The Ross procedure in children and young adults: A word of caution

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Background: Disease of the aortic valve in children and young adults is a complex entity whose management is the subject of controversy. The Ross and the Ross-Konno procedures have become the primary choices for aortic valve replacement in children because of growth potential, optimal hemodynamic performance, and lack of the need for anticoagulation. However, concern persists regarding the longevity of the pulmonary autograft, especially in patients with aortic insufficiency.

Methods: Between June 1993 and February 2000, 72 Ross and Ross-Konno procedures were performed at our institution: 81% of the patients were less than 15 years old. Preoperative, postoperative, and follow-up clinical, echocardiographic, and hemodynamic data were reviewed. Statistical analysis was performed to identify the risk factors for deteriorating autograft function.

Results: Aortic insufficiency was an indication for the Ross procedure in 17 patients and mixed lesions with predominant aortic insufficiency in 10. Of the 45 other patients, 32 had aortic stenosis and 13 had mixed lesions with predominant aortic stenosis. There were no deaths during a follow-up of 5 to 80 months. Autograft reoperation was necessary in the follow-up period in 7 patients for severe aortic insufficiency. Moderate insufficiency was identified in 5 additional patients. Aortic insufficiency or predominant aortic insufficiency, as a preoperative hemodynamic indication for the Ross procedure, reached statistical significance ($P = .031$) as a risk factor for autograft failure.

Conclusion: The Ross and the Ross-Konno procedures have changed the prognosis of children and young adults with complex aortic valve disease. However, the Ross procedure should be performed with caution in older children in whom aortic insufficiency is a preoperative hemodynamic indication. Further follow-up to delineate the risk factors for autograft dysfunction in children and young adults is necessary to better define the indications for the Ross procedure.

Aortic valve disease in children and young adults is often a difficult and complex problem whose management strategies are the subject of controversy.¹ In the past, traditional options included open surgical valvotomy or transcatheter balloon valvuloplasty. Treating significant residual lesions with conservative measures was considered reasonable because the only acceptable alternative would have been a prosthetic valve replacement.

The Ross and the Ross-Konno procedures have become an important option for aortic valve replacement (AVR) in patients with both congenital and acquired disease of the left ventricular outflow tract (LVOT).²⁻⁶ The acceptance of these procedures has been slow because of the technical demands of the operations and the inherent need for reconstruction of the right ventricular outflow tract, thereby placing two valves at risk. Although more than 3 decades have passed since the Ross procedure was first described, in the past 10 years it has been increasingly considered for pediatric patients with a wide spectrum of congenital abnormalities of the LVOT.⁴⁻⁷

The advantages of the autograft valve include growth potential, optimal hemodynamic performance, freedom from anticoagulation, and hemolysis.⁷⁻¹¹ However, concerns regarding the Ross procedure persist: potential dilatation of the autograft, reoperation for autograft dysfunction, and replacement of right ventricular outflow tract conduits. Further, doubts have been expressed by others regarding the indications for the Ross procedure in patients with a bicuspid aortic valve and with aortic valve insufficiency (AI).^{12,13}

We reviewed our experience to identify the risk factors for the failure of the pulmonary autograft and to determine whether the primary diagnosis (congenital aortic stenosis [AS] or AI) or preoperative indications (AS, AI, or mixed lesion) are risk factors for pulmonary autograft failure.

Methods

A retrospective review of all patients who underwent the Ross or Ross-Konno operation between June 1993 and February 2000 was performed. All patients had preoperative transthoracic echocardiographic evaluation, with the findings being confirmed by intraoperative transesophageal echocardiography. All patients were followed up clinically and with multiple transthoracic echocardiographic examinations.

We defined failure of the Ross procedure as (1) echocardiographic presence of at least moderate AI or (2) surgical intervention for pulmonary autograft dysfunction. Risk factors considered for autograft failure were as follows: preoperative hemodynamic indications (AI vs AS), sex, aortic valve anulus, pulmonary valve–aortic valve anulus mismatch, aortic crossclamp time, total bypass time, previous surgery on the LVOT, Ross-Konno procedure, attempted aortic valve repair, external noncoronary sinus support, and additional surgical procedures. In addition, the size of

Figure 1. Age distribution of patients.

the aortic anulus at the time of autograft implantation and its relation to the expected normal for the patient's body surface area were analyzed. The aortic valve anulus was categorized as stenotic if it was smaller than 2 standard deviations below the expected size for the patient's body surface area and as dilated if larger than 2 standard deviations above the expected size.¹⁴ There were too few failures for analysis of the primary diagnosis (4 categories) and aortic valve morphology (5 categories).

