

Editorial

## Bailout aortic balloon valvuloplasty – why without a stent-valve?

**Keywords:** Aortic balloon valvuloplasty; Stent-valves; Transcatheter aortic valve implantation; High-risk patient

Aortic valve stenosis (AS) is the most common acquired heart disease in the elderly and, because of the aging population, its incidence increased noticeably during the last decades [1,2]. The treatment of choice for patients carrying a severe symptomatic AS remains the open heart surgery for standard aortic valve replacement (AVR) with mean or mini-sternotomy, cardiopulmonary bypass, aortic cross-clamping and a valid cardioplegic arrest [3]. Advantages of this procedure are the full ablation of the diseased native aortic valve, the implantation of a reliable patient-matched biological aortic prosthesis and the evidence of very satisfactory mid-term and long-term results with low mortality and morbidity [4–8]. However, the elderly with concomitant severe comorbidities, left ventricular dysfunction and a critical preoperative state due to acute low cardiac output, carry a higher surgical risk with increased operative mortality and risk of onset of severe postoperative complications, such as renal or pulmonary insufficiency [5,6,9].

Hence, the very recent advent of transcatheter aortic valve therapies with minimal access procedures is most welcome in such a complex setting [10,11].

In fact, during the last decades, and in the absence of available transcatheter stent-valve therapies, alternative non-surgical procedures and medical protocols were proposed for the treatment of high-risk patients with severe AS and acute cardiac decompensation, judged as temporary inoperable patients. In particular, these procedures were developed to identify and treat, at first, the cause of the low cardiac output, and, subsequently, to improve the clinical and the hemodynamic effects of the AS and recovery the myocardial function before performing standard AVR.

The percutaneous balloon aortic valvuloplasty (BAV), performed few weeks before a standard AVR in temporary inoperable patients, seemed to be, at that time, an attractive alternative to urgent high-risk AVR, although a limited long-term valve function [12,13].

Doguet et al., in their limited series of 25 patients treated consequently with percutaneous BAV and standard surgical AVR, between 2002 and 2006, propose to re-introduce the primary BAV as an alternative bailout procedure in unstable, temporary inoperable, AS patients [14].

However, this approach has to be questioned with regard to efficiency and appropriateness.

In fact, percutaneous BAV carries some intrinsic risks related to the procedure itself, such as aortic valve regurgitation, peripheral vascular damages or calcium dislodgment from the valve leaflets. In addition, the hemodynamic results are, sometimes, not as good as required with no or little advantages for the patient in terms of improved left ventricular function, mean trans-valvular gradient and ameliorated aortic surface area [12–14]. Unfortunately, patients exposed to urgent BAV (and to the risk related to the procedure) with absence of post-BAV clinical improvements require further hospitalizations with dedicated medical treatments before undergoing surgical AVR, or need urgent valve replacement because of the hemodynamic deterioration.

Furthermore, percutaneous BAV has some technical limitations, such as the presence of severe peripheral vascular disease (typically in the elderly), and not all patients are good candidates for this ‘bridge-to-AVR’ transvascular procedure, as well underlined by Doguet et al. in their paper [14].

In such complex scenarios, the new transcatheter aortic valve implantation (TAVI) therapies have great potential and in many centers the implantation of transcatheter stent-valves, either through a transfemoral or a transapical access, has become a ‘routine’ procedure with encouraging early end mid-term results [15,16].

Thus, in the era of transcatheter stent-valves the treatment of decompensate aortic stenosis may be stratified as follows.

### 1. First scenario: elderly patient with AS and cardiogenic shock

#### 1.1. The patient fulfils the guidelines for TAVI (high-grade risk score) [3]

Primary TAVI, consisting of BAV plus stent-valve implantation under rapid pacing (Fig. 1), either via a transapical or a transfemoral access, represents, in this setting, the ideal

