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Congenital Aortic Valve Disease

Improved Survival and Quality of Life

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Objective
The purpose of the study was to assess the effect of recent trends in surgical management, including use of the Ross Operation, on improved survival and quality of life in patients treated surgically for aortic valve (AV) disease at Oklahoma Children's Hospital.

Background
Surgical treatment of congenital AV disease has proved to be palliative, but newer procedures may be improving outcomes.

Methods
A retrospective review of 301 patients, age 1 day to 26 years (median, 5 years), having a surgical AV procedure or aortic balloon valvuloplasty at Children's Hospital of Oklahoma between 1960 and February 1996, was conducted. Information was collected on all prior and subsequent operations, and follow-up within 1 year was 96% complete.

Results
Survival for all patients was 90% ± 2% at age 10 years and 73% ± 8% at age 25. By age 5, 52% ± 4% had required an AV procedure, 89% ± 3% by age 15. Patient survival was affected adversely by the diagnosis of valvar aortic stenosis, 79% ± 6% at age 25 compared to 95% ± 4% for subvalvar aortic stenosis or aortic insufficiency ($p = 0.01$). The AV morphology did not affect survival, but patients with a bicuspid or unicuspid valve required operative intervention at an earlier age. Survival after autograft replacement of the AV (Ross Operation) was significantly better than for other types of valve replacement ($p = 0.0043$). Quality of life as assessed by need for reoperation favors the use of the Ross Operation, with freedom from reoperation at 9 years of 87% ± 7% compared to 55% ± 5% in all patients after first AV surgery ($p = 0.003$).

Conclusions
The Ross Operation appears to have a significant advantage in survival and quality of life in children requiring a valve replacement as a first operation or after a prior AV procedure.

The modern era of direct vision aortic valve (AV) surgery for congenital AV disease was initiated by Swan and Kortz[1] in 1956 using in-flow occlusion. This success was followed in the same year by the performance of Lillehei et al.[2] of an open aortic valvotomy using cardiopulmonary bypass and retrograde coronary perfusion.[2] During the past 40 years, significant improvement in the medical and surgical management of children with AV disease has occurred; however, in most patients, surgical treatment has proved to be palliative. To assess the effect of recent trends in surgical management, including the use of the Ross Operation,[3] on improved survival and quality of life, a retrospective review was completed of all patients requiring a surgical AV procedure, resection of a discrete subvalvar membrane, or an aortic balloon valvuloplasty at the Children's Hospital of Oklahoma between January 1960 and February 1996.

METHODS

The medical records of the 301 patients included in this study were reviewed to obtain detailed information on the operative treatment, operative history, valve disease, subsequent need for operative treatment, and valve-related complications. All patients surviving their original procedure who had not had a medical evaluation at our institution during the past year were contacted by one of the authors (CM), and a detailed history was obtained. Contacts were successful in all but 12 patients for 96% complete follow-up.

Outcomes evaluated in this study were survival, need for reoperation, valve replacement, and current cardiac status. Patient characteristics that were evaluated included age at each AV operation, valve disease, and the presence of valvar or subvalvar aortic stenosis at the first operation. Operative procedures assessed included open valvotomy, resection of discrete subvalvar stenosis with or without a ventricular myomectomy, valve replacement, and combinations of these procedures.

Statistical Analysis

All analyses were performed using SAS System software (version 6.10; SAS Institute, Cary, NC). Between-group differences of continuous variables were analyzed using analysis of variance methods, and chi square or Fisher's exact methods were used to test differences between proportions. Patient survival analysis and actuarial estimates of freedom from postoperative events were accomplished using Kaplan–Meier methods on patients with complete follow-up. Survival curves are displayed to the point in time where the standard error of the estimate exceeds 10%, unless otherwise noted, and differences between survival distributions were assessed by log–rank and generalized Wilcoxon testing. Survival rates are presented with ± 1 standard error; $p < 0.05$ was considered significant for all tests. Multivariate analysis of survival time and reoperation-free time were performed using Cox proportional hazards regression. An alpha-level of 0.10 was used for entry and retention of variables in the model. Deaths in all analyses include deaths from all causes.

Table 1. AGE AT FIRST AORTIC VALVE PROCEDURE (AV1)

Years	No. of Patients
0–1	86
>1–5	66
>5–10	63
>10–21	82
>21–26	4

Median age, 4.98 years; mean age, 6.41 years.

