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Editorial

# Is it time to eliminate balloon valvuloplasty before transcatheter aortic valve replacement?

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Pre-deployment balloon valvuloplasty (BAV) was initially deemed necessary for transcatheter valve aortic replacement (TAVR) to optimize crossing the native valve for transcatheter valve positioning, and ultimately deployment [1]. There are data to suggest that BAV can be associated with hemodynamic disturbance, a higher stroke rate, conduction disorders, significant aortic regurgitation, and even myocardial injury [2,3]. The need for routine use of pre-TAVR BAV has been questioned after recent studies have suggesting the feasibility of direct TAVR without BAV [4–7]. Many TAVR centers are currently not performing routine BAV prior to TAVR, and only 9% of recent patients underwent pre-TAVR BAV at our center.

In the prospective multicenter observational study by Dumonteil et al. [8], 1544 patients were non-randomly assessed in direct TAVR (n = 772) or pre-TAVR BAV (n = 772) groups. This is the first and one of the largest prospective studies investigating outcomes of direct TAVR using a new generation Sapien 3 valve. One of the strengths of this study is that data are derived from the international SOURCE 3 registry which included an external adjudication of events. Both the direct TAVR and pre-TAVR BAV groups were retrospectively matched for baseline comorbidities, and echocardiographic and anatomic valvular characteristics using propensity score methodology.

Despite similar device and procedural techniques, patients who underwent direct TAVR had significantly shorter fluoroscopy and procedure time, received less contrast volume, and had a lower requirement for TAVR post-dilation. There were no significant differences in procedural or echocardiographic outcomes at 30-day. There were no differences in mortality, stroke, or paravalvular leak (PVL) at 30-days. Importantly there were also no significant differences in the majority of the safety endpoints such as coronary obstruction, vascular injury, or early failure of the new valve prosthesis. Inexplicably, however, the authors did report an increased rate of life threatening bleeds and need for permanent pacemaker implantation in the direct TAVR group.

In an age of cost containment, particularly in the TAVR realm, any data that might validate shorter procedural times and reduced resource use would be welcomed by operators and institutions alike. If the TAVR procedure could be performed with less fluoroscopy time, contrast use, requirement for post-dilatation, and overall procedural time without increasing the risk to the patient, than most would embrace the technique of direct TAVR for the Sapien 3 prosthesis.

The interpretation of nonrandomized data does, however, require some caution. The authors did an admirable job of propensity matching in an attempt to control for variables that might lead to bias. Despite this, however, there are a few patient characteristics the authors were unable to control for. Patients in the pre-BAV group had a higher Society of Thoracic Surgeon (STS) risk score and logistic EuroScore, but due to data collection limitations, these variables were not included in the matching process. Additionally, an assessment of frailty was also not included in their analysis. Perhaps the most important point for readers to consider when interpreting the results of this study is the potential selection bias regarding the choice of whether or not to perform pre-TAVR BAV. The procedure was performed by experienced operators, but the decision to perform pre-TAVR BAV was left to the judgment of the individual operator. There are many characteristics such as an aortic gradient $\geq$ 60 mm Hg, a horizontal aorta, an aortic angle >70 degree, a bicuspid valve, or a concern for coronary artery occlusion that might lead an operator to choose to perform a pre-TAVR BAV versus a direct TAVR procedure. There may be other reasons why a given operator might choose one technique over the other, and these cannot be completely accounted for, even with modeling.

The authors made an effort to understand the higher bleeding risk in direct TAVR patients, even on an individual patient level, but without success. Additionally they attempted to understand the need for more pacemaker implantation in the direct TAVR group. One of the known factors that can impact pacemaker implantation

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rates following a TAVR procedure is new prosthesis implant depth. Unfortunately this data was not available in the SOURCE 3 registry and therefore cannot help in further understanding the higher pacemaker rate.

The authors conclude that the outcomes of TAVR with and without BAV are comparable. In the only other available report regarding the feasibility of performing direct TAVR using only a Sapien 3 valve, significant PVL, stroke, mortality, balloon post-dilation, and need for pacemaker placement were comparable between the pre-BAV TAVR and direct TAVR groups [7]. There were, however, few patients in the BAV group (n = 34) compared with the direct TAVR group (n = 344). In a large retrospective analysis of 5887 patients from the UK there were similar outcomes between the pre-BAV and the direct TAVR groups using the Sapien valve, and outcomes were also comparable between the pre-BAV and the direct TAVR groups among those who had the procedure with Corevalve [4]. Initially, there were concerns about an association of direct TAVR with poor outcomes utilizing self-expanding valves due to the perceived risk of suboptimal valve deployment and possible PVL. Subsequent large prospective reports such as 5784 patient study from the FRANCE TAVI Registry appear to confirm the benefits of direct TAVR with both balloon expandable and self-expandable early generation valves [5].

The current and prior studies suggest that direct TAVR is feasible, can simplify the TAVR procedure, and is not inferior to TAVR with pre-BAV. There are two ongoing prospective randomized trials investigating the outcomes of direct TAVR using self-expandable (EASE-IT [Balloon Expandable Transcatheter Aortic Valve Implantation Without Predilation of the Aortic Valve] [NCT02127580]) and Sapein 3 valves (DIRECTAVI [Implantation of the Transcatheter Aortic Prosthesis SAPIEN 3 With or Without Prior Balloon Predilation] [NCT02729519]). These studies will hopefully fill the current knowledge gaps regarding the risks and benefits of a direct TAVR approach. While the direct TAVR approach is clearly not for every patient, the avoidance of pre-TAVR BAV does provide an opportunity to shorten the procedure for both operators and patients. The authors should be congratulated for helping to streamline a complex procedure for our patients.

## Declaration of competing interest

The authors report no relationships that could be construed as a conflict of interest.

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