Original Article

Balloon Aortic Valvuloplasty in Adults—A 10-Year Review of Auckland's Experience

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Background: **Patients with severe aortic stenosis, ineligible for surgical aortic valve replacement (AVR), may instead be offered balloon aortic valvuloplasty (BAV). However, initial international enthusiasm for BAV has waned due to early restenosis and symptom recurrence.**

Methods: **We retrospectively reviewed consecutive adult patients who had BAVs in Auckland over a 10-year period from 1997 to 2006 and recorded their clinical, echocardiographic, haemodynamic and follow-up data.**

Results: **Twenty-nine patients (17F) underwent 35 BAV procedures. There were 26 elderly patients (mean age 87; median logistic EuroSCORE 26%) and 3 patients requiring "bridging" prior to intended AVR at a later interval. Mean changes in left ventricular systolic pressure, aortic systolic pressure and mean gradient were −8%, +16% and −43%, respectively. In the 26 elderly patients, median time to death or recurrence of symptoms was nine months. There was a significant reduction in the number of cardiac-related admissions six months after BAV compared to six months before ($p = 0.02$). Actuarial survival of the elderly patients at 6 months, 1 year and 2 years was 88%, 64%, 31%, respectively. Complications of BAV were 2 reversible neurological events, 2 haematomas and 1 pseudoaneurysm. Re-do BAVs in 5 patients on ≥2 occasions resulted in an improved median actuarial survival of 36 months.**

Conclusion: **In our experience, BAV has a useful role in symptom palliation in severe aortic stenosis when surgical valve replacement is declined or inappropriate, and can be performed in selected patients with relatively few complications. Re-do BAVs in suitable patients may prolong symptom relief and survival.**

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Keywords. Balloon aortic valvuloplasty; Aortic stenosis

Introduction

Percutaneous balloon aortic valvuloplasty (BAV) was first described in 1986 [1,2] as an alternative treatment for severe aortic stenosis (AS) in the elderly but initial enthusiasm quickly waned due to significant complication rates and poor mid-term results caused by restenosis [3,4]. BAV has since been proposed as a short-term palliative procedure in patients who have prohibitive surgical risk and has been given a Class IIb recommendation in the American College of Cardiology/American Heart Association guidelines on management of valvular heart disease [5]. With increasingly acceptable surgical outcomes in the very elderly, BAV is now uncommonly performed as a primary procedure. The Euro Heart Survey of valvular heart disease revealed no single BAV procedure carried out during a four-month period in 2001 [6]. However, some centres have persevered with this procedure and, with refined technical factors and improved experience, recent studies have demonstrated that BAV can retain a useful palliative role with low procedural complications [7,8]. Furthermore, re-do BAV has been advocated to prolong symptom-free survival. In more recent years, BAV is routinely performed as a prelude to percutaneous aortic valve replacement (AVR) but might still continue to be preferred as a sole procedure in some circumstances.

We describe our own experience of BAV over a 10-year period, when general enthusiasm had reached its nadir, and report the clinical features and immediate and mid-term outcomes.

Methods

Twenty-nine consecutive adult patients with severe symptomatic AS had a total of 35 BAV procedures performed by the Green Lane Cardiovascular Service from January 1997 to December 2006. They were all evaluated for AVR and declined due to excessive surgical risks, including advanced age, severe left ventricular dysfunction, and associated co-morbidities. Patients with more than mild aortic regurgitation were not eligible for BAV. All procedures were performed by a single operator and primarily for symptom relief. In three patients, it was intended that

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AVR be undertaken at a later interval when co-morbid conditions improved.

Clinical and procedural notes were retrospectively reviewed to obtain baseline demographic, echocardiographic, haemodynamic and follow-up data. Subsequent hospital re-admissions and repeat procedures were also recorded. Individual logistic EuroSCOREs [9] were retrospectively calculated to provide an approximate estimate of perioperative cardiosurgical mortality.

All echocardiographic data were obtained and reviewed by experienced cardiac sonographers and cardiologists. Aortic valve area was derived from the continuity equation. Abnormalities were graded as mild, moderate or severe.

