Aortic valve replacement in children: are mechanical prostheses a good option?

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Abstract

Objective: The choice of the most appropriate substitute in children with irreparable aortic valve lesions remains controversial. The aim of this study was to assess early and late outcomes following aortic valve replacement (AVR) with mechanical prostheses in children. Patients: Fifty-six patients (42 male, 14 female, mean age 11.2, range 1–16 years) undergoing AVR with mechanical prostheses between October 1972 and January 1999 were evaluated. Thirty-six patients (64.2%) underwent previous cardiac surgery. Disease aetiology was congenital in 47 patients (congenital aortic stenosis in 33, and other congenital abnormalities in 14) (83.9%), infective in four (7.1%), rheumatic in two (3.4%), and three (5.3%) had connective tissue disorders. Haemodynamic indication for AVR was aortic regurgitation (AR) in 24 (42.8%), aortic stenosis (AS) in 22 (39.2%) and mixed disease in ten (17.8%). Twenty-eight patients (50.0%) were in New York Heart Association (NYHA) class III-IV before surgery. Concomitant procedures were performed in 31 patients (55.3%), including aortic root enlargement in 28 (50%). The mean size of implanted valves was 22.4 mm (range 17–27 mm). All patients received long-term anticoagulation treatment with sodium warfarin, aiming to maintain an international normalized ratio (INR) between 2.5–3.0. The mean follow-up was 7.3 years (range 0–26, total 405 patient-years). Results: Operative mortality was 5.3% (three patients). Three patients developed complete heart block requiring pacing, two of them permanently. Late events included valve thrombosis (one), transient stroke (one), paravalvular leak of a mitral prosthesis (one), aneurysm of sinus of Valsava (one) and pannus ingrowth (one). There was no major haemorrhagic event. Five patients required re-operation (8.9%), but none due to outgrowth of the valve. Regarding actuarial freedom from thrombo-embolism, any valve-related event and re-operation at 20 years was 93, 86.6 and 86.4%. There were three late deaths. Actuarial survival, including operative mortality, at 10 and 20 years was 91 and 84.9%. The actuarial survival for the group of the patients with congenital AS (n = 33) at 10 and 20 years was 93.5%, whereas for the children with other congenital heart problems (n = 14) this was 85.7 and 64.3% (P = 0.09). At the latest clinical evaluation, 44 children were in NYHA class I and six were in class II. The mean gradient across the aortic prosthetic valve on echocardiography was 17.9 mmHg (range 0–47 mmHg). Conclusions: Mechanical AVR, with enlargement of the aortic root if necessary, remains an excellent treatment option in children. It is associated with acceptable operative mortality, low incidence of late events and re-operation, and provides good long-term survival. It clearly represents a good alternative to available biological substitutes, including the pulmonary autograft (Ross procedure).

Keywords: Mechanical aortic valve replacement; Children; Irreparable aortic valve lesions

1. Introduction

The selection of the most appropriate substitute in children with irreparable aortic valve lesions remains controversial, with all the available options having certain drawbacks.

The mechanical prostheses carry the risks of thrombo-embolism, the need for anticoagulation and the potential of valve outgrowth for the growing young patient.

The porcine and pericardial bioprostheses are considered unsuitable for children due to their early degeneration [1,2], whereas the homografts, besides their tendency for early calcification, particularly in the youngest recipients [3], exhibit limited durability and may not be readily available [4].

The pulmonary autograft (Ross procedure), which is increasingly advocated as the ideal prosthesis for aortic valve replacement (AVR) in children [5], has the obvious disadvantage, in addition to the complexity of the insertion
technique, of jeopardizing the integrity of a normal right ventricular outflow tract, thereby putting two valves at risk.

In Southampton, implantation of mechanical valves with optional annular enlargement and long-term oral anticoagulation with sodium warfarin remains, with occasional exceptions, the standard treatment for children requiring replacement of an aortic valve.

The description and analysis of the early and late results achieved through this therapeutic approach is the objective of this paper.

2. Patients and methods


Five overseas patients were lost to follow-up and were excluded from this study. The remaining 56 patients, 42 male and 14 female with a mean age of 11.2 years, range 1–16 years, are the subjects of this report. Twenty-four (42.8%) children were up to 10 years, with the remaining 32 (57.1%) being over 10 years old.

