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Are Outcomes of Surgical Versus Transcatheter Balloon Valvotomy Equivalent in Neonatal Critical Aortic Stenosis?

Brian W. McCrindle, MD, MPH; Eugene H. Blackstone, MD; William G. Williams, MD; Rekwan Sittiwangkul, MD; Thomas L. Spray, MD; Anthony Azakie, MD; Richard A. Jonas, MD; and the members of the Congenital Heart Surgeons Society

Background—For neonates with critical aortic valve stenosis who are selected for biventricular repair, valvotomy can be achieved surgically (SAV) or by transcatheter balloon dilation (BAV).

Methods and Results—Data regarding 110 neonates with critical aortic valve stenosis were evaluated in a study by the Congenital Heart Surgeons Society from 1994 to 1999. Reduced left ventricular function was present in 46% of neonates. The initial procedure was SAV in 28 patients and BAV in 82 patients. Mean percent reduction in systolic gradient was significantly greater with BAV ($65\pm17\%$) than SAV ($41\pm32\%$; $P<0.001$). Higher residual median gradients were present in the SAV versus BAV group (36 mm Hg [range, 10 to 85 mm Hg] versus 20 mm Hg [0 to 85 mm Hg], $P<0.001$). Important aortic regurgitation was more often present after BAV (18%) than SAV (3%; $P=0.07$). Time-related survival after valvotomy was 82% at 1 month and 72% at 5 years, with no significant difference for SAV versus BAV, even after adjustment for differences in patient and disease characteristics. Independent risk factors for mortality were mechanical ventilation before valvotomy, smaller aortic valve annulus (z score), smaller aortic diameter at the sinotubular junction (z score), and a smaller subaortic region. A second procedure was performed in 46 survivors. Estimates for freedom from reintervention were 91% at 1 month and 48% at 5 years after the initial valvotomy and did not differ significantly between groups.

Conclusions—SAV and BAV for neonatal critical aortic stenosis have similar outcomes. There is a greater likelihood of important aortic regurgitation with BAV and of residual stenosis with SAV. (***Circulation***. 2001;104[suppl I]:I-152-I-158.)

Key Words: balloon ■ surgery ■ heart defects, congenital ■ valves ■ stenosis

M anagement of the neonate with critical aortic stenosis is a complex and difficult problem. The spectrum of aortic valvar and annular pathology, in addition to a variable degree of hypoplasia of the left heart, complicates treatment. Criteria for selecting biventricular repair versus univentricular palliation are evolving.[1–4] In neonates with critical aortic stenosis selected for biventricular repair, valvotomy has been the mainstay of therapy. Both surgical and transcatheter balloon valvotomy, however, are associated with important mortality, residual or recurrent valve dysfunction, and need for reintervention. Numerous reports cite the early and late outcomes of either one procedure or the other, and the few reports comparing surgical versus transcatheter valvotomy are limited by lack of adjustment for differences between groups.[5,6] There have been no randomized studies, and there are likely to be none. We previously published a formula for predicting survival benefit at 5 years for neonates with critical aortic stenosis for univentricular palliation versus biventric-

ular repair.[1] The purpose of this study is to compare outcomes of surgical versus transcatheter balloon aortic valvotomy in a large, multi-institutional, nonrandomized series of neonates selected for biventricular repair, with adjustment for important differences in patient characteristics.

Methods

Patient Population
Between January 1994 and February 2000, 320 neonates <30 days old and diagnosed with critical aortic stenosis were entered into a prospective, nonrandomized study by the Congenital Heart Surgeons Society. The present study population includes only those 110 neonates whose initial procedure for their aortic valve stenosis was a valvotomy, indicating an intended biventricular repair pathway. Participation in this study and submission of patient information was voluntary, and all information was kept confidential. Institutional ethical approval was not obtained for inclusion in the study in the early phases, but in the later time period, more institutions were requiring ethical approval, but not explicit parental consent. Critical

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aortic valve stenosis was defined as the presence of moderate to severe aortic valve stenosis, together with either reduced left ventricular function at the time of presentation or the presence of systemic perfusion dependent on right ventricular output through a patent arterial duct. Patients with other important cardiac anomalies, particularly abnormalities of atrioventricular or ventriculoarterial connections, were excluded.

