Long-term results after aortic valve-sparing operation (David I)†

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Abstract

OBJECTIVE: Aortic valve-sparing David procedure has gained broad acceptance. However, few long-term results have been published. We present our results.

METHODS: More than 450 David procedures have been performed in our institution so far. Of these, 126 patients were operated between July 1993 and December 2000. Median age was 57 (8-83) years and 46 (36.5%) were female. As many as 26 (20.6%) had Marfan syndrome, 21 (16.7%) had acute aortic dissection type A (AADA) and 67 (53.2%) had additional procedures.

RESULTS: There were six (4.8%) deaths in 30 post-operative period (POD), four of whom had AADA. In the follow-up, there were 32 (25.4%) late deaths, 11 (34.4%) of these were caused by cardiac or underlying disease or op-related. As many as 15 (11.9%) patients were re-operated; six (40%) were Marfan patients and two (13.3%) had early endocarditis. Follow-up echocardiography of 76 (60.3%) event-free patients showed valve insufficiency (AI) ≤ AI I° in 68 (89.5%) and grade II in 7 (9.2%) patients. Leaflet degeneration due to proposed leaftlet contact with the straight Dacron graft was not observed. A total of 36 (47.4%) patients were in New York Heart Association (NYHA) class I, 33 (43.4%) in NYHA II, and five (6.6%) were in class III. During the entire follow-up of 790 patient-years, there was no stroke or major bleeding. Survival at 1, 5 and 10 years was 93%, 85% and 70%, respectively. Freedom from valve replacement at 1, 5 and 10 years was 96%, 91% and 87%, respectively.

CONCLUSIONS: Regardless of the underlying pathology, valve-sparing David I procedure has acceptable long-term results. Valve-related complications such as stroke or major bleeding is exceedingly low.

Keywords: Aortic valve • Aneurysm • Valve sparing

INTRODUCTION

Composite replacement with a mechanical-valved conduit as first described by Bentall and DeBono has been the ‘gold standard’ for the treatment of a combined pathology of the ascending aorta and the aortic valve [1]. Excellent results have been achieved with this technique. However, a big disadvantage is the need for lifelong anticoagulation and potential problems associated with mechanical valves such as thrombo-embolic complications. In addition, in a large proportion of these patients, the native aortic valve is undamaged. The idea to preserve the undamaged native aortic valve led to the development of valve-sparing aortic root operations such the re-modelling (Yacoub) and the re-implantation (David) procedure [2,3]. Good short- and mid-term results have been published by several groups, including ours [4-20]. However long-term reports are rare.

Since 1993, we have used the ‘re-implantation’ (David) procedure in more than 450 patients. More than 400 of these were so-called ‘David I’ procedure with a straight Dacron graft. To our knowledge, this is the largest single centre cohort, worldwide. However, aortic valve-sparing operations are complex procedures and take a high level of surgical skill. Furthermore, several modifications of this ‘David’ procedure made comparison between different procedures difficult. Moreover, increased durability of modern tissue valves has raised additional questions about the necessity of these complex ‘valve-sparing’ operations [21]. The purpose of this study was to assess the long-term results after ‘re-implantation’ technique at a single centre.

MATERIALS AND METHODS

Patients

Individual consent was obtained from all patients to allow for follow-up examination.

Between July 1993 and December 2000, 126 patients were operated on using the aortic valve-sparing re-implantation technique with a straight Dacron graft (David I). This time frame was chosen to have follow-up of at least 8 years.

The indication for operation was the pathology of the ascending aorta with aortic valve insufficiency. The pre-operative data are given in Table 1.
Coronary angiography, echocardiography and computer tomography scans were routinely performed in elective patients. Aortic valve-sparing operation was considered if the pre-operative echocardiography showed undamaged aortic valve free of sclerosis or calcification. In acute aortic dissection type A (AADA), surgery was performed on an emergency basis. In all cases, the final decision to proceed with a valve-sparing operation was taken by the surgeon after inspection of the aortic valve.

