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.

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/m² end-diastolic volume).

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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) |
|----------|------------|---------|----------------------|-----------------------|----------|--------------|-------------|-------------|-------------|-------------|------------|----------|----------------------|
| 1        | 2          | 3.3     | 6.5                  | 7                     | Umbilical| 38           | 70          | 15          | 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        | 22                    | 38         | 3
| 4        | 11         | 4.2     | 7                    | 7                     | Umbilical| 15           | 96          | 29          | 155         | 104         | 17        | 9         | 0        | 18                    | 34         | 4
| 5        | 25         | 4.2     | 8                    | 7                     | Femoral  | 21           | 45          | 20          | 115         | 75          | 20        | 14       | 0        | 2                    | 20         | 35
| Mean     | 10.6       | 3.9     | 7.2                  | 7                     |           | 23.8         | 69          | 25.2        | 128         | 95          | 19.8      | 11.4     | 0        | 20                    | 34         | 6.2
| ± SE     | 3.9        | 0.2     | 0.3                  | 0.3                   |           | 3.8          | 8.4         | 3.3          | 8.6         | 9.3         | 2.3       | 0.9      | 1        | 0.05                  | 2.3        | 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.
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 E₁ 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. Kastein-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, Zezzi 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 transeptal 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.

**References**