EDITORIAL COMMENT

Balloon Post-Dilation After Transcatheter Aortic Valve Replacement

A Solution Worth Trying in Patients With Residual Aortic Insufficiency*

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Nobody can be uncheered with a balloon…

—Winnie the Pooh (1)

In daily practice, we are confronted with a dilemma: what to do if we find a relevant paravalvular leak (PVL) after transcatheter aortic valve replacement (TAVR): Should we optimize the hemodynamic result by post-dilating the valve prosthesis? Or should we accept the PVL? Are we willing to increase the procedural risk in order to reduce potential long-term sequelae? Balloon post-dilation (PD) is technically simple and effective in many occasions. Therefore, it has been frequently adopted as first-line therapy of PVL to reduce the degree of residual aortic regurgitation (AR). However, there is a scarcity of data to support this strategy, and many issues remain controversial: How relevant is a PVL? What is its real clinical consequence? What is the efficacy of PD? What is the risk of PD?

The PARTNER (Placement of AORTic TraNschatetER Valves) trial (2,3) suggested residual AR following transcatheter aortic valve implantation to be associated with a high risk of premature death. This is in contrast with the natural history of AR, which is a benign disease unless it progresses to a severe degree. Turina et al. (4) in 1987 reported in a cohort of 80 patients with isolated AR undergoing right and left heart catheterization that all patients with moderate AR were still alive after 4 years, and 10-year survival was as high as 79%, irrespective of symptom status.

After surgical aortic valve replacement, the incidence of PVLs is usually below 1% and is typically mild at most. PVLs after surgical aortic valve replacement showed a benign course up to 5 years (5), and do not affect long-term outcome (6).

By contrast, PVL after TAVR is a rather frequent finding, with an incidence of moderate or severe PVLs of about 12% (2,3).

Interestingly, although the hemodynamic consequences remain the same as in natural AR or PVL after surgical valve replacement, it seems that we are dealing with a different entity affecting outcome differently, and asking for different measures.

In AR after TAVR, decision making can be challenging because of a variety of issues: the difficulty to properly diagnose and quantify PVLs, the potential for spontaneous reduction of AR in the short term without any intervention (e.g., with self-expanding devices [7]), and the risk–benefit analysis in an individual patient.

Several factors will influence our decision whether to post-dilate after TAVR or not, such as the severity of the leak, the mechanism of PVL (low-implant, mismatch, underinflation, calcification, etc.), and the patient’s individual risk for post-dilation (PD). The individual risk of stroke or annular rupture that is due to PD depends on the severity of valvular calcification (in particular on the amount of calcification in the left ventricular outflow tract) and on the amount of prosthesis oversizing (8). To balance the risk, we need to know the benefit of an intervention. The main question, therefore, remains whether reduction of PVL will indeed translate into better clinical outcome. And more specifically: Is this the case even for mild or moderate PVLs? Current data are somewhat conflicting (3,7).

In this issue of JACC: Cardiovascular Interventions, the data of Hahn et al. (9) provide us very valuable answers to many important questions. Hahn et al. (9) assessed the outcome of 2,135 patients, whereof 261 underwent PD of their transcatheter valve, and 1,874 did not undergo PD.

That the clinical setting influences operators’ willingness to post-dilate is reflected by the fact that inoperable patients underwent PD less frequently than high-risk patients. Importantly, Hahn et al. (9) suggest that PD, in fact, can improve prognosis: whereas patients that underwent PD after valve implantation had overall worse 1-year outcomes (survival or stroke), in the subgroup of patients where PVL was virtually eliminated by PD (n = 102), 1-year outcome was not different as compared with patients without PVL after valve deployment. It, therefore, seems that successful PD indeed improves prognosis—but a selection bias cannot be ruled out (e.g., that healthier patients are better responding to PD).
Residual moderate and severe PVLs were predictors of 1-year mortality and the combined endpoint of mortality and stroke. This finding, in line with other data, suggests that moderate PVL itself negatively affects outcome, unlike what we know from native aortic valve regurgitation.

Another important finding from the Hahn et al. study (9) is that PD is not associated with early valve degeneration, despite the extra stress on the valve leaflets during multiple balloon inflations.

The bad news from Hahn’s data are, however, that PD can indeed cause harm: there were significantly more strokes within 7 days, with a numerical doubling of the stroke rate in the first 7 days in the group of patients undergoing PD (although at low absolute numbers).

Is this stroke risk due to the PD itself, or is it related to patient bias? The issue remains unanswered. A calcium score analysis would have helped to rule out a potential bias from more severe baseline calcification in patients undergoing PD, therefore implying a higher embolic and overall cardiovascular risk.

The decision whether to post-dilate or not was left at the discretion of the operator. The majority of patients comprised patients from the nonrandomized continuous access registry, thus, they were inoperable patients. This may explain why a rather large proportion of patients were left with moderate or severe PVL (8% in the patients without PD and 12% in the group with PD). This finding asks for technical solutions: larger valve sizes that allow for more generous oversizing and new valve technologies that reduce the incidence of PVLs—such as there are already on the market. The 2 prerequisites for future valves may, however, also be contradictory to each other by replacing one evil with another: patients that underwent PD in the Hahn et al. (9) study showed significantly less patient-prosthesis-mismatch (even after multivariable analysis). These data remind us that making the valve as big as possible is beneficial. This is an important finding—even or particularly in the era of new valves such as the Edwards SAPIEN 3 (Edwards Lifesciences, Irvine, California).

How should the study of Hahn et al. (9) change our daily practice? If the mechanism of PVL is such that PD has a chance to eliminate the PVL, it should be performed generously, thereby normalizing the prognosis of the patient.

If we have borderline annulus measurements from the screening imaging, the relatively low risk of PD allows for a stepwise enlargement of a balloon-expandable valve according to its hemodynamic performance: the valve can be underfilled with 1 to 3 ml of contrast and, if needed, gradually enlarged by adding the respective volume (10). This technique also allows performing ad-hoc TAVR where the size of the valve prosthesis is chosen on the basis of a transthoracic echocardiogram or even a fluoroscopic image. Also, “softer” parameters should be taken into account, such as the patient’s height and sex when performing ad-hoc TAVR. In case of borderline measurements, the bigger-sized valve is selected, underfilled, and if needed, gradually enlarged by adding some milliliters of saline to the balloon for PD. With this technique, balloon-expandable TAVR can be considerably simplified, while still keeping it a safe procedure—but, according to the Hahn et al. (9) data, at the price of a higher 7-day stroke rate, which is again balanced out at 30 days.

It must be clearly underlined that transcatheter aortic valve implantation should aim for perfect outcomes, balancing safety and efficacy, individualizing the approach by adapting to patient anatomy, clinical characteristics, and operator experience. Balloon PD should be done selectively, only when benefit is expected.

To stay with Winnie: if you have a balloon in your hands (and you use it wisely) everybody will cheer you!

**REFERENCES**


**Key Words:** balloon dilation ■ paravalvular leak ■ TAVR.