**Surgical technique**

We have tried to standardise the surgical technique. After a standard median sternotomy, extra-corporeal circulation is performed with cannulation of the aorta and the right atrium. This technique of cannulating the ascending aorta even in AADA has been published by our group [22]. For some haemodynamically unstable patients with pericardial effusion, arterial cannulation is performed via the femoral artery.

Blood cardioplegia is our preferred method of myocardial protection. After assessment of the valve, coronary ostia were excised as buttons. The aortic root is mobilised from outside to a level immediately below the nadir of the aortic annulus. The aortic sinuses are resected up to a rim of 4–5 mm of the aortic wall. The diameter of the prosthesis is then calculated. The free commissures are lifted by suture lines and slightly brought together. After achieving optimal cusp coaptation, the diameter is measured by insertion of a mechanical valve sizer (St. Jude Medical) between the commissures.

The diameter of the sinu-tubular junction determines the diameter of the graft, with an additional over-sizing of 1–2 mm. Valve coaptation is considered optimal if 30–50% of the cusp area is involved. In most of the patients, the diameter of the Dacron prosthesis is either 26 or 28 mm.

Thereafter, 12 threads of 2/0-coated polyester fibre (Ethibond, Ethicon Inc., Norderstedt, Germany) are placed, inside-out horizontally below the valve in a circumferential fashion and anchored in the Dacron graft. The Dacron graft is fixed by tying these 12 threads. The remnants of the aortic sinuses and the aortic annulus are sutured inside the graft using three 4/0 polypropylene sutures (Prolene, Ethicon Inc., Norderstedt, Germany). The commissures are maximally pulled up without stretching the Dacron graft and then re-inserted (Fig. 1). Even though a straight Dacron graft is used, these sutures create small neo-sinuses. The coronary ostia are re-implanted to their respective neo-sinuses by using 5-prolene. Further procedures depend on the accompanying pathology.

**Table 1: Patient characteristics**

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Median (range)</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>57 (8–83)</td>
<td>46 (36.3%)</td>
</tr>
<tr>
<td>AADA</td>
<td>21 (16.7%)</td>
<td></td>
</tr>
<tr>
<td>Marfan syndrome</td>
<td>26 (20.6%)</td>
<td></td>
</tr>
<tr>
<td>Mitral valve pathology</td>
<td>11 (8.7%)</td>
<td></td>
</tr>
<tr>
<td>Bicuspid aortic valve</td>
<td>5 (4.0%)</td>
<td></td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>18 (14.3%)</td>
<td></td>
</tr>
<tr>
<td>Chronic type B aortic dissection</td>
<td>4 (3.2%)</td>
<td></td>
</tr>
</tbody>
</table>

In patients with AADA and those with pathological arch, replacement of the arch is performed under hypothermic circulatory arrest (HCA). Until 1999, deep HCA was used under 15 °C, and later on moderate HCA (25–27 °C) with selective antegrade cerebral perfusion (SACP) was undertaken. The surgical result is controlled by intra-operative trans-oesophageal echocardiography.

After aortic valve reconstruction, patients are anticoagulated with coumadin or aspirin (at the discretion of the individual surgeon) to prevent thrombo-embolic complications only for 3 months. Thereafter, anticoagulation therapy is discontinued unless there are other indications.

**Follow-up**

All patients were contacted for follow-up. The follow-up was done according to the guidelines [24]. All patients, who still had their native aortic valve (n = 77), were examined after obtaining their informed consent. Mean follow-up was 10 ± 2 years.

Valve function was evaluated using trans-thoracic colour Doppler echocardiography. Valve morphology, systolic function and diastolic were assessed in accordance with published criteria [23]. Aortic insufficiency (AI) was assessed semi-quantitatively as follows: 0 = none; I = minimal; II = mild; III = moderate; and IV = severe. A questionnaire about infectious, thrombo-embolic and bleeding complications was recorded.

