

Balloon aortic valvuloplasty in the era of transcatheter aortic valve implantation (TAVI): an opportunity to revisit a previously discouraged treatment option

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CLINICAL VIGNETTE

A 74-year old man was referred to our unit with a short history of progressive dyspnoea, NYHA grade 4 at the time of referral. He had a past medical history of bladder resection for malignancy and had a functioning cystostomy. Clinical examination revealed signs of aortic valve stenosis (AS) which was confirmed with echocardiography: His LVEF was only 15% with severe AS evidenced by a valve area of 0.5cm². The mean gradient over the valve was 20mmHg in keeping with low gradient-low flow AS.

Angiography revealed critical stenosis at the bifurcation of the left main stem. His log EuroSCORE predicted 30-day mortality was 40%. He was presented at our multi-disciplinary cardiothoracic surgery meeting for aortic valve replacement and coronary artery bypass grafting. Due to the high risk for the procedure he was turned down. As we do not have access to transcatheter aortic valve implantation (TAVI) at our academic institution I recommended medical treatment. The patient was adamant that this was unacceptable as he was still employed and depended on his income. After obtaining written informed consent we proceeded to perform left main bifurcation stenting with 2 bare

ABSTRACT

Balloon aortic valvuloplasty (BAV) was described in the 1980's but early enthusiasm was kerbed by results indicating risk of stroke and early restenosis. It therefore fell out of favour and is only indicated as a bridge to definitive treatment in the majority of cases. With the advent of transcatheter aortic valve implantation (TAVI) as a new form of definitive treatment in high risk patients with aortic stenosis, there may be a new role for BAV. SAHeart 2012; 9:96-99

metal stents. This was followed by balloon aortic valvuloplasty (BAV) with a 22 x 40mm Tyshak™ balloon (Nu-Med™ Hopkinton, NY) under rapid ventricular pacing. The patient tolerated the procedure poorly with systolic blood pressures of 60mmHg. He recovered well though and at one month post procedure his functional class had improved to NYHA class 2. At repeat transthoracic echocardiography the mean gradient over the aortic valve had increased to 33mmHg with an increase in his LVEF to 35%. He was subsequently re-presented and accepted for conventional surgery in the form of prosthetic aortic valve replacement.

BACKGROUND

BAV was first performed in the 1980s with a number of groups describing fairly large series of experience with this procedure in a short period of time.⁽¹⁻⁵⁾ BAV enlarges the stenosed valve orifice by 3 mechanisms: Stretching of valve tissue; rupturing of commissural fusion; and release of calcific deposits. The last mechanism is probably the most effective in both tricuspid and bicuspid forms of AS to render the cusps more flexible and able to open and close effectively. Letac, et al. demonstrated on both fresh post-mortem specimens and also on post-mortem examination of cases that had had balloon valvuloplasty during life, that the marked increase in valve area obtained by the dilatation procedure was due to this mechanism.⁽³⁾ Three dimensional volume-rendering computer tomography has further added to our understanding of the pathophysiology that calcification stretching into the surrounding aortic

vascular wall limits the movements of the valve cusps and that it could, in all likelihood, also be improved by BAV.

COMPLICATIONS

Severe AR after the dilatation is fortunately rare (2% in the early series) but may be very poorly tolerated by the patient. Stroke can be a devastating complication but determining accurate rates is difficult as this complication tends to be underreported.^(2,5,6) Letac found in their series of 213 patients that only 3 patients developed acute strokes during the procedure but late stroke was not reported. The best data is probably from the NHLBI registry where stroke was encountered in 3% of cases.⁽⁷⁾ Other investigators did not comment on this complication. This initial enthusiasm was kerbed by a report of 84 patients by Block and Palacios, who found that although all cases had immediate improvement in symptoms, at a mean follow up of 5.5 months there was recurrence of symptoms, death or haemodynamic evidence of restenosis at repeat catheterisation in 56% of their patients.⁽⁶⁾ An attempt at slowing down the restenosis rate was made by using external radiation as described in the Radiation Following Percutaneous Balloon Aortic Valvuloplasty to Prevent Restenosis (RADAR) pilot trial. Restenosis in the RADAR pilot study was 20% at 12 months in a population with an average age of 89 years suggesting utility in elderly patients.⁽⁸⁾ This finding has however not been validated by others and is not widely used. The rapid rate of restenosis has led to a reduction in the number of BAV procedures performed and as a rule BAV should not be offered as standalone treatment.

DOES THE DARK CLOUD HAVE A SILVER LINING?

