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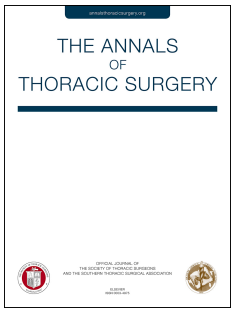

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Fate of the Aortic Arch Following Surgery on Aortic Root and Ascending Aorta in Bicuspid Aortic Valve

Running Head: Growth of the Arch in Bicuspid Aortopathy

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Abstract

Background. Recent guidelines support more aggressive surgery for aneurysms of the ascending aorta and root in patients with bicuspid aortic valve. However, the fate of the arch after surgery of the root and ascending aorta is unknown. We set out to assess outcomes following root and ascending aortic surgery and subsequent growth of the arch.

Methods. Between 2005 and 2016, 536 consecutive patients underwent surgery for aneurysm of the root and ascending aorta. 168 had bicuspid aortic valve. Patients with dissection were excluded. Arch diameter was measured before and after surgery, at six months and then annually.

Results. Of 168 patients, 127 (75.6%) had aortic root replacement and 41 (24.4%) had ascending replacement. Mean age was 57±12.8 years, 82.7% were males and five operations were performed during pregnancy. There was one (0.6%) hospital death. One (0.6%) patient had a stroke and one (0.6%) had re-sternotomy for bleeding. Median ICU and hospital stays were 1 and 6 days respectively. Follow-up was complete for 94% at a median of 5.9 years (1-139 months). Aortic arch diameter was 2.9 cm preoperatively and 3.0 cm at follow-up. There was 97% freedom from reoperation and none of the patients required surgery on the arch.

Conclusions. Prophylactic arch replacement during aortic root and ascending aortic surgery in patients with bicuspid aortic valve is not supported. Our data does not support long term surveillance of the rest of the aorta in this population.

Diseases of the aortic root and ascending aorta carry significant risks of morbidity and mortality [1]. There is an incremental risk of aortic dissection with increasing aortic diameter [2]. Until recently, guidelines recommended aortic surgery when the diameter reached ≥ 5.5 cm in non syndromic patients [2,3]. Despite these guidelines, up to one third of patients presenting with aortic dissection have diameters below 5.5 cm [1,4,5]. Several studies have demonstrated that operative management of patients with bicuspid aortic valves (BAV) should not be extrapolated from Marfan syndrome treatment algorithms [6]. Indications for concomitant intervention on the thoracic aorta at the time of aortic valve replacement (AVR) are controversial [6] and data are limited with regard to the aortic diameter at which the risk of dissection is high enough to warrant replacement of the ascending aorta at the time of AVR, particularly in patients with BAV [7]. Due to the paucity of data, and institutional differences in operative mortality, the referral for surgery in patients with aortic root and ascending aortic aneurysm varies.

Furthermore, there are no specific guidelines on whether or at what size to replace the arch prophylactically at the time of surgery for the aortic root and ascending aorta. We and others believe that BAV aortopathy is mainly confined to the ascending aorta and that the abnormal flow patterns created in the ascending aorta and arch as a result of BAV may potentially, in a small percentage of cases, cause dilatation of the arch. However, we believe that this hemodynamic effect is removed following valve, root, and ascending aorta replacement [8,9].

We set out to examine the outcomes of proximal thoracic aortic aneurysm surgery and to assess the subsequent growth of the aortic arch in patients with BAV who have undergone aortic root and / or ascending aortic replacement. The associated risk of arch surgery can only be justified if the arch grows following proximal aortic surgery.

Patients and Methods

Study Population

Between 2005 and 2016, data for consecutive patients undergoing elective and urgent ARR or ascending aorta replacement (AAR) with or without aortic valve replacement (AVR) and valve sparing root replacement (VSRR) under the care of one surgical team were prospectively collected.