Statistics

Descriptive statistics are expressed as median and range. Actuarial freedom from reintervention was determined by the Kaplan-Meier method. The Cox proportional hazards models (univariate and multivariate) evaluated potential predictors of time of autograft failure. Their effects are summarized by estimated hazard ratios, which are equal to 1.0 if there is no impact on risk of failure, greater than 1.0 if there is an increased risk of failure, and less than 1.0 if there is a reduced risk of failure. Statistical analysis was performed with SAS system software version 8.0 (SAS Institute, Inc, Cary, NC).

Demographics

Between June 1993 and February 2000, a total of 72 patients underwent a Ross or Ross-Konno procedure (excluding the patients with borderline hypoplastic left heart syndrome). There were 53 male (74.6%) and 19 female (26.4%) patients. Median age was 9.1 years, with a range between 4 days and 39.6 years (81% less than 15 years old) (Figure 1). Congenital AS was the primary diagnosis in 60 patients and congenital AI in 9. Two patients had rheumatic aortic valve disease and 1 had aortic valve endocarditis. Morphologic characteristics of the aortic valve are shown in Figure 2. A bicuspid aortic valve was present in 52 patients. The preoperative hemodynamic indication was AS in 32 patients, AI in 17 patients, and mixed lesion with predominant AS in 13 patients and predominant AI in 10 patients (Figure 3).

Figure 2. Aortic valve morphology.

Figure 3. Preoperative hemodynamic indications.

Operative Technique

Standard techniques of neonatal and pediatric cardiopulmonary bypass were used, with bicaval cannulation, moderate hypothermia, and antegrade cold crystalloid cardioplegia. A standard freestanding root technique was used for the Ross procedure (18 patients) and the Ross-Konno procedure (16 patients), as previously described.^{9,11} When a Ross-Konno procedure was being performed, the autograft was harvested with an extension of attached infundibular free wall muscle for use in patching the ventriculoplasty incision. The external noncoronary sinus support technique with native aortic tissue was applied in 38 of the 72 patients (sinus obliteration technique¹⁰). The patients were separated from bypass in the usual manner and transesophageal echocardiography was performed.

Results

There were no deaths. The follow-up ranged from 5 to 80 months. Seven patients underwent reoperation for pulmonary autograft dysfunction: Six patients received a mechanical aortic valve, and in 1 patient the autograft valve could be satisfactorily repaired. Actuarial freedom from autograft reintervention was $82\% \pm 6.2\%$ (standard error) at 80 months (Figure 4).

Five patients who had echocardiographic evidence of moderate AI are still being followed up without surgical intervention. Our review of the 12 patients with pulmonary autograft failure showed no evidence of AI at the intraoperative transesophageal echocardiogram, at the discharge transthoracic echocardiogram, and at the 1-year follow-up period. A review of all the operative reports reveals no concern about technical issues. All 12 patients with autograft failure were less than 15 years old (10 of 12 were less than 10 years old).

Preoperative hemodynamic indications for the Ross procedure in the 7 patients reoperated on for autograft dysfunction were severe AI in 3 patients, severe AS in 2 patients, and mixed lesions in 2 patients (1 predominant AI, 1 predominant AS). The primary diagnoses in these 7 patients were congenital AS in 6 patients and rheumatic disease in 1 patient.

Figure 4. Actuarial freedom from autograft reintervention. FU, Follow-up.

Our thresholds for autograft reintervention were dictated by early echocardiographic findings of left ventricular enlargement and severity of AI. All 7 patients undergoing reoperation had severe AI, but 5 of them were completely asymptomatic (New York Heart Association class I).

