CLINICAL REVIEW

Aortic valvuloplasty – is a revival merited?

Richard J Jabbour, Dion Stub, Antony S Walton

Authors

Richard J Jabbour
Foundation Year 2

St Mary's Hospital, Imperial College Healthcare Trust, London, W2 1NY

Dion Stub
Cardiology Research Fellow

Baker IDI Heart Diabetes Institute & Alfred Hospital, Commercial Road, Melbourne, Victoria 3004, Australia

Antony S Walton
Consultant Cardiologist

Epworth Hospital, Level 6, 89 Bridge Road, Richmond 3121, Victoria, Australia

Correspondence to:
Dr R J Jabbour
(richard.jabbour03@imperial.co.uk)

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Balloon aortic valvuloplasty (BAV), first developed last century for the management of symptomatic aortic stenosis, was met with great enthusiasm due to its new and minimally invasive technique, but it has now largely been abandoned due to suboptimal results and a high restenosis rate. However, with the development of new techniques and the arrival of transcatheter aortic valve implantation (TAVI), BAV's use is starting to increase. In this article we put forward the case for a revival in BAV by exploring the traditional uses and safety of BAV as a procedure as well as a novel role as a bridge to TAVI.

Introduction

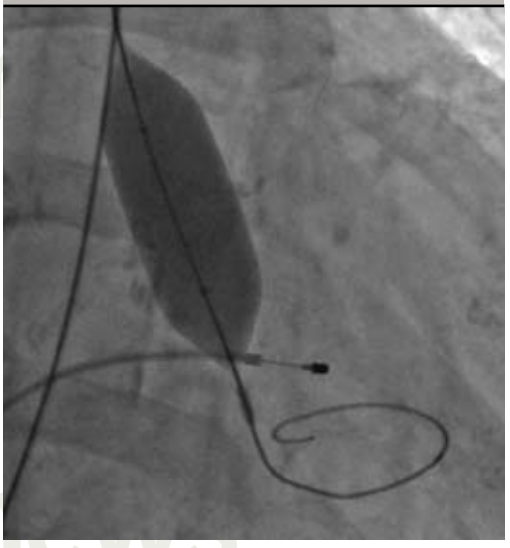
Balloon aortic valvuloplasty (BAV) was first developed by Alain Cribier over 30 years ago for the management of aortic stenosis (AS).[1] It was initially met with great enthusiasm due to its minimally invasive nature and possible alternative to surgery, but later fell from grace due mainly to high restenosis and complication rates. In addition, suboptimal results were obtained when compared with surgical aortic valve replacement (SAVR).[2] However, the evolution of techniques and devices culminating in transcatheter aortic valve implantation (TAVI) has drastically shifted the treatment options for high-risk patients with severe AS.

TAVI is a rapidly developing procedure, with which extensive criteria exist for assessing suitability.[3] BAV is used during TAVI to increase the orifice area of the native valve pre-implantation of the stent-based valve. TAVI has reinvigorated the use of BAV by interventional cardiologists as a means of improving symptoms, bridging patients to eventual SAVR, or as part of the TAVI procedure. A revival in the use of BAV is warranted in selected patients for the management of symptomatic AS.

History

The two main registries used last century to evaluate BAV were the National Heart Lung and Blood Institute (NHLBI) and the Mansfield Scientific.[4,5] The registries contained several hundred patients (674 *vs.* 492) of which many were non-surgical. The results showed

Figure 1. Balloon aortic valvuloplasty (BAV) via the retrograde approach. After correctly positioning across the stenotic valve the balloon is inflated with dilute contrast material. Note the temporary pacing wire in the right ventricle and the pigtail shaping of the left ventricular wire



that BAV improved both aortic valve area and haemodynamic status significantly, however, when compared with surgery the results were inferior. In addition, the complication rates were high (>20%), the most common of which was bleeding from the femoral artery site. Less common complications included stroke, emboli and ventricular perforation. Furthermore, BAV had no real effect on mortality when compared with the natural history of patients with symptomatic AS,[6,7] and the restenosis rate was unacceptably high (approximately 80% in 15 months).[8] These factors culminated in the decline of BAV, and to date BAV has largely been abandoned in most centres.