Patient Characteristics

The ages of the 301 patients (223 males and 78 females) are listed in Table 1. Twenty-seven patients had their first AV procedure in 1960 through 1969, 42 in 1970 through 1979, 132 in 1980 through 1989, and 100 in 1990 through February 1996. The first valve procedure was an aortic valvotomy, commissurotomy, or balloon valvuloplasty in 166 patients, 47 had a resection of a discrete subvalvar membrane, 52 had an AV replacement, and 36 had a combination of lesions repaired or an aortic valvuloplasty associated with repair of a ventricular septal defect. Thirty-two of the patients had a ventricular septal defect (VSD). Twelve of these patients had a tricuspid AV with aortic insufficiency thought to be related to the position of the VSD, and 9 of the 12 have required AV replacement. The remaining 20 patients with a VSD had subvalvar aortic stenosis (16) or valvar stenosis (4), and the VSD did not contribute to the long-term outcome of their aortic disease. Three of these 20 patients required AV replacement.

Of those patients in whom valve anatomy or disease could be determined, 186 had a bicuspid valve, 89 had a tricuspid valve, and 15 were described as a unicuspid valve. In the remaining 11 patients, the valve anatomy

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Table 2. DISTRIBUTION OF PATIENTS BY YEAR OF BIRTH

Year of Birth	No. of Patients	Late Survival (%)	Neonates at AV1	Autografts
1940–1959	19	58	0	1
1960–1969	32	69	0	6
1970–1979	79	95	3 (4%)	45
1980–1989	124	94	22 (18%)	59
1990–1996	35	86	17 (49%)	16
Total	289	88	42	127

could not be determined. Five of these had subvalvar aortic stenosis, and it is likely that they had a tricuspid AV.

The age at first aortic valve procedure (AV1) ranged from 1 day to 26 years of age with a median age of 5 years and a mean age of 6.4 years (Table 1). By 11 years of age, 75% of the patients had required their AV1. Increasing numbers of patients are having AV procedures at very young ages. In 17 of the 35 patients born between January 1, 1990, and February 1996, AV1 occurred during the first month of life (Table 2). Aortic valve replacement was required as the original AV operation or as a subsequent operation in 160 of the patients. The median age at first valve replacement was 11.5 years (range, 11 days—41 years) with a mean age of 11.9 years. During the study period, 192 valve replacement operations were needed in the 160 patients. Of these operations, 127 were Ross Operations, 10 were bioprosthetic valve replacements, 21 were allograft valve replacements, and 34 were mechanical valve replacements.

RESULTS

Survival

The operative mortality (30-day) for the AV1 in the 301 patients was 4.3%. Of the 13 operative deaths, 10 occurred in patients having an open aortic valvotomy or a balloon valvuloplasty, an operative mortality of 6%. In 131 of the 288 surviving patients, 178 additional operative procedures were required during the follow-up period, with operative mortality of 5.1%. For the total of the 479 AV operations, the operative mortality was 4.6%.

The actuarial survival (from birth) of the 289 patients is shown in Figure 1. Survival was 88.9% ± 3.2% at 20 years and 78.4% ± 6.2% at 30 years. Of the 22 late deaths, 9 were associated with reoperation for recurrence or progression of their AV disease. Details on the remaining 13 deaths are not complete, but the majority

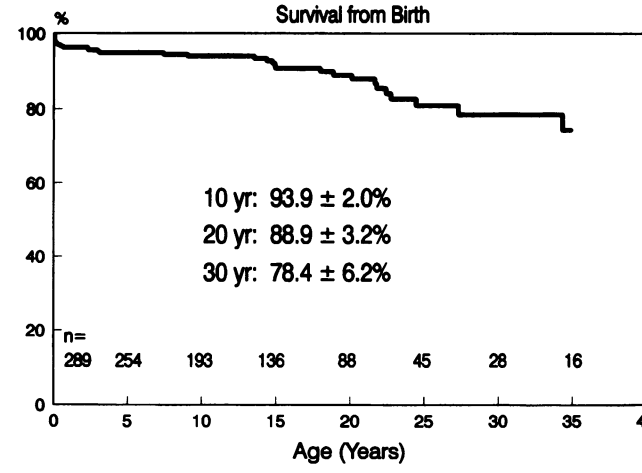

Figure 1. Survival from birth in 289 patients with complete follow-up.

were caused by their valvular heart disease. The actuarial survival of patients with discrete subvalvar stenosis was 98.5% ± 1.6% at 10 years and was 91.8% ± 6.3% at 20 years as compared to the patients with valvar stenosis, 92.3% ± 2.8% at 10 years and 86.9% ± 4.3% at 20 years, p = 0.0395 (Fig. 2).