All operations were performed by one attending (MJ) and residents of that team. The subset of patients with BAV is the subject of this study. Patients undergoing concomitant aortic arch replacement and those with type A dissection were excluded. The latter group were excluded since they invariably had a part of the arch removed and therefore it is difficult to assess the growth of the arch during follow-up. Additionally, patients with known connective tissue disease like Marfan syndrome were also excluded. Approval from the research ethics committee (IRB equivalent) was obtained.

Data collection was performed by two researchers and database manager, and checked with the main surgical database which is submitted to the National Institute for Cardiovascular Outcomes Research (NICOR) at The Society for Cardiothoracic Surgery of GB & Ireland (SCTS) [10,11].

Operative mortality, peri-operative complications, growth of the aortic arch and the need for further surgery or intervention either on the aortic root, valve or arch during follow-up were analysed.

Definitions

Elective surgery was defined as planned surgery performed at more than one week from the decision to operate. Urgent surgery was defined as surgery performed more than 24 hours, but less than one week, after unplanned hospital admission. Diagnosis of BAV was made by imaging and then confirmed at the time of surgery.

The presence of connective tissue disorder was confirmed with genetic analysis and/or histological examination of the excised aorta or by clinical criteria, such as the modified Ghent criteria [12]. Operative mortality was death before hospital discharge. Post-operative transient ischemic attack or stroke was based on new brain injury diagnosed either clinically or radiologically. Postoperative renal dysfunction was defined as needing hemofiltration in patients who were not previously dialysed.

Imaging Before Surgery and Measurements of Aorta at Follow-up

Aortic dimensions were measured either from CT scans or MRI. Based on the 2014 European Society of Cardiology (ESC) guidelines, measurement of the aorta included the aortic wall [3]. The mid aortic

arch was measured between the left common carotid artery and the left subclavian artery **(Fig. 1).** For aortic sinuses, transthoracic echocardiography was used, with measurements taken during diastole using the leading edge to edge technique [13].

Study Definitions

In the presence of aortic valve pathology, if the aortic root and/or sinuses were ≥4.5 cm, ARR was performed with ascending aorta replacement. If the aortic root was <4.5 cm, but ascending aorta was ≥ 4.5 cm, only the ascending aorta was replaced. AVR was performed based on standard indications [14]. In patients with dilated sinuses, but where the valve was normal or near normal, valve sparing aortic root replacement (VSRR) was performed. Other factors taken into account were positive family history, rate of growth and the decision of future pregnancy in females. Patients with pathology of the arch requiring arch replacement were excluded. Our standard practice is to replace the aortic arch at a diameter of ≥ 4.5cm.

Anesthetic Protocol and Perioperative Care

All patients underwent cerebral perfusion monitoring using near-infrared spectroscopy along with a treatment algorithm to manage low values during cardiopulmonary bypass (CPB). Hemoglobin on CPB was maintained above 8 g/dL. To assess coagulopathy, thromboelastography (Hemonetics™) and multiplatelet analyzer (Cobas Roche™) for platelet function were used. We have described our protocols for surgery in pregnant patients previously [15].

Surgical Technique

CPB was established at 35^{o}C through central or peripheral (axillary or femoral) cannulation and right atrial or bicaval cannulation. Circulatory arrest was not used in this cohort since patients requiring surgery for the arch were excluded. Myocardial protection was achieved using antegrade cold blood based cardioplegic solution.

Patients undergoing valve sparing root replacement (VSRR) underwent the remodelling technique [16]. For patients requiring a bioprosthetic valve, a composite valve graft was constructed

intraoperatively using either a porcine or pericardial valve and a vascular graft. For patients requiring a mechanical valve, a composite valve graft was used. The valve was seated using 2/0 teflon-pledgeted Ticron sutures in an interrupted mattress fashion. The coronary buttons were re-implanted into the graft using a continuous 5/0 Prolene™ suture (Ethicon). Tissue glue was seldom used and the use of Teflon was minimal. In patients undergoing ARR only, it is our routine practice to replace the ascending aorta, up to the site of aortic cross clamping.

Patients requiring AVR and AAR underwent surgery with standard aortic valve prostheses and the ascending aorta replaced with an appropriately sized vascular graft, up to the site of aortic cross clamping, as in ARR. If the proximal arch is dilated, we perform peripheral cannulation to allow clamping of the aorta as distal as possible.