Measurements

Participating study centers submitted copies of hospital admission and discharge summaries, reports from any diagnostic studies and procedures, and follow-up assessments to the data coordinating center. Follow-up regarding vital status and intervening procedures was performed on a yearly basis by questionnaire. The most recent follow-up for these patients enrolled in the present study occurred between May and September 1999. In addition, the available videotape recordings of the initial echocardiograms performed before any intervention related to the aortic valve were reviewed in a blinded manner by a single investigator (R.S.), who made observations and offline measurements as previously described.[1] Selected measurements were related to body surface area and converted to z scores on the basis of nonlinear regression equations as reported by Daubeney et al.[7] If the echocardiographic recording was not submitted or available, functional and morphological data were derived from the medical records from reports of cardiac catheterizations, echocardiograms, surgery, and autopsy.

Data Analysis

Data are described as frequencies, medians with ranges, and means with SDs as appropriate. Where information is missing, the number of nonmissing values is given. Demographic, morphological, and functional characteristics of patients who underwent initial surgical versus transcatheter balloon aortic valvotomy were compared by Fisher's exact tests, χ^2 tests, t tests, and Kruskal-Wallis ANOVA as appropriate. Time-related death after initial valvotomy was first calculated with Kaplan-Meier estimates and then modeled parametrically in the hazard domain by use of techniques described by Blackstone et al.[8] Factors associated with phases of time-related death were explored in multivariable analyses. The strategy for data handling and model building has been described.[1] In comparing survival of the surgical versus balloon aortic valvotomy patients, a propensity score was created from multiple logistic regression, incorporating differences in demographic, morphological, and functional characteristics into a model that provided a probability that a given patient belonged to one group versus the other. This variable was then entered into the parametric models to attempt to adjust for differences in characteristics between the 2 groups. A similar analysis was performed for time-related first reintervention for aortic valve disease (deaths were censored). All statistical analyses were performed with SAS statistical software Version 7 (SAS Institute, Inc).

Results

Study Population

Eighteen institutions contributed from 1 to 29 patients each for the study. The initial procedure was a surgical valvotomy in 28 and a transcatheter balloon aortic valvotomy in 82 patients. There was no significant difference between the 2 groups regarding the date of the initial valvotomy, with relatively constant proportions having surgical valvotomy throughout the data collection period. Table 1 shows the comparisons regarding demographic, morphological, and functional characteristics between the 2 groups. Surgical patients were significantly less likely to have had echocardiographic videotape recordings available for independent review and were more likely to have a persistent left superior vena cava, the presence of moderate or severe tricuspid

regurgitation, a parachute mitral valve, and a smaller mean subaortic diameter. Although the mean z scores in left-sided structures were uniformly lower in the surgical group, the differences were not significantly different between the 2 groups, with the exception of a smaller z score of mitral valve diameter in the 4-chamber view in the surgical group.

From a previous study of the Congenital Heart Surgeons Society of patients with neonatal critical aortic stenosis, predictors of survival for a Norwood versus a biventricular repair pathway were determined, and a regression equation was derived to give predicted survival benefit at 5 years after study entry for the optimal pathway based on a patient's characteristics.[1] When this regression equation was solved for the subset of patients included in the present study, a mean±SD survival benefit favoring a biventricular repair pathway was noted in both groups (surgical 2.8±21.9% versus transcatheter balloon aortic valvotomy 3.4±20.3%; $P=0.84$), although the magnitude of benefit was small and did not differ between groups.

Procedural Characteristics

Initial transcatheter balloon aortic valvotomy in 82 neonates was performed via the femoral approach in 52 patients (65% of n=80), the carotid artery in 18 (23%), and the umbilical artery in 10 patients (12%). The catheter approach to the aortic valve (n=80) was retrograde in 60 patients (75%) and antegrade in 20 (25%). The mean balloon-to–valve hinge point diameter ratio (n=63) was 0.99±0.13.

Initial surgical aortic valvotomy in 28 neonates was an open procedure in 19 patients (68%) and closed in 9 (32%). Of the 9 patients having a closed valvotomy, 8 were transventricular dilations with a Hegar dilator, with 1 patient having an intraoperative transcatheter balloon dilation. Associated surgical procedures included ligation of a patent arterial duct in 7, patent arterial duct ligation with aortic coarctation repair in 1, and an aortic patch reconstruction in 2 patients.