In August 1986, the pulmonary autograft replacement of the AV (Ross Operation) was introduced at this institution. Thirty-six have been done as AV1, 71 as AV2, 17 as AV3, 2 as AV4, and 1 as AV5. The operative mortality for the patients having a Ross Operation included in this series is 4.7%, and the actuarial survival is 95.3% ± 2.6% at 8 years.

Reoperation

One hundred thirty of the 276 patients surviving AV1 required a second AV operation or procedure, 41 required

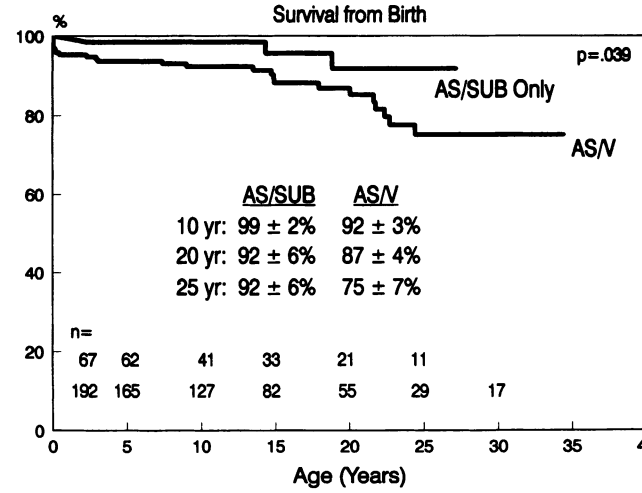

Figure 2. Improved survival from birth in 67 patients with discrete subvalvar stenosis over 192 patients with valvar stenosis (p = 0.039).

Table 3. SEQUENCE OF OPERATIVE PROCEDURES: VALVOTOMY, SUBVALVAR RESECTION, VALVE REPLACEMENT

Operative Sequence	Operation		
	Valvotomy	Subvalvar Resection	Valve Replacement
AV1	175	62	52
AV2	23	7	100
AV3	5	2	34
AV4	0	0	5
AV5	0	0	1

3, 5 required 4, and 1 required 5 (Table 3). Actuarial freedom from reoperation or death in patients surviving their first operation is shown in Figure 3. Freedom from reoperation or death was 47.9% ± 5.2% at 10 years and 25.2% ± 5.7% at 20 years.

In patients with valvar stenosis, the actuarial freedom from reoperation or death was 61.7% ± 5.2% at 10 years and 32.9% ± 5.7% at 20 years (Fig. 4). This is significantly different from patients with a discrete subvalvar stenosis only, where the actuarial freedom from reoperation or death was 89.9% ± 5.5% at 10 years and 63.7% ± 11.2% at 20 years, p = 0.0001. The difference between these two groups remains significant when one compares the survivors of AV1 (Fig. 5).

Patients surviving AV1 who have a bicuspid or unicuspid AV and a diagnosis of aortic stenosis appear more likely to require a reoperation or to die than do patients with aortic stenosis and tricuspid AV, although this was not statistically significant (p = 0.14) (Fig. 6).

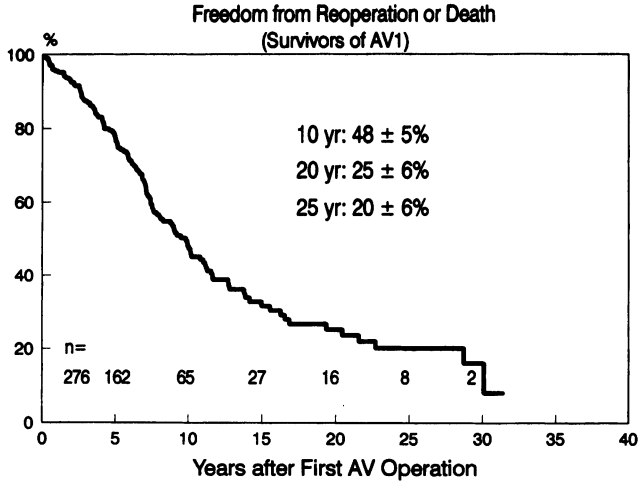

Figure 3. Actuarial freedom from reoperation or death in 276 patients surviving their first aortic valve operation.