The echocardiographic findings in the 7 patients undergoing reoperation were uniformly significant for severe AI, dilatation of the aortic anulus, dilatation of the sinuses of Valsalva, dilatation of the sinotubular junction, and lack of central leaflet coaptation with central jet regurgitation.

In the 7 patients who underwent reoperation for autograft failure, 6 patients required AVR with a mechanical prosthesis. In 1 patient, the valve was able to be repaired. Among the 6 patients who had AVR, the operative findings were uniformly consistent with dilatation of the aortic anulus, dilatation of the sinotubular junction, and lack of central leaflet coaptation. The leaflets were described

TABLE 1. Predictors of autograft failure in univariate Cox proportional hazards models

Predictor	Hazard ratio	95% CI	P value
Male	1.39	0.30-6.4	.67
Age (per year)	0.95	0.87-1.04	.30
Prior LVOT surgery	0.83	0.27-2.6	.75
Ross (vs Ross-Konno)	0.74	0.22-2.5	.62
Attempted repair	0.47	0.06-3.7	.47
Sinus obliteration technique	2.6	0.72-9.1	.15
Hemodynamic diagnosis of AI (vs AS)*	4.2	1.14-15.7	.031
AV anulus (per mm)	0.93	0.85-1.01	.099
Stenotic (vs normal)†	0.91	0.11-7.8	.93
Dilated (vs normal)†	0.42	0.10-1.8	.24
PV-AV (per mm)	1.07	0.92-1.23	.37
Crossclamp time (per hour)	0.90	0.39-2.1	.81
Total CPB time (per hour)	0.68	0.36-1.27	.23
Additional procedure	0.79	0.24-2.6	.70
Absolute PV anulus	1.01	0.80-1.27	.96
Absolute PV-AV anulus	1.7	0.33-9.3	.52

CI, Confidence interval; LVOT, left ventricular outflow tract; AI, aortic insufficiency; AS, aortic stenosis; AV, aortic valve; CPB, cardiopulmonary bypass; PV, pulmonary valve.

*AI only or predominant in mixed lesion.

†Defined as AV anulus > 2 standard deviations below (stenotic) or above (dilated) the expected value for the patient's body surface area.

uniformly as “thin.” The patient who underwent repair had prolapse of 1 leaflet that was partially resected and resuspended. Light microscopy showed a spectrum of histopathologic abnormalities. In a specimen that had been in place for 2 years, there was fibrosis at the free margin of the valve. Within this fibrosis was a myxoid extracellular matrix, a nonspecific change consistent with hemodynamic abnormality. Specimens that had been in place for 4 to 5 years had more dense fibrosis and less myxoid matrix. Preoperative hemodynamic indications for the Ross procedure in the 5 patients currently having echocardiographic evidence of moderate AI were severe AI in 2 patients and mixed lesions with predominant AI in 3 patients. The primary diagnoses were congenital AS in 4 patients and congenital AI in 1 patient.

Table 1 shows the estimated effects of predictors from univariate Cox proportional hazards models of time to any failure (reintervention or AI). Only preoperative hemodynamic indication of AI reached statistical significance, and all estimates have wide confidence intervals (CI), reflecting the presence of only 12 failures in the data set. In a 2-predictor model with hemodynamic indication of AI and aortic valve anulus size, both predictors reached statistical significance (AI: hazard ratio 5.7, 95% CI 1.4-22.3, $P = .013$; aortic valve anulus size: hazard ratio 0.90 per millimeter, 95% CI 0.83-0.98, $P = .016$). No other predictors reached statistical significance when added to models already containing hemodynamic indications.

Discussion

The Ross procedure (pulmonary autograft replacement of the aortic valve) is applicable to patients with both congenital and acquired disease of the LVOT.¹⁵⁻²⁰ Despite its slow initial acceptance, the procedure recently has been increasingly used for pediatric patients with a wide spectrum of congenital abnormalities of the LVOT.²¹⁻²⁴ The prognosis of infants, children, and young adults with severe and complex aortic valve disease has been substantially altered with the use of the pulmonary autograft technique. Complex and multilevel LVOT obstruction requiring aortoventriculoplasty, bicuspid or tricuspid aortic valve disease associated with AI, dilatation of the aortic anulus, and bacterial endocarditis are pathologic entities for which a pulmonary autograft is used in conjunction with modifications of the Ross procedure.^{12,13,25} The characteristics of the ideal valve, which comprise minimal transvalvular gradient, growth potential, no thromboembolism, and no anticoagulation-related hemorrhage, are satisfied. The broadening indications and the growing enthusiasm for the Ross procedure should be carefully weighed against the increasing concern regarding the durability of the autograft valve, the potential dilatation of the autograft, the incidence of reoperations, and the residual or increasing autograft insufficiency.