**Statistical analysis**

All data analyses were performed with PASW Statistics 18 for Windows (IBM Germany, Herrenberg, Germany). All continuous variables were not normally distributed. They were expressed as median with related range. Kaplan-Meier analysis was used for evaluation of survival and the risk for re-operation. Cox regression was chosen for univariate and multivariate prognostic analysis of long-time survival and the risk for re-operation. Prognostic variables of death within 30 post-operative period (POD) were evaluated by logistic regression. A value of p < 0.05 was considered significant.

**RESULTS**

There were 6 (4.8%) deaths within the 30-day POD. As many as four patients had AADA, the fifth a combined aortic arch
aneurysm with coronary artery disease and the sixth patient an aortic arch aneurysm with aortic dissection type B. The peri-operative data are shown in Table 2.

The post-operative echocardiography results are summarised in Table 3. The majority of the patients was discharged either with no valve insufficiency (84; 66.7%) or only minimal insufficiency, less than grade I (26; 20.6%). All others had AI grade I.

At the time of initial operation, the median age of the patients was 66 (17–83) years.

In follow-up, there were 32 (25.4%) late deaths – 11 (34.4%) of these were caused by cardiac or underlying disease or op-related, 6 (18.8%) patients died from other reasons and the cause of death for 15 (46.9%) patients were unknown.

As many as 15 (11.9%) patients underwent re-operation of the aortic valve; six (40%) of them had Marfan syndrome; three (20%) died, two immediately after re-operation. Both of them underwent re-operation due to early endocarditis within 5 months of the initial operation. The third patient died of cardiac arrest 2.6 years after re-operation. One of these patients with endocarditis had an initial diagnosis of AADA.

The remaining patients (12; 80%) were re-operated after a mean time of 4.8 ± 4.4 years and were still alive.

Follow-up was performed in all living patients who still had their native aortic valves (76; 60.3%). Echocardiography showed AI 0° in 68 (89.5%) and AI I° in 7 (9.2%) patients. The median age of these patients at the initial operation was 54 (16–75) years. Leaflet erosion due to proposed leaflet contact with the straight Dacron graft was not observed in any patient.

As many as 36 (47.4%) patients were in NYHA class I, 33 (43.4%) in NYHA II and 5 (6.6%) were in NYHA class III. During cumulative follow-up of 790 patient-years, there was no stroke or major bleeding.

Survival at 1, 5 and 10 years was 92%, 84% and 70%, respectively (Fig. 2). Freedom from valve replacement at 1, 5 and 10 years was 96%, 91% and 87%, respectively (Fig. 3).

Isolated elective David patients (excluding Marfan)

Isolated elective David procedure was done in 38 (30.2%) patients. There was no mortality in 30 POD. In the follow-up, there were six (15.8%) deaths (6.7 ± 3.2 years). One died after myocardial infarction, one died due to pneumonia and the rest (4; 66.7%) died of unknown causes. A total of four (10.5%) patients underwent re-operation on their aortic valves (mean time of 6.2 ± 6.2 years). At discharge, three of these patients had AI 0° and one AI I°. The initial operation in two of them was in early phase of our experience (1993–1994).

Table 2: Peri-operative data

<table>
<thead>
<tr>
<th>Factor</th>
<th>Patients (n = 126) Median (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiopulmonary bypass time (min)</td>
<td>153 (66–440)</td>
</tr>
<tr>
<td>Aortic cross-clamp time (min)</td>
<td>121 (54–205)</td>
</tr>
<tr>
<td>Circulatory arrest time (min), n = 70</td>
<td>28 (4–113)</td>
</tr>
<tr>
<td>ICU stay (days)</td>
<td>1 (0–9)</td>
</tr>
<tr>
<td>Combined procedures</td>
<td>No. of patients (%)</td>
</tr>
<tr>
<td>CABG</td>
<td>21 (16.7%)</td>
</tr>
<tr>
<td>Replacement of proximal aortic arch</td>
<td>7 (5.6%)</td>
</tr>
<tr>
<td>ASD closure</td>
<td>3 (2.4%)</td>
</tr>
<tr>
<td>Mitral valve reconstruction</td>
<td>7 (5.6%)</td>
</tr>
<tr>
<td>Total arch replacement</td>
<td>37 (29.4%)</td>
</tr>
<tr>
<td>Total arch replacement with Elephant trunk</td>
<td>1 (0.8%)</td>
</tr>
<tr>
<td>Resection of subclavian artery aeurysm</td>
<td>1 (0.8%)</td>
</tr>
<tr>
<td>Fenestration of abdominal aorta</td>
<td>2 (1.6%)</td>
</tr>
</tbody>
</table>

