T, Witt J, Krause K, Hansen L, Gehrckens R, Riess FC.

10. Conradi L, Seiffert M, Schirmer J, Blankenberg S, Reichenspurner

12. Bandali A, Parry-Williams G, Kassam A, Palmer S, Williams PD, de Belder MA, Roberts N, Yap J, Ozkor M, Mullen MJ. Balloon-expandable transcatheter aortic valves can be successfully and safely implanted transfemorally without balloon pre-dilatation using the Edwards Sapien XT valve. J Am Coll Cardiol. 2017;69: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 predilation. 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 predilation: a single-center experience. J Am Soc Echocardiogr. 2015;28:423–429.

20. Fairbairn TA, Mather AN, Bisterveld 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, Satler LF, 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, D’Elarocheilliere 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-dilation 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, Bonnassir 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 RITPEVA. J Cardiovasc Med. 2017;18:96–102.

24. Butter C, Bramlage P, Rudolph T, Jacobsbagen C, Rothe J, Trede H, Kerber S, Frank D, Seilerova L, Schymik G. Balloon expandable transcatheter aortic valve implantation via the transfemoral route with or without pre-dilation of the aortic valve—rationale and design of a multicentre registry (EASE-IT TF). BMC Cardiovasc Disord. 2016;16:223.