Aortic valve replacement in neonates and infants: An analysis of the Society of Thoracic Surgeons Congenital Heart Surgery Database

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Objective: We sought to describe early outcomes of aortic valve replacement in neonates and infants across a large multicenter cohort.

Methods: Neonates and infants in the Society of Thoracic Surgeons Congenital Heart Surgery Database undergoing nontruncal aortic valve replacement with the Ross-Konno procedure, Ross procedure, or homograft replacement from 2000 to 2009 were included. Preoperative characteristics, operative data, and early outcomes are described.

Results: A total of 160 patients (43 neonates, 117 infants) from 47 centers were included. Society of Thoracic Surgeons–defined preoperative risk factors were present in 76 patients (48%) and were most prevalent in neonates (67%) and patients undergoing homograft aortic valve replacement (93%). Concomitant arch repair or mitral valve surgery was performed in 30 patients (19%) and 19 patients (12%), respectively. Postoperative mechanical circulatory support was used in 17 patients (11%). Overall in-hospital mortality was 18% and was highest for neonates (28%) and patients undergoing homograft aortic valve replacement (40%). Concomitant arch repair was associated with higher in-hospital mortality (33% vs 15%, $P = .02$), whereas concurrent mitral valve surgery was not (21% vs 18%, $P = .73$). Postoperative mechanical circulatory support was also associated with increased in-hospital mortality (65% vs 13%, $P < .0001$).

Conclusions: Neonates and infants undergoing aortic valve replacement are a high-risk group, with hospital mortality comparable with some of the highest risk procedures in this age group. The requirement for arch repair or postoperative mechanical circulatory support was associated with an increased risk of death in this cohort. (J Thorac Cardiovasc Surg 2012;144:1084-90)

Aortic valve replacement (AVR) in neonates and infants is generally reserved for those instances when more conservative surgical procedures or catheter-based interventions have been unsuccessful or offer little chance of achieving an acceptable hemodynamic outcome. Because of the rarity of AVR in very young children, previous reports of outcomes have included limited numbers of neonates and infants. The largest multi-institutional report evaluating the Ross or Ross-Konno procedure in this population included 33 patients <3 years of age, of which 12 were neonates.[1] The largest single-institution report included 31 infants, of which 16 were neonates.[2] Numerous other reports describe individual center's experiences with 1 or more technique of AVR in the pediatric age group, but offer little information specific to neonates or infants.[3-17]

Contemporary benchmark data based on a larger multicenter cohort of neonates and infants undergoing AVR could potentially improve our understanding of outcomes in this challenging group of patients. We therefore sought to describe characteristics and outcomes for neonates and infants undergoing AVR across a large multi-institutional cohort using the Society of Thoracic Surgeons (STS) Congenital Heart Surgery Database.

PATIENTS AND METHODS

Data Source

The STS Congenital Heart Surgery Database is the largest pediatric heart surgery registry in the world and currently contains information on >200,000 children undergoing heart surgery in North America since 1998. Perioperative, operative, and outcomes data are collected on all children undergoing heart surgery at participating centers. Data quality are evaluated through intrinsic verification of data and a formal process of

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Abbreviations and Acronyms
AVR = aortic valve replacement
STS = Society of Thoracic Surgeons

site visits and data audits.[18] The Duke Clinical Research Institute serves as the data warehouse and analytic center for all the STS national databases. This study was approved by the Duke University Medical Center institutional review board, with waiver of informed consent, and by the Access and Publications Committee of the STS Workforce on National Databases.

Patient Population

The study population included patients ≤1 year of age undergoing an index operation of the Ross-Konno procedure, Ross procedure, or homograft AVR from 2000 to 2009. These inclusion criteria were met by 215 patients from 51 centers. Patients with missing data (n = 51) and those with a diagnosis of truncus arteriosus (n = 4) were excluded. Although the STS database contains nearly complete data for the standard core data fields required to calculate in-hospital mortality, not all centers submit complete data for all variables, such as patient preoperative characteristics or postoperative complications. Therefore, it is standard practice to exclude centers with >15% missing data for key study variables to maximize data integrity and minimize missing data.

