Balloon Dilation of Congenital Aortic Valve Stenosis
Results and Influence of Technical and Morphological Features on Outcome

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We evaluated dilation technique ($n=80$) and aortic valve morphology by two-dimensional echocardiography ($n=58$) in patients with congenital aortic valve stenosis to determine their influence on outcome. Patients’ age (9±9 years; range, 1 day–39 years) and a history of surgical valvotomy did not influence outcome. The number of dilating balloons (one vs. two) and balloon:annulus ratio based on the largest balloon used in each case (97±12%; range, 71–133%) did not demonstrably influence the percent reduction in valvar gradient. In contrast, with a balloon:annulus ratio greater than 100%, the incidence (26%) of significant, dilation-induced aortic regurgitation was higher than occurred when the ratio was equal to or less than 100% (11%). Fifty bicommissural and eight unicommissural valves were identified echocardiographically. Relief of obstruction was associated with apparent commissural division in 24 of 32 patients with suitable postdilation studies. The sites of fusion and stenosis relief did not influence percent reduction in valvar gradient. Substantial increases in aortic regurgitation (>three of five grades) occurred in three of eight unicommissural and one of 50 bicommissural valves. The presence of a thick valve was associated with a slightly lower gradient reduction (53±12%) than thin and pilant valves (63±24%) ($p>0.05$). Unlike all other congenital lesions we have studied, dilation technique and balloon size appeared to have a lesser influence on percent reduction in valvar gradient in congenital aortic stenosis, although balloon:annulus ratio influences the increase in aortic regurgitation. Valve morphology appears to assist with predicting the outcome of dilation. (Circulation 1988;78:351–360)

Since the initial description of balloon aortic valvotomy in 1984, several studies have demonstrated that the severity of congenital aortic stenosis can be reduced with minimal mortality and acceptable morbidity. To better understand the role of the procedure and the processes of gradient reduction and production of regurgitation, several questions require attention. Do the long- and short-term results of balloon dilation compare favorably with surgical valvotomy? Are procedural methodology and technique important in determining the success of the procedure? Do various anatomic forms of congenital aortic stenosis respond differently to balloon dilation? To address these latter issues, we reviewed our experience with 80 balloon aortic valvotomies.

Patients and Methods

Patients

From December 1984 to August 1987, the option of balloon dilation of valvar aortic stenosis was offered to parents and patients at The Children’s Hospital, Boston. Consent was obtained in accordance with the guidelines of the Committee on Clinical Investigation. Suitable candidates included children and young adults with a peak-to-peak pressure drop equal to or greater than 50 mm Hg as well as no greater than mild aortic regurgitation (AR) (no more than grade 2 of the five grades of the classification of Hunt et al$^{5,6}$). Neonates with critical aortic stenosis but smaller gradients were also candidates. In this
series of consecutive patients, we did not include or exclude any patient on the basis of age, clinical condition, valve calcification, or valve morphology.

Dilation Technique

The catheterization procedure and details of our dilation technique have been described elsewhere.\textsuperscript{5,7} In addition, we have found it useful to use an Amplatz extrastiff exchange guide wire (Cook, Bloomington, Indiana) to stabilize balloons at the annulus during dilation and to use additional catheters for monitoring systemic (contralateral femoral artery) and left ventricular (through a patent foramen ovale, when present) pressure. We performed dilation retrograde from a percutaneous femoral approach in 74 patients. In three neonates, dilation was performed through the umbilical artery; in three older patients, it was performed through an antegrade-transseptal approach. The initial balloon catheter was selected to yield a ratio of balloon diameter to annulus diameter (BAR) of 90–100%. The annulus diameters used for calculations of BAR were determined from cineangiograms. When a percent reduction of peak-to-peak pressure gradient (PRG) of less than 50% resulted from the initial dilation or no valve waist was seen, larger balloon sizes were then used. We attempted to avoid the use of a BAR greater than 110%.\textsuperscript{6} When a sufficiently large balloon was either unavailable or could not be stabilized across the valve, a double-balloon retrograde (two arteries) approach was used ($n = 10$), with balloon diameter estimated as for a single, circular balloon by calculation from the perimeter of the valve annulus subtended by two balloons.\textsuperscript{8}

Evaluation of Catheterization Data

Before- and after-dilation peak-to-peak gradients, PRG, and AR grade were determined in all cases. The increase in AR grade was calculated by subtracting the before-dilation grade from the after-dilation grade. The BAR evaluations were based on the diameter of the largest balloon used during a procedure. The aortic valve area was estimated with the technique described by Hakki for peak-to-peak pressure differences.\textsuperscript{9} Cardiac output was determined by thermodilution or by the Fick technique with measured (Waters, Rochester, Minnesota) oxygen consumption.

