Stentless aortic valve replacement in patients with bicuspid aortic valve disease: clinical outcome and aortic diameter changes during follow-up


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Abstract

Objective: A bicuspid aortic valve (BAV) may be associated with an aortopathy affecting clinical outcome. Our aim was to assess long-term outcome and analyse if progressive aortic dilatation occurs with time in patients with BAV disease who underwent stentless valve replacement.

Methods: Demographic, operative and clinical data were retrospectively reviewed. Patients were classified according to whether their native aortic valve was identified as tricuspid (TC) or bicuspid (BC) at the time of AVR. Serial transthoracic echocardiography was used to measure changes in ascending aortic diameter over time. Propensity adjustment and multivariate regression were used. Events over time were assessed using the Kaplan—Meier method, and the determinants of events were assessed with the Cox proportional-hazards model.

Results: Between January 1991 and January 2001, 215 patients underwent AVR. They had a serial follow-up echocardiography performed for a mean of 6.1/4.3 years postoperatively. Ninety patients (41%) had a BAV, and the BC group was younger (BC 62/15 years vs TC 71/12 years; p = 0.002). We found no difference in the increase in ascending aortic diameter over follow-up (BC 0.1/0.5 cm vs TC 0.0/0.5 cm; p = 0.34). BC morphology was not an independent predictor of increased overall mortality (propensity-adjusted hazard ratio: 0.79; 95% confidence interval (CI): 0.42—1.44; p = 0.44) or increased risk of reoperation (propensity adjusted hazard ratio: 1.84; 95% CI: 0.88—3.36; p = 0.11).

Conclusion: Stentless AVR is protective against progressive aortic aneurysmal disease and confers excellent clinical outcomes in patients with BAV and normal preoperative ascending aortic diameter.

Keywords: Stentless valves; Bicuspid valve; Aortic valve replacement; Aortic dilatation

1. Introduction

Bicuspid aortic valve (BAV) is the most common congenital cardiac anomaly. Clinically, the major implication associated with this condition is a tendency towards premature degeneration of the aortic valve with earlier presentation of calcific aortic stenosis or mixed aortic valve disease [1]. As with all structural diseases of the aortic valve, when aortic valve repair is not possible, the definitive and more common surgical treatment is aortic valve replacement (AVR). A further concern regarding these patients is the suggestion that BAV might be associated with a specific disease state involving the aorta. This proposed condition, termed bicuspid (BC) 'aortopathy', has been suggested to predispose to aeurysmal dilatation and other aortic complications such as dissection or rupture [2]. This has led surgeons to consider whether an additional aortic procedure should be performed at the time of AVR. The aim of such intervention is to avoid late complications from a presumed co-existent aortic disease, even when aortic dilatation is mild (4.0—4.5 cm) [3]. Some investigators suggest prophylactic replacement of a normal calibre or mildly dilated ascending aorta at the time of AVR in patients with BAV disease [4]. However, the data supporting this stance are conflicting and there remains no clear understanding of how the dimensions of the ascending aorta and aortic root change over the long term in patients with BAV. This is particularly true when stentless valves and other alternative techniques of valve implantation are used. We analysed a consecutive series of patients who underwent stentless AVR for BAV disease, sparing the native aorta from surgical intervention. By reviewing serial echocardiograms, we aimed to determine whether there was any change in the diameter of the ascending aorta over a long-term follow-up. Furthermore, with reference to concerns that late aortic events may compromise clinical outcomes, we compared the need for re-operation, and patient survival following AVR in patients with BC and tricuspid (TC) aortic valve disease. In order to assess the issues of matching, we used propensity analysis as our statistical method of choice.