2.1. Follow-up

Data on the patients preoperative clinical features, types of operations, peri-operative clinical course, late events, reoperations and survival were obtained through a detailed review of the hospital medical records. Additional information was sought from the referring physicians, family doctors and/or the patients’ families as appropriate.

Follow-up clinical information was available for all hospital survivors (n = 53) within 6 months, and echocardiographical data for 45 patients within 2 years from the closing date of this study (30 March 1999). Mean follow-up was 7.3 years (range 0–26 years) with a total of 405 patient-years. The mean age of the patients at the latest follow-up was 18.4 years (range 0.9–39.8 years), with 21 being up to 16, and 29 more than 16 years old.

2.2. Definitions and statistics

Operative mortality includes any death occurring within 30 days after the operation or during the same hospital admission. Late events include the events taking place after the patients discharge from the hospital.

Freedom from thrombo-embolism, anticoagulation treatment-related bleeding, any valve-related event, re-operation and survival were calculated using the product–limit method of Kaplan–Meier. Survival curves were compared with the log rank test. Statistical analyses was done with the statistical package SPSS PC (version 8.0) (SPSS, Inc, 444 N, Chicago, IL).

2.3. Clinical features

The aetiology of the disease was congenital in 47 patients (83.9%), infective in four (7.1%), rheumatic, affecting both aortic and mitral valves, in two (3.4%), and three (5.3%) had connective tissue disorder (Marfan’s syndrome in two and Still’s disease in one).

Thirty-three (70.2%) of the 47 children with congenital heart disease had valvar (n = 23), sub-aortic (n = 8) or supra-valvar (n = 2) congenital aortic stenosis (complicated by acute bacterial endocarditis acquired during a cardiac catheterization procedure in one child), with the remaining 14 (29.2%) having a variety of abnormalities; these were truncus arteriosus in four patients, ventricular septal defect (VSD) and aortic regurgitation (AR) in six, transposition of the great arteries in two, complete atrio-ventricular septal defect in one and interruption of the aortic arch and aortopulmonary window in one.

Thirty-six patients (64.2%) underwent 61 cardiac surgical procedures before having a mechanical AVR (Table 1). Twenty-eight (50.0%) were in New York Heart Association (NYHA) class III–IV, and 21 (37.5%) had impaired left ventricular function on echocardiography and/or angiography.

The haemodynamic derangement indicating AVR was AR in 24 patients, aortic stenosis (AS) in 22 patients and mixed AS and AR in ten patients.

2.4. The operation

The operations were performed through a median sternotomy and cardiopulmonary bypass (CPB), established via ascending aortic and single atrial or bicaval cannulation, and systemic (14.5–28°C) hypothermia. Prior to 1978, we used continuous coronary perfusion for AVR; subsequently, and up to 1995, myocardial protection was achieved with cold crystalloid cardioplegia (St Thomas’s solution). Since then, cold blood cardioplegia has been used.

Where the insertion of a suitable valve size was not feas-

Table 1

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<tr>
<th>Previous cardiac operations</th>
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<tr>
<td>Type of operation</td>
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<tr>
<td>Aortic valvotomy</td>
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<tr>
<td>Resection of subaortic stenosis</td>
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<tr>
<td>Repair of supravalvular aortic stenosis</td>
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<td>Repair of aortic valve</td>
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<tr>
<td>Closure of ventricular septal defect</td>
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<td>Repair of coarctation of the aorta</td>
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<tr>
<td>Mitral valvotomy</td>
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<tr>
<td>Repair of truncus arteriosus</td>
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<tr>
<td>Mitral valve replacement</td>
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<tr>
<td>Aortic valve replacement (homograft)</td>
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<tr>
<td>Pulmonary valvotomy</td>
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<tr>
<td>Repair of total atrioventricular canal</td>
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<tr>
<td>Repair of interrupted aortic arch with aortopulmonary window</td>
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<td>Correction of TGA (switch operation)</td>
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<td>Correction of TGA (Mustard operation)</td>
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*TGA: Transposition of great arteries.
ble, an aortic root enlargement procedure, by extending the aortotomy through the annulus down to the anterior leaflet of the mitral valve and inserting a patch of bovine pericardium or dura mater, was employed [6]. In the presence of valvular infection, standard operative principles included the debridement of all infected tissues and abscess cavities, meticulous washing of all affected areas with povidone iodine solution (Betadine) and the reconstruction of resulting defects using glutaraldehyde-treated autologous or bovine pericardium.