Data Collection

Patient characteristics included age at surgery, gender, surgery weight, any noncardiac/genetic abnormalities, and any STS-defined preoperative risk factors. Operative variables included cardiopulmonary bypass time, aortic crossclamp time, and other procedures performed at the time of aortic valve surgery such as mitral valve surgery (any type of mitral valve repair or replacement) or aortic arch repair (all methods of repair of aortic arch hypoplasia, interrupted aortic arch, or coarctation of aorta) with or without ventricular septal defect repair. Some details of type of arch repair (graft augmentation and so forth) were not captured consistently in the database and therefore were not analyzed.

Outcomes

The primary outcome measure was in-hospital mortality. Secondary outcome measures included postoperative length of stay and occurrence of postoperative complications as defined in the STS database, including postoperative mechanical circulatory support.[19]

Statistical Analysis

Study population characteristics and outcomes were described overall and across surgical and age groups (neonates, 0-30 days; infants, 31-365 days) using standard summary statistics. In recognition of the likelihood that certain anatomic and patient factors that may affect outcome in this cohort are not captured in the database, we focused on a descriptive analysis; formal statistical comparisons of outcomes in patients undergoing Ross, Ross-Konno, and homograft AVR were not made. The impact of concomitant procedures (aortic arch repair or mitral valve surgery) and postoperative mechanical circulatory support on outcome was evaluated using the χ^2 test. All analyses were performed using SAS version 9.2 (SAS Institute Inc, Cary, NC). A P value <.05 was considered statistically significant.

RESULTS

The study cohort consisted of 160 patients from 47 centers. Overall, 101 patients (63%) underwent the Ross-Konno procedure, 44 patients (28%) underwent the Ross procedure, and 15 patients (9%) underwent homograft AVR. Neonates and infants comprised 27% and 73% of the cohort, respectively.

Preoperative Characteristics

Table 1 summarizes the preoperative characteristics of the cohort. Median weight at surgery was 3.2 kg (z score, –0.9) for neonates and 5.4 kg (z score, –1.6) for infants. Valvar and/or subvalvar aortic stenosis was the most common primary diagnosis in all procedural and age groups whereas 16% of neonates and 22% of infants were coded as having a primary diagnosis of aortic insufficiency or combined stenosis and insufficiency. STS-defined risk factors were present in 76 patients (48%) and were most prevalent in neonates (67%) and patients undergoing homograft AVR (93%). Preoperative mechanical ventilation was common. Preoperative shock or acidosis was less frequent, although it occurred in 20% of patients undergoing homograft AVR. No patient received preoperative mechanical circulatory support.

Operative Characteristics

The Ross-Konno procedure was the most prevalent procedure in both age groups, followed by the Ross procedure. Homograft replacement was relatively uncommon in both age groups (Table 1). Table 2 summarizes the operative data. Cardiopulmonary bypass times were generally similar across procedure types, although were slightly longer for the Ross-Konno procedure. Concomitant mitral valve surgery was performed in 19 patients (12%), including 16% of neonates and 10% of infants. Among patients undergoing the Ross-Konno procedure, 14% had concomitant mitral valve surgery. Concomitant arch/coarctation repair was performed in 30 patients (19%), including 40% of neonates and 11% of infants. Among patients undergoing the Ross-Konno procedure, 25% had concomitant arch/coarctation repair.

Postoperative Outcomes

Table 3 summarizes early postoperative outcomes. In-hospital mortality in the overall cohort was 18%, and was 28% in neonates versus 14% in infants. Of the 3 procedure groups, those who underwent homograft AVR had the highest mortality rate (40%). Thirteen patients experienced postoperative cardiac arrest, including 9% of neonates and 8% of infants. Seventeen patients received postoperative mechanical circulatory support, including 19% of neonates and 8% of infants. In the Ross-Konno procedure group, 12% of patients received postoperative mechanical circulatory support. For the entire cohort, other major adverse outcomes included unplanned reoperation in 5.6%, reoperation for bleeding in 4.4%, renal failure requiring temporary or permanent dialysis in 4.4%, any