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2. Methods

This is a retrospective review of a consecutive series of patients who underwent subcoronary AVR with a stentless bioprosthesis for BC or TC aortic valve disease between 1991 and 2001. This cohort constitutes over half of our stentless valve database (n = 415), which also includes patients who underwent aortic root replacement. The descriptive comparison between the BC and TC group is presented in Table 1. All patients included in this series had aortic dimensions of less than 5 cm preoperatively; consequently, patients with unknown preoperative aortic dimensions were excluded. Patients were not excluded from analysis if they had additional concomitant cardiac procedures. The aortic valve was determined as BC by the surgeon and on the basis of previously published criteria [5].

2.1. Bioprosthetic stentless AVR

The Toronto stentless porcine valve (TSPV) was the predominant stentless valve used in this series. Two patients received the Medtronic Freestyle stentless bioprosthesis. Homograft valves were also used. The vast majority of homografts were cryopreserved. Two patients received a homovital homograft. An established homograft cryopreservation protocol has been in place at our institution for over 15 years.

2.2. Surgical technique

Operations were performed by a single surgeon (JP). All procedures were performed with the use of cardiopulmonary bypass and cooling to 28°C; myocardial protection was undertaken using antegrade and retrograde cold-blood cardioplegia. All bioprostheses were implanted in the subcoronary position. With homograft valves, the coronary sinuses were excised but the non-coronary sinus was preserved. The valve was then implanted with separate inflow and outflow suture lines. Interrupted sutures were used for the proximal suture line and continuous for the distal. Separate mattress sutures were used to secure the commissures.

2.3. Data acquisition

Demographic, clinical and operative data were obtained from individual patient hospital records. Mortality was determined using the National Health Service (NHS) strategic tracing system (NHS, UK) and survivors were contacted by telephone for interview.

2.4. Echocardiographic details

Patients in our series had annual echocardiographic follow-up at our institution. All echocardiographic studies were undertaken by two experienced echocardiographers in the Echocardiography Laboratory at the Royal Brompton Hospital. Both echocardiographers had participated in a previously reported randomised study on the assessment of stentless valves. All measurements were made in accordance with the relevant recommendations of the American Society of Echocardiography. The inter-observer and intra-observer variability of their echocardiographic measurements was previously assessed and reported as 0.71 and 0.81, respectively [6].

Transcatheter echocardiography was performed using the Hewlett Packard system Sonos 5000. Patients with an inadequate preoperative echocardiogram for assessment were not enrolled into the study. The required echocardiographic views (parasternal long-axis, apical four- and five-chamber views) with pre-specified two-dimensional (2D) cineloops, M-mode and Doppler were recorded. Measurements were obtained for a mean of three consecutive beats if the patient was in sinus rhythm or five consecutive beats if the patient was in atrial fibrillation.

Continuous-wave Doppler was used to determine the presence and severity of any regurgitation. Regurgitation severity grading was quantitative and was based on regurgitant volume, regurgitant fraction and effective regurgitant orifice area. The AR severity was graded as I = trace, grade II = mild, grade III = moderate and grade IV = severe.

Ascending aortic diameter was measured in all patients prior to and following AVR. The maximal ascending aortic diameter was obtained directly and measured above the sinotubular junction (STJ). All the different levels of aortic root diameter (basal ring, mid-sinus, STJ and above) were measured, guided by M-mode tracking using cross-sectional echocardiography in the long-axis view. The STJ was...
considered as the dimension of the aortic root at the level of commissural cusp-tip insertion into the aortic wall. Descriptions of the ascending aorta were reported as normal when the diameter was less than 4 cm; mild dilation was considered as a diameter of 4.0–4.4 cm; and moderate dilation as a diameter of 4.5–4.9 cm.

The annual rate of change in ascending aortic size was calculated by dividing the difference between the measurements at the level above the STJ by the time interval in years for each patient.

Although dilation was assessed in various aortic regions, progression was judged on the basis of changes in the diameter of the ascending aorta as dilatation is consistently seen in this region in patients with BAV. Participants were judged to have rapidly progressive dilatation of the ascending aorta if the rate of dilatation was 1.01 mm per year or greater, as previously reported. This demarcation was used in our study due to the absence of an established clinical definition of rapid aortic dilatation. Furthermore, rates of at least 1.01 mm per year are thought to be clinically meaningful as most of these patients are likely to require surgical intervention for aortic aneurysm within 5–10 years of diagnosis, thereby representing a high-risk group [7].