Possible factors responsible for autograft failure include technical imprecision, the type of replacement (freestanding root, root inclusion, and subcoronary implant), status of the

LVOT and ascending aorta, and inherent disease of the pulmonary valve.

All patients in our series underwent a Ross procedure as root replacement. Thirty-eight patients received the modification that we have called the *sinus obliteration* technique. Sixteen patients underwent the Ross-Konno procedure. Neither of these variables was identified as a statistically significant risk factor for autograft failure. All 12 patients with autograft failure were less than 15 years old, with 10 of them less than 10 years old. None of the 7 patients requiring reoperation were treated with the sinus obliteration technique. The pathologic findings suggested a progression of repair from myxoid extracellular matrix (indicative of turbulence) to dense fibrosis in the old specimens. The histopathologic characteristics were not helpful in ascertaining the precise cause of failure of the Ross procedure. A preoperative hemodynamic indication of AI, either isolated or as part of a mixed lesion, appeared to be a risk factor for development of autograft failure.

Elements that make AI a risk factor are speculative. One issue immediately considered is dilatation of the anulus. Larger aortic valve anulus appeared to be associated with reduced risk. This was particularly true in a model that also controlled for hemodynamic indications, but the small number of events makes this multivariate analysis tenuous. Size in relation to that expected for body surface area, however, did not appear to be predictive, nor did geometric mismatch (this was true for both the absolute magnitude of the mismatch and the magnitude as a percentage of the aortic valve anulus).^{14,15} It is possible, therefore, that other unknown factors influence this event. Perhaps chronic AI alters the geometry and tissue characteristics of the subvalvular LVOT, leading to failure of the Ross procedure. Another possibility is that these patients may have a subtle inherent abnormality of the pulmonary anulus or valve that becomes significant when the valve is placed in the systemic circulation.^{13,26,27} It has also been shown²⁸ that postoperative control of blood pressure may be critically important in avoiding structural and mechanical adaptation phenomena in the wall of the autograft (elastic fiber fragmentation), which can further progress to root dilatation. The potential of reducing the incidence of late autograft valve insufficiency is certainly available.^{20-22,24} We did not consider plicating the anulus because of the growth issue in the young patient population that we treated, although we agree that annular reinforcement should be a consideration in patients in whom adequate size has been achieved (over 15 years old). However, at present we recommend a bileaflet mechanical prosthesis, rather than the Ross procedure, as a first choice in this patient population.

It should be emphasized that AI, as a preoperative hemodynamic indication for surgery, is not an absolute contraindication to the Ross procedure, but a relative risk factor that needs

to be considered in the complex process of identifying the best option for an individual patient. Further multicenter studies to identify the risk factors for autograft dysfunction in children and young adults will be necessary to better define the selective indications for the Ross procedure.

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Discussion

Dr Ronald C. Elkins (*Oklahoma City, Okla*). Dr Laudito and the group from San Francisco are to be congratulated for bringing their concerns to all surgeons interested in the Ross operation.

The frequency of autograft reintervention in their 72 patients, based on the development of autograft insufficiency and left ventricular enlargement, is higher than one would anticipate on the basis of a review of current reported studies. This present report is unique in its high incidence of autograft failure, the particularly early occurrence of autograft failure, and also in the surgical technique used for the operation.

In an effort to maintain normal anatomic relationships, most surgeons performing the Ross operation implant the pulmonary root and its contained valve as a freestanding root with the coronaries implanted as buttons and do not support the pulmonary sinus or alter the sinotubular junction at the time of implantation.

During the 10-plus years in which a significant number of root replacements have been performed, several factors that affect pulmonary autograft valve function have been identified. Probably the most important of these is that the autograft pulmonary root does not remodel to become an aortic root and one should not force it to be one.