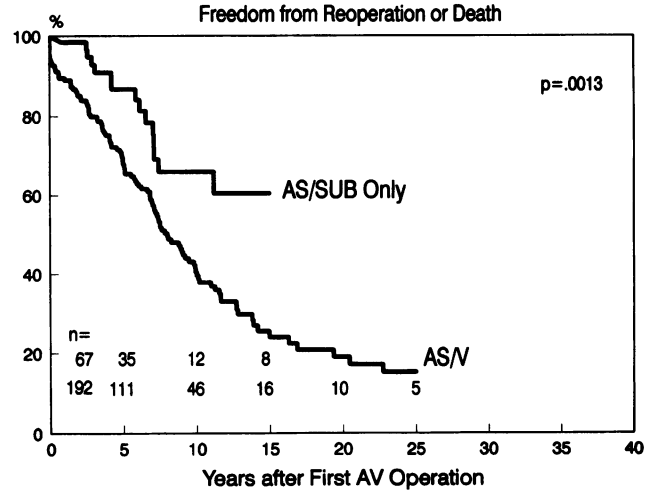

Figure 4. Actuarial freedom from reoperation or death in 67 patients with subaortic stenosis and 192 patients with valvar aortic stenosis after their first aortic valve operation. Freedom from reoperation or death is improved for patients with subvalvar stenosis (p = 0.0013).

Valve Replacement

Fifty-two patients required AV replacement as their AV1 operation. Thirty-six of these had a Ross Operation, 14 had a prosthetic or a bioprosthetic AV replacement, and 2 had an allograft valve replacement. One hundred additional AV replacements occurred during the period of follow-up. Seventy-one of these were Ross Operations, 11 were allograft AV replacements, and 18 were prosthetic or bioprosthetic valve replacements. Replacement of an AV prosthesis was performed 32 times in 28 pa-

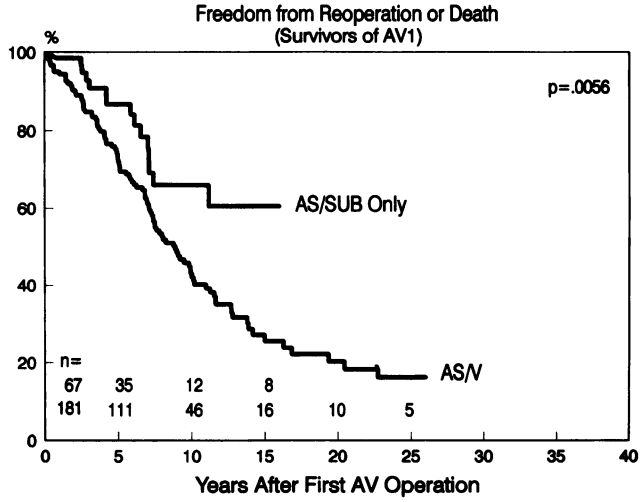

Figure 5. Actuarial freedom from reoperation or death in operative survivors of their first aortic valve operation in 67 patients with subvalve aortic stenosis and 181 patients with valvar stenosis. Patients with subvalvar stenosis have improved survival and decreased frequency of reoperation (p 0.0056).

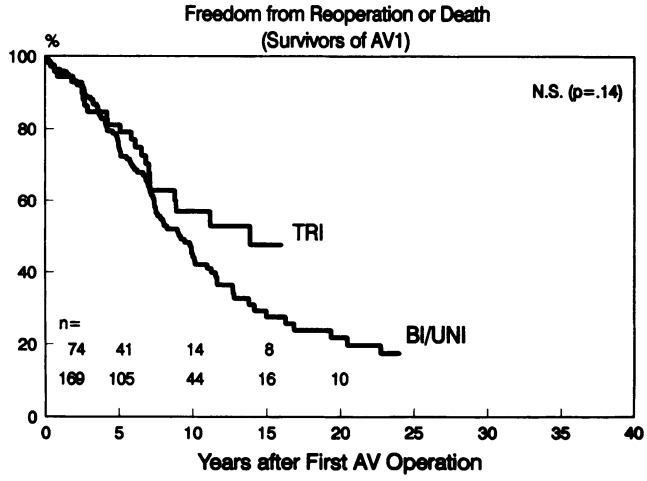

Figure 6. Effect of valve morphology on actuarial freedom from reoperation or death in patients with aortic stenosis surviving their first aortic valve operation.