A comparison of immediate results is given in Table 2. Surgical patients had a lower mean percent change in their peak instantaneous systolic gradient, as noted on preprocedure and postprocedure echocardiography, and had a higher median residual peak instantaneous systolic pressure gradient (postprocedure echocardiograms were obtained after the procedure and before hospital discharge at variable intervals). Patients who had a balloon valvotomy had a significant trend toward higher grades of aortic valve regurgitation after the procedure. A similar proportion of patients died before hospital discharge in both groups ($P=0.35$), although a higher proportion of patients in the surgical group required reintervention for aortic valve dysfunction before hospital discharge (25%) than in the balloon valvotomy group (13%; $P=0.16$). Surgical patients had a significantly longer duration of hospital stay.

Mortality

The Kaplan-Meier estimates and the parametric survival function after initial valvotomy for all patients are shown in Figure 1. The time-related survival was 82% at 1 month, 76% at 6 months, 74% at 1 year, and 72% at 5 years. Only a single

TABLE 1. Selected Patient Characteristics

| | Initial Aortic Valve Procedure | |
| | Surgical Valvotomy (n=28) | | Balloon Valvotomy (n=82) | | |
Variable	n	Value	n	Value	P
Median (range) age at entry, d	28	3 (<1, 29)	82	2 (<1, 27)	0.39
Sex, male:female	28	21:7	82	74:8	0.043
Mean (SD) birth weight, kg	13	3.02 (0.94)	50	3.18 (0.60)	0.45
Genetic or anomaly syndrome, n (%)	28	0	82	1 (1)	1.00
Noncardiac anomaly, n (%)	28	1 (4)	82	2 (2)	1.00
Echocardiogram independently reviewed, n (%)	28	16 (57)	82	67 (82)	0.009
Associated cardiac anomalies, n (%)	28	3 (11)	82	4 (5)	0.37
Persistent left superior vena cava, n (%)	28	3 (11)	82	0	0.015
Atrial septal defect (unrestrictive), n (%)	19	4 (21)	74	12 (16)	0.74
Ventricular septal defect, n (%)	18	2 (11)	74	5 (7)	0.62
Aortic coarctation, n (%)	24	4 (17)	79	7 (9)	0.28
Moderate or severe tricuspid regurgitation, n (%)	18	3 (17)	72	3 (4)	0.092
Left-sided morphology and function, mean (SD) *z* score					
Tricuspid valve diameter	15	−1.82 (2.37)	67	−1.28 (2.26)	0.41
Mitral valve diameter (4-chamber view)	16	−3.63 (2.01)	69	−1.89 (2.24)	0.006
Mitral valve diameter (long-axis view)	15	−1.72 (2.30)	67	−1.08 (1.92)	0.27
LV endocardial length (4-chamber view)	15	−0.91 (2.62)	68	−0.83 (2.19)	0.90
Aortic valve annulus (long-axis view)	22	−3.75 (2.13)	77	−3.60 (2.43)	0.79
Aortic valve at sinuses (long-axis view)	15	−3.21 (2.26)	67	−2.34 (2.31)	0.20
Aorta at sinotubular junction (long-axis view)	14	−1.30 (1.93)	67	−0.22 (2.28)	0.11
Mean (SD) ratio of left to right atrial area	15	1.04 (0.44)	65	0.90 (0.32)	0.18
Mean (SD) ratio of mitral valve area to total atrioventricular valve area	13	0.41 (0.12)	61	0.45 (0.08)	0.12
Moderate or severe mitral stenosis, n (%)	18	0	74	1 (1)	1.00
Moderate or severe mitral regurgitation, n (%)	24	4 (17)	79	6 (8)	0.24
Parachute mitral valve, n (%)	18	2 (11)	71	0	0.039
Grade of endocardial fibroelastosis	18		72		0.43
None, n (%)		7 (39)		40 (55)	
MV papillary muscles only, n (%)		9 (50)		25 (35)	
+Some endocardial involvement, n (%)		2 (11)		5 (7)	
+Extensive endocardial involvement, n (%)		0		2 (3)	
Mean (SD) LV ejection fraction, %	17	40 (21)	68	45 (23)	0.42
Moderate or severe subaortic obstruction, n (%)	18	1 (6)	75	1 (1)	0.36
Mean (SD) subaortic diameter, mm	16	5.0 (1.2)	66	5.6 (1.1)	0.045
Mean (SD) AV annulus diameter, mm	24	5.9 (1.1)	78	6.0 (1.0)	0.81
Mean (SD) ascending aorta diameter, mm	16	8.1 (2.6)	67	8.3 (2.0)	0.75
Mean (SD) peak gradient, mm Hg*	23	60 (22)	71	69 (33)	0.23
Prevalvotomy clinical condition, n (%)					
Use of inotropic agents	28	12 (43)	82	26 (32)	0.29
Mechanical ventilation	28	11 (39)	82	24 (29)	0.33
Circulatory collapse/shock	28	5 (18)	82	5 (6)	0.12