All prostheses were positioned in the sub-coronary position using the 3/0 ethibond-interrupted or the 3/0 prolene-continuous suture technique. Types of implanted valves were St Jude Medical in 24, CarboMedics in 23 and Bjork–Shiley in nine patients, and their mean size was 22.4 mm (range 17–27 mm; Fig. 1). Thirty one patients underwent 43 concomitant procedures. There was aortic root enlargement (Nicks procedure) in 28 patients (using patch of bovine pericardium in 15 and dura mater in 13), resection of subaortic membrane in two, mitral valve replacement (MVR) in eight, aortic root replacement in two, tricuspid annuloplasty in one, repair of aortic coarctation in one and insertion of an aortic homograft in the pulmonary region in one.

2.5. Anticoagulation treatment and postoperative assessment

All children were given sodium warfarin orally, aiming to maintain a closely-monitored international normalized ratio (INR) within the range of 2.5–3.0 for AVR and 2.5–3.5 for MVR. After their discharge from the hospital they were seen at 3-, 6- or 12-monthly intervals, as required by the cardiac surgeons and the cardiologists. Echocardiography was routinely performed before discharge from the hospital and during the outpatient visits.

3. Results

3.1. Operative mortality and morbidity

There have been three operative deaths (5.3%) amongst children who had previous cardiac surgical interventions and presented with severely impaired myocardial function. A 10-year-old boy with a dysplastic mitral valve and subaortic stenosis, had, 3 years earlier, an emergency MVR and resection of a subaortic membrane, while he was in a moribund condition. He developed recurrence of his mitral regurgitation and subaortic stenosis with myocardial ischaemia due to occlusion of the left main coronary artery by a grossly abnormal aortic valve. Following repeat MVR and an AVR, discontinuation from CPB was not achieved.

A 3-year-old boy, who had repair of an interrupted aortic arch and aorto-pulmonary window in the first week of life and an AVR with an aortic homograft 6 months later, sustained a cardiac arrest during a cardiac catheterization procedure and required an emergency AVR and MVR. On weaning from CPB, he developed right ventricular dysfunction and had a right internal mammary to right coronary artery graft. He died on the eighth postoperative day from low cardiac output.

The third patient, a 1-year-old girl who had repair of truncus arteriosus and a VSD 6 months earlier, had severe AR and died 6 days after an emergency AVR from multi-organ failure and sepsis.

Eight additional patients (14.2%) experienced significant post-operative complications. These consisted of complete heart block in three patients, two of whom needed a permanent pacemaker, pericardial effusion requiring drainage in three patients, left leg ischaemia, following an emergency left femoral cannulation, necessitating a fasciotomy and subsequent left below knee amputation in one patient, and right hemiplegia due to prolonged hypotension during institution of an emergency CPB in one patient.

![Fig. 1. Number of mechanical valves implanted in the aortic position/size (mean size, 22.4 mm).](image-url)
3.2. Late events and re-operations

Late complications included valve thrombosis in one patient, transient stroke in one, paravalvular leak of a prosthetic mitral valve in one, aneurysm of sinus of Valsava in one and pannus in-growth in one. The valve thrombosis and the thrombo-embolic event occurred in two patients who had stopped taking their warfarin tablets.

Maintenance of the INR within the range of 2.5–3.0 was difficult in two cases, but without adverse clinical effects. Minor self-limiting episodes of nose-bleed were recorded in four children, but there were no haemorrhagic events requiring blood transfusion. There has been no structural valve failure or episode of prosthetic valve endocarditis. Actuarial freedom from major anticoagulation treatment-related bleeding, thrombo-embolism and any valve-related complication at 20 years was 100, 93 and 86.6% (Fig. 2), with the corresponding linearized rates being 0, 0.3 and 1.3%/patient-year.

Five patients underwent further surgical interventions with no operative mortality. One patient underwent repair of an aneurysm of sinus of Valsava and repeat AVR for AR. Two needed a repeat AVR due to pannus in-growth and valve thrombosis, respectively and one required repair of a peripheral leak of a prosthetic mitral valve. The fifth patient had very poor biventricular contractility preoperatively, secondary to devastating effects of rheumatic fever, and following an AVR and MVR he developed global myocardial dysfunction and received a heart transplant. Actuarial freedom from re-operation at 10 and 20 years was 86.4% (Fig. 3), and the linearized rate was 1.3%/patient-year.