Table 3: Intra-operative/discharge echocardiography data

<table>
<thead>
<tr>
<th>Aortic insufficiency</th>
<th>Patients (n = 126) No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AI 0°</td>
<td>84 (66.7%)</td>
</tr>
<tr>
<td>AI O-1°</td>
<td>26 (20.6%)</td>
</tr>
<tr>
<td>AI 1°</td>
<td>9 (7.1%)</td>
</tr>
<tr>
<td>AI I-II°</td>
<td>3 (2.4%)</td>
</tr>
<tr>
<td>AI II°</td>
<td>1 (0.8%)</td>
</tr>
<tr>
<td>Unknown</td>
<td>3 (2.4%)</td>
</tr>
</tbody>
</table>

Figure 2: Survival after discharge.

Figure 3: Patients at risk for re-operation.
The rest (28; 73.7%) still had their native valves (mean follow-up 10.4 ± 1.7 years). At follow-up, 12 (42.9%) patients had AI O°, 12 (42.9%) AI I°, and four (14.3%) AI II°, respectively.

Survival at 1, 5 and 10 years was 100%, 95% and 86%, respectively. Freedom from valve replacement at 1, 5 and 10 years was 12 (42.9%) AI I°, and four (14.3%) AI II°, respectively. Freedom from death and re-operation at 1, 5 and 10 years was 97%, 90% and 78%, respectively.

Marfan syndrome
A total of 26 (20.6%) patients had Marfan syndrome. 6 (23.1%) had re-operation on their aortic valve during follow-up (mean time of 3.0 ± 2.7 years). As many as four of them had Al O° and two had Al I° at discharge. Two (7.7%) patients died, one after 5.6 years due to rupture of the descending aorta and the other after 4.9 years due to cardiac arrest. As many as 19 (73.1%) patients still had their native valves (mean follow-up 11.1 ± 2.2 years). At follow-up, eight (42.1%) of these patients had Al O°, nine (47.4%) Al I° and two (10.5%) had Al II°. Marfan syndrome was identified as a risk factor for re-operation and long-term mortality in the univariate analysis, whereas freedom from Marfan syndrome resulted in a better long-term survival (Table 4).

AADA
As many as 21 (16.7%) suffered from AADA; three (14.3%) patients died within the 30 POD and four (19.1%) during follow-up of unknown causes (mean time of 6.5 ± 2.7 years). One of the deceased patients with AADA had re-operation due to early endocarditis after 123 days of the initial operation. He had a Candida albicans plus Staphylococcus epidermidis infection. A second patient was re-operated after 5 years. The remaining 13 (61.9%) patients still had their native valves. As many as three (23.1%) patients had Al O°, eight (61.5%) had Al I° and two (15.4%) Al II° (mean follow-up 9.9 ± 1.6 years). AADA was identified as a risk factor for 30-day mortality in the univariate analysis (Table 4).

Univariate and multivariate analysis
Univariate analysis identified X-clamp time, cardiopulmonary bypass (CPB) time, AADA and AI before surgery as risk factors for 30-day mortality. In multivariate analysis, only CPB time and AI before surgery were significant.