Evaluation of Valve Morphology

With a Hewlett-Packard 77020A ultrasound module with narrow sector mode and 5.0-, 3.5-, or 2.5-MHz transducers, we performed two-dimensional echocardiograms before dilation in all patients and within 2 days after dilation in 64%. Before-dilation studies suitable for evaluation of valve morphology were available in 58 patients (73%).

In the parasternal, short-axis view, we performed sweeps of the aortic annulus and valve in motion to define the number and site of fused commissures. A fused commissure was not seen to separate at the level of the annulus and generally appeared as a dense "line" radially positioned between conjoined cusps. Major fusion was present when more than 50% of a commissure did not separate. A unicommisural valve had major fusion of one commissure and a minor degree of fusion of another\textsuperscript{10} (Figures 1 and 2).

In a parasternal, long-axis view, we assessed aortic valve thickness and mobility qualitatively (Figure 3). A thick valve had leaflets whose thickness appeared equal to or greater than the width of the ascending aortic wall (Figure 4, bottom panels). A thin valve was thinner (Figure 4, top left panel). Qualitative evaluation of valve thickness was used to accommodate the confounding effects on measurement of variable echo gain selection, transducer angulation, and patient age and size. Pliant valves
Figure 2. Parasternal short-axis view of a bicommissural aortic valve before (A) and after (B) dilation. The raphe (r) formed by fusion of the intercoronary commissure has been fractured (arrow) by dilation. Parasternal short-axis view of a unicommissural aortic valve in an infant before (C) and after (D) dilation. Before dilation, only a single commissure (the left coronary–non-coronary commissure) is seen. After dilation, all three commissures appear to separate during ejection. LCA, left coronary artery; l-n, left coronary–non-coronary commissures; l-r, left coronary–right coronary commissure; RCA, right coronary artery; r, raphe; r-n, right coronary–non-coronary commissure.
domed (Figure 4, left panels), while stiff valves (Figure 4, bottom right panel) moved in a “boardlike” fashion without doming. In some cases, there was uneven distribution of these parameters between cusps, and such valves were classified as asymmetrical (Figure 4, top right panel).

After balloon dilation, we attempted to determine both the means and site of stenosis relief.

**Complications and Follow-up**

We prospectively evaluated local vascular problems, arrhythmia, and need for urgent surgery.

**FIGURE 3.** Schematic representation of long-axis parasternal view of the aortic valve. Upper left panel: Normal valve is displayed in systole. Other panels demonstrate valves that are thin and pliant (1), thick and pliant (2), asymmetrical (3), and stiff and thick (4).

**FIGURE 4.** Long-axis parasternal views of valves that are thin and pliant (top left), thick and pliant (bottom left), asymmetrical (top right), and stiff and thick (bottom right).
Patient follow-up was at The Children’s Hospital or at referring institutions and included cardiac catheterization or Doppler echocardiographic assessment of gradient and aortic regurgitation. Doppler peak instantaneous gradients were determined with a modified Bernoulli equation, and AR was assessed according to published technique.\textsuperscript{11}

Statistical Analysis

Data, associations, and comparisons were evaluated with mean $\pm$ SD, paired t tests, or Z tests of proportion and linear regression. We performed analysis of variance if paired t tests of multiple comparisons indicated significance.

Results

Patient Profile

We performed 80 dilations (81 attempts) in 75 patients ages 1 day to 39 years (mean, 9 $\pm$ 9 years) (Table 1). These patients included 12 neonates, 22 patients less than 2 years old, and 15 patients who had a previous surgical aortic valvotomy. Significant associated lesions (hypoplastic left heart syndrome, $n=2$; coarctation of the aorta, $n=1$) were present in three neonates. Valve calcification was present in five patients (age, 25–39 years); two patients had Turner’s syndrome; and two had subaortic stenosis. A second procedure was undertaken in five patients who had had unsatisfactory results from earlier dilation attempts.

