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Balloon Valvuloplasty for Critical Aortic Stenosis in the Newborn: Influence of New Catheter Technology

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Between 1986 and July 1990, balloon valvuloplasty was attempted in eight newborns (<28 days of age) with isolated critical aortic valve stenosis. Balloon valvuloplasty could not be successfully accomplished in any of the three infants presenting before 1989. Since March 1989, when improved catheter technology became available, all five neonates presenting with critical aortic stenosis were treated successfully by balloon valvuloplasty. A transumbilical approach was utilized in all four infants in whom umbilical artery access could be obtained. One newborn who was 25 days of age underwent transfemoral balloon valvuloplasty.

Balloon valvuloplasty was immediately successful in all five newborns, as evidenced by a decrease in valve gradient and improvement in left ventricular function and cardiac output. Peak systolic gradient was reduced by 64% from 69 ± 8 to 25 ± 3 mm Hg (p = 0.005). Left ventricular systolic pressure decreased from 128 ± 9 to 95 ± 9 mm Hg (p = 0.02) and left ventricular end-diastolic pressure decreased from 20 ± 2 to 11 ± 1 mm Hg (p = 0.02). Moderate (2+) aortic regurgitation was documented in two infants after valvuloplasty. The time from first catheter insertion to valve dilation averaged 57 ± 14 min (range 26 to 94) and the median length of the hospital stay was 4 days.

With the use of recently available catheters, the transumbilical technique of balloon valvuloplasty can be performed quickly, safely and effectively in the newborn with critical aortic stenosis. It does not require general anesthesia, cardiopulmonary bypass or a left ventricular apical incision and it preserves the femoral arteries for future transcatheter intervention should significant aortic stenosis recur.

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Balloon valvuloplasty has been shown to provide effective gradient relief in children with congenital aortic valve stenosis (1–4), with minimal intermediate-term restenosis (5). There has been limited experience, however, with balloon valvuloplasty in the treatment of newborns with critical aortic stenosis. Femoral artery access may be difficult to obtain percutaneously in sick neonates with diminished pulses. Furthermore, we and others (5–7) have been concerned about the risk of femoral artery injury when percutaneous valvuloplasty procedures are performed transarterially during the newborn period. Nevertheless, because surgical treatment of critical aortic stenosis in the newborn is associated with significant morbidity and mortality (8–12), transcatheter therapy may have an important therapeutic role in this group of patients.

The purpose of this report is to describe the experience at our institution with balloon valvuloplasty in neonates with critical aortic stenosis. The impact of recent improvements in catheter technology on the successful application of transcatheter therapy in newborn aortic stenosis is documented. Since 1989, when improved angioplasty catheters became available at our institution, all neonates presenting with critical aortic stenosis have undergone successful balloon valvuloplasty. Furthermore, the transumbilical approach has been utilized in all infants <2 weeks of age, thus avoiding potential femoral artery injury.

Methods

Study patients. Between 1986 and July 1990, balloon valvuloplasty was attempted in eight newborns (<28 days of age) with isolated critical aortic valve stenosis. The patients ranged in age from 2 to 27 days and in weight from 3.3 to 4.2 kg. All had congestive heart failure and markedly diminished peripheral arterial pulses. Balloon valvuloplasty was offered as an investigational treatment alternative to surgical valvotomy and consent was obtained from each patient's family. The valvuloplasty protocol was approved by the Institutional Review Board at the University of Michigan Medical Center (May 14, 1985). We did not attempt balloon valvuloplasty in newborns with aortic stenosis and associated severe left ventricular hypoplasia (<20 ml/m^2 end-diastolic volume).

Balloon valvuloplasty could not be successfully accomplished in any of the three infants presenting before 1989. Since March 1989, however, when improved catheter technology became available at our institution, all five neonates

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presenting with critical aortic stenosis were treated successfully by balloon valvuloplasty.

Valvuloplasty attempts before 1989. All three valvuloplasty attempts before March 1989 were unsuccessful because of technical difficulties related to the balloon catheters available at the time. The first patient was a 5 day old infant (3.3 kg) with critical aortic stenosis. Transfemoral balloon valvuloplasty was attempted with use of a 6 mm balloon catheter (7F, Meditech). The catheter was introduced into the left femoral artery but could not be advanced beyond the iliac artery. With considerable difficulty, the catheter was removed and a cuff of intimal tissue was withdrawn along with the catheter. Hemostasis was easily obtained, but the left femoral pulse was lost. The child subsequently underwent surgical aortic valvotomy and has done well during a 3 year follow-up period. The left femoral pulse remains absent, but without apparent clinical sequelae.

