

Transvascular Balloon Dilation for Neonatal Critical Aortic Stenosis: Early and Midterm Results

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Objectives. We evaluated our immediate and midterm (mean 4.3 years) results of balloon dilation of critical valvular aortic stenosis in 33 neonates.

Background. Balloon dilation has been used as an alternative to surgical treatment. Reports to date consist of small series (largest 16 babies) with short-term follow-up (longest 4.8 years).

Methods. From 1985 to 1991, 33 neonates had dilation at a mean age of 13 days and a mean weight of 3.4 kg. Nineteen of the neonates (58%) were intubated and received prostaglandins, and 94% had other cardiac abnormalities.

Results. The dilation was completed retrograde in 31 of the neonates (umbilical artery in 11 and femoral artery in 20) and antegrade (femoral vein) in 2. The average immediate peak gradient and left ventricular end-diastolic pressure reductions

were 54% and 20%, respectively. The overall mortality rate was 12% (three early deaths and one late). All 20 neonates dilated through a femoral artery initially had pulse loss with restoration in 35% after thrombolytic therapy. At 8.3 years, survival and freedom of reintervention probability rates were 88% and 64%, respectively. At mean 4.3 years of follow-up, 83% of the survivors were asymptomatic; Doppler study revealed a maximal instantaneous gradient <50 mm Hg in 65% of neonates and significant aortic regurgitation in 14%.

Conclusions. This study confirms that dilation of aortic stenosis in neonates is effective; reintervention (mostly redilation) is frequent (40%); and midterm survival is encouraging (88%).

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Transvascular balloon dilation for critical aortic stenosis in neonates, initially reported in 1986 (1), has been shown as efficacious as surgical treatment in terms of gradient relief and appearance of aortic regurgitation (2-15). However, the largest study reported to date consists of 16 neonates (6) and the longest follow-up period is 4.8 years (15). This study was undertaken to review our experience in 33 neonates with a mid-term follow-up to 8.3 years (average 4.3) and to compare our results with other series so treated (2-15) and with those managed surgically (2,14-29) and by valvotomy, dilators or balloons.

Methods

Between August 1985 and October 1991, 46 neonates \leq 33 days of age and deemed to be possible two-ventricle survivors

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underwent balloon dilation for critical valvular aortic stenosis, including one neonate who had an arterial switch operation with severe stenosis of the neo-aortic valve. Excluded were babies with aortic or mitral atresia, or both, and clearly diminutive left ventricles who were referred for a stage I Norwood procedure. The echocardiographic anatomic risk factor score for two-ventricle repair by Rhodes et al. (30) was retrospectively applied to all patients. Because that study revealed that infants with echocardiographic scores >2 treated with balloon valvuloplasty have extremely poor outcomes, 13 neonates with such features (most included in that report) were excluded, except for brief comparison purposes, leaving 33 neonates as the basis of this report. All available records were reviewed, including electrocardiograms (ECGs), chest X-ray films, two-dimensional and Doppler echocardiograms, cardiac catheterization data and autopsy reports. Cineangiograms were reviewed by three observers (E.E., P.M., J.O.S.) to evaluate aortic regurgitation and mitral regurgitation (graded as absent, mild, moderate or severe). In addition, the aortic valve annulus diameter was measured from the lateral cineangiogram using catheter size to correct for magnification, and valve consistency was graded as thin when leaflets measured <2 mm, or thick (≥ 2 mm) on either anteroposterior or lateral cineangiograms.

Dilation was performed using techniques previously described in detail (2,8,31). Early death and early reintervention

Table 1. Associated Cardiac Abnormalities at Hospital Admission in 33 Neonates

Abnormalities	No. (%)
LV dysfunction	27 (82)
Mitral regurgitation	22 (67)
PDA	15 (45)
ASD/PFO	27 (82)
Mitral stenosis	1 (3)
Multiple VSD	1 (3)
PAPVC	1 (3)
DTGA, VSD, PS, after ASO	1 (3)

ASD/PFO = atrial septal defect/patent foramen ovale; ASO = arterial switch operation; DTGA = dextro transposition of great arteries; LV = left ventricle; PAPVC = partial anomalous pulmonary venous connection; PDA = patent ductus arteriosus; PS = pulmonary stenosis; VSD = ventricular septal defect.