TABLE 1. Preoperative characteristics

Characteristic	Overall (n = 160)	Ross-Konno (n = 101)	Ross (n = 44)	Homograft (n = 15)
Age, d, median (IR)	87 (23-185)	63 (16-194)	96 (52-171)	98 (79-171)
Age category, n (%)				
Neonates	43 (27)	35 (35)	7 (16)	1 (7)
Infants	117 (73)	66 (65)	37 (84)	14 (93)
Weight, kg, median (IR)				
Overall	4.8 (3.6-6.4)	4.0 (3.4-6.2)	5.2 (4.4-7.0)	4.8 (4.3-5.4)
Neonates	3.2 (2.9-3.7)	3.2 (3.0-3.7)	3.3 (2.8-4.1)	2.7 (2.7-2.7)
Infants	5.4 (4.4-6.9)	5.5 (3.9-6.9)	6.0 (5.1-7.2)	4.9 (4.5-5.4)
Weight-for-age z score, median (IR)				
Overall	–1.3 (–2.1 to –0.5)	–1.4 (–2.2 to –0.7)	–1.0 (–1.9 to 0.2)	–1.7 (–3.0 to –1.2)
Neonates	–0.9 (–1.5 to 0.1)	–0.9 (–1.3 to 0.0)	–0.5 (–1.5 to 0.5)	–2.1 (–2.1 to –2.1)
Infants	–1.6 (–2.2 to –0.8)	–1.7 (–2.4 to –1.1)	–1.1 (–1.9 to –0.1)	–1.7 (–3.0 to –1.2)
Non-CV/genetic abnormality, n (%)				
Overall	33 (21)	24 (24)	6 (14)	3 (20)
Neonates	7 (16)	7 (20)	0 (0)	0 (0)
Infants	26 (22)	17 (26)	6 (16)	3 (21)
STS-CHSD risk factors				
Any risk factor, n (%)				
Overall	76 (48)	47 (46)	15 (34)	14 (93)
Neonates	29 (67)	22 (63)	6 (86)	1 (100)
Infants	47 (40)	25 (38)	9 (24)	13 (93)
Mechanical ventilation, n (%)				
Overall	42 (26)	29 (29)	7 (16)	6 (40)
Neonates	19 (44)	15 (43)	3 (43)	1 (100)
Infants	23 (20)	14 (21)	4 (11)	5 (36)
Shock or acidosis, n (%)				
Overall	13 (8)	9 (9)	1 (2)	3 (20)
Neonates	4 (9)	4 (11)	0 (0)	0 (0)
Infants	9 (8)	5 (8)	1 (3)	3 (21)
Previous cardiac surgery, n (%)				
Overall	49 (31)	32 (32)	11 (25)	6 (40)
Neonates	3 (7)	1 (3)	2 (29)	0 (0)
Infants	46 (39)	31 (47)	9 (24)	6 (43)

Data are presented as median and interquartile range for continuous variables, and number and percent for dichotomous variables. *IR*, Interquartile range; *CV*, cardiovascular; *STS-CHSD*, Society of Thoracic Surgeons Congenital Heart Surgery Database.

postoperative neurologic deficits in 2.5%, and heart block requiring permanent pacemaker in 1.9% of patients. Median postoperative length of stay in the overall cohort was 12 days, and was 20 days for neonates versus 10 days for infants.

In the overall cohort, concomitant arch repair was associated with significantly higher in-hospital mortality (33% vs 15%, $P = .02$). In contrast, concomitant mitral valve surgery was not associated with a statistically significant difference in mortality (21% vs 18%, $P = .73$). Postoperative mechanical circulatory support was also associated with significant in-hospital mortality (65% vs 13%, $P < .0001$).