X-clamp time, CPB time, time of circulation arrest, age, freedom from Marfan syndrome, coronary artery disease, first thoracic operation and combined procedures were risk factors for long-term mortality in univariate analysis. Multivariate analysis only indicates age, X-clamp time and time of circulation arrest as significant, prognostic factors.

However, being younger, and male, having first thoracic operation and both pre- and post-operative AI were risk factors for re-operation in univariate analysis. When performing

### Table 4: Forward LR logistic and Cox-regression of variables affecting 30-day mortality, long-term mortality and re-operation.

<table>
<thead>
<tr>
<th>Risk factors</th>
<th>30-day mortality (n = 126)</th>
<th>Long-term mortality (n = 120)</th>
<th>Re-operation (n = 126)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Univariate Sig. (β)</td>
<td>Multivariate Sig. (β)</td>
<td>Univariate Sig. (β)</td>
</tr>
<tr>
<td>Age</td>
<td>n.s.</td>
<td>n.s.</td>
<td>&lt;0.001 (0.066)</td>
</tr>
<tr>
<td>Male gender</td>
<td>n.s.</td>
<td>n.s.</td>
<td>n.s.</td>
</tr>
<tr>
<td>Grade of AI pre-operatively</td>
<td>0.044, (-0.669)</td>
<td>n.s.</td>
<td>n.s.</td>
</tr>
<tr>
<td>AI pre-operatively (yes/no)</td>
<td>0.009, (-2.364)</td>
<td>0.067, (-1.897)</td>
<td>n.s.</td>
</tr>
<tr>
<td>Marfan syndrome</td>
<td>n.s.</td>
<td>n.s.</td>
<td>0.042, (-1.485)</td>
</tr>
<tr>
<td>AADA</td>
<td>0.049, (1.684)</td>
<td>n.s.</td>
<td>n.s.</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>n.s.</td>
<td>n.s.</td>
<td>0.046, (0.817)</td>
</tr>
<tr>
<td>Additional procedure</td>
<td>n.s.</td>
<td>n.s.</td>
<td>0.003, (1.205)</td>
</tr>
<tr>
<td>First thoracic operation</td>
<td>n.s.</td>
<td>n.s.</td>
<td>0.049, (0.733)</td>
</tr>
<tr>
<td>Cross-clamp time</td>
<td>0.003, (0.049)</td>
<td>n.s.</td>
<td>n.s.</td>
</tr>
<tr>
<td>CPB time</td>
<td>0.002, (0.022)</td>
<td>0.004, (0.019)</td>
<td>n.s.</td>
</tr>
<tr>
<td>Circulation arrest time</td>
<td>n.s.</td>
<td>n.s.</td>
<td>&lt;0.001, (0.027)</td>
</tr>
<tr>
<td>Grade of AI post-operatively</td>
<td>n.s.</td>
<td>n.s.</td>
<td>&lt;0.001, (0.009)</td>
</tr>
<tr>
<td>AI post-operatively (yes/no)</td>
<td>n.s.</td>
<td>n.s.</td>
<td>n.s.</td>
</tr>
</tbody>
</table>

Sig. = significance; β = regression coefficient; and n.s. = statistically not significant.

Age
A total of 30 (32.8%) patients, who underwent David procedure, were older than 65 years. As many as 20 (66.7%) patients died during the follow-up (mean time of 4.6 ± 3.1 years), seven (23.3%) of these died from cardiac or underlying disease or OP-related, five (25%) patient died from other reasons and the cause of death for eight (40%) patients was unknown. One of them underwent re-operation on the aortic valve. The remaining 10 (33.3%) were living with their native valves.

At the time of operation, 96 (76.2%) patients were younger than 66 years. As many as 18 (18.8%) patients died during follow-up (mean time of 4.2 ± 3.3 years), 10 (55.6%) patients died from cardiac or underlying disease or the death was OP-related, one died of cancer and the cause of death for others (7, 38.9%) was unknown. As many as 14 (14.6%) patients underwent re-operation on the aortic valve. The remaining 66 (68.8%) patients were living with their native valves.