AV indicates aortic valve; LV, left ventricle; and MV, mitral valve.
*All gradients were peak instantaneous systolic gradients as derived from Doppler echocardiography.

early hazard phase was noted. When the type of the initial valvotomy was tested in the parametric model, surgical patients had higher time-related mortality, although this did not reach statistical significance (Figure 2, *P*=0.11). When the additional factor of the propensity score was entered into the model to adjust for differences in characteristics between the 2 groups, survival appeared to be almost identical (Figure 3, *P*=0.92).

TABLE 2.   Immediate Results of Initial Aortic Valvotomy

Variable	Surgical Valvotomy (n=28)		Balloon Valvotomy (n=82)		P
	n	Value	n	Value	
Mean (SD) percent change in peak systolic gradient, %*	17	−41 (32)	78	−65 (17)	<0.001
Median (range) residual peak systolic gradient, mm Hg*	18	36 (10, 85)	80	20 (0, 85)	<0.001
Grade of aortic regurgitation	19		78		0.019
None, n (%)		5 (26)		12 (15)	
Trivial, n (%)		7 (38)		25 (32)	
Mild, n (%)		5 (26)		23 (30)	
Moderate, n (%)		1 (5)		17 (22)	
Severe, n (%)		1 (5)		1 (1)	
Moderate to severely reduced LV function, n (%)	21	4 (19)	75	15 (20)	1.00
Major complication, n (%)	28	0	82	3 (4)	0.57
Death before hospital discharge, n (%)	28	5 (18)	82	9 (11)	0.35
Reintervention for aortic valve dysfunction before hospital discharge, n (%)	28	7 (25)	82	11 (13)	0.16
Median (range) days to hospital discharge in survivors	19	8 (3, 32)	66	4.5 (1, 366)	0.023

LV indicates left ventricle.

*All gradients were peak instantaneous systolic gradients as derived from Doppler echocardiography.

Incremental risk factors for early-phase time-related death were explored further. Significant incremental risk factors are shown in Table 3 and include mechanical ventilation before valvotomy, lower z score of the aortic valve annulus, lower z score of the aorta at the sinotubular junction, and a lower absolute diameter of the subaortic region. Of note, the missing value indicator variable for the independent echocardiographic review was also significant and was entered into the model, thus adjusting somewhat for missing information. After adjustment for these variables, no other variable entered significantly into the final model, including the type of valvotomy.

Reintervention for Aortic Valve Dysfunction

Kaplan-Meier estimates and the parametric model for time-related reintervention for aortic valve dysfunction after initial valvotomy are shown in Figure 4. Estimates for freedom from reintervention were 91% at 1 month, 68% at 6 months, 58% at 1 year, and 48% at 5 years after the initial valvotomy. The indications for reintervention included failure of the biventricular repair pathway in 8 patients, residual aortic stenosis in 22, moderate to severe aortic regurgitation in 4, combined aortic stenosis and regurgitation in 4, residual aortic stenosis with the presence of other lesions in 9, and pericardial tamponade after a balloon aortic valvotomy in 1.

Subsequent procedures and outcomes for patients who had initial surgical valvotomy are shown in Figure 5. Of note, 4 patients failed the biventricular pathway and went on to have a Norwood-type connection. Subsequent procedures and outcomes in the balloon aortic valvotomy group are shown in Figure 6. Of note, 5 patients failed the biventricular pathway and had Norwood-type connections, and 11 children required aortic valve replacement during the study period. One additional child had a cardiac transplant.
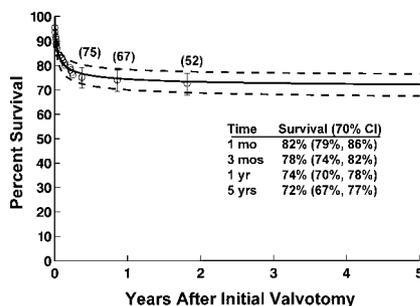