were defined as occurring within 30 days of the initial dilation. Follow-up information was obtained from charts, the referring cardiologist and parents by a mailed questionnaire. These data included current symptoms (fainting, dizziness, chest pain, palpitation, tachypnea, exercise limitation), medications, additional cardiac interventions, cardiac murmur intensity, presence of femoral pulses, left ventricular hypertrophy on ECG, heart size on chest X-ray film, presence and severity of aortic and mitral regurgitation on echocardiography and maximal instantaneous and mean Doppler gradients. When available, repeat catheterization data, including aortic peak to peak systolic ejection gradient, left ventricular end-diastolic pressure and degree of aortic and mitral regurgitation, were recorded. Collection of all follow-up information was completed in 1994. Written informed consent was obtained in accordance with the guidelines of the Committee on Clinical Investigation.

Statistical analysis. Data are expressed as mean value \pm SD. Predilation and postdilation comparisons of data were performed using the paired *t* test. A *p* value <0.05 was considered significant. An overall survival curve was constructed using the Kaplan-Meier method with the end point being death. Subjects who did not die were censored at the time of the last follow-up visit.

Results

Predilation observations (33 neonates). The 33 neonates ranged in age from 1 to 33 days (13 ± 12) and in weight from 1.9 to 5.5 kg (3.4 ± 0.8). Twenty-six were boys, and at the time of catheterization 19 were intubated.

On the ECG, left ventricular hypertrophy was present in 55% of the neonates, a strain pattern in 40%, and 15% had both. On chest X-ray film, cardiomegaly was present in 87%. Frequently associated cardiac abnormalities as shown by echocardiography or catheterization, or both, included left ventricular dysfunction (82%), atrial septal defect/patent foramen ovale (82%), mitral regurgitation (67%) and patent ductus arteriosus (45%) (Table 1).

Table 2. Immediate Results in 33 Neonates

Variable	
PSEG	
Pre	59 \pm 24
Post	27 \pm 18
<i>p</i> value	<0.001
LVEDP	
Pre	20 \pm 8
Post	16 \pm 6
<i>p</i> value	0.024
BAR	0.8 \pm 0.1
Technical success	24/33 (73%)

Data presented are mean value \pm SD or number (%) of patients. BAR = final balloon/aortic annulus ratio; LVEDP = left ventricular end-diastolic pressure (mm Hg); Pre and Post = before and after dilation, respectively; PSEG = peak to peak systolic ejection gradient (mm Hg).

Immediate results (Table 2). Dilation was completed in retrograde fashion in 31 neonates (94%)—from the umbilical artery in 11 (33%) and the femoral artery in 20 (61%)—and in anterograde fashion in 2 (6%) through a femoral vein. The average gradient reduction was 54% and left ventricular end-diastolic decrease 20%, and the incidence of technical success (defined as gradient reduction $>50\%$ with no significant aortic regurgitation) was 73%. There was no correlation between valve thickness and either catheterization peak gradient reduction or aortic regurgitation. The average final balloon/aortic annulus ratio was 0.8.

Procedure complications (Table 3). There were three procedure-related deaths. Of these, one was due to sepsis after a prolonged attempt at dilation through the umbilical artery, and another to severe aortic regurgitation resulting from wire perforation and subsequent cusp dilation. Both were very early in this series. The other died of wire perforation of the left ventricle, causing tamponade. Other major complications included cardiac arrest in four (all resuscitated) babies, left anterior descending coronary artery occlusion in one and aortic arch flaps later found on echocardiography in two. All 20 neonates dilated through a femoral artery initially had pulse loss, but after thrombolytic therapy the pulse returned in 35% of them.

Overall mortality and survival. The overall mortality rate was 12% (4 of 33 neonates)—with 3 (9%) early and 1 (3%) late (12 months) death. All three early deaths were related to

Table 3. Procedure Complications in 33 Neonates

Mortality—3 (9%)
Wire perforation of LV with tamponade—1
Cusp perforation by wire, then BD, then severe AR—1
Sepsis associated with prolonged umbilical artery approach—1
Cardiac arrest—4 (12%)
Sepsis—3 (9%)
AR (moderate to severe)—2 (6%)
LAD occlusion—1 (3%)

AR = aortic regurgitation; BD = balloon dilation; LAD = left anterior descending coronary artery; LV = left ventricle.