COMMENT

This analysis of a large multi-institutional cohort of neonates and infants undergoing AVR from the STS Congenital Heart Surgery Database demonstrates that AVR in neonates and infants is associated with high rates of in-hospital mortality—28% in neonates and 14% in infants. To put these figures in perspective, evaluation of a recent harvest report from the STS Congenital Heart Surgery Database (2007 to 2010) reveals that the mortality associated with neonatal AVR ranks among the highest of all procedure-specific mortality rates in this age group (arterial switch with arch repair, 18.2%; stage 1 Norwood, 17.6%; Ebstein's repair, 30.2%).[20] For infants, in-hospital mortality associated with AVR ranks in a similar manner (hybrid stage 2, 22.6%; scimitar, 14.3%; right/left heart assist device, 14%).[20]

The results of our study are considered in the context of recent single-center reports from institutions with significant experience managing neonates and infants with critical left ventricular outflow obstruction. In the largest single-center series, Shinkawa and colleagues[2] reported 31 patients (16 neonates) who underwent the Ross or Ross-Konno procedure during the first year of life. Early mortality was 16%. Of note, in that series, all early mortality

TABLE 2. Operative characteristics

Characteristic	Overall (n = 160)	Ross-Konno (n = 101)	Ross (n = 44)	Homograft (n = 15)
CPB time, min, median (IR)				
Overall	202 (150-270)	212 (159-280)	192 (136-249)	196 (133-226)
Neonates	226 (152-293)	226 (157-293)	228 (152-386)	129 (129-129)
Infants	198 (149-258)	210 (160-271)	189 (136-224)	200 (135-226)
Clamp time, min, median (IR)				
All ages	132 (96-167)	143 (106-174)	118 (74-156)	108 (86-139)
Neonates	138 (88-182)	132 (92-182)	148 (87-188)	86 (86-86)
Infants	131 (100-162)	145 (111-173)	116 (63-144)	118 (91-139)
Concurrent arch repair, n (%)				
Overall	30 (19)	25 (25%)	4 (9%)	1 (7%)
Neonates	17 (40)	15 (43)	2 (29%)	0 (0%)
Infants	13 (11)	10 (15%)	2 (5%)	1 (7%)
Concurrent mitral surgery, n (%)				
Overall	19 (12)	14 (14)	3 (7)	2 (13)
Neonates	7 (16)	5 (14)	2 (29)	0 (0)
Infants	12 (10)	9 (14)	1 (3)	2 (14)

Data are presented as median and interquartile range for continuous variables, and number and percent for dichotomous variables. *CPB*, Cardiopulmonary bypass; *IR*, interquartile range.

occurred within the subset of patients who underwent concomitant surgery on the aortic arch or mitral valve. The early mortality rate of 0 among the 17 patients who required neither arch nor mitral valve repair makes that series unique with respect to our multi-institutional report and to other published single-institution series. Another single-center report from Alsoufi and associates[3] described outcomes among 21 patients (8 neonates, 13 infants) who underwent Ross or Ross-Konno procedures. More than half of patients had undergone prior intervention on the aortic valve or aortic arch. Mortality was 19% at 1 month and 30% at 1 year.[3] Similar to the results of our study, a recent Congenital Heart Surgeons Society multicenter study by Hickey and coworkers[1] reported somewhat higher mortality rates compared with previous single-center studies. Their study included 13 patients with the Ross procedure and 26 patients with the Ross-Konno procedure (12 neonates and 8 additional patients <3 months of age). Survival for these 39 patients was 74 ± 7%, 67 ± 8%, and 67 ± 8% at 1, 5, and 7 years, respectively, with 80% of deaths occurring within 2 months of surgery.[1]

Although highly experienced teams at several institutions have achieved good outcomes with appropriately selected patients, outcomes reported from both the STS database and from the Congenital Heart Surgeons Society research database indicate that neonates and infants who require AVR are, overall, a high-risk group. This is perhaps not unexpected, in light of some of the issues that characterize this specific patient population—challenging and often dire clinical circumstances requiring AVR at such a young age, prior interventions, the multilevel nature of left-sided obstructive disease, the complexity and magnitude of the surgical procedures, and/or the challenge in certain patients of predicting suitability for a 2-ventricle repair.