The second patient was a 2 day old infant (3.4 kg) with critical aortic stenosis who presented with severe congestive failure and diminished peripheral pulses. The femoral arteries could not be entered percutaneously and an attempted transumbilical valvuloplasty procedure was unsuccessful. Through an umbilical artery, a 5 mm coronary angioplasty catheter (4.3F, Schwarten) was introduced over a 0.016 in. (0.04 cm) coronary exchange wire. It was extremely difficult to advance the catheter through the umbilical-iliac artery system and 60 min of catheter and wire manipulation were required before the balloon was positioned in the ascending aorta. Before the balloon was positioned across the aortic valve, a single inflation was performed and the balloon burst. The procedure was therefore abandoned and the infant prepared for emergency surgical valvotomy. He died in the operating room.

The third patient was a 4 day old infant (3.8 kg) with critical aortic stenosis. Because of extremely poor pulses, only one femoral artery could be entered percutaneously. A 5 mm coronary balloon catheter (4.3F, Schwarten) was utilized to dilate the aortic valve. Although the balloon was

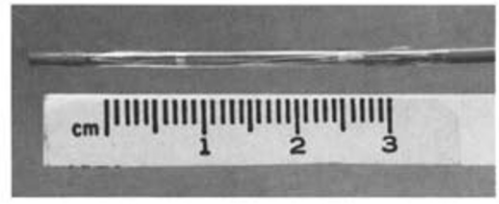

Figure 1. Proflex 5 catheter with balloon deflated. The low profile of the uninflated balloon facilitates introduction and manipulation of the catheter through the newborn umbilical artery system.

recognized to be undersized for the valve anulus diameter (8 mm), on the basis of our earlier experience, it was believed that a larger catheter would pose excessive risks to the femoral artery. The valvuloplasty procedure reduced the peak systolic gradient transiently from 70 to 40 mm Hg, but severe stenosis recurred within several days and surgical valvotomy was required. The infant has done well, with a present but diminished right femoral pulse.

Valvuloplasty procedures since March 1989. In March 1989, new balloon catheter technology became available at our institution. The catheter consists of a 5.3F shaft on which a 6, 7 or 8 mm diameter balloon is mounted (Proflex 5, Peripheral Systems Group, Advanced Cardiovascular Systems). The uninflated balloon has a very low profile (Fig. 1) and the catheter itself is coated with a silicone-based material that enables it to easily traverse the umbilical-iliac artery system over a 0.035 in. (0.089 cm) guide wire. Utilizing this catheter, all five newborns with critical aortic stenosis who presented between March 1989 and July 1990 underwent successful transcatheter therapy (Table 1). Furthermore, all four infants in whom umbilical artery access could be obtained underwent valve dilation using the transumbilical approach. One newborn who was 25 days of age underwent transfemoral balloon valvuloplasty.

Valvuloplasty technique. The transumbilical technique of balloon aortic valvuloplasty has been remarkably simple. If

Table 1. Pertinent Clinical and Hemodynamic Data From Five Newborns With Critical Aortic Stenosis Undergoing Successful Balloon Valvuloplasty (March 1989 to July 1990)

Case No.	Age (days)	Wt (kg)	Anulus Diameter (mm)	Balloon Diameter (mm)	Approach	Fluoro (min)	Grad (mm Hg)		LVS (mm Hg)		LVED (mm Hg)		AR (0 to 4+)		LVSF (%)		Hospital Stay (days)
							Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	
1	2	3.3	6.5	7	Umbilical	38	70	15	120	72	28	12	0	2	*	30	16
2	6	3.9	6.5	7	Umbilical	21	60	30	110	104	14	12	0	0	*	35	4
3	9	4.1	8	7	Umbilical	24	74	32	142	120	20	10	0	0	22	38	3
4	11	4.2	7	7	Umbilical	15	96	29	155	104	17	9	0	0	18	34	4
5	25	4.2	8	7	Femoral	21	45	20	115	75	20	14	0	2	20	35	4
Mean	10.6	3.9	7.2			23.8	69	25.2	128	95	19.8	11.4			20	34	6.2
± SE	3.9	0.2	0.3			3.8	8.4	3.3	8.6	9.3	2.3	0.9			1	01	2.5
p value								0.005		0.02		0.02				0.005	

*Measurement not obtainable because of paradoxic septal motion. AR = aortic regurgitation; Fluoro = total duration of fluoroscopy; Grad = peak systolic gradient; LVED = left ventricular end-diastolic pressure; LVS = left ventricular systolic pressure; LVSF = left ventricular shortening fraction (by echocardiography); Post = after valvuloplasty; Pre = before valvuloplasty; Wt = weight.