Cardiac Catheterization and the Influence of Technique

Gradient reduction and clinical profile. The mean gradient was 76 $\pm$ 26 mm Hg before dilation and 34 $\pm$ 20 mm Hg immediately after (mean PRG, 55 $\pm$ 22%). There was no significant difference in PRG between those patients who had had a previous surgical valvotomy (PRG, 51 $\pm$ 9%) and those who had not (PRG, 55 $\pm$ 26%). The neonatal group had lower predilation gradients but a similar PRG when compared with older patients (Table 1). These measurements, however, may not be representative of true changes in gradient because impaired myocardial function and right-to-left ductal shunt was present in some babies ($n=6$).

Gradient reduction and balloon size. The average BAR was 97 $\pm$ 12% and did not differ with age, history of previous surgical valvotomy, number of balloons used, or valve morphology. Surprisingly, although the range of final BAR was relatively wide, BAR had no influence on PRG ($r=0.06$). The selection of final balloon size in any individual was influenced by intended outcome; this may partly explain the lack of correlation, although similar approaches in both valvar pulmonary stenosis\textsuperscript{12} and recurrent aortic obstruction\textsuperscript{13} resulted in strong correlations between balloon size and gradient reduction.

Aortic regurgitation. Before the procedure, 38 patients had no AR, and 37 had grade 1 or 2 AR. Of

### Table 1. Findings at Balloon Dilation of Aortic Stenosis

<table>
<thead>
<tr>
<th></th>
<th>All dilations</th>
<th>Age &lt;1 month</th>
<th>Age &gt;1 month</th>
<th>Single balloon</th>
<th>Double balloon</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>80</td>
<td>12</td>
<td>68</td>
<td>58+</td>
<td>10+</td>
</tr>
<tr>
<td>Age (years)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(1 day–3 years)</td>
<td>9.2 $\pm$ 8.9</td>
<td>0.03 $\pm$ 0.03</td>
<td>10.7 $\pm$ 8.7</td>
<td>8.5 $\pm$ 7.5</td>
<td>21 $\pm$ 7.4</td>
</tr>
<tr>
<td>(6 weeks–39 years)</td>
<td>8.9 $\pm$ 7.5</td>
<td></td>
<td>8.0 $\pm$ 7.5</td>
<td>8.5 $\pm$ 7.5</td>
<td>21 $\pm$ 7.4</td>
</tr>
<tr>
<td>Before-dilation gradient</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(mm Hg)</td>
<td>(10–160)</td>
<td>(10–130)</td>
<td>(10–160)</td>
<td>(10–130)</td>
<td>(10–130)</td>
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<tr>
<td>After-dilation gradient</td>
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<td></td>
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<tr>
<td>(mm Hg)</td>
<td>(0–100)</td>
<td>(0–100)</td>
<td>(0–100)</td>
<td>(0–100)</td>
<td>(0–100)</td>
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<tr>
<td>Percent reduction in</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>gradient (%)</td>
<td>55 $\pm$ 22</td>
<td>52 $\pm$ 27</td>
<td>55 $\pm$ 21</td>
<td>56 $\pm$ 22</td>
<td>54 $\pm$ 23</td>
</tr>
<tr>
<td>Before-dilation valve</td>
<td>0.59 $\pm$ 0.23</td>
<td>0.57 $\pm$ 0.26</td>
<td>0.59 $\pm$ 0.23</td>
<td>0.56 $\pm$ 0.2</td>
<td>0.58 $\pm$ 0.25</td>
</tr>
<tr>
<td>area* (cm$^2$/m$^2$)</td>
<td>0.79 $\pm$ 0.3</td>
<td></td>
<td>0.79 $\pm$ 0.3</td>
<td>0.79 $\pm$ 0.3</td>
<td>0.69 $\pm$ 0.25</td>
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<tr>
<td>After-dilation valve area*</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(cm$^2$/m$^2$)</td>
<td>27+</td>
<td>3</td>
<td>24</td>
<td>15</td>
<td>4</td>
</tr>
<tr>
<td>After-dilation gradient</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;35 mm Hg</td>
<td>22+</td>
<td>5</td>
<td>17</td>
<td>21</td>
<td>3</td>
</tr>
<tr>
<td>Percent reduction in</td>
<td>Measured</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>gradient &lt;50%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Balloon:annulus ratio</td>
<td>97 $\pm$ 12</td>
<td>94 $\pm$ 18</td>
<td>97 $\pm$ 11</td>
<td>96 $\pm$ 11</td>
<td>102 $\pm$ 10</td>
</tr>
<tr>
<td>(71–133)</td>
<td></td>
<td></td>
<td>(71–120)</td>
<td>(71–120)</td>
<td>(91–113)</td>
</tr>
<tr>
<td>Before-dilation aortic</td>
<td>0.6 $\pm$ 0.6</td>
<td>0</td>
<td>0.7 $\pm$ 0.6</td>
<td>0.7 $\pm$ 0.7</td>
<td>0.7 $\pm$ 0.5</td>
</tr>
<tr>
<td>regurgitation (grade)</td>
<td>(0–2)</td>
<td></td>
<td>(0–2)</td>
<td>(0–2)</td>
<td>(0–1)</td>
</tr>
<tr>
<td>After-dilation aortic</td>
<td>1.3 $\pm$ 1.1</td>
<td>1.1 $\pm$ 1.6</td>
<td>1.3 $\pm$ 1</td>
<td>1.3 $\pm$ 1</td>
<td>1.6 $\pm$ 1.3</td>
</tr>
<tr>
<td>regurgitation (grade)</td>
<td>(0–5)</td>
<td>(0–5)</td>
<td>(0–5)</td>
<td>(0–4)</td>
<td>(0–5)</td>
</tr>
<tr>
<td>Increase in aortic</td>
<td>0.7 $\pm$ 1</td>
<td>1.1 $\pm$ 1.6</td>
<td>0.7 $\pm$ 0.9</td>
<td>0.6 $\pm$ 0.9</td>
<td>0.9 $\pm$ 1.2</td>
</tr>
<tr>
<td>regurgitation (grade</td>
<td>(0–5)</td>
<td>(0–5)</td>
<td>(0–5)</td>
<td>(0–4)</td>
<td>(0–4)</td>
</tr>
<tr>
<td>change (grade)</td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