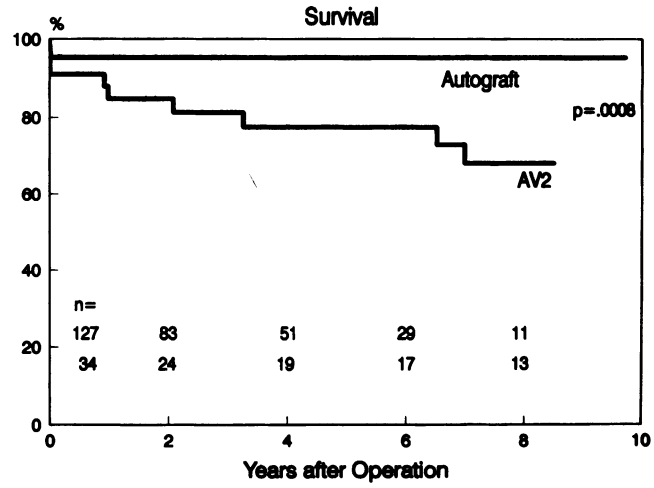

Figure 7. Improved actuarial survival of 127 Ross Operation patients *vs.* 32 patients having their second aortic valve operation (p 0.0008).

tients. Nine bioprostheses were replaced in seven patients: seven for degenerative failure and two for bacterial endocarditis. Three aortic homografts were replaced for biologic valve failure. Eighteen mechanical valves were replaced in 14 patients: 6 for prosthetic valve stenosis, 6 for thromboembolic problems or a desire to discontinue anticoagulation, 3 for paravalvular leaks, and 3 for bacterial endocarditis. Two pulmonary autografts were replaced, 1 due to technical failure at implantation and 1 due to valve failure with prolapse and adherence of a valve leaflet to a VSD patch. The replacement valve in all of these reoperations was a pulmonary autograft valve (Ross Operation) in 14, an aortic homograft in 9, a mechanical valve in 8, and a bioprosthesis in 1. There were 2 operative deaths and 4 subsequent deaths (2 valve-related) in these 28 patients.

In an effort to assess the impact of the Ross Operation on survival, the survival of all patients who have had a Ross Operation was compared with that of patients who survived AV1 and required an additional AV procedure that was not a pulmonary autograft procedure (Fig. 7). Survival of the autograft patients was significantly greater ($p = 0.0008$) at 5 years. When freedom from reoperation or death for Ross Operation patients is compared with that for patients having an AV2 or a mechanical or bioprosthetic valve, the survival of the Ross Operation patients was significantly greater ($p = 0.0001$) (Fig. 8).

Allograft valve replacement (aortic homograft in nine and pulmonary homograft in one) was used in patients with active endocarditis, patients in whom a Ross Operation was planned and an abnormal pulmonary valve was encountered, patients with ascending aortic disease, and patients who were not candidates for anticoagulation before our initiation of the use of the pulmonary autograft procedure.

To evaluate factors related to time to reoperation or death among survivors of first AV operations (284 patients), proportional hazards regression analysis was performed (Table 4) with independent variables: age at first operation, AV replacement, presence of valvar aortic stenosis, presence of subvalvar stenosis, AV morphology, aortic valvotomy, and subvalvar resection. Univariate analysis showed that young age at first operation ($p = 0.0001$) and presence of valvar aortic stenosis ($p = 0.0104$) were predictive of early reoperation or death. Subvalvar resection was predictive of longer reoperation–survival times. With multivariate analysis, younger age at first operation ($p = 0.0001$), AV replacement ($p =$