Age was identified as a risk factor for re-operation and long-term mortality in univariate and multivariate analysis; as a result, younger patients underwent more often re-operations (Table 4).
multivariate analysis, only age, male gender and post-operative AI were significant risk factors (Table 4).

**DISCUSSION**

‘Bentall’ operation and its modifications have been seen as the ‘gold standard’ for the treatment of combined pathology of the ascending aorta and the aortic valve [1]. A major disadvantage remains the need for lifelong anticoagulation as well as the potential problems associated with mechanical valves such as thrombo-embolic complications.

Valve-sparing aortic operations such as re-modelling (Yacoub) or re-implantation (David) procedures have been proposed as alternatives [2,3]. The supposed advantage of these operations was the absence of long-term anticoagulation. However, increased durability of modern tissue valves has raised additional questions about the necessity of these complex ‘valve-sparing’ procedures.

In the current study, 15 patients underwent re-operation on their aortic valve. This includes patients from our early collective where so-called ‘learning curve’ may have been a factor. Our group mentioned in earlier publications that at least some of these re-operations were due to technical failure, where the reconstructed valve was not properly re-implanted in the Dacron pros thesis, which led to late failure [10–12]. In our opinion, it is of utmost importance that the commissures should be maximally pulled up without stretching the Dacron graft and then re-inserted.

Erosion due to supposed leaflet contact with the straight Dacron graft in ‘David I’ procedure was not observed in a single patient. Thus, the original re-implantation procedure using a straight graft does not seem to have a negative impact on the leaflets.

During the entire follow-up of 790 patient-years, no stroke or any incidence of major bleeding was recorded. In this regard, ‘David I’ seems to be superior to the published reports with biological-valved conduits. Etz et al. reported a stroke rate of 0.85/100 patient-years and a rate of haemorrhage of 0.3/100 patient-years [21].

Not a single case of endocarditis was observed during the entire follow-up, apart from the two early cases. We believe that the ‘spared’ native aortic valve in this procedure is living tissue and thus more resistant to infection than prosthetic valves.

In view of univariate analysis of our data and published literature, valve-sparing operations do not seem to have superior long-term results compared to biological-valved conduits in elderly patients [21]. These procedures are technically complex and the reconstructed valve may not be competent at the end of the operation making a valve replacement necessary and thus prolonging X-clamp time. The majority of the elderly patients died during follow-up due to non-cardiac-related reasons. In this context, it remains questionable if elderly patients do really profit from a technically demanding procedure.

In isolated elective David patients excluding Marfan patients, short-term results were excellent with no peri-operative deaths. Two out of four patients, who underwent re-operation, were from our early experience and most probably part of the ‘learning curve’.

At 10 years in this subgroup, freedom from re-operation was 92% and survival was 86%. This shows that long-term results after isolated elective ‘David I’ procedure are acceptable.

In patients with Marfan syndrome, the long-term results show a mixed picture. Although all of them survived the initial operation, six (6/26) underwent re-operation on their aortic valve in the follow-up. Four of these patients were discharged with no aortic valve insufficiency (AI 0°) and two with AI I°. In two of these patients, re-operation became necessary due to technical problem, as mentioned by our group previously [20]. Even if initial results are good, there may be valve insufficiency later on probably due to the ongoing disease process. Univariate analysis did not identify Marfan syndrome as a risk factor for both re-operation and long-term mortality. However, there is a need for careful intra-operative inspection of the valve to identify patients with significant cusp prolapse. Morphological changes in the texture of the valve may negatively influence long-term outcome. In these cases, a Bentall procedure may be a better alternative [20]. On the other hand, 19 patients (19/26) still had their native valves even after a long follow-up, showing that in this cohort, the late results are good in a significant proportion of the patients.