Figure 1. Non–risk adjusted time-related survival after initial aortic valvotomy (n=110). Circles represent Kaplan-Meier estimates for survival at each death, with solid line representing parametric determination of continuous point estimates, and dashed lines enclose 70% CI.
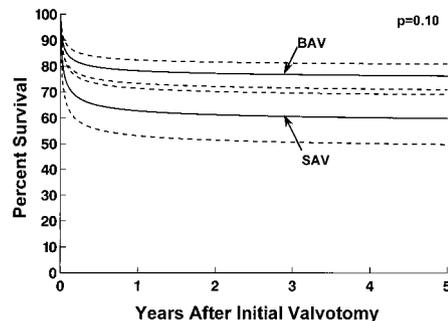

Figure 2. Time-related survival stratified by type of initial aortic valvotomy but unadjusted for any other factors. Solid lines represent parametric determination of continuous point estimates, and dashed lines enclose 70% CI. BAV indicates balloon aortic valvotomy; SAV, surgical valvotomy.
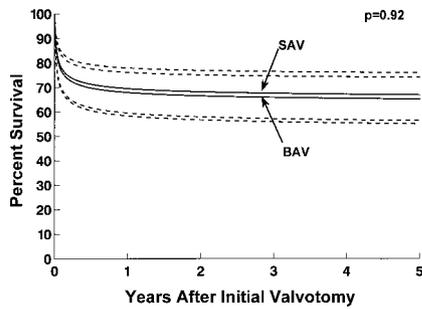
Figure 3. Time-related survival stratified by type of initial aortic valvotomy, adjusted for differences in group characteristics as reflected by a propensity score derived from multiple logistic regression. Solid lines represent parametric determination of continuous point estimates, and dashed lines enclose 70% CI. Abbreviations as in Figure 2.

Figure 4. Non–risk-adjusted time-related freedom from subsequent aortic valve–related reintervention after initial aortic valvotomy (n=110), with patients who died before reintervention censored at time of death. Circles represent Kaplan-Meier estimates for freedom from reintervention at each event, with solid lines representing parametric determination of continuous point estimates, and dashed lines enclose 70% CI.

When the type of the initial valvotomy was tested in the parametric model, patients who had surgical valvotomy were more likely to have initial reintervention, although this did not reach statistical significance (Figure 7; $P=0.56$). Likewise, when surgical valvotomy patients were grouped into closed versus open procedures, there was no significant difference between groups. When the additional variable of the propensity score was entered into the model to adjust for differences in characteristics between the 2 groups, patients who had balloon valvotomy had a poorer freedom from reintervention, although this did not reach statistical significance (Figure 8; $P=0.63$). Incremental risk factors were then tested for their relationship with time-related initial reintervention. Significant factors are shown in Table 4 and include the prevalvotomy use of inotropic agents, the presence of moderate to severe aortic valve regurgitation after initial valvotomy, and a lower weight at initial valvotomy. After adjustment for these variables, no other variable entered significantly into the final model, including the type of valvotomy, and there were no significant interaction terms.

Discussion

Summary
The results of the present study indicate that the outcomes of surgical versus transcatheter balloon aortic valvotomy in neonates with critical aortic stenosis are comparable mortality and risk of reintervention, even after adjustment for differences in patient characteristics. The overall risk of mortality
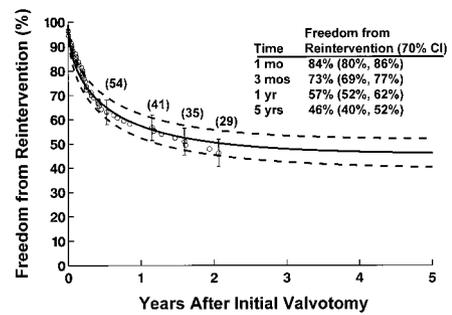
is increased by hypoplasia of structures of the left ventricular outflow tract (aortic valve annulus, sinotubular junction, subaortic region) as well as poorer preprocedural condition of the infant. Many of these neonates might have been better served by a palliative univentricular approach. Our previous study of these patients showed that, on the basis of patient characteristics, ≈52% would have had better predicted survival at 5 years with a Norwood procedure.[1] Neonates having transcatheter balloon aortic valvotomy had lower residual gradients, greater degrees of aortic regurgitation, but significantly shorter duration of hospitalization. The rate of reintervention is high (>50% at 5 years). Risk factors for reintervention are poorer prevalvotomy clinical condition, lower weight, and production of important aortic regurgitation after valvotomy.