2.5. Statistical methods

Baseline characteristics were presented as means ± standard deviation (SD) or medians with interquartile ranges (IQRs) for normally and non-normally distributed measures, respectively.

In order to assess the effect of several variables in progressive aortic dilatation, univariate and multivariate regression analyses were used.

Patients were grouped according to whether their native aortic valve was BC or TC and dichotomous outcome compared using the chi-square or Fisher’s exact test. Actuarial survival and freedom from re-operation was compared with Kaplan–Meier curves and multivariable Cox proportional-hazards regression. The Kaplan–Meier curves were compared using the log-rank test.

The statistical analysis addressed confounding factors (patient selection) by use of a propensity score and heterogeneity (risk factors) with multivariate risk factor analysis [8,9]. The following models were used in our analysis:

1. unadjusted model,
2. model adjusted for propensity score and
3. model adjusted for covariates.

2.6. Propensity model

A propensity score for each patient was calculated to determine individual patient factors associated with either a BC or TC native valve morphology (TC = 0 vs BC = 1) using a non-parsimonious logistic regression model. The variables listed in Table 3 were included in this model, along with significant interactions. The score was subsequently incorporated into a proportional-hazards model as a continuous covariate. We used the propensity score for adjustment, and not for matching, to avoid reduction in study size. The propensity score analysis was performed as previously recommended [10,11].

2.7. Model adjustment for covariates

To elucidate the causative factors associated with the outcomes of interest, a multivariable regression analysis was performed. Initially, univariate regression analysis was used to determine all significant confounding variables (covariates). The associated confounding variables were subsequently included in the multivariable regression model. Only statistically ($p \leq 0.05$) or clinically significant causative factors from the univariate analysis were adjusted for (included) in the multivariable model. All statistical analysis was performed using SPSS 14.0 (SPSS Inc., Chicago, IL, USA).

3. Results

Between January 1991 and January 2001, 215 patients underwent AVR with subcoronary implantation of either the TSPV or a homograft. Ninety patients had a BC native aortic valve and in the remaining 125 patients the valve was TC. Patient characteristics, according to native valve morphology, are shown in Table 1. Patients with BAVs were significantly younger ($p = 0.002$) and were more likely to be males ($p = 0.002$). Aortic stenosis was more likely to be the presenting lesion in patients with a BC valve ($p = 0.003$), whereas mixed aortic valve disease was more prevalent amongst TC patients ($p = 0.03$). Correspondingly, aortic valve calcification was significantly more prevalent amongst those with BC valves ($p = 0.02$). There was a trend towards more severe symptoms amongst TC patients as assessed by the New York Heart Association (NYHA) functional status. The use of the TSPV and aortic homograft for subcoronary AVR was equally distributed between both groups. At operation, patients with BAV disease received a significantly larger prosthesis (25.4 vs 24.7 mm; $p = 0.04$). Furthermore, there was a trend towards more patients in the BC group presenting with an ascending aortic diameter greater than 4.0 cm ($p = 0.07$). Both the frequency of concomitant coronary artery bypass grafting (CABG) and the number of grafts constructed were significantly greater amongst TC patients undergoing AVR.

