Is there still a role for balloon dilatation before transcatheter aortic valve replacement—or, indeed, for transaortic access?

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Central Message

Balloon aortic valvuloplasty before transcatheter aortic valve replacement adds little to current clinical practice.

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Balloon aortic valvuloplasty (BAV) dilatation before transcatheter aortic valve replacement (TAVR) was considered a mandatory procedural step in the early years of TAVR. BAV was used to confirm annular sizing and to enhance transcatheter heart valve (THV) deliverability. In addition, BAV was believed to maximize THV expansion to optimize hemodynamics and reduce paravalvular leak. The need for BAV fell, however, with the advent of systematic computed tomographic assessment of the aortic annulus, newer catheters with superior deliverability, and features such as sealing skirts to address paravalvular leak.

In this issue of the *Journal*, Bonaros and colleagues¹ present data on the utility of pre-TAVR BAV dilatation in patients undergoing TAVR through transaortic access from the multicenter prospective Registry of the Utilization of the TAo-TAVI Approach Using the Edwards SAPIEN Valve (ROUTE) trial. A total of 222 patients undergoing TAVR with preprocedural BAV dilatation and 78 undergoing direct TAVR without BAV were included in the analysis. It is important to recognize that patients were not randomly allocated between the groups; rather, the decision to perform BAV was at the discretion of the operator. Predictably, patients who had undergone BAV at an earlier date were more likely to be selected for direct TAVR. Without randomization, it is impossible to determine whether clinical or anatomic factors that influenced the operator's decision explain the differences observed between groups. For example, the rates of complete atrioventricular block and periprocedural permanent pacemaker implantation were higher in the BAV group, but it is possible that operators deliberately avoided BAV in patients with heavy annular calcification or small left ventricular outflow tract. Indeed, the rate of permanent pacemaker implantation at 30 days was not different between the groups (9.1% vs 8.1%), and avoiding BAV should therefore not have been interpreted as a way to reduce the need for a permanent pacemaker on the basis of these data. It is also important to

emphasize that all patients in this study received a balloon-expandable THV, and the findings should therefore not be generalized to other THV platforms, including self-expanding devices.

Transaortic access has the advantage of providing a direct trajectory to the aortic valve, imparting excellent control on the THV during delivery. As expected, inability to cross the aortic valve was not observed in the direct TAVR group, and there did not appear to be an increased need for BAV dilatation after the procedure. There was no difference in THV hemodynamics, including gradient and paravalvular leak, between groups. After adjustment for baseline characteristics, multivariate analysis confirmed that the decision not to perform BAV dilatation before the procedure had no significant effect on Valve Academic Research Consortium 2 (VARC-2) criteria for early safety or clinical efficacy at 30 days. This study thus parallels the data for transfemoral and transapical TAVR. Performing BAV before transaortic implantation of a balloon-expandable THV does not significantly increase procedural complications, and the decision not to perform BAV does not appear to affect THV hemodynamics. Two conclusions can be drawn. First, regardless of access route, direct TAVR is safe. Second, operator preference to perform BAV in selected cases, for example to improve THV deliverability in the setting of horizontal aorta and critical aortic stenosis, is reasonable.

Finally, transthoracic access—specifically transapical or transaortic access—is associated with increased mortality relative to transfemoral access. In the Placement of Aortic

Transcatheter Valves 2 (PARTNER 2) study of TAVR in intermediate-risk patients,² transthoracic access was an independent predictor of all-cause mortality, with a hazard ratio of 1.55 (1.23-1.96; $P < .001$). Transthoracic access was also associated with higher rates of stroke (9.8% vs 4.2%), stage III acute kidney injury (3.9% vs 0.5%), and life-threatening bleeding (22.6% vs 6.7%) than were seen with transfemoral access. This raises the question of whether transthoracic approaches, including transaortic and transapical approaches, still have a place in the contemporary TAVR era, now that less morbid extrathoracic access options are available, such as subclavian,³ transcaval,⁴ and carotid.⁵ Indeed, many operators have already made the switch to extrathoracic access without the need for pre-TAVR valve dilation.

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