3.3. Late survival and functional assessment

There were three late deaths (5.3%). An 11-year-old male, who initially underwent repair of a VSD and aortic valvotomy, followed by a homograft AVR for congenital AS, died 1 year after his repeat mechanical AVR due to cardiac failure, bronchopneumonia and mediastinitis. A 9-year-old female with previously-repaired transposition of the great arteries using a switch procedure, died 6 months following a mechanical AVR for AR from congestive cardiac failure. The third patient, a 15-year-old male, underwent an emergency AVR and MVR for rheumatic heart disease and died 11 years later from severe myocardial dysfunction.

Fifty patients were alive at the end of the study period, including all seven patients with endocarditis or connective tissue disorders, one of the two patients with rheumatic heart disease, and 42 amongst 47 patients with congenital heart disease (31 of 33 of those with congenital AS and 11 of 14 patients with other congenital heart disorders).

The actuarial, Kaplan–Meier, survival for all patients at 10 and 20 years was 91.0 and 84.9% (for the hospital survivors this was 96.1 and 89.6%) (Fig. 4). The 20-year actuarial survival for the patients with congenital AS was 93.5%, and 64.3% for those with other congenital problems ($P \approx 0.09$) (Fig. 5).

At the latest clinical evaluation, 44 (88.0%) were in NYHA class I, with the remaining six children being in NYHA class II. The mean gradient across the aortic prosthesis on echocardiography was 17.9 mmHg (range 0–47 mmHg). This was less than or equal to 30 mmHg in 40 (88.8%), and above 30 mmHg in six patients (11.4%) (Fig. 6).
4. Discussion

Given the certain drawbacks of each available substitute, the lack of general agreement as to what constitutes the best treatment option in children requiring replacement of an aortic valve is not surprising.

Following the realization of the unsuitability of the porcine and pericardial bioprostheses in the early eighties [1,2] and the reports of early accelerated calcification and degeneration of the aortic homografts [3], mechanical prostheses were, despite their own problems, established as a reliable option for AVR in children [7–9]. More recently, however, there has been a renewed interest in the pulmonary autograft, which is being proposed as the ideal option for paediatric AVR [5].

We believe that the simplicity, safety and reproducibility of the implantation technique, ability to address the often co-existing cardiac abnormalities, good haemodynamic performance and low incidence of valve-related events are important features of an adequate aortic valve substitute.

Despite the differing opinions in several aspects of this controversial subject, the importance of the long-term follow-up in ascertaining the validity of each treatment approach is universally accepted.

4.1. Operative morbidity and mortality

The operative mortality (5.3%) and morbidity in this series was acceptable, with all three deaths and major morbid events occurring in patients in poor preoperative haemodynamic status undergoing emergency re-do procedures, and were, quite clearly, not attributable to the mechanical AVR.

Although Champsaur et al. [10] had an operative death rate of 15.2%, mainly in children with severe preoperative pulmonary hypertension, mortality rates ranging between 0 and 5% in cohorts of children having a wide variety of disease aetiology have been reported from other centres in Europe, USA, Japan and India [7–9,11–13].

4.2. Late events and anticoagulation

While the risks of infection and/or valve outgrowth are shared with the biological prostheses, the thrombo-embolism and the anticoagulation treatment-related haemorrhages are problems specifically linked with the mechanical valves. The prevalence of such complications in this series was, however, low.

There have been two episodes of thrombo-embolism in patients who had stopped taking their warfarin, producing a linearized rate of 0.3%/patient-year and an actuarial freedom from thrombo-embolism of 93% at 10 and 20 years. These low rates are similar to those reported elsewhere for children undergoing a mechanical AVR. Mazzitelli et al. [11] and Iyer et al. [13] have reported a 20- and 8-year freedom from thrombo-embolism of 91.2 and 98.8%, Champsaur et al. [10] and Milano et al. [8] reported a linearized rate of 0.3 and 0.7%/patient-year, whereas there have been no thrombo-embolic events in the series of Ibrahim et al. and Lupinetti et al. [9,14].

The anticoagulation treatment-related side effects were limited to minor bleeding episodes in four, and difficulties in achieving the targeted level of INR in two children, there being no record of significant bleeding in our series. Linearized rates of anticoagulation treatment-related bleeding of 0.3%/patient-year, or no haemorrhagic event at all for patients undergoing a mechanical AVR and receiving...
long-term anticoagulation treatment with warfarin have been described by other authors [7,8,10,14].