3.1. Ascending aortic dilatation

Follow-up echocardiography was performed $6.1 \pm 4.3$ years postoperatively. The preoperative ascending aortic diameter was similar (BC: $3.2 \pm 0.5$ cm, TC: $3.2 \pm 0.5$ cm; $p = 0.56$). There was no difference in the increase in ascending aortic diameter over follow-up (BC: $0.1 \pm 0.5$, TC: $0.0 \pm 0.5$ cm; $p = 0.34$). Ascending aortic diameter at late follow-up was not significantly different between groups when measured at echocardiography (Fig. 1). Furthermore, there was no difference between groups in the number of patients with even moderate ascending aortic dilatation (>3.5 cm) at follow-up. The prevalence of 2+ or greater aortic regurgitation was also comparable as were the number of patients who had an increase in aortic diameter of greater than 1.0 cm over the course of follow-up (Table 2).
We also performed regression analysis to analyse whether there was any association between progressive annual aortic dilatation and BC valve morphology. No significant relationship was identified (BC morphology: beta coefficient = 2.77, standard error = 3.06 (95% confidence interval: 3.28—8.81; p = 0.36)). This relationship remained unchanged when we performed multivariate regression analysis with the following variables included in the analysis: BC morphology (BC = 1, TC = 0), the type of valve implanted (stentless = 0, homograft = 1) and a preoperative ascending aortic diameter greater than 4 cm (>4.0 cm = 1, <4.0 cm = 0) to assess their independent effect on the annual aortic wall dilatation. None of these variables were associated with an increased rate of annual aortic wall dilatation (BC morphology: beta coefficient = 2.88, standard error = 3.1 (95% CI: 3.2—9; p = 0.35)), type of valve implanted; beta coefficient = 1.41, standard error = 3.2 (95% CI: 4.9—7.7; p = 0.66) and preoperative ascending aortic diameter >4 cm; beta coefficient = −2.13, standard error = 6.67 (95% CI: 15—11; p = 0.74).

We also analysed whether there was a difference in the number of patients with a clinically significant increase (more than 1.01 mm per year) in the rate of annual aortic dilatation during follow-up in patients with BC and TC native aortic valves. No significant difference was identified (chi-square = 0.72, df = 1, p = 0.39).

### 3.2. Propensity analysis model and 'adjustment for covariates' model

In BC patients, the median propensity score (0 = TC, 1 = BC) was 0.56 (IQR = 0.31); in TC patients, the median score was 0.31 (IQR = 0.29). Variables included into the logistic regression to develop the propensity score model are listed in Table 3.

### 3.3. Mortality

Mean follow-up time was 7.1 years (SD 4.3). Actuarial survival was determined by using the Kaplan–Meier product-limit method. There were 92 deaths: 27 BC and 65 TC. The Kaplan–Meier 1-, 5- and 8-year actuarial survival was 97%, 85%, and 75% for patients with BC native aortic valve compared to 95%, 71% and 48% for the TC patients (Fig. 2). Comparison between the two groups revealed a significantly improved survival amongst patients with BAV undergoing AVR (log-rank chi-square = 13.1, p < 0.001). On univariate analysis (Table 4), BAV was associated with a significantly decreased risk of mortality across follow-up (hazard ratio, 0.44; 95% CI: 0.28—0.70; p < 0.0001). When included in a multivariate model that adjusted for covariates, there was no longer a significant association between BC valve morphology and improved survival (unadjusted for propensity

### Table 2

Echocardiographic data.

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<td>Bicuspid</td>
<td>Tricuspid</td>
<td>p</td>
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<td>Time to follow-up echocardiogram (years, SD)</td>
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<td>6 (4)</td>
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<td>Ascending aortic diameter (cm, SD)</td>
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<td>Increase in aortic diameter &gt;1.0 cm (n, %)</td>
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<td>Ascending aortic diameter &gt;3.5 cm (n, %)</td>
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hazard ratio, 0.78; 95% CI: 0.44–1.39; \( p = 0.40 \)). After propensity risk adjustment (Table 5), there remained no association between native valve morphology and an increased risk of overall mortality during follow-up (adjusted hazard ratio, 0.79; 95% CI: 0.43–1.44, \( p = 0.43 \)). The only independent predictors of overall mortality were age (adjusted hazard ratio, 1.06; 95% CI: 1.02–1.09; \( p = 0.001 \)) and the need for concomitant CABG at operation (adjusted hazard ratio, 2.16; 95% CI: 1.27–3.68; \( p = 0.005 \)). The presence of sinus rhythm postoperatively was associated with a protective effect against mortality (adjusted hazard ratio, 0.42; 95% CI: 0.20–0.86; \( p = 0.02 \)).