When compared with the normal aortic route, the pulmonary root immediately dilates when placed in the systemic circulation. Several studies have now identified that this dilatation involves the anulus, the sinus, and to a lesser extent the sinotubular junction. The increase is about 9% in the first postoperative week and another 10% in the first year. From that point on, in most patients this dilatation remains very stable.

If one reviews our own study, we have 208 patients who fit in an age group similar to that which Dr Laudito described, and 123 of these patients are less than 16 years of age. The total follow-up on this patient group is 754 patient-years with 61 patients having been followed up for 5 years or more.

The actual freedom from reoperation for autograft valve insufficiency in this group is 91%. The actual freedom from valve replacement is 96%. When we analyze this group of patients on the basis of their primary valve lesion or their predominant hemodynamic lesion, we can find no indication that either of these factors affects the incidence of autograft valve insufficiency or reintervention.

As I reviewed the manuscript, several factors concerned me. First, there is no discussion of the operative findings associated

with autograft valve insufficiency. Why did these valves leak? Can you provide some information? There is no discussion of the surgical pathology of the explanted autograft valves.

You identified in your analysis that there was no difference between the Ross and Ross-Konno operations in terms of outcome. However, you did not discuss any of the impact that your sinus obliteration technique might have on late outcome. Is it possible that the subtle alterations in the sinotubular junction during your coronary implantation for prevention of the normal, early dilatation of the noncoronary sinus produced an unfavorable effect on your results?

We have previously identified the importance of preoperative aortic annular dilatation and its impact on late results. Except in young children with significant growth potential, we have adopted a policy of annular reduction and fixation of the aortic anulus with a maximum follow-up of 4 years in this group of patients. It appears that this practice has reduced our incidence of moderate autograft insufficiency and early autograft failure. How have you managed the patients in your series with AI who have significant aortic anulus dilatation?

Dr Laudito. Thank you, Dr Elkins, for your kind comments. Most of what I have learned about the Ross procedure was obtained through your published data.

It is true that we did not discuss the pathologic findings of the valve in our manuscript. We had 7 patients; 6 underwent mechanical AVR and 1 underwent aortic valvuloplasty. In the majority of these patients, the pathologic finding was thinning of the leaflet with almost uniform dilatation of the root. That essentially is the remarkable point.

Regarding the sinus obliteration technique, both we and the statistician at our university performed both univariate and multivariate analyses, and we found no statistical difference. We believe from a surgical point of view that it is not a positive or negative point at present.

Regarding annular dilatation, as you mentioned earlier, even your 1994 article described pathologic evidence. The anulus dilates in the first year and then there is the potential for growth. Because we are treating patients who are very young, except for those rare adult patients in our statistics, we are very concerned about the potential growth of these patients. That is why we are not performing annular reduction.

Regarding your question of how to handle a dilated anulus, I have to make a separation between 2 case scenarios. In 15-, 16-, or 17-year-old patients, weighing about 50 kg, we will present the 2 options of the Ross procedure to the parents of the patient, along with our assessment of the risk factors. However, in a patient of that age and body size, we recommend AVR with a mechanical valve. If the situation instead involves a younger patient, 3 or 4 years old, we will perform the Ross operation without any annular reduction.

Dr Zohair Al-Halees (*Riyadh, Saudi Arabia*). Although our population of patients is different from yours, I think some inferences can be made from examining our patients. Among 250 patients who underwent the Ross procedure at our hospital, about 70% have rheumatic etiology of their aortic valve disease, with an incidence of reoperation in the range of 16%. However, when we evaluate the reoperations more closely, we find that all of them,

except for one, occurred in patients who initially had AI. Actually, in the 1 patient with AS who required reoperation, the reason for the reoperation was endocarditis.