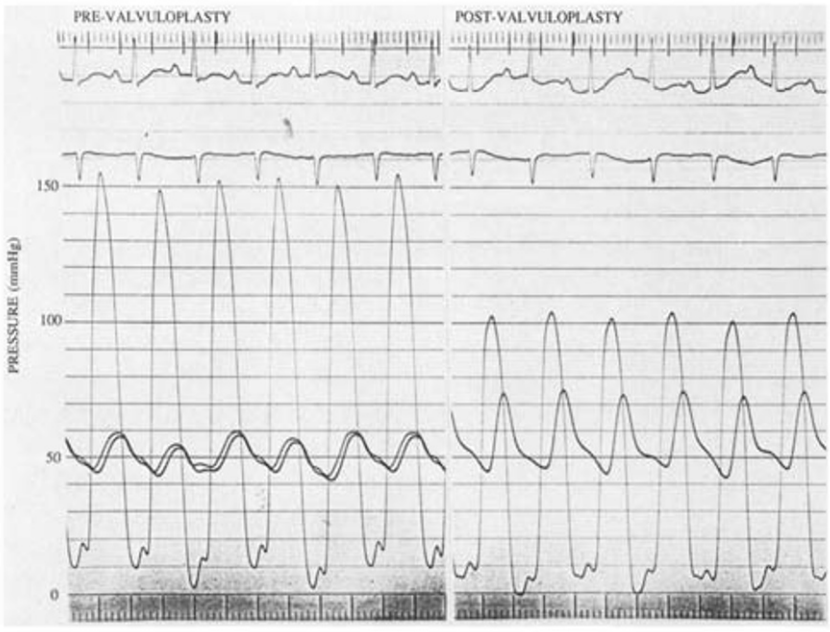

Figure 2. Case 4. Aortic and left ventricular pressures before and after transumbilical valvuloplasty in an 11 day old neonate with critical aortic stenosis. A catheter was inserted into each umbilical artery (note two aortic tracings before valvuloplasty) to permit accurate hemodynamic monitoring during and after valve dilation without the need to exchange the valvuloplasty catheter. In this infant, valvuloplasty immediately reduced the peak aortic valve gradient from 96 mm Hg to 29 mm Hg and the left ventricular end-diastolic pressure from 17 mm Hg to 9 mm Hg.

possible, we prefer to introduce a 5F umbilical catheter into each umbilical artery and a 4 or 5F transvenous catheter into the left ventricle through the foramen ovale. Thus, both left ventricular and aortic pressures can be monitored throughout the procedure (Fig. 2). Over a 0.021 in. exchange wire, a 4F pigtail catheter (Universal Medical Instruments) is exchanged for one umbilical artery catheter. In a retrograde fashion, the pigtail catheter is advanced across the aortic valve to the left ventricular apex. The 4F pigtail catheter is then removed and a 5F pigtail catheter (Universal Medical Instruments) is advanced over the exchange wire into the left ventricle. The 5F catheter is utilized to introduce a 0.035 in. curved-tipped exchange wire into the left ventricle. The pigtail catheter is removed and the valvuloplasty catheter advanced over the exchange wire. The Proflex 5 catheter tracks a 0.035 in. exchange wire very well and easily traverses the umbilical-iliac artery system. The balloon size is chosen to approximately equal the valve anulus diameter as estimated by echocardiography (angiography is minimized before valvuloplasty); in all five cases, a 7 mm diameter balloon catheter was utilized.