Mortality
Early mortality after palliative valvotomy for critical aortic stenosis in the neonate is high, with reports ranging from 0% to 59%.[5,6,9–12] Surgical valvotomy in the present era carries a mortality of 10% to 20%, and the use of open versus closed techniques does not seem to affect early mortality.[5,11]

Reported early mortality after balloon aortic valvotomy is comparable to that of surgery.[5,6,13–18] Bu'Lock[13] and Kasten-Sportes[14] reported early mortality of 25% to 30%, which in selected patients may be as low as 10% to 12%.[5,17] When patients with various degrees of hypoplasia of the left-sided

TABLE 3.   Incremental Risk Factors for Time-Related Death After Initial Aortic Valvotomy

Variable	Parameter Estimate* (SEE)	P
Mechanical ventilation before valvotomy	1.605 (0.435)	<0.001
Lower z score of aortic valve diameter at the level of the hinge points (annulus)	0.205 (0.092)	0.029
Lower z score of aortic valve diameter at the level of the sinotubular junction	0.234 (0.104)	0.025
Lower absolute diameter of the subaortic region (mm)	0.601 (0.277)	0.03

*For a single early hazard phase; adjusted for whether or not the independent review of initial echocardiograms had been performed.
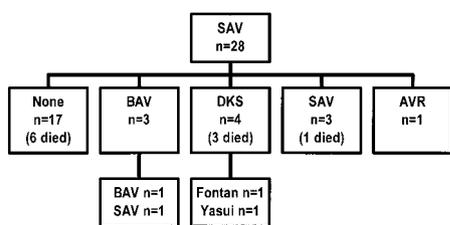
Figure 5. Subsequent procedures and mortality for patients who had an initial surgical valvotomy (n=28). AVR indicates aortic valve replacement; DKS, Norwood. Other abbreviations as in Figure 2.

structures were included, early mortality estimates have been 24%.[17]

Formal studies comparing outcomes of surgical versus transcatheter balloon aortic valvotomy are lacking.[5,6] Nonrandomized, single-institution comparisons of nonconcurrent patients have reported similar mortality rates for neonates with critical aortic stenosis undergoing either approach[5,6] and have not adequately adjusted for differences in patient characteristics.

Ongoing mortality may occur, with mid-term survival after surgical aortic valvotomy reported to be ≈65% to 73% at 5 to 10 years.[5,9,11] Similarly, mid-term survival after balloon aortic valvotomy ranges from 50% to 63%[5,13,17] and in selected patients (excluding patients with hypoplastic left heart complex) approaches 88%.[17]

Numerous studies have assessed risk factors for death after valvotomy in neonates and small infants with critical aortic stenosis. Morphological features reported to increase mortality include lower-indexed aortic root/annular dimension[2,3]; lower ascending aortic or arch dimensions[3]; lower-indexed mitral valve area or mitral valve dimension[2,19]; lower left ventricular end-diastolic dimensions, cross-sectional area, length, or volume[2–4,10,20]; increased presence of endocardial fibroelastosis[12,20]; and lower body surface area.[2] Physiological variables have also been reported to increase mortality, including elevated pulmonary artery pressures or left ventricular end-diastolic pressures,[10,12] retrograde direction of ascending aortic blood flow,[3,21] and lower ejection fraction.[12,20] The cause of death in neonates with critical aortic stenosis after balloon or surgical valvotomy is often low output syndrome due to an inadequate left heart. Many infants might be better served having a Norwood-Fontan track palliation.[1]

Reintervention for Aortic Valve Dysfunction
The risk of reintervention after initial valvotomy is high. After surgical valvotomy, the risk of reintervention ranges
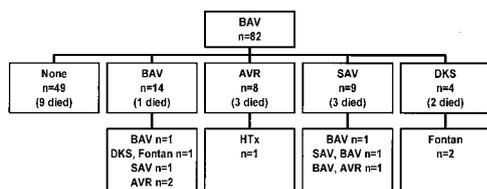