However small the incidence of thrombo-embolism and/or haemorrhage in this series, it does highlight some of the difficulties associated with the long-term administration of sodium warfarin in this sensitive group of patients. It has been suggested that the combination of an antiplatelet agent, like aspirin, with dipyridamole, constitutes an adequate anticoagulation treatment for children following a mechanical AVR, particularly if they have normal cardiac rhythm [15]. There have also been claims that low-profile, bileaflet-mechanical valves are the least thrombogenic, and therefore, no anticoagulants should be prescribed [16]. Such a policy, however, did result in a disappointingly high incidence of severe thrombo-embolic events in a series producing a 5-year freedom from thrombo-embolic events as low as 68.0% [17]. We feel that the administration of sodium warfarin following implantation of a mechanical valve is of paramount importance if catastrophic thrombo-embolic events are to be avoided.

The management of anticoagulation during pregnancy remains a problem. Warfarin may cause embryopathy during the first trimester and has the risk of central nervous system damage throughout pregnancy. The administration of long-term subcutaneous heparin may provoke retropelcentral and maternal bleeding events, the therapeutic requirements are not standardized, anticoagulation is hard to control and its efficacy in preventing arterial thromboembolism is by no means established [18]. Sbarouni and Oakley [19] have, in their survey across the major European specialist centres, including 182 women having 214 pregnancies with artificial heart valves (151 mechanical and 63 bioprosthetic), found that warfarin treatment was safe, causing no embryopathy, and effective, whereas subcutaneous heparin was linked with more thrombo-embolic and bleeding complications. There was, also, no significant difference in the outcome of pregnancy between women having mechanical or bioprosthetic implants, although more than one third of the bioprostheses had to be replaced urgently during or soon after pregnancy [19].

4.3. Re-operation and aortic root enlargement

The 86.4%-actuarial freedom from re-operation at 10 and 20 years in this series is relatively low. Freedom from surgical re-intervention rates ranging between 70.2 and 91.0% at 10 years [9,13], and 53.2% at 20 years [11], have been reported from elsewhere. The considerable variability in the reported re-intervention-free period may reflect, at least partly, the wide spectrum of the aetiology and severity of the disease of the children undergoing a mechanical AVR in various centres.

If it is necessary to replace the valve in a small child, it is almost inevitable that the child will outgrow the prosthesis. Utilization of various techniques allows a widening of the aortic root by 2–8 mm, facilitating the implantation of a larger size valve. The senior authors’ (JLM, MPH) preference is the patch aortoplasty technique as described by Nicks et al. [6]. By employing this technique, it was possible to implant an adult sized, 21-mm or more, prosthesis in 24 (85.7%) of 28 patients. Eight children received a prosthesis smaller than 21 mm (Fig. 1), but in four of them an aortic root enlargement manoeuvre had not been undertaken. Six of these children remain alive (two having died from cardiac non-valve-related causes), they are clinically well, and although recent echocardiography demonstrated an aortic valve gradient of >40 mmHg in two (42 and 47 mm), none of them have required a re-operation so far (Figs. 1 and 6).

4.4. Late survival

The actuarial 91.3 and 84.9% 10- and 20-year survival for all patients (Fig. 4) in this series is rewarding. Survival rates,
70.2–91% at 10 years and 72% at 20 years, are quoted in other series [7,8,10–14]. Differential long-term survival data for children with congenital heart disease undergoing mechanical AVR are scanty. This series demonstrates the gratifying survival expectancy for children with congenital AS (93.5% at 20 years) contrasting with 85.7 and 64.3% at 10 and 20 years, respectively for those with more complicated forms of congenital heart disease (Fig. 5).

Besides long-term survival, the functional status of the patient and the haemodynamic performance of the mechanical aortic implants are very important. The most recent echocardiographical data and clinical assessments were encouraging in this respect, since 45 patients were in NYHA class I, leading a normal or near-normal life, and 43 had minimal or only small gradients across the aortic valve (Fig. 6).

