Longer-term Outcomes after Bicuspid Aortic Valve Repair in 142 Patients

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Abstract

Background The aim of this study was to evaluate the longer-term results of bicuspid aortic valve (BAV) repair with or without aortic root replacement. Methods From 1999 to 2017, 142 patients with or without aortic root dilatation who underwent repair of a regurgitant BAV were included in the study. Ninety-four patients underwent isolated BAV repair (Group 1; mean age 45±14 years) and 48 patients underwent valve-sparing aortic root replacement plus BAV repair (aortic valve reimplantation – Group 2; mean age 49±13 years. Median follow-up time was 5.9 years (range 0.5-15) in Group 1 and 3 years (range 0.5-16) in Group 2, respectively. Results In-hospital mortality was 1% in group 1, and 2% in Group 2 (p=0.6). The 5- and 10-year survival was 93±2.9% and 81±5.8% in Group 1 and 96±3.1% and 96±3.1% in Group 2, respectively (p=0.31). Eleven patients of Group 1 (1.7% /patient-year) and 5 patients of Group 2 (2.2%/patient-year) underwent reoperation of the aortic valve (p=0.5). The 5- and 10-year freedom from reoperation were 93.0±2.1% and 77.1±7.1% in Group 1 and 93.0±5.0% and 76.7±9.6% in Group 2 (p=0.83), respectively. At latest follow-up only 2 patients of Group 1 and 1 patient of Group 2 had AR=2° (p=0.7). The cumulative linearized incidence of all valve-related complications (bleeding, stroke, endocarditis, reoperation) was 2.9%/patient-year in Group 1 and 4%/patient-year in Group 2, respectively (p=0.6). Conclusions Isolated BAV repair and combined aortic valve reimplantation plus BAV repair provide good clinical longer-term outcomes with relatively low reoperation rate and durable valve function.

Title page

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Abstract

Background

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Results

In-hospital mortality was 1% in group 1, and 2% in Group 2 (p=0.6). The 5- and 10-year survival was 93±2.9% and 81±5.8% in Group 1 and 96±3.1% and 96±3.1% in Group 2, respectively (p=0.31). Eleven patients of Group 1 (1.7% /patient-year) and 5 patients of Group 2 (2.2%/patient-year) underwent reoperation of the aortic valve (p=0.5). The 5- and 10-year freedom from reoperation were 93.0±2.1% and 77.1±7.1% in Group 1 and 93.0±5.0% and 76.7±9.6% in Group 2 (p=0.83), respectively. At latest follow-up only 2 patients of Group 1 and 1 patient of Group 2 had AR=2° (p=0.7). The cumulative linearized incidence of all valve-related complications (bleeding, stroke, endocarditis, reoperation) was 2.9%/patient-year in Group 1 and 4%/patient-year in Group 2, respectively (p=0.6).

Conclusions

Isolated BAV repair and combined aortic valve reimplantation plus BAV repair provide good clinical longer-term outcomes with relatively low reoperation rate and durable valve function.

Keywords: aortic valve repair; aortic valve-sparing; aortic root replacement

Text

Introduction

Bicuspid aortic valve (BAV) morphology is a well-known cardiac anomaly with an incidence of about 2% in the adult population [1]. In comparison to tricuspid morphology BAV is more frequently associated with pathologies such as valve incompetence due to leaflet dysfunction, dilatation of the aortic annulus, aortic root, and/or ascending aorta, its prevalence varies between 20%-80% [2-4]. Repair of the BAV is technically challenging because of the complex pathology like changes in aortic root geometry with or without primary cusp pathology. There are durable surgical strategies for the treatment of BAV related aortic regurgitation or aortic root dilatation that have been developed over the past 25 years [5-7].

The aim of this study was to analyze the longer-term results of BAV repair with and without aortic root replacement.