The balloon is positioned across the aortic valve and inflated by hand, with a mixture of contrast medium and saline solution, until the waist created on the balloon by the valve disappears. Balloon inflation is limited to a 5 to 10 s period, after which the catheter is withdrawn to the descending aorta. Left ventricular and aortic pressures are measured to document the acute hemodynamic effects of valvuloplasty (the second umbilical artery and transvenous left ventricular catheters facilitate this measurement without the need to first remove the valvuloplasty catheter) (Fig. 2). The valvuloplasty catheter is then removed and a pigtail catheter advanced to the ascending aorta, where an aortogram is filmed to evaluate the degree of valve regurgitation that may be present after the procedure. Hemostasis was obtained easily in all patients by using only digital pressure on the umbilical artery. After an episode of staphylococcal sepsis in one child, we now provide antibiotic coverage during transumbilical valvuloplasty procedures.

Results

Clinical and hemodynamic features. Table 1 presents pertinent clinical and hemodynamic data for all five neonates with critical aortic stenosis who underwent balloon valvuloplasty between March 1989 and July 1990. This group represents all newborns with isolated critical aortic stenosis presenting to our institution during this period. The infants ranged in age from 2 to 25 days and in weight from 3.3 to 4.2 kg. All had severe congestive heart failure. Two-dimensional echocardiograms demonstrated markedly diminished left ventricular systolic function in all five infants, with a left ventricular shortening fraction ranging from 18% to 22% (shortening fraction could not be measured in two children because of paradoxic septal motion). The aortic valve anulus ranged from 6.5 to 8 mm in diameter. In all five infants the 12 lead electrocardiogram (ECG) showed left ventricular hypertrophy with ischemic ST-T wave changes. The 2 day old infant was intubated and received dopamine and prostaglandin E_1 infusions during the procedure.

Hemodynamic response (Table 1). Balloon valvuloplasty was acutely successful in each newborn, as evidenced by a decrease in valve gradient accompanied by an immediate improvement in left ventricular function and cardiac output. Peak systolic aortic valve gradient was reduced by 64% from 69 ± 8 to 25 ± 3 mm Hg ($p = 0.005$). Left ventricular systolic pressure decreased from 128 ± 9 to 95 ± 9 mm Hg ($p = 0.02$) and left ventricular end-diastolic pressure decreased from 20 ± 2 to 11 ± 1 mm Hg ($p = 0.02$). Because of the urgent nature of the valvuloplasty procedure in these infants, car-

diac output was not routinely measured. Mixed venous oxygen saturation was measured in three infants and increased by >10% immediately after valvuloplasty in each case (from 53 ± 4% to 70 ± 6%, p = 0.10). Moderate (2+) aortic regurgitation was documented in two infants after valvuloplasty. The time from first catheter insertion to valve dilation averaged 57 ± 14 min (range 26 to 94) and the duration of fluoroscopy (anteroposterior and lateral planes) for the five procedures averaged 24 ± 4 min (range 15 to 38).

Clinical response (Table 1). In parallel with the hemodynamic changes, almost immediate clinical improvement was noted in each infant. After valvuloplasty, the peripheral arterial pulses normalized promptly and the signs and symptoms of congestive failure resolved. Within 1 to 2 days after valvuloplasty, left ventricular shortening fraction returned to normal in all five infants. The ischemic ST-T changes on the ECG resolved in two infants and improved in one infant. The median length of the hospital stay was 4 days. One infant (Case 1) remained hospitalized for 16 days primarily because of complications related to a subclavian venous line. A second infant (Case 3) became febrile 4 days after hospital discharge and a blood culture grew *Staphylococcus epidermidis*. He was readmitted and successfully treated for sepsis; there was no evidence of omphalitis or endocarditis.

The five infants have been followed up for 2 to 16 months after valvuloplasty. All are doing well without recurrence of severe stenosis and none has required repeat valvuloplasty or surgical intervention during this brief follow-up period. All four infants who underwent transumbilical valvuloplasty have normal femoral artery pulses and the 25 day old infant who required a transfemoral procedure has a diminished but palpable femoral pulse.