Our observation that the Ross-Konno procedure was the most frequently performed of the 3 types of AVR (81% of neonates and 56% of infants) is undoubtedly related to the multilevel nature of left-sided obstructive disease presenting during the first year of life. Even in patients with predominantly valvar disease, it is often necessary to enlarge the annulus to accommodate an appropriately sized valve substitute. In the 2 series reported by Shinkawa and colleagues[2] and Alsoufi and associates,[3] the frequency of annular enlargement (Ross-Konno procedure) was 25/31 (81%) and 14/21 (67%), respectively. Our finding that 40% of patients in the Ross-Konno group underwent concomitant surgery on the mitral valve or aortic arch supports further the multilevel nature of left-sided disease in this age group. Corresponding figures from the series by Shinkawa and colleagues[2] and Alsoufi and associates[3] are similar to ours—14/31 (45%) and 10/21 (48%), respectively.

Our finding of a particularly high rate of mortality in the homograft AVR group (40% in the homograft AVR group vs 9% in the Ross procedure group) stands without comparison in the literature because, to our knowledge, there are no prior reports comparing homograft AVR with the Ross procedure in infants. Although Najm and coworkers[17] reported in 1999 on a series of 30 children who underwent valve replacement with an aortic allograft (22 patients) or pulmonary autograft (8 patients), the mean age was 5.4 years. Only eight patients were infants. Nearly all deaths were in patients <2 months of age with acute aortic insufficiency after balloon angioplasty. When considering factors in our cohort that could have influenced the choice of homograft replacement, a substantial difference in morphology of the left ventricular outflow tract between the 2 groups seems unlikely, because both procedures are generally used to address similar anatomic substrates. Abnormality of the pulmonary valve is also an

TABLE 3. Early postoperative outcomes

Outcome	Overall (n = 160)	Ross-Konno (n = 101)	Ross (n = 44)	Homograft (n = 15)
In-hospital mortality, n (%)				
Overall	29 (18)	19 (19)	4 (9)	6 (40)
Neonates	12 (28)	10 (29)	2 (29)	0 (0)
Infants	17 (14)	9 (14)	2 (5)	6 (43)
Cardiac arrest, n (%)				
Overall	13 (8)	9 (9)	2 (5)	2 (13)
Neonates	4 (9)	2 (6)	1 (14)	1 (100)
Infants	9 (8)	7 (11)	1 (3)	1 (7)
Mechanical circulatory support, n (%)				
Overall	17 (11)	12 (12)	3 (7)	2 (13)
Neonates	8 (19)	6 (17)	2 (29)	0 (0)
Infants	9 (8)	6 (9)	1 (3)	2 (14)
Length of stay, d, median (IR)				
All ages	12 (6-26)	15 (8-28)	8 (5-14)	10 (5-28)
Neonates	20 (14-39)	20 (15-39)	17 (9-72)	75 (75-75)
Infants	10 (6-19)	11 (7-25)	7 (5-13)	10 (5-23)

Data are presented as median and interquartile range for continuous variables, and number and percent for dichotomous variables. *IR*, Interquartile range.

unlikely factor, because neonates and infants requiring aortic valve surgery rarely have significant pulmonary valve disease. We did observe a significantly higher prevalence of certain preoperative risk factors in the homograft replacement group. It is plausible that unfavorable preoperative status may have influenced the selection of procedure type (homograft replacement perhaps being considered a more expedient option for the sicker patients) and may have exerted an influence on outcome. In view of the limited preoperative anatomic and physiologic information captured currently in the database, and the small number of patients in the homograft group even in this multicenter data set, detailed risk-adjusted comparison of procedure types was not able to be performed. Although the observed 4-fold higher mortality associated with homograft AVR within the context of comparable cardiopulmonary bypass times does raise questions concerning the comparative ''expediency'' of homograft AVR and its effectiveness at offsetting risk, the actual reasons for the high rate of operative mortality are a matter of speculation. During the study era, procedures coded in the STS Congenital Heart Surgery Database were not classified with respect to urgency, (elective, urgent, salvage), so no inferences can be drawn reliably concerning the relative urgency of homograft AVRs.