$^*$n = 56 before; $^+$patients older than 1 month; $^\dagger$includes 11 patients with 0% reduction in valvar gradient.
these patients, 31 had some increase in AR grade after dilation (Table 2). The average increase in AR grade was 0.7 ± 1 after dilation. There were 12 patients who had greater than a 1/5 increase in AR grade after the procedure (Table 2). AR grade increased more in those patients with a larger PRG (increase in grades 0–1 AR, PRG = 53 ± 21%; grades 2–5, PRG = 75 ± 18%; p > 0.05). There was an 11% risk of greater than 1/5 increase in AR with a BAR less than or equal to 100% (6/57) and a 26% risk with a BAR greater than 100% (6/23) (p > 0.05) (Figure 5).

Number of balloons used. Patients dilated with two balloons were significantly older (p > 0.01), but the hemodynamic results of dilation were not significantly different from patients dilated with a single balloon (Table 1), with the exception of slightly smaller after-dilation estimated valve area (p = 0.01). Four of the five patients with valve calcification were dilated with two balloons.

Echocardiographic Evaluation and Influence of Valve Morphology

Studies. We examined the echocardiograms of 45 patients retrospectively and 35 prospectively. Studies available and suitable for analysis were present in 58 (73%) patients before and 32 (40%) patients after dilation. Excluded studies included those whose inadequate echo windows or image quality prevented evaluation of valve characteristics. In some patients, after-dilation studies were not performed.

Morphology. There were 50 bicommissural valves and eight unicommissural valves (Table 3). Fusion of the commissure between the left and non-coronary cusps did not occur in any bicommissural or unicommissural valve reviewed.