From this, we conclude that patients who start with pure AS or who have a mixed lesion (AI and AS) with AS being the predominant lesion do very well with the Ross procedure, with a very low incidence of reoperation for up to 9 years of follow-up. Therefore, one can safely say that the Ross procedure is the treatment of choice for young patients with AS or mixed lesions with AS as the major lesion. However, patients who initially have AI are the high-risk group, particularly if they have a dilated aortic root. In our patients who fit this category, we modify the techniques and selection somewhat. We started to exclude patients with dilated aortic roots of more than 28 mm. We believe these are not good candidates for the Ross procedure. Borderline size aortic roots we reinforce with Teflon or a pericardial strip. Unlike what Dr Elkins has mentioned, we have not adopted the root reduction techniques because I believe that dilated roots will continue to dilate. Some roots will even dilate after reinforcement with Teflon or pericardium. We also found that concomitant severe mitral valve regurgitation requiring surgical intervention is a strong predictor of Ross procedure failure.

With this information, have you changed anything in your approach to patients who have AI?

Dr Laudito. Thank you for the question and thank you for giving me the opportunity to further stress two concepts. We have a high incidence of autograft failure because we are very aggressive with the echocardiographic follow-up of the patients concerning the protection of left ventricular function. If there is any evidence of enlargement of the left ventricle, we immediately recommend surgical intervention.

Regarding the issue of reinforcing the anulus of patients presenting with AI, we are limited by the element of growth in our young patient population. When the patient reaches adult size around 15 years of age, we recommend a bileaflet mechanical prosthesis.

Tatoulis (J Heart Valve Dis 1996;5:491-7) reported a follow-up of 14 years on aortic valve replacement with a mechanical prosthesis where the incidence of reoperation is lower than that of the pulmonary autograft, but there is also a presence of morbidity, related to the anticoagulant therapy, absent in the series with the Ross procedure.

Dr Gerhard Ziemer (Tuebingen, Germany). I have an 11-year experience with the Ross procedure, but I have restricted myself mainly to patients less than 5 years of age. My first neonate to receive a Ross procedure has 11 years of very satisfactory follow-up. Most recently, with the advent of the Internet, the patients and parents are almost demanding the Ross operation, so at some point you have to do it. The result is that within the past 12 months, I

have my first 2 failures. These are 2 patients, 11 and 24 years old, who within 3 months postoperatively had grade 4 AI. Both had initially left the hospital without AI. In the 11 year old, we did sinus plasty as a secondary operation. Although the patient left the hospital again with no AI, 3 months later grade 3 AI was detected. The 24 year old had received anulus reinforcement with Dacron primarily, but grade 4 AI developed. At reoperation, he had nice coaptation of the leaflets but frank rupture in 2 of 3 leaflets. Pathohistologic examination showed myxomatous degeneration.

I have 2 questions: First, have you seen any pathologic conditions like that? Second, what did you really change in your practice through the Ross experience and how do you use your word of caution in your own practice?

Dr Laudito. Thank you for the questions. What we were concerned with in the beginning of the study was the importance of the primary diagnosis in autograft failure. What we learned is that part of the patients who start with congenital AS and end up having surgical balloon valvotomy, valvuloplasties are losing the diagnostic identity of AS and are acquiring the hemodynamic diagnosis of AI. This event will be significant for the future failure of the pulmonary autograft.

Answering the second question, in the beginning, we were very supportive of the Ross procedure. We are still performing the procedure in neonates, infants, and children, but we are changing our manner of treating patients who are more than 15 years old with an adult body size. We recommend in this patient population a bileaflet mechanical prosthesis.

Dr William G. Williams (Toronto, Ontario, Canada). I would like to ask Dr Elkins to comment on the role of reoperation for repair of an autograft that is failing. What is the timing of that in your series?

Dr Elkins. I would reoperate on a patient who has central autograft insufficiency in which there is echocardiographic evidence that the autograft anulus has dilated since the initial operation and that central AI is progressing. That patient would be treated by anulus reduction. If the sinotubular junction was dilated, that would also be restored to normal.

Early in our experience with the Ross operation a number of patients required repair, but since introducing our techniques of fixation of the autograft anulus, we have had fewer reoperations. If a patient weighs 50 kg and has a 23-mm aortic anulus, the valve will fail unless something is done. That is an abnormal anulus size for that patient. I do not wait for symptoms to appear. I operate relatively early. In over 70% of the patients, we have been able to restore the autograft valve function to normal. Our longest follow-up period in a patient with an autograft repair is 7 years and he is still doing well.