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EDITORIAL

Balloon Aortic Valvuloplasty in the Transcatheter Aortic Valve Replacement Era: *A "Die-Hard" Procedure*

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Percutaneous balloon aortic valvotomy (also known as balloon aortic valvuloplasty [BAV]) was first described in 1984 by Lababidi and Neuhaus[1] and was reported for the treatment of congenital aortic stenosis (AS) in children and young adults. In 1986 Cribier was the first to perform BAV in adults with calcific AS.[2] In this setting the procedure was so successful that it led to the birth of registries for the analysis of the results.[3,4] Aortic valvuloplasty turned out to be a simple and reproducible procedure, but with a high recurrence of early restenosis, and with a very limited effect on survival and disease progression.[3,4] Therefore, this procedure was selectively used as a palliative remedy, in cases of patients with severe AS with no surgical alternatives.[5]

The introduction of transcatheter aortic valve replacement (TAVR) and its global adoption by a growing number of centers worldwide[6] has produced two scenarios that are conceptually opposite: on one hand, it has renewed the interest in BAV procedures, mostly due to the willingness of operators to familiarize themselves with materials and techniques that would be useful later for TAVR procedures; on the other hand, TAVR has further reduced the indications of BAV to very compromised patients with poor life expectancy.[5] Furthermore, BAV has also been proposed as a "bridge procedure," to determine the therapeutic response of a reduction in aortic gradient in borderline patients, to assess symptomatic and hemodynamic improvement prior to consideration of definitive TAVR or surgical intervention.[7]

Over the last years, several valvuloplasty devices have become available with different features: Basically, there exist semi-compliant or non-compliant aortic balloons. Semi-compliant balloons usually have a lower profile and therefore require smaller vascular access sheaths, which can help in reducing vascular complications in elderly and very high-risk patients. The drawback, however, is that they have less predictable inflation diameters than the non-compliant balloons and have lower-rated burst pressures.[8]

In this issue of *Structural Heart*, Htun and colleagues report the first-in-human study of a novel AngioSculpt valvuloplasty scoring balloon catheter (Spectranetics Corporation, Colorado, USA) for the treatment of severe calcific aortic valve stenosis.[9] The investigators enrolled 25 very elderly (mean age 83.6 ± 5.8 years) consecutive patients treated in two Canadian centers during a timeframe of 25 months. Although this device has been demonstrated to be fairly safe, with no cases reported of severe aortic regurgitation, in-hospital death, stroke or emergency cardiac surgery, the primary efficacy endpoint (defined as a > 50% increase in the aortic valve effective orifice area or a ≥ 30% decrease in the mean aortic valve gradient and ≤ 2+ valvular regurgitation post-BAV) was only met in one third of the patients, with an average of ~6 mmHg reduction of transaortic gradient at discharge. This value is less than these reported by previous series using convectional aortic valvuloplasty balloons.[8] Unfortunately, a high proportion of patients left the study before the final follow-up, thus making it impossible to assess even the mid-term efficacy of BAV using this novel device. Also, it is not possible to draw a meaningful conclusion on the change in New York Heart Association (NYHA) functional class due to the small sample size and a high rate of early study exit.

The reasons for such somewhat disappointing results can be several: the first regards the methodology of the study, which encompasses a very small cohort of patients with poor adherence to the study protocol. The second probably stands in the mechanism of function of this device: The AngioSculpt valvuloplasty scoring balloon catheter incorporates a semi-compliant balloon with an attached nitinol spiral cage (scoring element). The scoring element has 12 spiral struts and four cross-linking stabilizing rings that wrap around the balloon. Theoretically, these struts should create focal amplification of the forces exerted by the valvuloplasty balloon along the edges of the scoring element. As for other valvuloplasty balloons, the predominant mechanism of dilatation of the AngioSculp balloon is the fracture of calcified nodules, the separation of fused commissures in rheumatic valve disease, and microfractures along stromal cleavage planes[10]; restenosis has been correlated, instead, to remodeling with fibrotic scarring of the fissures created by the balloon on calcified nodules, to a mechanism of heterotopic ossification and to the elastic rebound of the previously dilated aortic annulus.[10] According to the observations made by Htun and coworkers, a clinically significant and lasting reduction of the transaortic gradient probably cannot be obtained by only increasing the forces exerted by the scoring valvuloplasty balloon. The investigators used the most accurate strategies for choosing the correct balloon diameter (transesophageal echocardiography or computed tomography angiography), thus assuming that sub-optimal balloon sizing was not responsible for this minor effect on the post-procedure aortic gradients. It is also hard to tell if different valvuloplasty techniques (additional

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and more prolonged inflations) may translate in more favorable outcomes; for sure these can increase the risk of developing valve rupture and significant aortic regurgitation.

In conclusion, Htun and colleagues should be congratulated for exploring new solutions for a technique that also in the future will maintain its niche in the management of very complex populations affected by severe AS. This first-in-human study demonstrates only the feasibility of BAV using the AngioSculpt valvuloplasty scoring balloon catheter; however, larger and more accurate analyses should assess the real efficacy of this new technology in comparison with standard balloons.

Disclosure statement

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