AADA is an absolute emergency with an extremely dismal outcome without immediate surgery. Even then, these patients have a high risk of adverse outcome [25]. Therefore, the decision to proceed with valve-sparing operation should be weighed very carefully in this cohort. Although, 3/21 (14.3%) died within 30 POD, the survivors did well. Univariate analysis showed that AADA is a prognostic factor for 30-day mortality. Whether such a complex technique should be used in an emergency situation is still a subject to controversy. However, we believe that as long as the surgeon is well experienced in these types of operations, he/she could proceed with this technique even in AADA patients.

These results indicate that ‘David I’ procedure has an acceptable long-term success, especially as elective, isolated procedures in not connective tissue disease. We started with valve-sparing David I procedure in 1995 and we stuck to this technique as the early results were good (as shown by our early publications) and we have standardised this technique instead of modifying this procedure every few years as has been done by others. Our collective was operated by 11 surgeons. Although technically demanding, this procedure is reproducible and with low mortality in experienced hands.

**LIMITATIONS**

The mid-term results of these patients were published previously [19]. However, this is the first series of patients with a mean follow-up of 10 years. Unfortunately, not all of the patients were examined routinely at our institution; therefore, no conclusion about patients, who died during the follow-up, is possible.

**CONCLUSIONS**

Valve-sparing ‘David I’ procedure, especially in isolated, elective situations and in non-Marfan patients, has excellent long-term results.

Valve-related complications such as stroke, major bleeding and endocarditis are exceedingly low.

Thus at our centre, all patients with significant aortic root aneurysm are potential candidates for valve-sparing procedures. However, in the elderly or in patients with Marfan syndrome, careful selection is indispensable. Perhaps, in view of our study, patients above the age of 65 years could be treated with a biological-valved conduit.
Conflict of interest: none declared.

REFERENCES


APPENDIX A. CONFERENCE DISCUSSION

Dr R. De Paulis (Rome, Italy): This paper is very important because it comes from a group, the group from Hannover, who exclusively used the David I operation. I think it’s the only group still performing the original David operation.

The second important point is that the same operation has been done by a number of surgeons, most of whom are now very well-recognized surgeons, and so this has added to the reproducibility and standardisation of the procedure.

The third important fact is that this is a true 15 years follow-up, because recruitment was stopped in the year 2000.

Unfortunately, the multivariate analysis (probably because of few patients at risk) didn’t show any significant risk factors. However, if you look at the univariate analysis, you can find three subgroups that perform less well compared to the rest of the population: old people, people with Marfan, and people with an aortic dissection.

So my first question is partially answered already. Do they now have, after another 10 years, a cut-off for age even though they’re facing a normally functioning aortic valve?

The second question is, in Marfan patients, do they think that the absence of sinuses can be important in a group of patients that have intrinsic leaflet abnormality at higher risk of earlier failure than normal groups?

And the third question relates to dissection. Do they think that dissection is an optimal indication for a valve-sparing procedure or, because of the general condition of the patient, that maybe a faster and simpler operation is better?

And then another two small questions about the leaflet-plasty. Do they consider leaflet-plasty as a part of this operation, or is this considered an additional risk factor?

And finally, I’ve seen that the graft sizes were in the range of 26 and 28, which is to me rather small for a large German population. So the question is, have they increased the size of the graft in the last 10 years?

Dr Shrestha: First question, the age. As I said before, if you are very experienced with the David, even if someone is 70 and you are doing isolated David, maybe you could do it. But, of course, you also have to look at the patient. Some patients are 70 and look like 60, but some are 70 and look like 80. So in those patients maybe I’d go for a quick operation and do a Bentall. Because, at the end of the day, we are just service providers and it’s not up to us to decide what to do for our egos. I think we have to remember that the patient has to live, and that’s the most important thing. So I would say that it depends upon the experience.

Second, I think from our results I would say that the most important thing in Marfan is to catch them early. If the leaflets are still intact, I think the sinuses (because we do cut out all the sinuses in this operation) would not make much difference, but the leaflet has to be relatively okay. If there is too much elongation, then maybe it’s not a good idea to do a David. But if the leaflets are still okay, I’d do it.