4.5. Alternative options

Aortic homografts and pulmonary autografts have the merit of not requiring anticoagulation, and have both demonstrated good haemodynamic characteristics [4]. The pulmonary autograft is, in addition, bio-compatible and is believed to grow with the young recipient [20]. However, as it has already been discussed, both have their problems and limitations. The complexity of the Ross operation and the potentially highly morbid learning curve [21] are aspects warranting due consideration. Most studies related to the pulmonary autografts in children have short- or medium-term follow-up and only limited long-term data are available. Gerosa, McKay and Ross [4] reported on 146 children undergoing an AVR with an aortic homograft (n = 103) or pulmonary autograft (n = 43). The early mortality for the aortic homograft and the pulmonary autograft group was 15.6 and 11.6%, the late mortality 16.7 and 13.2%, the 15-year actuarial freedom from re-operation 54.0 and 68.0%, and 97.0 and 75% from endocarditis, respectively. Matsouki et al. [22] have reported on 241 patients, including adults, having a Ross operation with a 30-day mortality of 6.6% and a 19-year freedom from re-operation on the pulmonary autograft of 40.5%.

More recently Elkins et al. [5] reported on 149 children who underwent a pulmonary autograft AVR with a mean follow-up of 3 years. The early mortality was 2.7%, the 8-year actuarial freedom from re-operation in the left ventricular outflow tract 90.0%, and 89.0% in the right ventricular outflow tract, the freedom from all valve-related complications 72.0% and the actuarial survival 97.3%. Although these intermediate results in the Elkins et al. [5] report show that low operative mortality, in centres performing large numbers of operations, is feasible, the questions regarding the long-term consequences of the Ross procedure remain largely unanswered. The need for further numerous operations in a previously healthy right ventricular outflow tract, in addition to that required in the systemic part of the circulation, seems to be a source of particular concern. The

7-year freedom from structural valve deterioration was 46.6% for the pulmonary homografts, and 32.3% for the aortic homografts in the series of Fiane et al. [23], freedom from allograft wall calcification in children under 2 years of age at 18 months was only 46% in the report of Schorn et al. [24], whereas all homografts less than 16 mm were outgrown and had to be replaced within 7 years in the series of Weipert et al. [25]. In a recent review of 334 aortic and/or pulmonary homografts used to reconstruct the right outflow tract, the mean interval between the insertion of the conduit and its first replacement was 12 years, suggesting that, for a child undergoing an AVR with a pulmonary autograft, at least two to three re-interventions for the management of the right outflow tract should be anticipated over a life-time (unpublished data quoted in the paper of Homann et al. [11]).

The mechanical low-profile bileaflet prostheses, currently in use, have certain distinct advantages, making them an attractive option in our view, particularly for the male children. The technique of their implantation is simple, safe and readily reproducible, they have good haemodynamic performance and durability, can be used in a variety of complex congenital and/or degenerative conditions, and as it has been shown in this series, can be remarkably resistant to infection. Perhaps even more importantly, if the insertion of an adult-sized mechanical prosthesis is possible, a re-operation over the life-time may not be required. The need for anticoagulation remains, of course, a significant problem; however, provided the facilities for meticulous monitoring are available, the anticoagulants in this young group of patients seem to be well tolerated.

On the other hand, in childbearing women the benefits provided by the mechanical valves have to be balanced against the potential risks accompanying the oral administration of warfarin during pregnancy, and in this patient population the use of a biological substitute may be indicated.

5. Conclusions

Mechanical AVR, with optional enlargement of the aortic root and long-term anticoagulation, remains an excellent treatment option in children. In our experience it has been associated with acceptable, non-prosthesis-related, operative mortality, low incidence of thrombo-embolism, anticoagulation treatment-related haemorrhage and re-operation and good long-term survival. We believe it represents a good alternative to available biological substitutes, including the pulmonary autograft (Ross procedure).

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their clinical contribution in the management of these children.

References


Appendix A. Conference discussion

Dr J. Oury (Missoula, MT, USA): I note that the mean gradient on these patients was 19 mm when they were tested postoperatively. Our studies in athletes who have undergone the Ross procedure, when studied at maximum exercise, indicates that the pulmonary autograft is unquestionably superior to any other alternative that we currently have available. One question would be, have you studied any of these patients at exercise rather than at rest?

Two, I would like you to, if you could, just comment a little further on the spectrum between minor complications related to anticoagulation and your category of major complications related to anticoagulation.

And three, if you would please just comment on the apparent observation that now, as we approach the end of the 20th century, there has been a real paradigm shift in that mechanical valves are now compared to the Ross procedure as the gold standard.