Previous reports emphasizing outcomes in the neonatal or infant population have cited various risk factors for mortality—younger age, associated arch or mitral valve disease, emergency presentation with severe aortic insufficiency after balloon dilatation, duration of cardiopulmonary bypass and/or myocardial ischemia, postoperative mechanical circulatory support, and suitability for biventricular repair.[1-3,5,6,14,15,17,21-23] Although risk factor analysis was not a primary objective of our study because of the nature of the database, we did observe higher mortality in neonates in comparison with infants. Mortality was also higher in patients who had concomitant arch repair or received postoperative mechanical circulatory support.

Limitations

Although this study provides a contemporary, multi-institutional perspective of patterns of practice and outcomes in this high-risk group of surgical patients, it is subject to constraints inherent to observational studies and the nature of the STS Congenital Heart Surgery Database. To preserve integrity of the data, nearly one third of patient records were excluded. However, mortality in this group of patients was evaluated and was similar to the mortality of patients included in the report. We also acknowledge that a data set limited to patients treated with AVR precludes making inferences about the appropriateness of biventricular repair or the superiority of valve replacement over other surgical or catheter-based interventions. During the study period, the STS Congenital Heart Surgery Database did not collect consistently certain types of information that would permit more thorough characterization of preoperative status (prior surgical or catheter-based interventions, hemodynamic data, echocardiographic or angiographic data, and emergency/urgent/elective status of the procedure). Therefore, the nature of the data set precluded the possibility of undertaking multivariable analyses to examine potential independent associations among patient factors, procedure type, and early outcome. Likewise, lack of follow-up data precluded evaluation of reintervention rates and longer term outcomes. Recent and currently planned improvements in the STS Congenital Heart Surgery Database include expansion of the patient-level data pertinent to preoperative status, as well as important historical information including history of previous catheter-directed balloon valvotomy. The implementation of these changes will address some of the limitations of the current study, thereby improving substantially the versatility and utility of the database for future investigations.

CONCLUSIONS

AVR in neonates and young infants is associated with substantial mortality, ranking among the highest risk of all cardiac procedures in these age groups. A majority of neonates undergo procedures additionally directed at the aortic subvalvar outflow tract, aortic arch, or mitral valve. Neonatal age, arch repair, and postoperative mechanical circulatory support are associated with increased risk of death. A multi-institutional effort based on a patient and disease-oriented approach may lead to an improved understanding of both patient selection and the role of medical,

catheter-based, and/or surgical intervention in the management of these challenging patients.

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Discussion

Dr Christopher Caldarone *(Toronto, Ontario, Canada).* Dr Woods, my congratulations on an excellent presentation. This study is very important because it clearly demonstrates the value of widely adopted registries like the STS database, and not surprisingly, you have shown that the mortality rate for these procedures is much higher than in single-center reported series, which we all know are biased toward reporting favorable results, and therein I suspect lies the most important message of your study. The price for this broad perspective, however, is an inevitable loss of detail, and this is where I would like to ask a few questions.

Forty percent of the infants in your series underwent surgical procedures prior to the index procedure described in your analysis. In addition, there is some unknown number of cardiology-based procedures that also may have been performed. For those in the audience not familiar with this particular problem, patients with left ventricular outflow tract obstruction commonly have associated lesions at the mitral, ventricular, valvar, and aortic arch levels. Can you shed some more light on the impact of these preoperative procedures on the procedure-based cohort you have described?

Dr Woods. Thank you for your question, Dr Caldarone. To address the issue of procedures either prior to or subsequent to the aortic valve replacement procedure with the STS database would require both a combination of linkage potentially across multiple admissions as well as a greater level of granularity in the data pertaining to additional procedures, particularly catheter-based procedures.

And as you are probably aware, the upgrade schedule for the database in January of next year will have some important changes. It will include diagnostic codes that include status postprocedural codes to provide additional procedural information. It will also permit linkage not only across admissions, but also to potential other sources of data and, in particular, the IMPACT registry of the American College of Cardiology. So with these changes I think, in the future, it should be possible to address some of these issues that you bring up.