3.4. Re-operation

Actuarial freedom from re-operation was also determined using the Kaplan–Meier product-limit method. Thirty-one patients required aortic valve re-operation: 20 BC and 11 TC. The Kaplan–Meier 1-, 5- and 8-year actuarial freedom from re-operation was 100%, 99% and 75% for patients with BAV disease compared to 99%, 97% and 90% for TC patients (Fig. 3). This was not a significant difference when the curves were compared using the log-rank test (log-rank chi-square = 2.7, \( p = 0.10 \)). Overall mean time to re-operation was 8.3 years (SD 2.6). For TC patients who required re-operation, this was undertaken 7.6 years (SD 3.1) following primary AVR, compared to 8.7 years (SD 2.3) between operations for BC patients. This difference in time to re-operation was not significantly different, \( p = 0.1 \).

Univariate analysis was performed to identify predictors of re-operation (Table 4). BC morphology was not a predictor for increased re-operation risk (unadjusted hazard ratio, 1.84; 95% CI: 0.88–3.86, \( p = 0.11 \)). Age was the only variable identified to be significantly associated with an increased risk for re-operation (unadjusted hazard ratio, 0.96; 95% CI: 0.93–0.98, \( p < 0.001 \)). After propensity risk adjustment, age no longer remained an independent predictor of re-operation (adjusted hazard ratio, 0.97; 95% CI: 0.94–1.01; \( p = 0.1 \)).
dilatation in patients with BAV disease requiring AVR [12].
replacement of the ascending aorta secondary to aortic
investigators have demonstrated an increase in the need for
analysis, the BC morphology was not an independent
increased requirement for re-operation.
Furthermore, using the propensity-adjusted multivariate
aortic diameter in patients with BC valves following AVR.
Therefore, we did not find a greater increase in the ascending
aortic diameter in patients with BC valves following AVR.
Furthermore, the BC morphology was not an independent
predictor of either impaired long-term survival or an
increased requirement for re-operation.
BC morphology of the aortic valve has been associated
with aneurysmal dilatation and aortic dissection [1]. Bauer
and colleagues reported that aortography in patients with
BAV disease revealed a significantly larger ascending aortic
diameter compared to those with TC valves [12]. These
investigators have demonstrated an increase in the need for
replacement of the ascending aorta secondary to aortic
dilatation in patients with BAV disease requiring AVR [12].
Furthermore, it has been reported that the process of aortic
enlargement continues following AVR in these patients [1]. A
deficiency of fibrillin-1 content in blood vessels of patients
with BC valves has been identified and suggested to result in
an increased production of matrix metalloproteinases [12—
14]. Abnormalities in the elastic and fibrillar elements of the
vasculature have also been demonstrated and have been
proposed as a pathogenic mechanism for aortopathy [15].
However, in contrast to previous studies, using serial
echocardiography, we did not demonstrate a difference in
increase in ascending aortic diameter over time.
Another concern relating to the aorta of BC patients
following AVR is the possibility of re-operation from
complications of ascending aorta. Borger and colleagues
conducted a 15-year retrospective study in 201 patients with
BAV undergoing AVR [16] and concluded that concomitant
ascending aortic replacement should be considered for
patients with moderate ascending aortic dilatation, defined
as a diameter greater than 4.5 cm but less than 5.0 cm.
Twenty-two of the 201 patients (11%) in their series had
moderate ascending aortic enlargement compared to only
three patients in our study, one with a BC valve and two with a
TC valve. In this group of patients, the 15-year freedom from
ascending aortic complications reported in the above study
was only 43%. In their series, in patients with an aortic
diameter of less than 4.5 and 4.0 cm the freedom from
complication rate was only 81% and 86%, respectively.
Re-operation was required in 44 patients, predominantly for
aortic prosthesis failure, 18 patients required ascending
aortic replacement for aneurysm and one patient required
repair for aortic dissection. Thirty-one patients in our study
required re-operation for prosthesis failure, with no patient
needing a further operation for an aortic complication. Using
a propensity-adjusted multivariate model, BC morphology
was not an independent predictor of re-operation.
There are no prior studies that compare long-term survival
between patients with TC and BC valves undergoing stentless
AVR. In our series, unadjusted Kaplan—Meier analysis initially
suggested impaired long-term survival amongst patients with
TC valves. However, using the multivariate analysis adjusted
for propensity score, TC morphology was not associated with
improved long-term survival. Independent predictors for
impaired survival outcomes included increasing patient age
and the need for concomitant coronary artery surgery at
operation, indicating the negative influence of co-existent
coronary artery disease on patient outcome. Preservation of
normal sinus rhythm was also noted to have a strong protective
effect against mortality in patients undergoing AVR.
We performed a comprehensive analysis based on
propensity matching to compare clinical outcomes following
stentless AVR in patients with BC and TC native aortic valves.
The impetus was to determine whether the ‘aortopathy’
associated with BAV disease might be responsible for
clinically important aortic events following AVR. Some
investigators have advocated the use of additional aortic
procedures, ranging from a simple ascending aortic inter-
position graft to full composite aortic root replacement to
avoid such consequences [3,16]. Although some series have
failed to identify any increase in mortality [3,17,18]
associated with these more extensive procedures, conflicting
reports suggest that operative mortality is likely to be
increased compared to subcoronary root-preserving AVR [19].
We have presented comprehensive data acquired over 5 years
of follow-up, which indicate that patients with native BAV, in
particular those with normal preoperative ascending aortic
diameter, are not at an increased risk of postoperative
ascending aortic dilatation. Furthermore, we did not identify
an increased risk of mortality or re-operation in these
patients, which might be expected if a significant co-existent
aortic pathology was present.