Follow Up

All patients underwent echocardiography prior to discharge and were followed up at 8 weeks, 6 months and then annually with echocardiography and CT/ MRI. During follow up, 73% had CT and the remainder had MRI. More recently, we have been performing pre operative and follow up MRI to assess aortic dimension. All measurements were made by one radiologist and subsequently was confirmed by the first author (RB).

Statistical Analysis

Continuous variables are expressed as mean ± SD and percentage for categorical variables. Median is provided for continuous variables not following normal distribution. Student's t-test was used as appropriate to assess the difference between aortic diameter, pre and post operatively, with values of $p<0.05$ considered statistically significant. Analyses were performed using SPSS® (Statistical Package for Social Sciences, USA) version 24.

Results

Between 2005 and 2016, 536 patients underwent ARR or AAR ± concomitant procedures under the care of one surgical team. One hundred and sixty eight patients had BAV and satisfied the inclusion

criteria. One patient during the study period underwent arch surgery and was excluded from the study. Clinical characteristics are shown in Table 1, aortic measurements and BAV fusion pattern in Table 2 and operative details in Table 3. Isolated ARR or AAR was performed in 127 (75.6%) and 41 (24.4%) patients respectively. There were 2 patients (1.2%) who underwent redo surgery. Five (3%) were pregnant at the time of surgery. Homograft ARR was performed in 3 (1.8%) patients with endocarditis, one was during pregnancy. Although patients requiring arch or hemiarch replacement are not the subject of this study, the median cross clamp, cardiopulmonary bypass and circulatory arrest times for arch surgery were 83, 106 and 28 minutes respectively.

Early Mortality and Complications

Operative mortality and complications are shown in Table 4. There was one (0.6%) in-hospital death. The cause of death in this patient was multi-organ failure. The patient developed acute respiratory distress syndrome and renal failure following surgery. Of the 5 patients who were pregnant at the time of surgery, there were no maternal deaths, however there was one peri-operative fetal death. One patient who had VSRR required coronary artery bypass graft surgery. It was not possible to perform a coronary angiogram in her prior to surgery due to access problems and she had a CT angiogram instead which showed fairly normal coronary arteries. However, an hour following cessation of bypass she developed ECG changes in the lateral leads and bypass grafts were performed. She did well and was discharged 12 days later. A later angiogram revealed ostial narrowing of the circumflex vessel.

Median intensive care unit (ICU) and hospital stay were 1 and 6 days respectively.

Follow up and Growth of the Aortic Arch

The median aortic arch dimension measured on CT and / or MRI scan before surgery was 3 cm (range 2.4-4.1 cm). At a median follow up of 5.9 years (1-139 months), median post operative aortic arch dimension was 3 cm (2.4-4.2 cm) . This growth was not significant.

Outcomes Following Hospital Discharge and Later Intervention on the Arch

Follow-up was complete in 94% of the patients. At a median follow up of 5.9 years (1-139 months), there was 97% freedom from reoperation and prosthetic valve dysfunction. Five (3%) patients underwent redo surgery at a mean interval of 5.3 ± 4.1 years from their first operation. Two were due to bioprosthetic valve failure, one due to homograft failure and two due to endocarditis. None of the patients required surgery on the arch or the remaining of their aota. The cause of death, collected from family members and medical records, was non cardiac in 7 patients (4.2%).

Comment

We have shown that over a median follow up of nearly six years, the aortic arch dimensions following surgery on proximal aorta in patients with BAV remained unchanged and that surgery for aortic arch dilatation after replacement of the root and ascending aorta is uncommon. This is consistent with recent findings from Iribarne and colleagues [17] who demonstrated a low re-intervention rate in patients underoing proximal aortic surgery, with a freedom from reintervention of 92.9% at up to 9 years. In particular, of the 308 patients with bicuspid aortopathy, only 3 (0.9%) required re-intervention during follow up, although they have not specified whether this was due to arch dilatation. As a result, they have suggested a less aggressive follow up regime in such patients, with CT/MRI and transthoracic echocardiogram every 2 years. Park and colleagues [18] reported their results of 422 patients with BAV over a 19 year period who underwent aortic root or ascending aortic surgery. Paired echocardiographic measurements of the aortic arch diameter were 3.3 cm preoperatively compared to 3.2 cm postoperatively at a median follow-up of 4.2 years.