Discussion

Critical aortic stenosis of the newborn must be treated promptly and effectively. Surgical therapy, either open valvotomy or closed valve dilation, has been associated with significant morbidity and mortality (8–12). Surgical treatment requires general anesthesia, cardiopulmonary bypass and, in the case of closed valve dilation, an incision in the left ventricular apex. Transcatheter therapy, therefore, may offer significant advantages over surgical treatment in this group of patients. In the current report, we have documented that balloon valvuloplasty can be performed quickly and effectively utilizing newly available balloon catheters. Since March 1989, valvuloplasty was applied successfully in all five neonates presenting to our institution with critical aortic valve stenosis. Balloon aortic valvuloplasty reduced the peak systolic gradient from an average of 69 ± 8 mm Hg to 25 ± 3 mm Hg, with an associated improvement in left ventricular function and cardiac output. Severe aortic regurgitation was not created and congestive heart failure resolved in all children. The infants were discharged after a median hospital stay of 4 days' duration.

Previous reports. Balloon valvuloplasty in neonates with critical aortic valve stenosis has been reported previously. Kasten-Sportes et al. (13) attempted transfemoral balloon valvuloplasty in 10 newborns with critical aortic stenosis and reported effective gradient reduction in all 7 infants who had a technically satisfactory procedure. In one infant, the aortic valve was perforated by an exchange wire and subsequently dilated, causing severe aortic regurgitation and death. Similarly, Zeevi et al. (14) reported balloon valvuloplasty in 16 neonates with critical aortic stenosis. The procedure was performed by means of the transumbilical approach in six, but technical aspects of the transumbilical dilation were not described. A satisfactory outcome was obtained in all neonates without a hypoplastic left ventricle. Follow-up hemodynamic evaluation 17.6 months after valvuloplasty in nine infants documented an average residual gradient of approximately 45 mm Hg, without moderate to severe aortic regurgitation in any infant.

Risk of femoral artery injury. Because available valvuloplasty catheters have been large in relation to femoral artery size, transfemoral angioplasty procedures have been associated with a substantial incidence of femoral artery complications when performed in infancy (5–7,15). Burrows et al. (6) reported ileofemoral artery thrombosis, aneurysm, disruption or tearing with prolonged bleeding in 28 of 72 infants and young children after transfemoral balloon angioplasty procedures. Similarly, Saul et al. (15) described femoral artery occlusion in 9 of 13 infants <2 years of age after transfemoral balloon dilation of postoperative aortic obstruction. Several strategies have been reported in an attempt to decrease the risk of femoral artery injury after balloon angioplasty of left-sided obstructive lesions in infancy. These have included double balloon dilation to allow insertion of smaller valvuloplasty catheters (3,16), transvenous angioplasty by means of the transseptal route (17) and intraoperative angioplasty through a thoracotomy (18). Fischer et al. (19) recently reported performing balloon valvuloplasty of newborn aortic stenosis through a right common carotid artery cutdown. The rationale for all of these approaches has been to avoid potential femoral artery injury that may occur with transfemoral arterial angioplasty in infancy.

The transumbilical approach with improved catheters. In the current report, we documented that balloon valvuloplasty can be performed quickly and effectively in the newborn with critical aortic stenosis by using a transumbilical approach that does not require catheterization of the femoral artery. At our institution, successful application of the transumbilical technique has been the direct consequence of recent improvements in catheter technology. Balloons 6 to 8 mm in diameter are now available on a 5.3F catheter (Proflex 5) that tracks the umbilical artery course with ease. Since obtaining the Proflex 5 catheter, we performed valvuloplasty successfully in all five neonates with critical aortic stenosis who presented to our institution. The transumbilical approach was utilized in the four newborns

<2 weeks of age and all have normal femoral pulses. The fifth child was 25 days old and had no umbilical access. He therefore underwent transfemoral valve dilation utilizing the same 5.3F catheter and subsequently has a mildly diminished femoral pulse.

Conclusions. Balloon valvuloplasty appears to be an effective treatment alternative to surgery in newborns with critical aortic stenosis. Furthermore, utilizing new catheter technology, the transumbilical approach can be successfully employed, thus providing an easily accessible route for aortic valvuloplasty that does not require femoral artery catheterization. Although data based on five patients must be considered preliminary, we have adopted transumbilical balloon valvuloplasty as our preferred treatment for the newborn with critical aortic stenosis. It does not require general anesthesia, cardiopulmonary bypass or a left ventricular apical incision (utilized with closed surgical valvotomy) and preserves the femoral arteries for future transcatheter intervention should significant aortic stenosis recur. If umbilical access is unavailable, surgical valvotomy remains a satisfactory option because of the risk of femoral artery injury when transfemoral aortic balloon valvuloplasty is performed in early infancy.

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