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# Balloon aortic valvuloplasty: modern indications and techniques for a niche therapy

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**“...the immediate hemodynamic and symptomatic gains achieved by balloon aortic valvuloplasty were not durable...”**

Degenerative aortic stenosis (AS), previously termed ‘senile’ AS, is the most common clinically significant cardiac valvular lesion in developed countries [1], and there are no effective medical treatments for the disorder. Definitive therapy via traditional operative aortic valve replacement (AVR) is recommended for patients with severe symptomatic AS who are not at high risk of perioperative mortality or morbidity [2]. AS is predominantly a disease of old age; elderly patients comprise an increasing proportion of subjects considered for AVR. While the guidelines specify that advanced age should not be considered a contraindication to AVR [2], the elderly are at increased risk of operative mortality and morbidity [3,4] and poor quality of life after surgery. Transcatheter aortic valve implantation (TAVI) is currently being offered only in select centers as an alternative to traditional AVR in high-risk patients. While the technology is promising, to date there are no published randomized outcome data comparing TAVI to standard therapy.

## History of balloon aortic valvuloplasty

Percutaneous balloon aortic valvuloplasty (BAV) was first described as an alternative to AVR in 1986 [5], concurrent with the emerging interest in catheter-based therapy for coronary disease. The original technique described retrograde transfemoral valvuloplasty with a noncompliant balloon. The cardiology community adopted BAV with some enthusiasm initially, as there were acceptable improvements in post-procedural symptoms and hemodynamics.

In fact, subjects in the largest registry, maintained by the National Heart, Lung and Blood Institute (NHLBI) [6], had a mean age of 78 years, suggesting that BAV may have been offered as an alternative to AVR patients at lower risk. However, the early interest in BAV waned quickly, even within the first 3 years of the technique [6], for several reasons. Chief among these was the realization that the immediate hemodynamic and symptomatic gains achieved by BAV were not durable; virtually all subjects developed severe and symptomatic restenosis within the first year [7]. BAV could therefore not be considered a viable alternative to AVR in surgical candidates.

**“The development of transcatheter aortic valve implantation has led to a renewal of interest in balloon aortic valvuloplasty.”**

The NHLBI registry also demonstrated high rates of acute complications from BAV [6]. Procedural mortality was 3%, and major hemodynamic or arrhythmic complications occurred in up to 25% of patients. Importantly, local vascular complications were not uncommon at the site of the femoral arteriotomy: 20% of patients required a transfusion and 5% operative vascular repair.

## Contemporary & experimental techniques in BAV

The development of TAVI has led to a renewal of interest in BAV. Valvuloplasty is performed during TAVI, and many centers

are reporting increased volumes of BAV procedures in preparation for acquisition of TAVI. Several new techniques have been described that aim to improve the durability of the therapy and/or reduce complications.

We recently published the results from an initial series of 20 subjects who underwent BAV using a low-profile balloon [8]. The Tyshak® balloon (NuMED, NY, USA) is a thin-walled, compliant balloon initially designed for pulmonic valve dilatation in the pediatric population. Owing to its low profile, the balloon can be inserted through a smaller sheath than traditional aortic valvuloplasty devices, 8 or 9 French for a 22 or 23-mm diameter balloon, respectively. In our study of predominantly elderly subjects (mean age: 79 years), the average estimated mortality from AVR was 12.5% owing to high rates of concomitant comorbidities leading to increased risk from AVR. Procedural and fluoroscopy times were short (80 and 18 min, respectively), despite the fact that more than half of the patients underwent additional catheter-based investigation or intervention. Small sheath sizes allowed simple vascular closure in the majority of patients.

