Does radial balloon aortic valvuloplasty have a place in the TAVI era?

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After its first description from Cribier *et al* in 1986, balloon aortic valvuloplasty (BAV) became in the 1990s a common procedure worldwide for high-risk patients with severe aortic stenosis offering a relevant immediate reduction of the transvalvular gradients.[1] However, BAV exposes to a small risk of postprocedural severe aortic regurgitation while gradients return to significant levels in a high percentage of patients within a few months.[2] In a recent study, no difference was observed after 1 year between conservative treatment and BAV.[3] Thus, BAV indication is limited by the poor mid-term and long-term results due to the high rate of restenosis.

Regardless of these findings and the recent improvements of transcatheter valve replacement, which are now established even in low-risk patients, BAV procedures increased over the last years.[4] The reason is probably due to multiple factors. With the success of transcatheter aortic valve implantation (TAVI), primary care is more inclined to refer to tertiary centres high-risk and frail patients who were previously treated palliatively.[5] In this setting, a TAVI procedure may be considered futile and operators could opt for BAV, which requires fewer resources. In fact, in patients with severe comorbidities, BAV allows to evaluate whether the gradient reduction could impact the global clinical patient's condition. Moreover, BAV could have a diagnostic utility in low-gradient severe aortic stenosis with left ventricular impairment allowing to understand whether the left ventricle is able to recover after removing the afterload caused by the stenosis. A further reason of BAV diffusion worldwide is its use as a bridge to decision before urgent major surgery in patients with unclear prognosis. However, BAV exposes patients to periprocedural risks and vascular complications that must be considered in particular in light of its short-lasting results.

Tumscitz and colleagues present a new study aiming to assess the safety and feasibility of mini-invasive radial BAV.[6] A reduction of BAV complication burden may support and justify its use even in light of the limited long-term results. Of the 330 patients recruited in 16 centres, BAV was achieved through radial or ulnar access in 314 of the cases (95%). Authors report a reduction of the transvalvular gradient by at least 30% in 86% of the patients. Of note, no Valve Academic Research Consortium-2 major criteria occurred and most of the patients were mobilised within 24 hours. The investigators conclude stating that mini-invasive radial BAV is feasible, reduces vascular complication and allows fast mobilisation and discharge. The authors should be congratulated for providing such a novel data set on this interesting approach. However, some aspects of this study need further discussion.

The access success rate in this trial was surprisingly high. In fact, a large randomised study reported that in the less invasive coronary interventions, usually requiring a 6F sheath, radial access failure rate was higher than 5% and it increases in elderly women.[7] In how many elderly patients is an 8F or 9F radial access feasible? In particular, females are characterised by smaller radial artery that may not be suitable for radial BAV.[8] Providing radial size of the study cohort could add further information. A subanalysis or a further study should address this issue.

A second concern is that the maximum balloon size available with an 8F sheath is 20 mm (used in 87% of the study cohort). This could lead to balloon undersizing and consequently insufficient reduction of transvalvular gradients. Of note, the use of balloons larger than the aortic annulus in previous studies led to a significant improvement of the valvular area without increasing complications.[9] The balloon size limitation could drastically reduce the short-term benefits provided by the BAV procedure. The authors defined as success a reduction by at least 30% of the transvalvular gradient, achieved in 86% of the procedures. However, it remains unclear whether such a moderate gradient reduction is enough to provide clinical benefits and further studies should focus on this problem.

Another interesting aspect investigated by the author is that BAV could reduce symptoms and improve patients' fitness before TAVI. However, previous experiences showed limited benefits of preoperative rehabilitation before valve surgery in frail patients.[10] Only randomised trials can prove whether a two-step approach (BAV followed by prehabilitation and TAVI) is superior to the one-step TAVI treatment.

With the constant improvements in TAVI technology and materials, with smaller sheaths and better designs, TAVI costs and complications are expected to continue to decrease. In this context, can transradial BAV find its place in the interventionalist toolbox? Certainly, it will be an important procedure in different settings: first, to evaluate the clinical impact of transvalvular gradient reduction in patients with reduced ejection fraction and unclear functional reserve before definitive TAVI therapy; second, to allow urgent major surgery in severely ill patients with unclear prognosis; third, as a bridge to decision or to definitive surgical or percutaneous treatment in countries with limited technologies and budget. Moreover, transradial BAV may improve in the future allowing the use of smaller sheaths and larger balloons.

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