Method

BAV is an interventional procedure that involves the inflation of a balloon across a stenotic valve, thereby increasing the orifice area. The exact mechanism by which the orifice is increased is, however, unknown.[2] The retrograde approach is the main approach used,

Table 1. Haemodynamics before and after aortic valvuloplasty. *p<0.05 when compared with baseline

	Before	After	Change
Mean aortic valve gradient (Cath)			
Mean ± SD (mmHg)	43 ± 18.07	25 ± 14.36*	–18 ± 9.43
Range	20–97	11–55	
Mean aortic valve gradient (Echo)			
Mean ± SD (mmHg)	52 ± 16.34	44 ± 14.9*	–8 ± 16.43
Range	25–100	6–69	
Peak-to-peak aortic gradient			
Mean ± SD (mmHg)	45 ± 19.8	25 ± 13.19*	–20 ± 12.78
Range	17–83	5–49	
Aortic valve area			
Mean ± SD (cm^2)	0.58 ± 0.12	0.75 ± 0.14*	+0.17 ± 0.16
Range	0.4–0.9	0.5–1.0	

involving the femoral artery and the positioning of a guide wire across the valve from the aorta and inflation of the balloon afterwards (**figure 1**). Early techniques involved large catheters and guide wires leading to greater complications, which included strokes and bleeding from the femoral puncture site. The introduction of smaller catheters (10–12F) and vascular closure devices have reduced these complications. In addition, rapid ventricular pacing, a technique where the ventricle is paced rapidly between 180 bpm and 220 bpm arresting the ventricle temporarily to enable the balloon to be inflated quicker and less often, as well as preventing the dislodgement of the balloon from the orifice of the valve, has further reduced complications (**figure 2**).[9]

Current guidelines

Current guidelines from the European Society of Cardiology (ESC) state that BAV has Class IIb recommendations in patients who are haemodynamically unstable as a bridge to surgery or in patients with severe symptomatic AS who require urgent major non-cardiac surgery, but state that BAV could only be considered in non-surgical candidates as a palliative measure.[10] Similar guidelines exist from the American College of Cardiology/American Heart Association (ACC/AHA), but an additional Class IIb recommendation exists as a palliative measure in non-surgical patients with AS.[11]

BAV as a bridge to TAVI

At present no guidelines exist regarding BAV as a bridge to TAVI. Registry data indicate TAVI to be a safe procedure for high-risk patients, including octogenarian and nonagenarian patients with severe AS.[12] There are a number of clinical, anatomical and device restrictions that may deem some patients temporarily or permanently unsuitable for TAVI. In some cases BAV can be used as a bridging procedure to eventual TAVI. Although significant questions remain regarding bridging BAV to TAVI, the technique has provided another therapeutic option in high-risk patients.[13,14]

Australian series

In the last five years at three major centres in Melbourne, 51 cases (22 males, 29 females) of mean age 82 (26–97) years have undergone BAV, with a large proportion of our cohort being acquired in the last year due to the arrival of TAVI. All were non-surgical candidates, with contraindications ranging from severe heart failure, redo surgery, porcelain aorta, refusal of surgery, advanced age, frailty, sepsis, and malignancy. Femoral artery access was used with 10–12F sheaths in all cases and balloon sizes varied from 18 mm to 25 mm. In addition, rapid ventricular pacing was used and vascular closure devices such as PROSTAR XL™ (AbbottCorp, Redwood City, CA, USA) utilised for haemostasis.

Figure 2. Aortic and left ventricular traces pre- and post-valvuloplasty. The mean aortic pressure gradient has reduced significantly from 50 mmHg to 25 mmHg

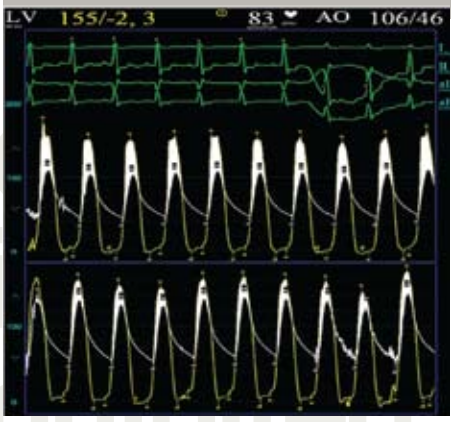
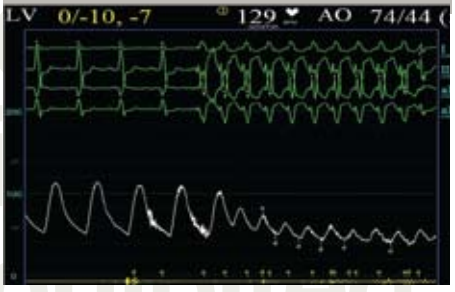