**“...the average estimated mortality from aortic valve replacement was 12.5% owing to high rates of concomitant comorbidities leading to increased risk from aortic valve replacement.”**

Using the Tyshak balloon, we demonstrated significant improvement in hemodynamics: a reduction in mean aortic gradient by 42% to a mean of 30 mmHg, and an increase in aortic valve area of 43% to a mean of 0.89 cm<sup>2</sup>. This was associated with symptomatic improvements in the majority of patients, with mean New York Heart Association functional class improving from 3.5 to 2.7. Importantly, the procedure was relatively safe: there were no procedural deaths and no cases of acute severe aortic incompetence. In-hospital mortality was 5%. Complete heart block necessitating implantation of a pacemaker occurred in one patient, and balloon rupture occurred in one procedure. We observed no vascular complications in our cohort, which compares favorably with the NHLBI registry and also a contemporary study, which showed an in-hospital mortality rate of 18% with a 16% rate of major vascular complications [9].

Another valvuloplasty technique that has been used in recent years is an antegrade trans-septal approach. Traditional aortic valvuloplasty or Inoue balloons may be used [10]. Because the principal vascular puncture is venous, this procedure may be advantageous in subjects with severe peripheral arterial disease who may be at higher risk of vascular complications. However, the antegrade approach is more technically demanding than the retrograde procedure, and does carry a risk of complications of trans-septal puncture. In addition, while a small study suggested that an antegrade approach resulted in greater acute hemodynamic gains than the retrograde procedure [11], the most recent and largest published comparison demonstrated no significant difference in hemodynamic improvements [9].

Rapid ventricular pacing using a temporary transvenous electrode is another recent improvement to the BAV technique [12]. Pacing at between 180 and 220 beats/min greatly reduces antegrade

blood flow through the aortic valve; this reduction in cardiac output allows for more precise positioning of the valvuloplasty balloon prior to inflation and, during inflation, decreases the risk of cardiac injury due to balloon movement. The efficacy and safety of rapid pacing has been examined by Wtitzke *et al.*, who found that while pacing tends to improve the accuracy of balloon position and reduces the number of inflations, procedures performed during rapid pacing resulted in a lower final aortic valve area than those performed without [13]. Pacing did not appear to be associated with any prolonged adverse hemodynamic consequences.

Studies have also been conducted examining methods to decrease restenosis following BAV. Pedersen *et al.* examined the role of external beam radiation therapy after BAV in 20 patients [14]. Restenosis appeared reduced in the high-dose group compared with the low-dose group, but the study suffered for a lack of a true control group. Spargias *et al.* reported decreased restenosis in pigs after valvuloplasty with a balloon coated with paclitaxel, a lipophilic antimitotic agent [15]. This technique has not yet been tested in man.

### Modern indications for BAV

In view of recent advancements in BAV techniques, what are the indications for the procedure in contemporary practice? BAV can still not be recommended as primary therapy for severe symptomatic AS in patients with acceptable operative risks during traditional AVR. TAVI should be considered in patients at prohibitively high surgical risk. In this group, BAV is performed during the definitive procedure but should not be recommended as sole therapy.

**“Balloon aortic valvuloplasty can still not be recommended as primary therapy for severe symptomatic aortic stenosis in patients with acceptable operative risks during traditional aortic valve replacement.”**

We feel that BAV has a role for palliation of patients with severe symptoms who are at unacceptably high risk from AVR and who do not have access to or have contraindications to TAVI. BAV may be used to ‘buy time’ for patients until TAVI becomes more freely available. The technique will continue to have a role for patients with acute hemodynamic compromise due to AS, either cardiogenic shock or refractory heart failure. We also consider BAV in patients with severe AS who must undergo significant noncardiac procedures; for example, major surgery or intensive chemotherapy, prior to which traditional AVR is not feasible. BAV may also be used for diagnostic purposes in subjects with AS but other potential causes for their symptoms, such as severe lung disease; a temporary improvement in symptoms after BAV supports AS as the cause.

### Conclusion

Balloon aortic valvuloplasty has a ‘niche’ role in the management of degenerative AS. While it still cannot be considered definitive therapy, recent advancements, such as the use of low-profile balloons and rapid right ventricular pacing, have made the procedure safer and easier.

# Financial & competing interests disclosure

The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes

employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

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