Materials and Methods

Study Population

From January 1999 through December 2017, 142 consecutive patients underwent repair of a regurgitant BAV with or without root or ascending aorta enlargement at our hospital. Patients with isolated BAV repair (n=94; Group 1) and patients with valve-sparing aortic root replacement plus BAV repair (aortic valve reimplantation –

David procedure; n=48; Group 2) were included in this analysis.

Before surgery, all patients were routinely examined by transthoracic echocardiography (TTE), coronary angiography and/or cardiac computed tomography (CT). An intraoperative transoesophageal echocardiography (TEE) was performed in all patients to evaluate valve function pre- and post-cardiopulmonary bypass to facilitate the surgical procedure and to assess the immediate result of AV surgery as well as the left ventricular function during weaning from cardio-pulmonary bypass and adequacy of de-airing of cardiac chambers. The echocardiographic classification of residual/recurrent AV regurgitation was as follows: grade 0 – none/trace; grade 1 – trivial; grade 2 – mild; grade 3 – moderate; and grade 4 – severe. Every patient received a TTE at discharge.

All patients were followed-up prospectively and systematically by means of annually mailed questionnaires or phone interviews and/or by clinical assessment and TTE in our outpatient clinic. For patients not seen personally we retrieved clinical assessment and echocardiography reports from the attending cardiologist.

The mean age of Group 1 was 45±14 years (14% female) and 49±13 years (10% female) in Group 2, respectively (p=0.05). The median age of Group 1 was 43 years (range 18-70), 48 years (range 24-71) in Group 2, respectively. Most of the patients had aortic regurgitation (AR) [?]grade 2 (83% in Group 1 and 73% in Group 2; p=0.2). 17% of Group 1 patients had AR=1deg and aneurysm of the ascending aorta. In Group 2 the aortic root and ascending aorta was enlarged with mean diameter of 4.5+-0.7 cm and 5.0+-0.9 cm), respectively. The patient's preoperative characteristics are summarized in Table 1.

Clinical follow-up was complete in 98% for both groups. Mean follow-up was 6.6+-4 years (Group 1) and 4.7+-4 years (Group 2). Median follow-up time was 5.9 years (range 0.5-15) in Group 1 and 3 years (range 0.5-16) in Group 2, respectively.

This study was approved by the local ethics committee (reference number: 422/12) and informed consent was obtained from each patient.

Surgical techniques

The aim of BAV repair was to reconstitute the valve's normal geometry and function. Valve repair was performed only in patients with delicate leaflets without calcification or postendocarditic defects. Therefore, accurate preoperative echocardiography with precise evaluation of cusp quality and intraoperative inspection of the aortic cusps were essential. The ascending aorta and right atrium were cannulated for cardio-pulmonary bypass (CPB), respectively bicaval venous cannulation was applied in concomitant mitral or tricuspid valve procedures. The right axillary artery was cannulated for CPB in patients who underwent additional aortic arch replacement. The aorta was cross-clamped, a transverse aortotomy was performed and cold blood cardioplegia was administered selective through the coronary ostia.

Cusp plication, pericardial patch augmentation

The standard surgical repair technique we applied in patients with BAV has been described previously [5,8,9]. The asymmetry of the bicuspid aortic root often results in a higher coaptation level of the nonfused leaflet. We observed a higher localization of the annular attachment of the fused leaflet in the outflow tract. To compensate the mismatch in the coaptation level and surface of BAVs the fused leaflet was corrected correspondingly by plication and/or pericardial patch augmentation (Figure 1).

In detail, the free margin of the cusp was plicated by using a central plication with a 5-0 suture (Cardionyl(r), Peters Surgical, Bobigny Cedex, France) until the free margin reached the height of the non-prolapsing reference cusp. Additional pericardial patch augmentation was applied to augment the fused leaflet and overcorrect the coaptation height to increase the coaptation surface and restore the valve's normal geometry. We used an autologous pericardial patch that was treated with 0.9% glutaraldehyde solution for 10 minutes before application. The patch was then sutured to the free edge of the fused leaflet with a running suture using a 5-0 suture (Cardionyl(r), Peters Surgical, Bobigny Cedex, France). Afterwards, the patch was cut to a height of about 2 mm above the corresponding cusp.