The morbidity and mortality related to BAV disease accounts for more than that related to all other congenital cardiac diseases combined [19]. BAV aortopathy is multifactorial and is caused by a combination of hemodynamic abnormalities and imbalance of matrix metalloproteinases [20]. Using MRI and computational fluid dynamics, we have shown that patients with BAV have greater aortic flow asymmetry, higher wall shear stress and lower oscillatory shear index in the ascending aorta [8] with highest in the greater curvature. This region of the BAV aorta has been associated with medial degeneration [21], and extracellular matrix dysregulation and higher elastin degradation [22]. This may help explain why some aortas smaller than intervention criteria develop acute aortic dissection. It

may also explain why replacement of the aortic valve slows the progression of aortic dilatation [23]. However, BAV aortopathy is a heterogeneous condition, and post-AVR aortic dilatation can occur, particularly in severe BAV regurgitation [24].

There was no growth in the aortic arch supporting that high shear stresses are found predominantly in the ascending aorta of BAV patients. This may also lend some insights into the possible role of proximal aorta hemodynamics in aneurysm formation in patients with connective tissue disorders. Indeed, the increased prevalence of aortic complications during pregnancy is likely to be related to the increased hemodynamic stresses of a high cardiac output state.

Cusp fusion pattern has been noted to have an impact on the region of downstream aortic dilatation, with the less common pattern of right and non coronary cusp fusion being recognized as exterting greater wall shear stress on the aortic arch and as a result dilatation of the aorta [25]. In our cohort, only 7.7% had right and non coronary cusp fusion which may reflect the low number of patients with dilated aortic arch. The lack of progression in aortic arch diameter again supports our, and others', hypothesis that removal of the bicuspid 'source' prevents dilatation of the downstream aorta.

Despite this, some groups have argued for the routine replacement of the aortic arch in patients with BAV [26]. Their results of cluster analysis show that dilatation in BAV tends to fall into 4 clusters: aortic root dilatation only; isolated ascending aorta dilatation; dilatation of the ascending aorta and tranverse arch and dilatation of the root, ascending aorta and transverse arch, with the latter being the most prevalent. As a result, they have recommended that patients with transverse arch dilatation should undergo ARR/AAR and replacement of the transverse arch. Our results do not support this view. In our cohort, in which the largest arch diameter was 4.1cm, there was no dilatation of the arch at almost 6 years follow up. We would not therefore advocate prophylactic replacement of the arch, with its associated risks, in BAV patients, unless they meet criteria for replacement as we have already detailed.

With regard to follow up, we would recommend that imaging and follow up for the valve in all patients is required. However, imaging of the remaining native aorta seems unnecessary. Patients

who have cusp fusion pattern of right/non may benefit from follow up due to the predilection of this pattern giving rise to arch aneurysms.

We have been screening patients with aortic aneurysm, BAV and connective tissue disease and have been following the recently published ACC/AHA guidelines of operating at 5.0-5.5 cm if there is no AV disease and at 4.5cm if there is concomitant AV dysfunction [7]. This decision making is partly based on the estimated risk of dissection in patients with BAV to be eight times higher than that in the general population [27]. Our series, for elective and urgent cases, is the largest reported in the UK to date with favourable results compared to series reporting mortalities of 7-16% and others reporting elective and urgent mortality of 3.5-9% [10,28–30]. Stamou and colleagues [31] analyzed the STS database and reported that the median number of procedures per year was 2 per center with an operative mortality of 4.2%. However, mortality is lower in centers with high operative volume and earlier diagnosis [32,33]. This has recently been reflected in the statement from the American College of Cardiology and American Heart Association relating to patients with BAV [7].