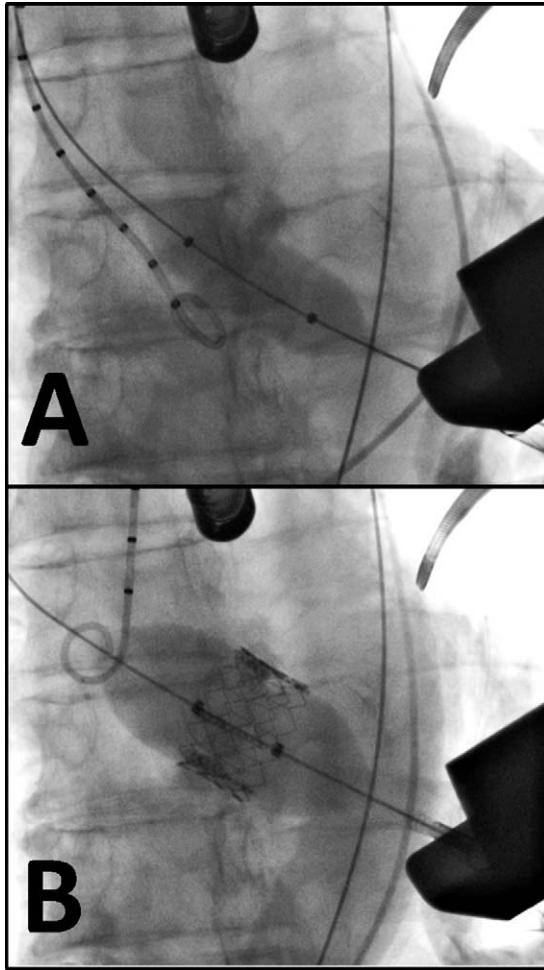


Fig. 1. Fluoroscopy views taken during a transapical TAVI. The balloon aortic valvuloplasty (A) is performed immediately before the stent-valve implantation (B).

strategy for elderly patients with decompensate isolated AS carrying a high logistic euroSCORE (above 20%), and suitable for a biological heart valve implantation. In fact, once the technical skills are acquired by the team, primary TAVI in unstable high-risk patients is the logical step-forward instead of performing percutaneous BAV as a bridge to open AVR. In our 2-year clinical experience with transapical TAVI (62 cases), 5% of patients were in critical preoperative state with severely decompensate AS and low cardiac output [17]: in all but one patients, the hemodynamic improved remarkably immediately after the stent-valve implantation with decreased inotropic drug infusions, improved mean blood pressure and improved left ventricular function.

### 1.2. The patient does not full-fills the guidelines for TAVI [3]

Patients with e.g. apical thrombus and severe peripheral vascular disease are not suitable for any kind of TAVI (the trans-subclavian pathway remains, at the time being, an off-label use). In this rare scenario, a standard AVR in urgency remains a valid option but, alternatively, a bailout percutaneous BAV performed through a subclavian or a humeral

access prior to standard AVR can be also taken into consideration.

## 2. Second scenario: younger patient with AS and cardiogenic shock

Despite frequent surgical exceptions in the clinical practice, younger patients with isolated AS and low logistic euroSCORE (below 20%) are not yet considered good candidates for TAVI because of the unknown durability of the available implants. The following clinical situations should be distinguished.

### 2.1. Young AS patient in cardiogenic shock without multi organ failure (low-grade risk score) and resistant to the optimal medical therapy

This scenario requires a standard AVR in urgency with a mechanical heart valve implantation. Following our experience, the standard operation is well tolerated and the patient recovery will benefit from the hemodynamic ameliorated after the valve replacement. AVR performed in urgency requires optimal strategic thinking from the surgeon and a valid team-work involving the surgeon, the anesthesiologist and the intensive care unit team. In case of concomitant disease (e.g. coronary disease or dilated ascending aorta), the procedure can be performed temporarily.

### 2.2. Young AS patient in cardiogenic shock and multi organ failure

In this critical situation, the use of cardiopulmonary bypass for surgical AVR is not encouraged and urgent BAV for restoration of the patient's hemodynamic, appears to be an option as long as no randomized trial is available. However, an urgent transapical or transfemoral TAVI has also to be taken into consideration as a rescue procedure in case of failed BAV, or primarily.

Now, if we look at the Doguet's series of patients treated with a bailout BAV as a bridge to surgical AVR and limited availability of transcatheter aortic stent-valves, we would have to look at them differently today. All of them carry a high-risk profile with a mean logistic euroSCORE of 18.6% and the majority is certainly suitable for biological valve prosthesis (mean age: 71.9 years). In particular, patients presenting with pulmonary edema, global cardiac decompensation, cardiogenic shock and syncope are good candidates for TAVI. Only one case, the patient with a very low ejection fraction (below 10%) did obviously not fit the guidelines for TAVI and the urgent BAV was the procedure of choice. One more patient underwent a Bentall procedure and, also in this case, the BAV appears to be the suitable treatment prior to replacement of the aortic valve and the ascending aorta.

In conclusion, TAVI procedures are the logical evolution of percutaneous BAV but, unlike the latter, they allow for a rapid recovery of the patients' valve hemodynamic, once the stent-valve is in place (low trans-valvular gradient and absent or trivial valve insufficiency).

Obviously, the landscape of aortic valve therapies is changing rapidly and we trust that new technologies will further improve the outcome for our patients.

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