Concomitant reduction aortoplasty, ascending aorta or aortic arch replacement were performed in patients with aortopathy or aneurysm.

Dilatation of the aortic root

In patients with aortic root dilatation the aortic valve reimplantation (David procedure) was performed [10]. Briefly, a Dacron straight graft (Hemashield, Maquet, Germany) was used for the David procedure. The Dacron graft was sized according to the formula (leaflet height in mm x 1.5) + 2 mm. Over the years we modified the David procedure: we placed three stitches at the annular base of the Dacron graft creating pseudoneosinuses and later we added three additional stitches at the level of the commissures to create a neosinus in order to obtain a more physiological shape [11].

The repaired BAV was assessed by intraoperative transoesophageal echocardiography. Anticoagulation was not required postoperatively except in case of atrial fibrillation or history of pulmonary embolism.

Statistical Analysis

Statistical analyses were calculated with the Biometrical Analysis of Sampling (BIAS 11.06 Software, Frankfurt, Germany). Categorical data were presented as percentages. Continuous data were illustrated as mean value +- standard deviation. Continuous and discrete variables are expressed as mean +- SD or median and range for data not normally distributed. Comparison of the two groups were analysed using the chi-square test, Fisher's exact test for qualitative data and Mann-Whitney U test for quantitative data, respectively. Survival was calculated applying the Kaplan-Meier estimates and additionally compared with log rank test between the two groups. A p-value of less than 0.05 was defined statistically significant.

Results

Surgical procedures

Minimally invasive approach via partial upper sternotomy was performed in the majority of patients (61% in Group 1 and 67% in Group 2; $p<0.01$). The remaining patients were operated via complete sternotomy. The perioperative results and surgical procedures are summarised in Table 2.

Isolated ascending aorta replacement for treatment of aortic aneurysm was performed in 4 patients (4%) of Group 1 and 38 patients (79%) of Group 2 ($p<0.01$; Table 2). In Group 2 additional hemiarch replacement was performed in 9 patients (19%) and 1 patient received complete aortic arch replacement using elephant trunk technique due to a greater extent of aortic arch aneurysm. Reduction aortoplasty was performed in 19 patients (20%) of Group 1. Significantly more patients of Group 1 received pericardial patch augmentation (n=84) in comparison to Group 2 patients (n=34; $p<0.01$). The rate of leaflet plication was similar in both groups (80 patients of Group 1 and 42 patients of Group 2; p=0.8).

Concomitant procedures

There was no significant difference in the rate of concomitant procedures between both groups. Additionally, 8 patients of Group 1 and 1 patient of Group 2 underwent mitral valve repair (p=0.2). Coronary artery bypass grafting was performed in 2 patients of Group 1 and 4 patients of Group 2 (p=0.1). Four patients of Group 1 underwent tricuspid valve repair (Table 2).

Early postoperative outcomes

There was no operative death. In-hospital mortality was 1% (n=1) in Group 1 and 2% (n=1) in Group 2 (p=0.6). Cause of death was multiorgan failure (n=1, Group 1) and low cardiac output syndrome (n=1, Group 2). There was no significant difference between the two groups regarding intensive care unit stay (mean of 1.1+-2 days in Group 1 vs mean of 1.6+-1.5 days in Group 2; p=0.2). Cardio-pulmonary bypass time was significantly longer in Group 2 (mean of 132+-41 minutes in Group 1 vs 191+-52 minutes in Group 2; $p<0.01$). Similar results were observed for the cross-clamp time (Table 2). Reexploration for bleeding was necessary in 6 patients of Group 1 and in 7 patients of Group 2, respectively (p=0.1). No neurological events were observed in both groups.