The third point is about the type A dissections. I know that you are right, that it is a very complicated operation and, even without doing David, the patient is at high risk. Therefore in recent years, if the size of the aorta is normal and the aortic valve is okay, we are now doing the so-called Hannover technique of root stabilisation. And we go for that, where you don’t have to reimplant the aortic ostia, so you’re finished in 15 minutes. But if the root is dilated and the sinuses are dilated and you have to go either for the Bentall or for the David, then I think it is very important to consider the experience of the surgeon when you’re operating. If you’re operating at 3 o’clock in the morning with a young resident, then perhaps, even if you can do a David, maybe you should do a Bentall because the primary consideration is that the patient has to survive. It depends upon how and when you are operating, and with whom, and how old the patient is, and how wide the dissections go. If you have to do a total arch, then maybe it’s better to do a
quick operation, but we are doing more and more root stabilisation now if
the valve is intact.

And the size. In this series in the beginning, of course, there were many
formulas proposed by Tirone David and others, to choose the size of the
graft. In Hannover, at that time, working many years with Wolfgang
Harringer, it was usually 26 and 28, 26 for smaller people and 28 for bigger
ones. Because it's also important that the graft is not too large that you have
to do the distal anastomosis also, that there is not too much excess Dacron at
the distal anastomosis. We use normal mechanical valve sizeers. After pulling
up the three commissures, you can adapt it a little bit and see which valve
size is the best, so that you have enough coaptation. Then it's usually 28, but
in some of the patients it was 30. Because in Marfan's, of course, they are big
and you'd rather go for 28 or 30.

**Dr S. Nashef (Cambridge, UK):** I am curious about what you define as
re-operation in Marfan's. You said that Marfan's was found to be a risk factor
for the need for re-operation. And of course, we all know that Marfan
patients often need multiple procedures for some other reasons such as the
aorta elsewhere and the mitral and so on. How did you define re-operation
in this group?

**Dr Shrestha:** We are only talking about the aortic valve here. The Marfan
patients were operated for the distal aorta. We did not include them. It's only
for the aortic valve.

**Dr M. Borger (Leipzig, Germany):** You said six Marfan patients needed
re-operation. Two were early technical failures. What was the cause of the
failure in the other four?

**Dr Shrestha:** To be frank, we did not know. Because at the time of this
series, they went with aortic insufficiency grade 0 or 0 to 1. So at
re-operation, we didn't know. It was not a technical failure, it's only four of
the patients. So what is important to know is that I think that if the valves are
already elongated too much, even if you get a good coaptation and a good
result in initial operation, because the disease progresses, I think it is a factor.
That was also not the original indication for the David as you know.

**Dr K. Kallenbach (Heidelberg, Germany):** I would like to comment on this
problem, because we published the Hannover data on the first 284 David
patients in 2005. We reported experience of the period from 1993 up to
2004, therefore I don't know how much overlap there is with your patients.
However, we had seven failures and already in this paper we reported that
Marfan syndrome is a risk factor for re-operation.

However, we must look in detail at these patients for the underlying
reasons for limited durability. Three patients had a coaptation underneath
the proximal edge of the prosthesis; we know that this is a risk factor for
early failure from studies from Pethig as well from Khoury. Another two
patients had intra-operative technical problems such as myocardial failure
with consecutive transplantation. The valves were intact. Therefore only
two patients in this study, published in Circulation in 2005, were
re-operated after 4 and 7 years for progressive valve failure. I don't know
how much overlap exists with the patients you are presenting, I don't
know if there was another failure on top, but we have to analyse these
data very carefully. In our study, the underlying reason for re-operation
was more a technical problem and probably learning curve related than
really valve failure due to deterioration in Marfan's. I still believe Marfan
and David I works very well.

**Dr Shrestha:** Yes, I agree with you. But the key is to have these patients
come early enough before the valve gets damaged.