



## EDITORIAL COMMENT

# Balloon aortic valvuloplasty in the transcatheter aortic valve replacement era: A challenge to organization of the heart team<sup>☆</sup>



## Valvuloplastia aórtica de balão na era das válvulas aórticas percutâneas. Um desafio à dimensão organizativa dos programas multidisciplinares

Rui Campante Teles<sup>a,b</sup>

<sup>a</sup> *Unidade de Intervenção Cardiovascular (UNICARV), Hospital de Santa Cruz, CHLO, Carnaxide, Portugal*

<sup>b</sup> *Centro de Estudos de Doenças Crónicas (CEDOC), NOVA Medical School, Lisboa, Portugal*

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Balloon aortic valvuloplasty (BAV), first introduced by Cribier et al. in 1986, has seen a resurgence in popularity in the transcatheter aortic valve replacement (TAVR) era.<sup>1,2</sup> Thanks to improved training and technical advances, BAV is now safer, with periprocedural mortality of 2.2% and in-hospital mortality of 7.1%, and rates of stroke of 1.1%, severe aortic regurgitation of 1.1% and major vascular complications of 7.0%, even though today's patients are more complex and hemodynamic improvement remains modest.<sup>3,4</sup>

Given the increasing use of TAVR, the main challenges of BAV nowadays are related to organization of the heart team to treat aortic stenosis, the most common valve disease in developed countries. Portugal's population currently includes around a million people aged over 75 years, 3.4% of whom present severe aortic stenosis and of these, 75% are symptomatic.<sup>5</sup> Of these 25 000 individuals, around 4500 will have indication for TAVR due to high surgical risk or inoperability, according to the guidelines on valvular heart disease.<sup>6–8</sup> The Portuguese TAVR registry includes around

850 implantations from 2007 to 2015, 300 of which were performed in 2015. Although there is no national registry of cardiac surgery, it is estimated that approximately 2000 surgical aortic valve replacement (SAVR) procedures, either isolated or with bypass grafting, were performed in 2015. This corresponds to a BAV/SAVR ratio of 1:6, while the ratio in many other European countries is 1:15.<sup>9</sup>

The pressure on heart teams involved in TAVR has grown as they have had to adapt to an enormous increase in numbers of patients, many of whom do not have a primary indication for TAVR. The major issues to be addressed at present are:

1. Implementation of a fast track protocol, through which clinical assessment and the main diagnostic exams (cardiological and surgical consultations, laboratory tests, cardiac computed tomography, transthoracic and possibly transesophageal echocardiography, catheterization and possible angioplasty) can be performed in two or three sessions;
2. The indications for BAV in the latest guidelines of the European Society of Cardiology and the American College of Cardiology/American Heart Association on valvular heart disease (class IIb recommendation) do not reflect improved outcomes in the TAVR era.<sup>7,8</sup> Given that many of the associated complications may recur when initial BAV is followed by TAVR, the situations in which it is

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E-mail address: [rcoteles@outlook.com](mailto:rcoteles@outlook.com)

acceptable to subject a patient to the increased risk of BAV must be carefully considered:

- (a) BAV is only acceptable as a palliative measure to relieve severe symptoms (on compassionate grounds), or as a bridge to definitive treatment, due to a severe comorbidity, which may be temporary or have an uncertain prognosis, and/or the patient has an expected survival of less than a year (typically due to cancer or an urgent intervention that does not allow for dual antiplatelet therapy, or to enable very elderly patients with other significant and irreversible disease to be discharged home);
  - (b) all other indications for BAV should be carefully weighed, particularly those related to access to prompt treatment, which there is an obligation to provide, or if there are doubts concerning the benefit of TAVR as noninvasive methods can be used for the same purpose (most commonly to treat left ventricular dysfunction and/or severe mitral regurgitation);
3. Prompt and appropriate action in the event of complications: once the indication has been established, survival is 1-3 years in symptomatic patients.<sup>2,10,11</sup> Whatever the therapeutic option, however arbitrary the decision may be, the procedure should be performed within two weeks to two months, depending on severity. In the case of BAV, since this is a palliative procedure the possibility of clinical instability or complications that can be treated by TAVR – typically severe aortic regurgitation or stroke – must be borne in mind, and the heart team must be prepared to proceed with TAVR (an appropriate device being readied) and/or bailout surgery, as in TAVR.

The article by Francisco et al.<sup>12</sup> published in this issue of the *Journal* provides valuable information that enables the importance of BAV to be judged in the light of the above considerations. The study, a retrospective analysis of the experience of a high-volume TAVR center in patients who had undergone BAV, concludes that the procedure led to significant improvement in most patients.

The study's principal merit is that it is the first to analyze a Portuguese experience in the TAVR era. It is based on a single-center observational registry of 23 patients treated between January 2005 and October 2013, and compares outcomes with larger previous series of 45-473 individuals. Patients were followed for around nine months and the results were analyzed retrospectively.

The most frequent indication for BAV was as a bridge to definitive treatment (43% of cases), unlike most other series, in which the main indication was palliative, with only 18% as a bridge. Except for a higher prevalence of diabetes, this cohort is generally less complex than others, both demographically and clinically.<sup>3</sup>

In terms of technical details, the article does not specify how balloon size was determined or how rapid pacing was performed, particularly by what access route or the rate achieved, since a sustained pressure fall is crucial for stable balloon positioning. Undersizing the balloon by 1-2 mm allows for a less aggressive approach, which, together with smaller introducers and vascular closure devices, appears to be responsible for the reduced rate of complications seen nowadays.<sup>2,3</sup>

There was no periprocedural mortality or severe aortic regurgitation. There was one in-hospital death due to stroke (4.3%) and the rate of major vascular complications was 8.6%; it should be borne in mind that three refractory patients under mechanical ventilation were successfully extubated. The favorable course at nine months of the patients treated definitively by TAVR attests to the effectiveness of the stratification process and the reasonable outcomes now achieved with the technique.

In conclusion, the study by Francisco et al.<sup>12</sup> is significant for its analysis of the current risk associated with BAV in Portuguese patients in the TAVR era. Prediction of the risk of palliative treatment is important and heart teams should be organized in such a way as to provide a rapid response to patients with indication for TAVR, thus avoiding BAV as a palliative procedure for those awaiting definitive treatment by TAVR or SAVR, since complications remain significant despite the experienced gained.

## Conflicts of interest

The author has no conflicts of interest to declare.

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