Postoperative echocardiography data before discharge from hospital

Echocardiographic results before discharge revealed 98% (n=92) of Group 1 had AR[?]1deg (80% had no AR) and 98% (n=47) of Group 2 had AR[?]1deg (94% had no AR) (p=0.7). Only one patient of Group 1 had AR=2deg. Aortic regurgitation >2deg was not observed at the time of discharge. There was no significant difference between the two groups regarding left ventricular ejection fraction (LVEF) at time of discharge (53+-10% mean in Group 1 vs 55+-9% mean in Group 2; p=0.3). The mean aortic valve gradients (Pmean) were similar in both groups (11+-6 mmHg in Group 1 vs 9+-4 mmHg in Group 2; p=0.1).

Follow-up results

Mean follow-up time of Group 1 was 6.6+-4 years and 4.7+-4 years in Group 2, respectively. We observed 10 late deaths in Group 1 and one in Group 2, respectively (p=0.07). Cause of death was cardiac related in 4 patients of Group 1 and one patient in Group 2, respectively. The estimated 5- and 10-year survival was 93+-2.9% and 81+-5.8% in Group 1 and 96+-3.1% and 96+-3.1% in Group 2, respectively and did not differ between the groups significantly (p=0.31; Figure 2).

During the follow-up 16 patients required reoperation of the AV, 11 patients of Group 1 (1.7%/patient-year) and 5 patients of Group 2 (2.2%/patient-year) (p=0.5). The estimated 5- and 10-year freedom from reoperation was 93.0+-2.1% and 77.1+-7.1% in Group 1 and 93.0+-5.0% and 76.7+-9.6% in Group 2, respectively and did not differ significantly between the two groups (p=0.83, Figure 3). We analysed the cause of reoperation in detail. Group 1: cause of reoperation was severe AR due to endocarditis in 4 patients. Four other patients underwent reoperation due to severe AR as a consequence of leaflet perforation (n=1), leaflet prolapse (n=1), detachment of the pericardial patch at the commissure (n=1) or root dilatation (n=1). A re-repair was possible in the patient with detachment of the pericardial patch. Root replacement (biological valved-conduit) was performed in one patient. The remaining 6 patients received aortic valve replacement. Aortic valve stenosis due to calcification of both leaflets was the cause of reoperation in three other patients. They underwent AV replacement. Group 2: three patients underwent reoperation due to endocarditis. Two other patients were reoperated because of severe AR. In one of them the regurgitation was caused by a leaflet prolapse. In the other case AR was due to calcification of the fused leaflet. In both cases the pericardial patch was intact. The AV was replaced in all 5 patients.

During the follow-up period 4 patients of Group 1 and 3 patients of Group 2 developed AV endocarditis (p=0.6). There was no significant difference in the late stroke rate as the linearized incidence was 0.2%/patient-year in Group 1 vs 0.4%/ patient-year Group 2 (p=0.6). The follow-up results are listed in Table 3. The rate of bleeding events was not significantly different between the two groups (p=0.4). One patient of Group 1 developed gastric bleeding, another one (also Group 1) had cerebral bleeding with minor stroke. One of them was on anticoagulation (coumadin) because of atrial fibrillation. At the latest follow-up, mean New York Heart Association (NYHA) class was 1.4+-0.6 in Group 1 and 1.4+-0.5 in Group 2, respectively (p=0.5). The cumulative linearized incidence of all valve-related complications (bleeding, stroke, endocarditis, and reoperation) was 2.9%/patient-year in Group 1 and 4%/patient-year in Group 2, respectively (p=0.6).

At the latest follow-up 70 patients (97%) of Group 1 and 40 patients (98%) of Group 2 had AR<2deg (p=0.7). Only two patients of Group 1 and 1 patient of Group 2 had AR=2deg, respectively (p=0.7). We did not observe patients with AR>2deg. The AV mean gradient was significantly higher in Group 1 (17+-12 mmHg) in comparison to Group 2 (9+-5 mmHg) (p<0.01; Table 4).