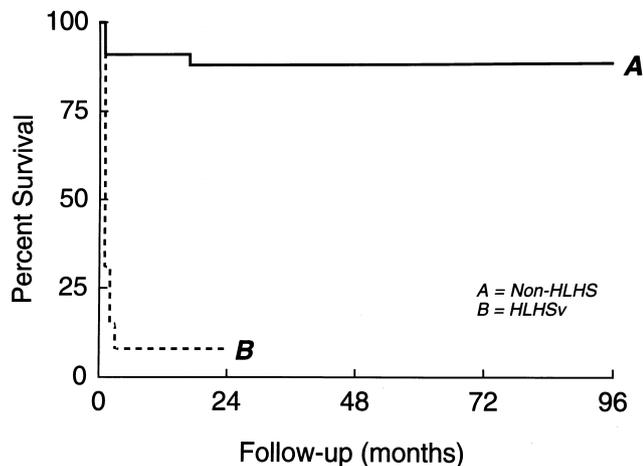


Figure 1. Kaplan-Meier survival curve for neonates after balloon dilation as initial treatment for critical aortic stenosis. HLHS(v) = hypoplastic left heart syndrome (variant group, echocardiographic score ≥ 2 [30]).

dilation complications, and the late death (overseas) occurred in the baby whose neo-aortic valve was dilated after an arterial switch operation. In this last patient with moderate aortic regurgitation at most following the dilation, we were unable to obtain any other follow-up details. The predicted survival rate was 88% up to 8.3 years of follow-up, in contrast to only 8% at 24 months in those with an echocardiographic score ≥ 2 (Fig. 1).

Reintervention. A second procedure was performed in 12 patients (40%). This second procedure (mostly redilation) was undertaken by 1 month in 12%, by 4 months in 31% and by 96 months in 36% of the neonates. A third redilation procedure was performed in two patients, one of whom later underwent a surgical valvotomy followed by heart transplantation.

Midterm results. Of the 33 neonates, 29 (88%) were alive at completion of the study, and follow-up data were obtained in all at 4.3 ± 1.8 years (range 2.2 to 8.3) after dilation (Table 4). Clinically, 83% of them were asymptomatic. No episodes of bacterial endocarditis or serious arrhythmia were noted. Murmurs of aortic stenosis ($\leq 4/6$) were present in all neonates, and aortic regurgitation in 24%. The femoral pulse was absent in nine babies, but without any obvious leg length discrepancy. At the most recent Doppler study, the instantaneous gradient was 53 ± 19 mm Hg (range 15 to 98), and aortic regurgitation was graded as moderate to severe in four (14%). At cardiac catheterization in 19 neonates, performed in the majority because of suspected significant residual obstruction, at 2.4 ± 2 years (range 0.1 to 6.6) after dilation, the gradient was 53 ± 31 mm Hg (range 9 to 95), left ventricular end-diastolic pressure 19 ± 9 mm Hg (range 10 to 40) and cardiac output (measured in 13) 4.1 ± 1.0 liter/min per m^2 (range 2.1 to 6.6). Aortic regurgitation, moderate to severe, was present in 11%. An occluded external iliac-common femoral artery was identified in four patients with adequate collateral flow as shown by angiography.

Table 4. Follow-Up Data

Variable	No. (%)
Clinical	
Symptoms	5 (17)
On medication	11 (38)
Murmur	
Systolic	29 (100)
Diastolic	7 (24)
ECG	
LVH	15 (52)
Strain pattern	3 (10)
Chest X-ray film: cardiomegaly	10 (35)
Echocardiography	
MIG >50 mm Hg	10 (35)
Moderate to severe AR	4 (14)
Catheterization*	
PSEG >50 mm Hg	5 (26)
Moderate to severe AR	2 (11)

*Available in 19 patients only. AR = aortic regurgitation; ECG = electrocardiography; LVH = left ventricular hypertrophy; MIG = maximal instantaneous gradient; PSEG = peak systolic ejection gradient.

Additional defects were encountered in 10 patients, consisting of mitral stenosis in four, membranous subvalvular aortic stenosis in three, coarctation of the aorta in two, double-chambered right ventricle in one and partial anomalous pulmonary venous return in another. On review of the initial echocardiographic and catheterization data, all but the last and one stenotic mitral valve appeared to have developed during follow-up. In contrast, some abnormalities present before dilation had spontaneously resolved or improved during follow-up. Decreased left ventricular function, initially present in 23 (79%) of 29 neonates (severe in 13), improved in all, being normal in 87%. Mitral regurgitation, noted in 18 patients (62%; moderate in 6), improved in 13 (72%), being absent in 9 (50%) and mild at most in the other 9. A small atrial defect, with or without left to right shunting and noted initially in 23, had spontaneously closed in 21 neonates (91%). No patient had a patent ductus arteriosus at follow-up, all 11 having closed spontaneously.