Influence of morphology on outcome. The site of valve fusion in bicommissural valves did not influence PRG or the increase in AR grade (p > 0.1, Table 3). However, large increases in AR (greater than two of five grades, n = 4) occurred in three of eight unicommissural valves (in one neonate, a BAR of 120% was used; in an older patient, a BAR of 84% was used) but in only one of 46 bicommissural valves (BAR 107% used). In one neonate with a unicommissural valve, severe AR resulted after dilation of a cusp rather than the valve orifice after passage of the wire through the valve tissue. Thin and pliant valves had a greater PRG (63 ± 24%) when compared with valves with any degree of thickening (53 ± 15%) (p > 0.05) and, particularly, with uniformly thick valves (51 ± 12%) (p > 0.01) (Table 3). Valve thickness alone did not influence the increase in AR grade (Table 3). In one unusual bicommissural valve, however, there was dense thickening of the edges of the cusps while the ‘‘body’’ was thin, and in this case attempted dilation was unsuccessful (PRG, 35%).

### Table 2. Aortic Regurgitation and Changes With Dilation

<table>
<thead>
<tr>
<th>Aortic regurgitation grade</th>
<th>Change in aortic regurgitation grade</th>
<th>After dilation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before dilation</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>0</td>
<td>38 (9)</td>
<td>20</td>
</tr>
<tr>
<td>1</td>
<td>31 (0)</td>
<td>18</td>
</tr>
<tr>
<td>2</td>
<td>6 (0)</td>
<td>4</td>
</tr>
<tr>
<td>3</td>
<td>...</td>
<td>...</td>
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<tr>
<td>4</td>
<td>...</td>
<td>...</td>
</tr>
<tr>
<td>5</td>
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</tbody>
</table>

( ), Neonates.

### Table 3. Aortic Valve Morphology

<table>
<thead>
<tr>
<th>Commissures, fusion site</th>
<th>Thin, pliant</th>
<th>Thick, pliant</th>
<th>Thick, stiff</th>
<th>Asymmetrical</th>
<th>Total</th>
<th>PRG</th>
<th>IAR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bicommissural R/L</td>
<td>11 (1)</td>
<td>9 (1)</td>
<td>1 (1)</td>
<td>2 (…)</td>
<td>23 (3)</td>
<td>57 ± 21</td>
<td>0.7 ± 0.9</td>
</tr>
<tr>
<td>Bicommissural R/N</td>
<td>15 (…)</td>
<td>4 (…)</td>
<td>4 (1)</td>
<td>4 (…)</td>
<td>27 (1)</td>
<td>59 ± 19</td>
<td>0.7 ± 0.8</td>
</tr>
<tr>
<td>Unicommissural</td>
<td>1 (1)</td>
<td>1 (…)</td>
<td>5 (5)</td>
<td>1 (…)</td>
<td>8 (6)</td>
<td>52 ± 33</td>
<td>1.5 ± 2</td>
</tr>
<tr>
<td>Total</td>
<td>27 (2)</td>
<td>14 (1)</td>
<td>10 (7)</td>
<td>7 (…)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| BAR (%)                  | 96 ± 11      | 95 ± 10       | 99 ± 21      | 99 ± 20      |       |
| PRG (%)                  | 63 ± 24      | 53 ± 12*      | 49 ± 13*     | 59 ± 8*      |       |
| IAR                      | 0.7 ± 1.0    | 1 ± 1.2       | 1 ± 1.8      | 1 ± 0.9      |       |

PRG, percent reduction in gradient; IAR, increase in aortic regurgitation grade; R/L, major fusion between right and left coronary cusps; R/N, major fusion between right and noncoronary cusps; BAR, balloon:annulus ratio; ( ), neonates included; *combined PRG thick, pliant and thick, stiff and asymmetrical (53 ± 12%); combined PRG thick, pliant and thick, stiff (51 ± 12%).
Means of stenosis relief. We examined the site of stenosis relief in 55% of those studied before dilation. In 24 of 32 patients, there was separation of a fused commissure by the division of either the site of major fusion (n = 14; PRG, 65 ± 24%), giving the valve a "tricommisural" appearance, or of the site of minor fusion (n = 10; PRG, 60 ± 11%), increasing the orifice of the bicommissural valve. In six patients, no definite difference could be appreciated (PRG, 52 ± 13%). Although the PRG of this subgroup was lower, it was not significantly different from the former groups. Of the four patients with serious increases in AR after dilation, one had partial disruption of the left coronary cusp from the annulus, one had a cusp perforation and tear, and inadequate image quality prevented echocardiographic evaluation in the other two.