Discussion

Patients with BAV present with multiple configurations of the cusps, commissures, sinuses with/without additional aortopathy [13]. The mechanism of AR in BAV can be diverse. Cusp prolapse, fenestration or a restrictive cusp can cause AR. In addition, annulus dilatation or root enlargement can be existent. Therefore, during BAV repair, the surgeon has to consider all aspects of pathological changes in cusp and aortic root in order to restore the valve geometry [7]. Aortic valve repair is a feasible alternative to valve replacement that is referred to as Class IC indication in the 2017 European Association for Cardio-Thoracic Surgeons/European Society of Cardiology Guidelines for management of valvular heart disease [14]. Reconstruction of BAV has been already described in the 1990's by Cosgrove and colleagues with triangular resection and plication of the prolapsing cusp [15]. We used that technique and modified it in our series to create a larger coaptation surface. The pericardial patch augmentation was evolved in addition to the mid-leaflet plication technique [5]. In patients with BAV and additional root dilatation we combined BAV repair with aortic valve reimplantation procedure (David procedure) to create a competent valve and restore the root geometry. We performed a subgroup analysis and compared the results of isolated BAV repair (group 1) with the David procedure in patients with BAV. In our series the in-hospital mortality was 1% (n=1) in group 1, and 2% (n=1) in group 2 (p=0.6). We did not observe any neurological events (stroke) perioperatively. The BAV repair data of our study demonstrate that it is a safe procedure and comparable to published in-hospital mortality rates between 0 and 1% [7,16]. CPB duration was significantly longer in group 2 (132+-41 minutes in group 1 vs 191+-52 minutes in group 2, p<0.01). Similar results were observed for cross-clamp time. This might be related to additional root reimplantation technique in Group 2 that is a complex procedure. The fact that significantly more patients of Group 1 received pericardial patch augmentation (89%) in comparison of Group 2 patients (71%, p<0.01) did not have an impact on the reoperation rate when comparing the two groups. The 5- and 10-year freedom from reoperation were similar in both groups, (p=0.83). Reported 10-year freedom from reoperation ranges between 78% and 81% in large series with BAV repair which is comparable to our results [16,17]. In our series, we observed a high number of endocarditis (n=7) at the late follow-up which was the cause of reoperation in 44% of patients. It is hard to explain why the observed endocarditis rate is so high. The aortic valve mean gradient was significantly higher in group 1 (17+-12 mmHg) in comparison to group 2 (9+-5 mmHg, p<0.01; Table 4). This could be related to a slightly higher aortic valve mean gradient of group 1 patients preoperatively that increased in course of time.

Pericardial patch augmentation seems to have a negative impact on AV repair durability as 92% of patients of Group 1 who had to be reoperated on the AV or had AR[?]2deg in the follow-up period received pericardial patch augmentation at time of primary operation. Similar results were observed in Group 2 (67%).

Our 5- and 10-year survival were good in both groups and did not differ significantly (p=0.31; Figure 2). Other published data with reported 10-year survival between 92% and 100% are comparable to our results [7,16,17]. The inferior 10-year survival in Group 1 in comparison to Group 2 might be related to a longer follow-up period of Group 1 and could also be influenced by more concomitant procedures at time of operation that have been performed in Group 1 (mitral and tricuspid valve procedures; Table 2). The cumulative linearized incidence of all valve-related complications (bleeding, stroke, endocarditis, reoperation) was 2.9% /patient-year in group 1, respectively 4%/patient-year in group 2, (p=0.6) which is lower to the reported incidence of prosthetic valve complications of 5% per patient per year [18]. Our results demonstrate that BAV repair techniques are safe and feasible. The mid-term durability of BAV repair is encouraging.

Study limitations

We have to point out that the comparison between bicuspid aortic valve repair and bicuspid David repair was initially performed for subgroup analysis within BAV repair techniques. However, due to different aortic valve/root pathology these two groups are not appropriately comparable. Therefore, we put emphasis on bicuspid repair techniques as a whole and for better illustration of the results the two subgroups were described.