Discussion

Critical aortic stenosis in neonates is a rare lesion; among infants it accounts for 2% of life-threatening heart disease (32). Although it may be tolerated in fetal life when increased flow through the right heart can compensate for reduced flow across the aortic valve, after closure of the patent ductus arteriosus after delivery, left ventricular failure with its sequelae rapidly develops. Initially surgical valvotomy was the sole hope of survival in these neonates, but in recent years management by transvascular balloon dilation has been introduced as an alternative (1-15).

Survival (Table 5). In surgical series reviewed (2,14-29) from 1974 to 1995, among 212 cases reported, there were 136

Table 5. Surgical and Transvascular (percutaneous, umbilical) Balloon Dilation Management of Neonatal Critical Aortic Stenosis

	No. of Cases (range)	Survival Rate		Reintervention Rate (range)	Mean Follow-Up Period (yr) (range)
		Early	Late		
Surgical	212	64%	58%	17%	2.5
1974-1994*	(7-40)	(0-91%)	(50-100%)	(0-50%)	(0.4-4.7)
BD in other studies	85	69%	63%	24%	1.1
1986-1995†	(2-16)	(46-100%)	(50-100%)	(0-60%)	(0.3-3.1)
BD in this study	33	91%	88%	36%	4.3
(HLHS group included)	(46)	(76%)	(63%)	(41%)	

*Includes valvotomy, dilators and balloon management; see references 2, 14-23 and 27-29. †See references 1, 3-7, 9-11, 14 and 15. BD = balloon dilation; HLHS = hypoplastic left heart syndrome with an echocardiographic score of 2.

(64%) early and 123 (58%) late survivors at a mean 2.5 years of follow-up. In many of these series, neonates with hypoplastic left heart features were included. If we include 13 such infants initially managed by balloon dilation during the same period, then of our total 46 neonates, early and late survival rates are 76% and 63%, respectively. In some of the surgical series (15-18,20,23), neonates with hypoplastic left heart syndrome features were excluded: in the valvotomy series of Turley et al. (23), early and late survival rates were 87.5% and 52.5%, respectively, and in the series of Mosca et al. (15), in which Hegar dilators were used, the rates were 90.5% and 86%, respectively. In percutaneous and umbilical balloon dilation series (2-7,9-11,13-15), among 85 neonates (1986 to 1995), there were 59 (69%) early and 53 (63%) late survivors at a mean 1.1 year of follow-up. Some authors (3,10,11) excluded neonates with hypoplastic left heart syndrome features. If we include our 13 neonates with an echocardiographic score ≥ 2 , then in our total of 46 neonates, there were 35 (76%) early and 29 (63%) late survivors at a mean 4.3 years of follow-up. Although our results in those with hypoplastic left heart syndrome features (echocardiographic score ≥ 2) were very poor (39% early, 8% late survival), in those with an echocardiographic score < 2 the survival rates were most encouraging—91% early and 88% late survival rates with the longest follow-up reported to date. Thus, our results suggest that transvascular balloon dilation is comparable to the more recent surgical results as the initial method of management of these babies without hypoplastic left heart syndrome features.

Reintervention (Table 5). Among surgically managed neonates, the incidence of a second cardiac procedure, most commonly a repeat surgical valvotomy, ranged from 0% to 50% (mean 17%), undertaken at a mean 2.5 years of follow-up. Among the balloon dilation-managed neonates from other institutions, a second procedure was undertaken in 24% during a mean follow-up of 1.1 year. Repeat dilation, surgical valvotomy and Norwood stage I operation were the most common reintervention procedures. In the current series, a second procedure was carried out in 40% during a mean follow-up period of 4.3 years, most commonly a repeat dilation. It is likely that the higher incidence of reintervention in our study group is related to our propensity to repeat dilation at lower

gradient levels (> 50 mm Hg) and to our longer follow-up time. At our own institution, among 148 older patients who underwent dilation during the same era as the current series, 25% underwent reintervention within 4 years of follow-up, a lower incidence than that in our neonatal patients (33).