BAV was performed by the retrograde femoral approach under conscious sedation. Balloon dilatation catheters used in the procedures were the Cribier–Letac single or stepped diameter balloon (Boston Scientific) in 23, Cristal balloon (Balt, Montmorency, France) in 11, Mansfield balloon (Boston Scientific) in 1 (Table 2). The BAV catheters were introduced through a 12F arterial sheath for 20 mm Cribier–Letac balloons; 14F for the 23 mm Cribier–Letac balloons, or 9F for the Cristal balloons. The aortic valve gradient was measured by two separate catheters, one in the left ventricle and one in the proximal ascending aorta. Each balloon was filled with diluted contrast and dilated with maximum force, applied with the use of the two-syringe technique (20 ml and 10 ml syringes), and usually two or more inflations were undertaken. Balloon rupture occurred in 12% of procedures. Brief rapid right ventricular pacing was utilised in 11 patients to improve the stability of the balloon across the aortic valve during inflations. Dobutamine infusion was used in 57% of procedures, at doses <5 μg/kg min. Haemostasis was obtained with manual pressure or Femstop only, without the use of closure devices. In 17 out of 35 procedures in the series, cardiac output measurements by thermodilution technique were made and aortic valve area calculated before and after the procedure. Subsequently, cardiac output measurements were largely omitted. Echocardiographic estimations of mean aortic gradients one to two days pre- and post-BAV procedures were obtained in all but one patient, and aortic valve areas in 15 patients.

The Green Lane Hospital Cardiothoracic Surgery Database was reviewed to obtain baseline characteristics and inpatient outcomes of patients who underwent aortic valve replacements in the same time period.

Statistical analysis was performed with SAS statistical software (SAS Institute Inc., release 9.1, Cary, North Carolina). Results were reported as mean (standard deviation) for continuous variables; and counts (percentages) were reported for categorical variables. Pair sample Wilcoxon rank tests were applied to test the change in echocardiographic and haemodynamic measurements after BAV. Kaplan–Meier methods were applied to calculate and visualise post-BAV event-free survival at different time points. Univariate and multivariate Cox regression was used to identify risk factors for post-BAV death. Secondary analysis was performed to further characterise patients who had re-do BAV.

Results

Patient Population

A total of 35 procedures were performed in 29 patients (17 females) with severe symptomatic AS, characterised predominantly by dyspnoea, heart failure or syncope. Mean age was 82 ± 13 years (range 34–93). Three patients had BAV with the intention to "bridge" to AVR. One suffered from morbid obesity (weight of 190 kg), one from hepatic failure secondary to autoimmune cirrhosis, and one was 19-weeks pregnant.

The remaining 26 elderly patients underwent BAV for symptom relief, with mean age 86 ± 4 (range 78–93). Whereas approximately two-thirds of these elderly patients were older than 85 years and one-third older than 90, only nine of 1014 patients undergoing surgical AVR at this institution during the study period were older than 85.

Predominant symptoms were shortness of breath (83%), paroxysmal nocturnal dyspnoea (59%), angina (41%) and syncope (38%) (Table 1). BAV was not performed for relief of angina in the absence of dyspnoea, heart failure or syncope. Eleven (42%) of the elderly patients had a documented history of prior myocardial infarction. Nine patients had coronary angiography, and six demonstrated coronary artery disease that would necessitate bypass grafting had surgical treatment been undertaken. On echocardiography, LV systolic function in the elderly patient group was moderately or severely impaired in 23% and 15%, respectively (Table 3).

Other associated co-morbidities are outlined in Table 1. Chronic renal impairment was present in just under half of the elderly patients. The prevalence of important pulmonary disease and past cerebrovascular events was both approximately one quarter. For the 26 elderly patients, the median logistic EuroSCORE was 26% (range 8–50%).

Haemodynamic Results

Procedural details of the 35 BAV procedures are outlined in Table 2. The immediate results of the BAV procedure were assessed by both echocardiographic and haemodynamic criteria. Doppler measurements of mean aortic gradient and aortic valve area were generally obtained within one to two days before and after BAV. Haemodynamic measurements of the left ventricular and aortic pressures, and peak-to-peak and mean transaortic gradients were obtained during the procedure (Table 3).

Excluding bridging and re-do BAV procedures, mean aortic gradient from catheter traces and echocardiogram fell 43% and 34%, respectively. Aortic valve area increased from 0.7 cm^2 to 0.9 cm^2, with a mean individual increase of 53% in aortic valve area.

There were six procedures done as re-do BAVs. The magnitude of change in the above catheter trace and echocardiographic parameters was not significantly different from the 21 first-attempt non-bridging BAVs (Table 4). Haemodynamic results did not differ in patients over 90 years of age, when compared to the patients under 90.