Conclusion

In summary, aortic valve repair in BAV pathology, with or without additional root repair (David procedure) provides good longer-term outcomes with a relatively low mortality and an acceptable reoperation rate. We can conclude both technics are suitable for treatment of bicuspid aortic valve disease.

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Tables

Table 1: Patient characteristics

	All
Number	142
Age (median, range; years)	47 (18-71)
Male	124 (87%)
Hypertension	82 (58%)
Diameter of ascending aorta (cm)	4.5±0.9
Group 1: bicuspid AV repair; Group 2: bicuspid AV reimplantation; AV: Aortic valve.	**Group 1: bicuspid**

Table 2: Perioperative results and surgical procedures

	Group 1	Group 2	p-value
Surgical procedures (n)			

Isolated ascending aorta replacement	4 (4%)	38 (79%)	<0.01
Ascending aorta and hemiarch or arch replacement	0	9 (19%)	<0.01
Elephant trunk	0	1 (2%)	0.3
Reduction aortoplasty	19 (20%)	0	<0.01
Complete sternotomy	37 (39%)	16 (33%)	<0.01
Partial upper sternotomy	57 (61%)	32 (67%)	<0.01
Leaflet plication of the aortic valve	80 (85%)	42 (88%)	0.8
Pericardial patch augmentation	84 (89%)	34 (71%)	<0.01
Concomitant procedures (n)			
Coronary artery bypass grafting	2 (2%)	4 (8%)	0.1
Mitral valve repair	8 (9%)	1 (2%)	0.2
Tricuspid valve repair	4 (4%)	0	0.2
Perioperative data			
CPB time (min)	132±41	191±52	<0.01
Myocardial ischemic time (min)	90±29	141±29	<0.01
Intensive care unit stay (median, range; days)	1 (1-14)	1 (1-7)	0.2
Need for re-exploration	6 (6%)	7 (15%)	0.1
Neurological event (stroke)	0	0	
In-hospital mortality	1 (1%)	1 (2%)	0.6

Group 1: bicuspid AV repair; Group 2: bicuspid AV reimplantation; AV: Aortic valve; CPB: Cardio-pulmonary bypass.

Table 3: Follow-up data

	Group 1	Group 2	p-value
Late mortality; n (%/pt-yr)	10 (1.6)	1(0.4)	0.07
Endocarditis; n (%/pt-yr)	0	3 (1.3)	0.6
Stroke	1 (0.2)	1 (0.4)	0.6
All cases of bleeding; n (%/pt-yr)	2 (0.3)	0	0.4
Anticoagulation related bleeding	1 (0.2)	0	0.7
Remaining AR=2°	2 (0.3)	1 (0.4)	0.7
Reoperation; n (%/pt-yr)	11 (1.7)	5 (2.2)	0.5
Valve related complications; n (%/pt-yr)	18 (2.9)	9 (4)	0.6

Group 1: bicuspid AV repair; Group 2: bicuspid AV repair; AV: Aortic valve; pt-yr: patient-year; AR: aortic regurgitation.

Table 4: Echocardiographic data

Preoperative	Group 1 (n=94)	Group 2 (n=48)	p-value
AR<2°	16 (17%)	13 (27%)	0.2
AR[?]2°	78 (83%)	35 (73%)	0.2
Ejection fraction (%)	57±7	58±12	0.7
LVEDD (cm)	6±1	6±1	0.2
Pmax AV (mmHg)	17±8	14±8	0.1
Pmean AV (mmHg)	10±5	8±5	0.1