Figure 6. Subsequent procedures and mortality for patients who had an initial transcatheter balloon valvotomy (n=82). HTx indicates heart transplant; other abbreviations as in previous figures.
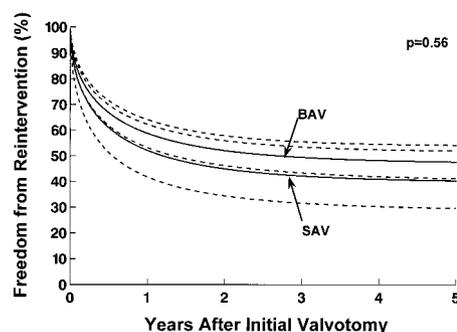

Figure 7. Time-related freedom from aortic valve–related reintervention stratified by type of initial aortic valvotomy, but unadjusted for any other factors. Solid lines represent parametric determination of continuous point estimates, and dashed lines enclose 70% CI. Abbreviations as in previous figures.

from 25% to 40% at 5 years, with even higher rates at 10 years of follow-up.[5,9,11] Residual gradients after surgical valvotomy at mid-term to long-term follow-up range from 40 to 100 mm Hg.[6] Persistence or progression of aortic stenosis is the most common reason for initial reintervention, although with longer follow-up, later reoperations are usually for management of progressive aortic regurgitation.[12]

Reintervention after initial balloon aortic valvotomy at mid-term to long-term follow-up ranges from 20% to 60%[5,6,13,14,17] and is higher than reintervention after balloon aortic valvotomy in nonneonatal patients with aortic stenosis.[16] Moore et al[16] reported that the risk of reintervention after balloon aortic valvotomy was increased in children who had more than moderate aortic regurgitation (or abnormal valve cusps). In a large series of neonates treated with balloon aortic valvotomy, Egito et al[17] reported the presence of moderate to severe aortic regurgitation in 14% and residual gradients >50 mm Hg in 35% at mid-term follow-up. Sholler et al[22] noted that when the balloon-to-annulus diameter ratio was >1.00, postdilation aortic regurgitation increased substantially (11% for a ratio ≤1.00 versus 26% for a ratio >1.00). Shaddy et al[23] reported that important postdilation aortic regurgitation developed in a substantial number of patients, even if the balloon-to-annulus ratio was ≤1.00. Of
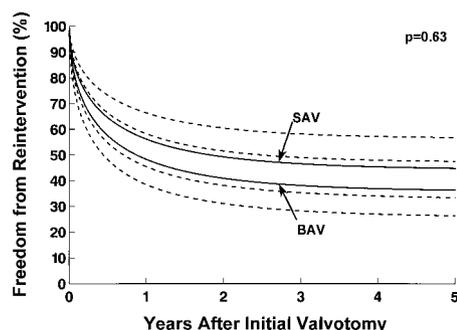

Figure 8. Time-related freedom from aortic valve–related reintervention stratified by type of initial aortic valvotomy, adjusted for differences in group characteristics as reflected by a propensity score derived from multiple logistic regression. Solid lines represent parametric determination of continuous point estimates, and dashed lines enclose 70% CI. Abbreviations as in previous figures.

TABLE 4. Incremental Risk Factors for Time-Related First Subsequent Valve-Related Reintervention After Initial Aortic Valvotomy

Variable	Parameter Estimate* (SEE)	*P*
Prevalvotomy use of intravenous inotropic agents	0.684 (0.336)	0.042
Presence of moderate or severe aortic regurgitation after aortic valvotomy	0.771 (0.398)	0.053
Lower weight at aortic valvotomy (kg)	0.379 (0.222)	0.087

*For a single early hazard phase.

the 31% of patients who developed important aortic regurgitation and the 22% who developed aortic valve prolapse, none had dilation with a balloon diameter greater than that of the aortic annulus. The use of a transvenous antegrade approach has been reported to minimize the risk of cusp perforation and peripheral arterial thrombosis while achieving comparable hemodynamic relief.[24]

The role of the Ross procedure (pulmonary autograft) in the management of neonates with critical aortic stenosis could not be evaluated in this study, because no neonates had a Ross procedure as their initial procedure. Although controversial, the Ross procedure is compelling because of the potential normalization of hemodynamics, avoidance of residual lesions, and theoretical long-term preservation of ventricular function.[25] Reoperation for pulmonary conduit management would be unavoidable. An alternative to a primary Ross procedure might be to perform a valvotomy initially and reserve the Ross procedure for when the patient needs valve replacement at a later age. Ultimately, the Ross procedure needs to be compared with aortic valvotomy in a prospective, multi-institutional study in neonates in whom the published regression equation predicts better survival with biventricular repair pathway.[1]

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