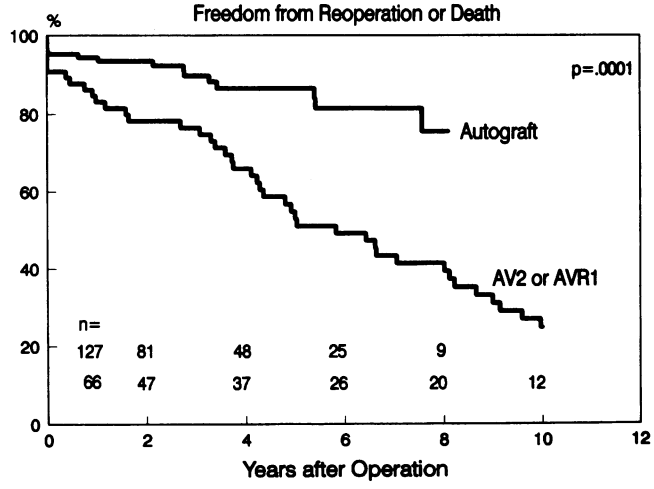

Figure 8. Actuarial freedom from reoperation or death in 127 Ross Operation patients compared to 66 patients having their second aortic valve operation or their first aortic valve replacement that was not a Ross Operation ($p = 0.0001$).

Table 4. PROPORTIONAL HAZARDS REGRESSION FOR OUTCOME: REOPERATION OR DEATH AMONG OPERATIVE SURVIVORS OF FIRST AORTIC VALVE OPERATIONS

	Univariate p Value*	Multivariate p Value*	Risk Ratio (95% CI)
Age at first AV operation	0.0001 (−)	0.0001 (−)	0.91 (0.88–0.94)
AVR	0.2230	0.0002 (+)	2.7 (1.6–4.7)
Presence of valvar AS	0.0104 (+)	0.0682 (+)	1.4 (1.0–2.1)
Presence of subvalvar AS	0.3586 (+)	>0.10	
AV morphology (bicuspid or unicuspid *vs.* tricuspid)	0.0981 (+)	>0.10	
Aortic valvotomy	0.2198	>0.10	
Subvalvar resection	0.0131 (−)	>0.10	

AV = aortic valve; AVR = aortic valve replacement; AS = aortic stenosis; CI = confidence interval.
* p values <0.10 are followed by (−) to indicate increased risk with smaller values or absence of factor; (+) indicates increased risk with larger values or presence of factor (or first level of factor).

0.0002), and presence of valvar aortic stenosis (p = 0.0682) were predictive of reoperation or death.

A second proportional hazards regression analysis was conducted to evaluate the outcome of reoperation or death among operative survivors of each AV replacement operation (192 operations, Table 5). The model considered variables included in the previous analysis plus aortic prosthesis equal to mechanical or bioprosthetic *versus* autograft or homograft, and year of AV replacement. In the multivariate analysis, a mechanical or bioprosthetic valve was more likely to predict reoperation or death with a risk ratio of 3.5 and a 95% confidence interval of 1.9 to 6.6. These results suggest that a reduced reoperation rate with autograft valve replacement holds even when other risk variables are taken into account.

DISCUSSION

Surgical treatment for congenital aortic stenosis has evolved over the period of this study. Children with critical aortic stenosis are now being managed with operative or interventional cardiologic techniques within hours of diagnosis, and patients are better prepared for operative intervention by our pediatric intensivist and cardiologic colleagues. With the demonstration of safe and effective operative procedures for obstructive lesions as well as for those associated with aortic insufficiency, patients are being referred for operative correction at an earlier age, even when AV replacement is required. The availability of a valve replacement (Ross Operation) that does not require anticoagulation, that enlarges proportional to the somatic growth of the patient (autograft growth), and that has a low operative risk and limited restrictions on lifestyle has altered the management of AV surgery at our institution.[4]

The current study shows the palliative nature of most nonvalve replacement procedures and clearly shows the negative impact on survival of patients with valvar aortic stenosis. Morris and Menashe[5] reported that the survival

Table 5. PROPORTIONAL HAZARDS REGRESSION FOR OUTCOME: REOPERATION OR DEATH AMONG OPERATIVE SURVIVORS OF AORTIC VALVE REPLACEMENT

	Univariate p Value*	Multivariate p Value*	Risk Ratio (95% CI)
Prosthesis = [mechanical or bioprosthetic] *vs.* [autograft or homograft]	0.0001 (+)	0.0001 (+)	3.5 (1.9–6.6)
Year of AVR	0.0027 (−)	>0.10	
Age at first AV operation	0.9072	>0.10	
Age at AVR	0.3977	>0.10	
AV morphology	0.2202	>0.10	
Presence of valvar AS	0.6546	>0.10	
Presence of subvalvar AS	0.7759	>0.10	