Postoperative (before discharge from hospital)	Group 1 (n=93)	Group 2 (n=47)	p-value
AR<2°	92 (99%)	47 (100%)	0.7
***AR=2°**	1 (1%)	0	0.7
Ejection fraction (%)	53±10	55±9	0.3
LVEDD (cm)	6±1	5±1	0.2
Pmax AV (mmHg)	17±8	15±5	0.1
Pmean AV (mmHg)	11±6	9±4	0.1
Latest follow up	Group 1 (n=72)	Group 2 (n=41)	p-value
AR<2°	70 (97%)	40 (98%)	0.7
***AR=2°**	2 (3%)	1 (2%)	0.7
Ejection fraction (%)	58±9	59±7	0.4
LVEDD (cm)	5±1	5±1	0.5
Pmax AV (mmHg)	26±18	15±9	<0.01
Pmean AV (mmHg)	17±12	9±5	<0.01

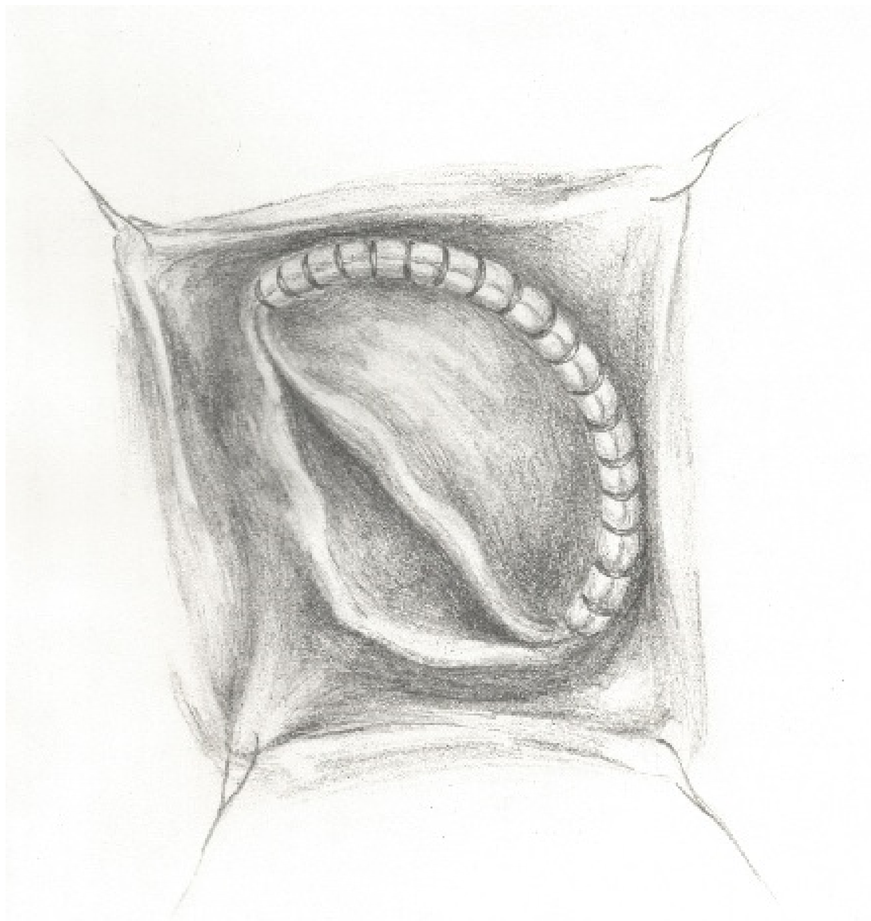
Group 1: bicuspid AV repair; Group 2: bicuspid AV reimplantation; AV: Aortic valve; AR: Aortic regurgitation; LVEDD: Left ventricular end-diastolic diameter (cm); Pmax AV: maximal pressure across the aortic valve (mmHg); Pmean AV: mean pressure across the aortic valve (mmHg). * AR[?]3° was not observed.