Mr Alexiou: My answer to your first question is no. These children had echocardiograms during their routine visits to the clinics; they were not examined at exercise.

With regard to your second question, well, thrombo-embolism and anticoagulation treatment-related bleeding are problems linked specifically with mechanical valves. The incidence of these problems in our series was, however, low. There has been one episode of valve thrombosis and one transient stroke, both in patients who had stopped taking their warfarin tablets, and no major bleeding event. This would show that administration of warfarin maintaining an INR between 2.5 and 3 is effective and safe. Our experience, in this respect, echoes experiences from other centres across the world, reporting, also, low rates of thrombo-embolic and bleeding complications in children.

Now, regarding the shift to the Ross procedure, well, the aim of our study was to determine the long-term results which can be expected if one uses the approach that has been used in Southampton. Although the Ross procedure may be indicated in some children, particularly in the neonatal age group, it should not be forgotten that it has certain disadvantages. An obvious one is the need for further re-operations of unknown frequency over the lifetime of these children. The mechanical AVR on the other hand, has the clear advantage of the simplicity and reproducibility of its technique. It does carry the problem of the need for anticoagulation, but this is, as I have already mentioned, really well tolerated.

Dr D. Saksena (Bombay, India): It is very reassuring for us who have to deal with small children and who don’t have access to the Ross procedure because of various logistic problems. Our experience exactly is like yours: we have had excellent results with ARVs in children. The two questions I have for you, one is a large number of patients that we have operated, small children, have bacterial endocarditis. In our experience, when we have placed the mechanical valve, the incidence of bacterial endocarditis following surgery has been very low.

And number two is always we have had to have root-widening proce-
dures, and though you mentioned the Nicks procedure, most of the time we find that that is not enough, even to get a 19 valve in a small child, and most of the time we have had to have a Manougian procedure to go all the way to the anterior leaflet to be able to get adequate size, at least a 19 valve, in a child. Initially we were using pericardium as a substitute for widening the patch, and now we are using the same autologous pericardium, which is treated with glutaraldehyde on the operating table. Do you have any evidence of degeneration in these patches or do you have any experience with the Konno procedure in this group of patients?

*Mr Alexiou:* Nicks procedure was the aortic root enlargement technique employed in this series. This procedure was applied in 24 of the 48 children who had a 21-mm or larger size valve implanted. The remaining eight children received a less than 21-mm valve, but in four of them an aortic root-widening manoeuvre had not been undertaken. Although other options for the widening of a small aortic annulus are available, the technique described by Nicks is the one favoured in our institution, and perhaps Mr Monro would like to comment on this.

*Mr J.L. Monro:* Yes, I think we would use the Konno procedure if necessary, and have on a few occasions, or a modified Konno. The Nicks procedure, as described, has really been very satisfactory, and we would always try to insert a 21 valve. I think the practice in India may be different when you are dealing with smaller children. We do try very hard to repair valves rather than replace. So many of the smaller children will have a repair and maybe a repeat repair before resorting to a replacement.

But as Mr Alexiou said, our real reason for presenting this was to stimulate a comparison with the Ross procedure. And I don’t think you quite answered the question before. We do appreciate that the ability to do sport, and so on, is going to be much better after a Ross procedure, but remember, this series goes back a long time and it is really just a comparative study.

*Dr M. Antunes (Coimbra, Portugal):* I concur with most of your conclusions. Our previous experience from South Africa corresponds to that which Dr Saksena also reports from India. We found, in those ages, that the mechanical replacement was the only procedure which was acceptable for these patients, at least comparing with biological valves.

I am not sure if you mentioned what type of valves you used, but in our experience we thought that an INR lower than those levels that you indicated was sufficient for children, with a lower incidence of hemorrhagic episodes. I know that you had very few in your series. Still, we believe that an INR of around 2 or, at most, 2.5 is adequate for this group of patients.

*Mr Alexiou:* At the early years of the study period Bjork–Shiley valves were used, and over the last 16 years bileaflet prostheses were utilized. Types of implanted valves were 9 Bjork–Shiley, 24 St Jude Medical and 23 Carbomedics.

The thrombo-embolic rates following mechanical valve replacement, particularly with the new generation low-profile bileaflet prostheses, in children are, as already discussed, low. This may explain why some units apply different regiments running INR at lower levels than ours and some others use aspirin alone following implantation of a mechanical valve in the aortic position.