Figure 3. Rapid ventricular pacing stabilises the balloon when it is inflated. A pacing catheter is placed in the right ventricle. Rapid ventricular pacing is initiated at approximately 180–220 bpm and temporarily leads to a drop in systemic pressure. The balloon is inflated only after the pacing rate is reached and the blood pressure drops, and pacing is also continued until the balloon is deflated



Our results show that the mean aortic pressure gradient fell from 52 to 44 mmHg (p<0.05) when determined by echocardiography, and 43 to 25 mmHg (p<0.05) during catheterisation. The peak-to-peak gradient fell from 45 to 25 mmHg (p<0.05), and aortic valve area increased from 0.58 to 0.75 cm^2 as determined by echocardiography (p<0.05) (**table 1**). Although these benefits are modest, the symptomatic benefit is what is most striking in the series with 100% of surviving patients in New York Heart Association (NYHA) I/II at time of discharge.

Three repeat procedures were used at an average of six months after the first valvuloplasty due to a return of symptoms. Procedural mortality was 2% (n=1), and survival to discharge was 92%. One death was attributable to retroperitoneal bleeding and co-morbidities. The remaining causes of death were unrelated to the procedure and included sepsis, renal failure, intractable heart failure and pneumonia. Non-fatal complications (10%) were related to the site of entry of the femoral sheath. Surgery was required in two cases (4%), involving closure of the femoral artery and correction of an arteriovenous fistula. Of note, no strokes were suffered by any of the patients. An important point of our experience is that with the arrival of TAVI and the use of BAV as a prerequisite to implantation, our complication rates have reduced with only one complication of minor bleeding occurring in the most recent 30 patients of our dataset. This suggests that in our experience, when the use of TAVI proliferates, the procedure will facilitate interventional cardiologists being able to perform BAV with a very low complication rate.

Clinical case

An 80-year-old woman presented for pre-operative assessment before hysterectomy for uterine cancer. She had no history of cardiac disease but described mild NYHA II heart failure symptoms. An echocardiogram revealed a left ventricular ejection fraction of 60% with severe AS; mean pressure gradient 50 mmHg and aortic valve area of 0.6 cm^2.

The patient did not wish to undergo open SAVR. The patient was offered BAV to which she and her family consented. A retrograde approach with a 20 mm balloon was used. One inflation was performed across the aortic valve during simultaneous rapid ventricular pacing at 220 bpm. The post-valvuloplasty mean gradient was reduced to 25 mmHg, and the aortic valve area increased to 0.95 cm^2 (**figure 3**). The patient underwent uncomplicated hysterectomy and salpingo-oopherectomy for stage 1a uterine cancer. Four months later, recovered from her laparotomy, the patient again refused open SAVR. She, therefore, underwent retrograde percutaneous aortic valve replacement with a 26 mm CoreValve without complication. Three months post-procedure the patient is NYHA I. An echocardiogram revealed a left ventricular ejection fraction of 70% and a well-seated CoreValve with mean aortic pressure gradient of 6 mmHg and aortic valve area of 2.3 cm^2.

Discussion

In an era of TAVI, the option of 'medical management' for very high-risk or elderly patients with severe AS has decreasing clinical utility. With careful case selection and evolving techniques, BAV has an important role in non-surgical candidates with AS. Whether it is as a bridge to SAVR or TAVI, part of the TAVI procedure or merely to improve symptoms, BAV will have an increasing role in managing severe AS

Conflict of Interest

None declared.

Key messages

- Until recently, balloon aortic valvuloplasty (BAV) has had limited clinical utility due to high restenosis and complication rates
- BAV can be performed safely and effectively as the procedure has evolved
- BAV can be used as a bridge to transcatheter aortic valve implantation (TAVI)

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