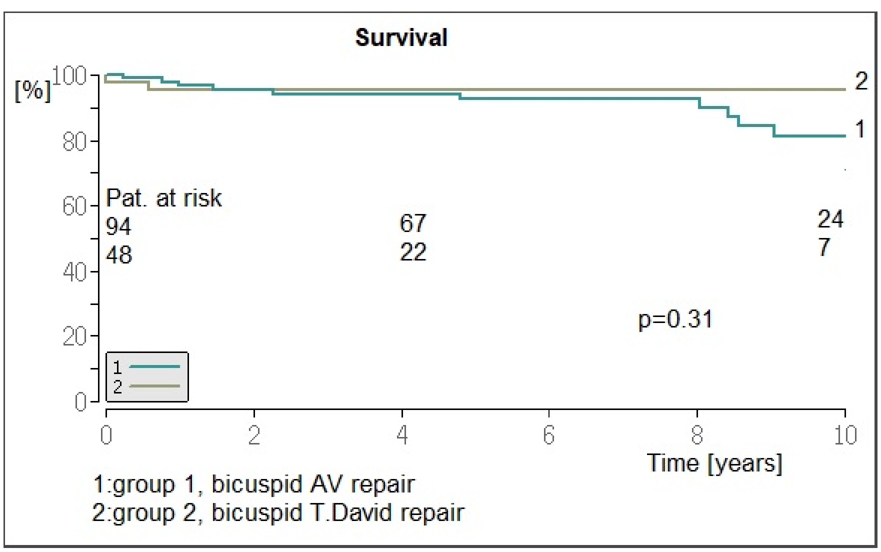
Figure legends

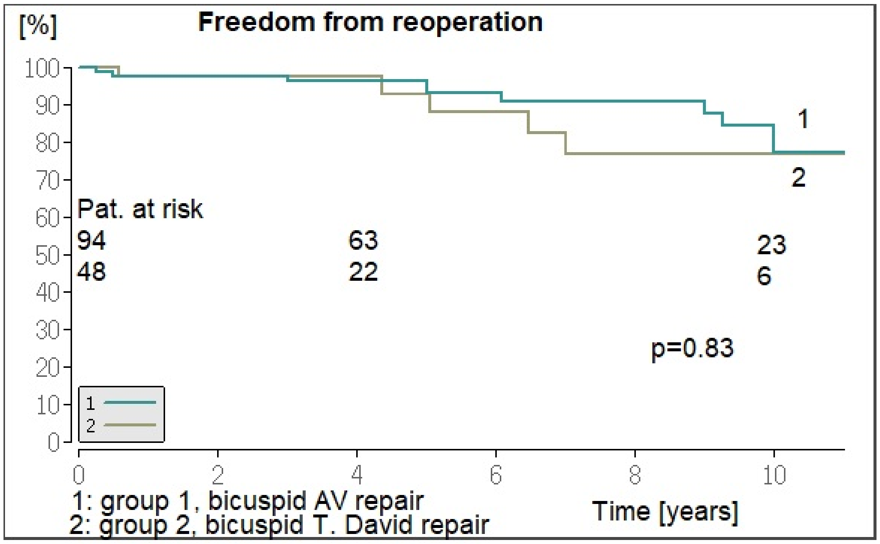
Figure 1: Pericardial patch augmentation in a bicuspid aortic valve repair

Figure 2: Kaplan-Meier curve showing survival after bicuspid aortic valve repair versus aortic valve reimplantation

Figure 3: Kaplan-Meier curve showing freedom from reoperation after bicuspid aortic valve repair versus aortic valve reimplantation




Survival
[%]
100
80
60
40
20
0
2
1
Pat. at risk
94
48
67
22
24
7
p=0.31
1
2
0
2
4
6
8
10
Time [years]
1:group 1, bicuspid AV repair
2:group 2, bicuspid T.David repair


[%]
Freedom from reoperation
100
90
80
70
60
50
40
30
20
10
0
1
2
Pat. at risk
94
48
63
22
23
6
p=0.83
1
2
0
2
4
6
8
10
1: group 1, bicuspid AV repair
2: group 2, bicuspid T. David repair
Time [years]