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Editorial

Balloon Aortic Valvuloplasty in the Era of Transcatheter Valve Replacement

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Cribier et al[1] first described the use of balloon aortic valvuloplasty (BAV) to treat 3 elderly patients with severe calcific aortic stenosis (AS) in 1986. All patients survived the procedure with significant reductions in valve gradients and improvements in symptoms.

In 2002, this same group reported first-in-human transcatheter aortic valve replacement (TAVR) in an inoperable patient.[2] Collectively, these 2 events have been considered "the most important advancement in the field of interventional cardiology" since coronary angioplasty. Since introduction, the exponential growth in TAVR has been supported by a rigorous clinical trial evidence base and has rapidly eclipsed surgical aortic valve replacement for AS. Generational iterations in TAVR technology and procedural technique have reduced periprocedural complications, facilitated operator ease of use, and expedited hospital discharge.

With such focus centered on TAVR, it is pertinent to ask: what is the role of BAV in the era of TAVR?

In this issue of *JSCAI*, Zhong et al[3] present a timely review of the indications, outcomes, and technical advances in BAV. The authors present a pooled analysis of 25 studies including 14,300 patients treated with BAV over the past 3 decades. The rates of serious intraprocedural complications were low (death, 1.9%; stroke, 1.2%; and vascular complications, 4.7%) and seemed better than those reported by the first National Heart, Lung, and Blood Institute (NHLBI) Balloon Valvuloplasty Registry for 674 patients treated in the early BAV experience (25% of the patients experienced $\geq$1 serious complication within 24 hours of the procedure, with blood transfusion [23%] and vascular surgery [7%] being the most common).[4] Since that early report, the iterative reduction in BAV balloon profiles, such as the development of nonocclusive balloons and double-balloon techniques using radial or brachial arterial access, coupled with the development of vascular closure devices have increased procedural safety and expanded the pool of eligible patients, such as pediatric patients with congenital AS. For example, the Tyshak II balloon dilatation catheters (B. Braun Interventional Systems) can treat annular dimensions of 4.0-30.0 mm through 4F-10F introducer catheter sheath sizes. The Z-Med and Z-Med II balloon dilatation catheters (B. Braun Interventional Systems) can treat annular diameters $\leq$40.0 mm and $\leq$30.0 mm, respectively, using 5F-11FR catheter sheath sizes. BAV balloons are available in multiple lengths (20.0, 30.0, 40.0, 50.0, and 60.0 mm), which allows to tailoring to the anatomy. In general, longer lengths can mitigate balloon slippage during BAV and shorter lengths can avoid interaction, with a narrow, "tapered" left ventricular outflow tract and/or low sinotubular junction height.

Despite improvement in procedural safety and efficacy, BAV has failed to demonstrate sustained improvement in long-term outcomes or a change in the natural history of symptomatic severe AS. Indeed, in the PARTNER extreme surgical risk population, those patients randomly assigned to medical therapy (no TAVR) experienced 51% mortality at 1-year follow-up despite 84% of these patients underwent adjunctive BAV.[5] Therefore, BAV should be considered in the context of aortic valve replacement as either a procedural adjunct or bridge to clinical decision-making and, possibly, for palliative symptom relief.

BAV as a bridge to clinical decision-making

A portion of patients with severe AS present acutely decompensated with multiple futility markers (eg, malnutrition, shock, renal failure, cancer, recent surgery, stroke, and immobility), which may be amenable to intervention after an initial period of clinical stabilization. By effectively reducing transvalvular gradients and improving symptoms, BAV can provide a window of opportunity to improve or reverse comorbidities that could adversely affect clinical outcomes of TAVR. Although the simplicity of TAVR has enabled rapid evaluation and treatment of many patients with acute-decompensated AS, this practice may not be appropriate for all patients. In some instances, a "BAV first" approach, followed by close outpatient follow-up to optimize risk factors, is necessary to ensure the performance of TAVR is appropriate and likely to provide meaningful clinical benefit. BAV can safely buy time for recovery in left and right ventricular function, improved nutritional status, and physical rehabilitation to optimize patient status for subsequent TAVR. The use of BAV to facilitate prehabilitation as opposed to rehabilitation can also expedite patient discharge after a deferred admission for TAVR, which may improve both patient outcomes (patient discharged to home rather than to a skilled nursing facility) and hospital economics for the procedure.

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BAV as a as a procedural adjunct to TAVR

Balloon predilation was considered mandatory in the early days of TAVR.[6] Its importance was predicated on the ability of BAV to facilitate valve delivery, size the device, and optimizes device implantation and expansion. The natural evolution, and subsequent clinical adoption, of TAVR devices with lower profiles and sealing skirts, and improved device sizing with computed tomography, challenged the need for preparatory BAV in deference to "primary TAVR."[7]

In certain anatomical subsets (bicuspid anatomies in particular with a fused and/or calcified raphe, heavily calcified leaflets, and very high-transvalvular gradients), predilation remains an important procedural adjunct. Similarly, certain valve platforms such as ACURATE Neo (Boston Scientific) and NAVITOR (Abbott Structural Heart) require routine predilation to optimize valve expansion.

As the prevalence of perivalvular regurgitation (PVL) after TAVR has decreased considerably with new TAVR platforms, the need for balloon postdilation has declined in clinical practice.[8] However, postdilation may provide additional benefits beyond PVL mitigation. For example, computed tomography substudies have revealed an association between hypoattenuated leaflet thickening and nonuniform expansion of TAVR prostheses, resulting in frame deformation and smaller neosinus volume.[9] Similar to coronary stents deployed in a calcified coronary artery, balloon postdilation may help optimize device stent expansion in a calcium-rich environment. Whether routine postdilation results in reduced hypoattenuated leaflet thickening or improved valve durability deserves further study.

Bioprosthetic valve remodeling and fracture

Bioprosthetic valve fracture (BVF) is a technique that intentionally disrupts the stent frame of the surgical heart valve (SHV) to facilitate optimal expansion of the transcatheter heart valve. BVF reduces residual gradients and increases the effective orifice area after valve-in-valve TAVR.[10] Bench testing of commercially available SHVs has demonstrated that most SHVs can be fractured with a high-pressure balloon inflation.[11] A recent analysis of the Transcatheter Valve Therapy registry showed that BVF was attempted in 21% of the valve-in-valve TAVR cases and was associated with larger aortic valve areas (1.6 vs 1.4 cm^2; $P < .01$) and lower mean gradients (16.3 vs 19.2 mm Hg; $P < .01$) compared with no BVF.[12]

With more than 30 years of clinical experience, the indications and techniques for BAV have evolved and made the procedure more safe and predictable. Although the number of BAV procedures is increasing in the United States, significant institutional variability exists, and most procedures are performed at teaching hospitals.[13,14] Despite improvements in TAVR, BAV remains an important procedural adjunct to facilitate valve delivery and optimal expansion and to mitigate PVL. In addition, BAV can provide time to optimize patient status before TAVR. Zhong et al have provided a valuable contemporary perspective regarding BAV in the era of TAVR.

Peer review statement

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Declaration of competing interest

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