4. Discussion

In this 15-year retrospective study, we investigated
whether patients undergoing stentless AVR for BAV disease
demonstrated a greater increase in ascending aortic
diameter over time in comparison to patients with TC
valves. In addition, we assessed whether there was any
difference in survival or the need for re-operation between
these two groups. Through analysis of serial echocardiograms,
we did not find a greater increase in the ascending
aortic diameter in patients with BC valves following AVR.
Furthermore, using the propensity-adjusted multivariate
analysis, the BC morphology was not an independent
predictor of either impaired long-term survival or an
increased requirement for re-operation.

5. Advantages and limitations of the study

Our study is the first in the literature to examine the
effects of stentless AVR in patients with BC, as opposed to TC,
native aortic valves. In addition, for all outcomes assessed
(mortality, re-operation and aortic dilatation) the mean
follow-up time was greater than 5 years and the propensity scoring methodology was used for adjustment.

Despite these aspects, several limitations can be identified. Echocardiography as a modality for assessing aortic dilatation over time is associated with several drawbacks. The diagnostic accuracy of a transthoracic echocardiogram is inferior to that of the computed or magnetic resonance tomography in measuring the diameter of the ascending aorta. Furthermore, despite the fact that echocardiograms were undertaken by experienced echocardiographers and in accordance with established protocols, the assessment was not blinded or random, and these characteristics may have introduced bias into our results. It is also important to note that although only one surgeon performed all of the operations in our series, the use of homograft implantation with maintenance of the non-coronary sinus could have influenced our results, as this constitutes a remodelling procedure for the aortic root. We assessed if the type of valve implant had an effect on the progression of aortic dilatation but were unable to demonstrate any difference between the Toronto stentless porcine valve and the homograft. It is important that this question be re-addressed in studies with a longer duration of follow-up in the future.

6. Conclusion

Additional aortic procedures at the time of stentless AVR intended only to protect against progressive aortic aneurysmal disease in patients with BAV and normal preoperative ascending aortic diameter are not justified.

References