There was only a very small number of BAV patients who presented with normally functioning aortic valve who could benefit from VSRR. This population of patients seems to be smaller in the UK compared to the European and US series. Centres with established experience of VSRR technique have reported that only 10% of patients undergoing VSRR have BAV and that the majority of these patients undergo either mechanical or biological ARR [33]**.** In our practice, this may reflect late referral by our cardiologists. During the period of the study we performed 94 VSRR where only 3 had BAV.

Our study is limited by the length of follow up and it may be that at a longer follow up, the arch dilates, particularly in the right/non coronary cusp fusion pattern. In addition, the mean age of patients was 57. It may be that in younger patients wth longer follow up, some aortas are found to dilate.

In conclusion, our study does not support hemiarch or total arch replacement during ARR or AAR in BAV aortopathy and therefore we do not believe that screening the rest of the aorta at mid and long term follow-up in these patients is justified. It also shows that aortic root and ascending aortic surgery for aneurysm in BAV patients can be done very safely with low complication rate.

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Table 1. Baseline clinical characteristics

Demographic	Total (n = 168)
Age (years)	57 ± 12.8
Male sex	139 (82.7%)
Logistic EuroSCORE	5.3 (2-21.3)
Hypertension	67 (40%)
Diabetes mellitus	12 (7.1%)
Coronary artery disease	**19 (11.3%)**
Endocarditis	**6 (3.6%)**
Pregnancy	5
Left ventricular function	
Good (EF > 45%)	101 (60.1%)
Moderate (EF = 30-45%)	47 (28.0%)
Poor (EF < 30%)	20 (11.9%)
Aortic valve pathology	
Stenosis	107 (63.7%)
Regurgitation	58 (34.5%)

EuroSCORE = European System for Cardiac Operative Risk Evaluation; BMI = body mass index; EF = ejection fraction. Values presented as mean ± SD or median (range)

Table 2. Baseline aortic dimensions

Aortic diameter	Total (n = 168)

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Aortic diameter	Total (n = 168)
Aortic sinus diameter (cm)	4.3 (3.2-5.5)
Ascending aorta diameter (cm)	4.9 (3.3-6.5)
Mid arch diameter (cm)	**3 (2.4-4.1)**
BAV cusp fusion pattern	
Left and right	**128 (76.2%)**
Right and non coronary	**13 (7.7%)**
Left and non coronary	**27 (16.1%)**

BAV = bicuspid aortic valve. Values presented median (range). *Diameters less than 4.5 cm represent patients who have undergone surgery for endocarditis involving the root

Table 3. Operative details

Operative detail	BAV (n = 168)
Procedure type	
Biological ARR	59 (35.1%)
Mechanical ARR	62 (36.9%)
VSRR	3 (1.8%)
Homograft ARR	3 (1.8%)
AAR ± AVR	41 (24.4%)
Concomitant Procedures	
CABG	19 (11.3%)
Mitral valve repair	2 (1.2%)
Mitral valve replacement	2 (1.2%)
Redo surgery	2 (1.2%)
Cross clamp time (mins)	84 (45-153)
Cardiopulmonary bypass time (mins)	104 (55-203)

ARR = aortic root replacement; VSRR = valve sparing root replacement; AAR = ascending aorta replacement; AVR = aortic valve replacement; CABG = coronary artery bypass graft surgery. Values presented as median (range).

Table 4. Operative outcomes and complications

Outcome	Total (n = 168)
In hospital mortality	1 (0.6%)
TIA/Stroke	1 (0.6%)
Re-sternotomy for bleeding	1 (0.6%)
Hemofiltration	3 (1.8%)
Myocardial infarction	1
Peripheral vascular injury	0
Laparotomy/Gastrointestinal complications	0
Intensive care unit stay (days)	1 (1-17)
Hospital stay (days)	6 (5-48)

TIA = transient ischemic attack. Values of hospital and intensive care unit stay presented as median (range).

Figure Legend

Fig 1. Measurement of mid aortic arch diameter