AV = aortic valve; AVR = aortic valve replacement; AS = aortic stenosis; CI = confidence interval.
* p values <0.10 are followed by (−) to indicate increased risk with smaller values or absence of factor; (+) indicates increased risk with larger values or presence of factor (or first level of factor).

of 133 patients having surgical treatment of valvar aortic stenosis from 1958 to 1989 was 76% ± 6% at 20 years. During a similar period, the survival for our 204 patients with valvar aortic stenosis was 79% ± 7% at 20 years. There are no other reported large series (greater than 100) that have 20-year follow-up results. The current series differs from the Oregon series in the increased use of AV replacement as AV1. Jones et al.[6] reported the cardiac event-free survival of 41 patients having an aortic commissurotomy for valvar aortic stenosis. At 15 years, 33% ± 8% were free from residual or recurrent aortic stenosis, moderate or severe aortic insufficiency, bacterial endocarditis, or reoperation. In our patients, freedom from reoperation or death in the 184 survivors of surgical treatment of valvar aortic stenosis was 51.2% ± 11% at 15 years and 41.9% ± 12.5% at 20 years. The availability of echocardiography has led to a more critical analysis of postoperative result and has led to early reoperation in many of our patients.[7]

Surgical treatment of discrete subvalvar aortic stenosis had an improved long-term survival of 83.6% ± 12% in the current series when compared to that of Jones et al.,[6] who reported a survival of 67% ± 11% at 20 years in 27 patients. In those patients who survived AV1 in our series, the freedom from reoperation or death at 20 years was 53% ± 15% and at 25 years was 40% ± 20%, a result not dissimilar to the cardiac event-free survival of 40% ± 10% at 25 years reported by Jones et al.[6] The need for reoperation in the current series is less than that reported by Stewart et al.[8]; however, the two series are dissimilar in that our subvalvar analysis series does not include patients with combined valvar and subvalvar stenosis or complex congenital cardiac disease. The addition of a septal myomectomy along with resection or enucleation of the discrete fibrous membrane was initiated at our institution in 1987 and was used in 23 of the 67 patients with discrete subvalvar stenosis. Actuarial freedom from reoperation or death was not improved in these patients when compared to the experience with patients treated with subvalvar resection only. This experience does not confirm the experience reported by Lupinetti et al.[9]; however, the group without a myomectomy was an older group of patients, and the indication for reoperation frequently was recurrence of the subvalvar stenosis and the development of significant aortic insufficiency that required AV replacement in 13 of the 15 reoperative patients.

Patients with congenital AV disease eventually will require AV replacement in most, if not all, surviving patients. The choice of valve replacement in many centers continues to be a prosthetic valve because of familiarity with the valves, ease of implantation, low operative risk, good hemodynamic function, and low complication rate in the early postoperative period. The late complications consist of thromboembolic complications that are at least 1% to 2% per patient-year, a 3% to 5% risk of anticoagulant-related bleeding, and 0.2% to 1.2% incidence of endocarditis per patient-year.[10,11] Reoperation for prosthetic AVs is required for valve thrombosis, tissue in-growth with prosthetic valve stenosis, stenosis related to somatic growth of a child with development of prosthetic obstruction, paravalvular leak, and anticoagulant- or thromboembolic-related problems. The incidence of reoperation in children or young adults with a prosthetic AV has not been well delineated. In this series of patients, 29 had a prosthetic AV, 8 of whom have died, and 16 (76%) of the 21 survivors have required replacement of their mechanical prosthesis. The freedom from reoperation for the most popular mechanical prosthesis (St. Jude Medical valve) is reported at 80% to 85% at 10 years, and the freedom from all valve-related events is approximately 50% at 10 years.[12] This compares to the freedom from reoperation or death of the patients having an autograft valve replacement in this series of 82% at 6 years. This freedom from reoperation is for both the autograft AV and for the homograft pulmonary valve.

Allograft valve replacement was used in this series for the indications indicated previously in this series. Recent reports have suggested that freedom from structural deterioration of the allograft valve in patients younger than 20 years of age is only 43%.[13] We have elected to use allograft valves in this younger group of patients to avoid anticoagulation, to allow for somatic growth of the patient, and to allow for continued improvement in the types of valves available and the likelihood that significant improvement in prosthetic or tissue valves will occur.

Analysis of this series of patients strongly suggests that the Ross Operation has reduced the frequency of reoperation in patients who require AV replacement, even including reoperations involving the reconstruction of the right ventricular outflow tract (pulmonary homograft).