With the advent of transcatheter aortic valve implantation (TAVI) as a definitive treatment option for high risk patients with degenerative AS should we reconsider our indications for BAV? During the TAVI procedure the patient is exposed to a BAV as predilatation, but in contrast to isolated BAV this is offered as part of a definitive treatment plan. Another question raised is what the impact of newer techniques and equipment would have on procedural safety. Several technical and procedural improvements are now available for BAV that did not exist 20 years ago when Cribier first described the procedure.⁽⁹⁾ Rapid ventricular pacing

(180 to 220 beats per minute) is now utilised to arrest mechanical systole to preserve balloon stability across the aortic valve during inflation. Furthermore, inflation–deflation times are faster (generally 3 seconds as opposed to an average of 23 seconds in the NHLBI registry of 674 cases).⁽⁷⁾ The procedure is no longer performed via an antegrade transvenous route and modern balloons can be passed through sheaths as small as 7-French.

Cribier's group published a further cohort 10 years after the initial procedure: Of 86 patients ≥ 80 years of age who received BAV via the retrograde approach, no myocardial perforations occurred and only 1 patient developed severe aortic regurgitation. Of these 86 patients only 1 suffered stroke and the overall periprocedural mortality was 2.2%.⁽¹⁰⁾ Whether this indicates a temporary satisfactory result in patients who are not candidates for valve replacement is debatable, however this procedure is offered to numerous patients in some centres with some even advocating repeated procedures as a reasonable option.⁽¹¹⁾

The landmark PARTNER trial of TAVI versus standard medical treatment was in fact criticised for the fact that the standard treatment arm included BAV in 84% of patients. This certainly does not reflect standard treatment in South Africa. It is noteworthy that balloon aortic valvuloplasty changed from a class III to a class IIb recommendation in the most recent guidelines of the American College of Cardiology and American Heart Association (AHA)⁽¹²⁾ and is also a class IIb recommendation in the European Society of Cardiology Guidelines⁽¹³⁾ in the setting of severe AS.

ESTABLISHED INDICATIONS FOR BAV

There are a small number of clinical scenarios in which it remains appropriate to perform BAV.⁽¹⁴⁾ These include young people with sub-aortic ridges or mobile valve leaflets and patients with critical AS who require other urgent high risk surgical procedures where aortic valve replacement is not an option. In the latter group a multi-disciplinary team approach to evaluate the different treatment options is absolutely mandatory.⁽¹⁵⁾ These indications are however, not the focus of this discussion.

Potential new indications for BAV in the TAVI era include:

- **Patients who do not qualify for TAVI on grounds of poor LV function or haemodynamic instability.** Both the Edwards SAPIEN™ and Medtronic™ CoreValve™ devices are registered to be used in patients with an ejection fraction of greater than 20%. In unstable cases who are otherwise potentially suitable candidates for TAVI our group has performed BAV with good results. The patient is afforded the time to stabilise, with usually an increase in systolic function, and the option of either TAVI or even open valve replacement can be performed under much more controlled circumstances.
- **To evaluate the contribution AS makes to a patient with multiple comorbidities that may be responsible for symptoms.** TAVI candidates very often have a multitude of comorbidities that may cause dyspnoea and there is often doubt as to whether the AS is a significant contributor. Echocardiography performed by a skilled operator can usually provide a reasonable answer to this question, but in selected cases uncertainty may remain. In these rare cases BAV may be performed as a “diagnostic” procedure to determine the contribution the AS makes to symptoms of breathlessness. Justifying the risk of BAV in this setting has to be done in conjunction with an informed patient. It has been our experience that in patients with multiple comorbidities where BAV was used as a tool to stabilise them, non-response to BAV was almost invariably associated with a poor response to TAVI. Although this has not been described by others our team has incorporated a poor response to BAV as a relative contra-indication to TAVI.
- **Buying time for a patient who is unwell and awaiting TAVI.** The TAVI procedure is often delayed for a number of logistical reasons, including: Waiting for a proctor to be available to help with the case; waiting for the correct size device to become available; and waiting for funders to decide if a procedure will be funded. In such cases it is reasonable to offer the patient BAV if the clinical condition is such that a prolonged delay is deemed a significant risk.

- **To evaluate if a patient with AS of uncertain severity will respond to TAVI.** Elderly patients with calcified aortic valves often present a diagnostic dilemma with regards to AS severity. Paradoxical low gradient with good ejection fraction is one such scenario. Despite all the diagnostic tests available, including valvulo-arterial impedance, transoesophageal echocardiography and dobutamine stress echo there sometimes is uncertainty as to whether the AS is truly severe. We have used BAV in such cases and if the patient has a clear symptomatic response to BAV we would offer TAVI.

CONCLUSION

BAV is a procedure that fell out of favour 10 years after first being used because of rapid restenosis rates and the perception that it carries a high risk. Due to improvements in technique and the new modality of TAVI it may however be considered as a bridge to definitive treatment in specific clinical scenarios.

Conflict of interest: none declared.

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