Associated lesions. It has been suggested that isolated critical aortic stenosis in the neonatal period represents the favorable end of the hypoplastic left heart syndrome spectrum, whereas those patients with atresia of one or more structures are the most severely affected (34-36). Between these two extremes are babies with aortic stenosis with less severe hypoplasia of one or more left heart structures in whom survival with two ventricles and a valvotomy alone is questionable. Balloon dilation in such neonates, identified using the scoring system as described by Rhodes et al. (30), has been shown to be ineffective. Indeed, when we attempted a Norwood procedure after dilation in the ensuing weeks, some now with aortic regurgitation, survival was only 16%. Thus, at present we use this scoring system to guide management, and since this series of 30 neonates with both aortic and mitral stenosis, there have been 12 survivors (30%) after a Norwood operation as the first procedure. In the present series of 33 neonates, all with a score < 2 , the early survival rate was 91% with dilation, and among these clearly there were some lesions that improved after dilation alone. Atrial defects closed spontaneously in 91% of these babies, and mitral regurgitation was noted in 62%, decreased in 72% and resolved completely in 50%. Dysfunction of the left ventricle improved in all the neonates, becoming normal in 87%, as has been reported by other investigators (15). In these survivors, other lesions previously not evident and necessitating treatment appeared during follow-up, such as mitral and subaortic stenosis, coarctation of the aorta and double-chambered right ventricle.

Balloon dilation-related complications. There were three deaths (9%) related to the procedure—namely, sepsis due to a prolonged attempt to dilate through the umbilical artery (8), cusp perforation by wire with subsequent cusp dilation (8) and tamponade due to wire perforation of the left ventricle. These occurred early in the series and all are considered avoidable. These complications have also been described by other investigators (4,10,14,28). Aortic regurgitation, at least moderate in

degree, was present initially in 6% of neonates (and 11% at follow-up catheterization), a complication also described in other dilation series (10,11,14,15) and in surgical reports (15,16,20,21,23,28,29). Although unpredictable, we believe it prudent to initially use a balloon that is 90%, at most, the annular size. We have encountered two instances of aortic arch flaps visible echocardiographically among survivors, without hemodynamic sequelae, which may be related to the use of an 0.018-in. (0.045-cm) torque wire with a stiff mandril, along with a balloon with a larger internal diameter lumen. Preshaping this wire to the aortic curves, along with a matched balloon lumen, should eliminate this problem. Femoral pulse loss occurred initially in all our neonates who underwent dilation through a femoral artery, with resolution occurring in 35% after thrombolytic therapy. Although pulses were palpable in 71% of babies at follow-up, patency was uncertain (37,38). Use of the umbilical artery (8) in 33% in this series and also advocated by others (4,15), or anterogradely from a vein (technically the most difficult), eliminates this problem, as would the novel subscapular artery cut-down approach recently described (39) or the carotid artery approach with which we have no experience (3).

Follow-up (Table 4). At a mean follow-up of 4.3 years (range 2.2 to 8.3), 83% of the survivors were asymptomatic, 65% had an instantaneous gradient <50 mm Hg echocardiographically, 86% had mild aortic regurgitation and 64% were free from reintervention. Although this follow-up is the longest to date, these results are similar to those in the more recent dilation and surgical reports (14,15,23).

Study limitations. This is a retrospective review, and some of these patients have been included in previous reports (2,8,30,31). Small variations in measurement of variables used in the echocardiographic scoring system (30) can influence the resultant score, and although a score ≥ 2 retrospectively predicted 100% nonsurvival for a two-ventricle repair, further refinements of this approach are clearly necessary.

Conclusions. This study confirms that transvascular balloon dilation of critical aortic stenosis 1) results in survival rates better than those in most surgical series of neonates with adequate-sized left heart structures, and 2) is ineffective in those with hypoplastic left heart syndrome features. This procedure continues to be our treatment of choice for this lesion. Although femoral artery pulse loss was frequent, since completion of this study in 1991, catheter technology has continued to advance. For example, balloon catheters up to 6 mm in diameter on a shaft size under 4F with an 0.018-in. lumen are now available (Medi-Tech, Boston Scientific Corporation). We believe such equipment improvements, along with more frequent use of the umbilical artery and antegrade venous approaches, have resulted in less pulse loss.

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