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Discussion

DR. ERLE H. AUSTIN, III (Louisville, Kentucky): Dr. Cameron, Dr. Copeland, Members, and Guests. It should be known to this audience that Dr. Elkins deserves the credit for reintroducing the pulmonary valve autograft technique for aortic valve replacement to the cardiac surgery community. Although the operation was first performed clinically by Mr. Donald Ross back in 1967, the technical challenge of the procedure and what were perceived as "better" or, at least "easier to perform" alternatives, pushed the Ross operation into the realm of historic interest before 1980.

By the mid-1980s, however, the shortcomings of prosthetic valve replacement were becoming more apparent. Dissatisfied with the long-term results achieved with mechanical or bioprosthetic valve replacements, particularly in children, Dr. Elkins felt it was time to re-evaluate Mr. Ross's original premise that the best replacement for a malfunctioning aortic valve is the patient's own pulmonary valve.

A little more than ten years ago, at a time when most surgeons seriously questioned the judgment of turning a "simple" single valve replacement into a more complex double valve operation, Dr. Elkins, with both courage and commitment, initiated his experience with the Ross procedure.

Before long he was able to show that the Ross operation could be performed at a low mortality, sparing patients the persisting risks of thromboembolism and lifetime anticoagulation. Dr. Elkins' reaffirmation of Mr. Ross's experience has resulted in a resurgence of interest in and application of this operation across the world.

Based on Dr. Elkins' early success, I began to apply this technique in 1991 to children requiring aortic valve replacement. In a modest experience of 35 patients, I have been fortunate enough to have no mortality and only one patient requiring reoperation for neoaortic insufficiency. I, too, have come to recognize the importance of this operation, especially for children.

Many cardiovascular surgeons have a tendency to favor the procedure that can be performed most expeditiously and with the lowest short-term risk. Dr. Elkins hypothesized that pulmonary autograft replacement of the aortic valve, despite its greater technical demands and potentially higher operative risk, may provide longer complication-free and reoperation-free survival than conventional prosthetic replacement of the aortic valve. Now, 10 years after reintroducing the Ross operation, Dr. Elkins has carefully analyzed his own patient population and confirmed his hypothesis.

I expect that this study will encourage more surgeons to learn and employ this operation in children, but many, including those of us who have been performing the procedure, still worry about the long-term fate of the pulmonary valve in the aortic position and that of the allograft in the right ventricular outflow tract. We all wait anxiously to see how Dr. Elkins' Ross patients do at 15, 20, and 25 years follow-up.

I have three questions for Dr. Elkins. First, can any of the differences you observed between the Ross operation and other types of valve replacement reflect differences in the eras in which they were primarily utilized at your institution?

Secondly, would you discuss the relative incidence of complications other than reoperation such as endocarditis, thromboembolism, and hemorrhage.

And, finally, update us, if you will, with what has been the fate so far of the allografts that you have inserted to replace the relocated pulmonary valve.

I thank the Association for the privilege of discussing this important paper.

DR. RONALD C. ELKINS (Closing Discussion): I would like to thank Dr. Austin for his very kind comments. And in an effort to answer your questions, I would point out that we looked closely at the era of valve surgery in this series of patients. We repeated the multivariate analysis, dealing with those patients who had a valve replacement from 1986 to the present time, which is our time period for the pulmonary autograft, versus that group of patients who had a prosthetic or a bioprosthetic valve, and during this period they were all prosthetic valve replacements.

The factors that were important were shown clearly and again the autograft was significantly freer of reoperation than the patient who had a prosthetic valve implant in the same time frame.

In terms of endocarditis in the patients who have undergone operation in our center, we have had two episodes. One involved a patient who left the center, resumed her use of IV drugs, developed neoaortic valve endocarditis, and required replacement of her aortic valve to correct it.

One other patient had endocarditis that was hospital-acquired. And because of inadequate therapy in a home health environment, this patient lost the autograft.

Those are the only two patients of endocarditis we have had in a group of a little more than 270 patients.

In terms of the fate of the allograft, it is a question that is very much in the minds of most people. In our 270 patients, which we have looked at carefully, the actuarial freedom from reoperation on the allograft is 91%. The freedom from reoperation on the allograft really appears to be in two phases. There is a group of patients who experience a failure mode in which