What we are left with at present is what has been published, and certainly you and your colleagues from the Congenital Heart Surgeons Society I believe published in the *European Journal of Cardiothoracic Surgery* in 2010 and more recently this year in February in the *Journal of Thoracic and Cardiovascular Surgery* regarding some of these issues. Based on those results, multiple procedures are not uncommon and overall survival appears to be compromised by the cumulative procedural risk.

Dr Caldarone. You reported that concomitant aortic arch surgery is associated with higher mortality, suggesting that greater left-sided hypoplasia is associated with more mortality. Surprisingly, concomitant mitral surgery was not a risk factor for death. Do you suspect that we as a profession have successfully neutralized the mitral valve issue or are we simply getting better at identifying irreparable mitral anomalies and shunting these patients into a single ventricle pathway, an event that would not be detected in your analysis?

Dr Woods. What you imply or suggest may be true, but our study wasn't designed to look at temporal trends and outcomes with concomitant mitral surgery nor in improvements in patient selection. I acknowledge the manuscript that you and your

colleagues from Toronto published I believe in the *Annals of Thoracic Surgery* recently in which you evaluated mitral surgery versus no mitral surgery in the Ross-Konno group. Clearly, there was higher mortality with concomitant mitral surgery. I don't need to cite your own data to you, you know it very well, but for the sake of the audience, as I recall, there were 8 patients who had mitral surgery and their median age was approximately 300 days. For the group that didn't have mitral surgery, there were approximately 12 patients, and their median age approached almost 6 years. That is considerably older than the group of patients with concomitant mitral surgery in the current cohort. To the extent that is relevant, I don't know. In the study from Ann Arbor, mortality occurred exclusively in patients who had either concomitant arch or mitral surgery, but actually I think there were only 2 patients in that study who had concomitant mitral surgery.

From an intuitive standpoint I think many of us, myself included, would be expecting higher mortality with concomitant surgery. The cohort we present today certainly has the largest number of patients with concomitant mitral surgery, but that doesn't really answer the issue because we don't know for those patients in the current cohort who didn't have mitral surgery, the degree to which they were actually free of mitral valve disease, and I think without that information it is hard to really know the true answer. So I think it is an unresolved issue.

Dr Caldarone. Well, like all good studies, you have raised more questions than you have answered. So I congratulate you and urge you and your colleagues to continue studying this very interesting cohort.

Dr Vaughan Starnes *(Los Angeles, Calif).* Dr Woods, thank you for the information that you have just presented. I am going to ask you to speculate. Given that the mortality and the complications with homograft insertions are equal to that of the Ross procedure, and knowing the limited survival rate of those homografts in infants, anywhere from 5 months to 1 year durability, would you say that homografts are still indicated in that age group?

Dr Woods. Thank you for your question, Dr Starnes. I don't think our data really answer that question. In an elective setting for aortic stenosis, with rare exception, the Ross procedure would seem to be the preferred approach. For those patients who present acutely with wide-open insufficiency in a really compromised state, it may be that their early outcomes are defined more by the presenting physiologic condition as opposed to the type of procedure. It is a difficult question and I am not certain I have an answer for you, Dr Starnes.

Dr Starnes. Thank you.

Dr Emile Bacha *(New York, NY).* Ron, a great talk. Thank you for pointing out the hard, cold fact that these patients have a high mortality and comparing them with other high-mortality procedures that we do, such as the Norwood procedure. I would like to have your impression on whether this is not maybe a judgment problem rather than a technical problem. We can do AVRs in neonates, but it should be a very rare procedure, and so the question is really whether some of these patients shouldn't have had an AVR and rather gone down the single ventricle route.

Dr Woods. That is really the home run question, I think, Dr Bacha, as you point out. Certainly, early survival is the first goal, and based on the present cohort, a neonatal Ross-Konno appears to have a higher mortality than a stage 1 Norwood. I think when confronted at the bedside with a patient and one is considering a single versus a biventricular strategy, if that patient has disease at more than just the valvar and subvalvar levels, particularly if the ventricle is on the smaller side and/or some degree of endocardial fibroelastosis is present, I think one would be very prudent to think long and hard before pushing that patient down an initial biventricular pathway.