Correlations between echocardiographic and surgical findings. Intraoperative observations were available in three patients. In one, a laceration of the anterior mitral valve leaflet during dilation necessitated surgery, at which time a bicommissural aortic valve had the appearance predicted by two-dimensional echocardiography, and the dilation-induced division of a minor site of commissural fusion could not be improved surgically. In another patient, a "failed" dilation prompted surgery. The appearance of the bicommissural valve also matched two-dimensional echocardiographic prediction of commissures divided to the annulus, and the residual gradient was attributed to subaortic obstruction. In a 17-year-old boy with a unicommissural valve who developed severe AR after dilation, a thick, hard, platelike unicommissural valve was found at subsequent aortic valve replacement (8 months later). The presence of a unicommissural valve had been predicted by echocardiography.

Follow-up

Follow-up evaluation was based on the last study performed in 45 of 77 survivors. In 29 patients, evaluation was by Doppler echocardiography 6.5 ± 7 (range, 1–24) months after dilation. In this group, the follow-up maximum instantaneous gradient was 40 ± 22 mm Hg, and the estimated AR grade was 0.9 ± 1. In 16 patients, the last evaluation was by cardiac catheterization 8.4 ± 7 (range, 1–25) months after dilation. In this group, the follow-up peak-to-peak gradient was 45 ± 29 mm Hg, and the AR grade was 1.5 ± 1.1. In six cases, the gradient (all estimated by Doppler) was more than 15 mm Hg greater than the immediate after-dilation figures, and in four of these, the increase in estimated valve area at the initial dilation had been less than 25%. In five cases, the AR grade (all estimated with Doppler) decreased by one, and in seven cases, it increased [by one grade in six patients (four estimated with Doppler) and by three grades in one patient]. The patient with a three-grade increase in AR at 2-year follow-up has since undergone aortic valve replacement.

Complications

Pulse loss. Thirty percent of patients had temporary or permanent pulse loss. The incidence of pulse loss in infants less than 2 years old (60%) was greater than in older patients (15%) (p > 0.05). In 10% of all dilations, there was permanent pulse loss despite the routine use of anticoagulants-fibrinolytics.14

Arrhythmia. Left bundle branch block was noted during 17% of cases. In all but one instance, this resolved by hospital discharge. Transient, nonsustained ventricular ectopy was often noted. Three patients (4%) had ventricular arrhythmias that required cardioversion; two of the patients were less than 2 years old. All were successfully resuscitated.

Anatomic complications and surgery. In a 4-year-old boy, the anterior mitral valve leaflet was damaged after inflation of the balloon within the ventricle and with a posterior wire position. Moderate mitral regurgitation, so far not requiring surgery, resulted. Surgery related to the procedure was required in four patients within the 1st week after dilation. In a 14-year-old boy, a 20-mm balloon separated from the catheter shaft in the ascending aorta before dilation and was successfully removed at surgery. A 9-year-old boy suffered a laceration of the anterior mitral valve leaflet after dilation performed antegrade-transseptally. The mitral valve was successfully repaired 2 days later at surgery. One neonate with a unicommissural valve and hypoplastic left ventricle, in whom severe AR was produced with a BAR of 120%, underwent surgical repair of avulsion of the attachment of the right and non-coronary cusps from the annulus. At the conclusion of the procedure, a Norwood I procedure was performed. The patient did not survive surgery. Finally, a 2-month-old infant, early in the series,
suffered rupture of the femoral artery, requiring surgical repair later the same day.

Death. There were three deaths in the series (4%), all in neonates who presented in the 1st week of life. One has been described above. Another died from sepsis 2 days after a prolonged and unsuccessful attempt at dilation had been performed through the umbilical artery. Another neonate died after persistent metabolic acidosis (preceding dilation) and induction of moderate AR with little gradient relief after perforation of the anterior portion of the valve by a guide wire and subsequent dilation of the valve cusp rather than the orifice (as described above).

Discussion

Balloon dilation of congenital aortic valve stenosis is a relatively effective means of palliation in our experience and carries a low risk of serious complications in most patients. We achieved a mean PRG of 65% and after-dilation valve area of 0.79 cm²/m²; in 65% of patients, the gradient after dilation was less than 35 mm Hg. These results are comparable with other reviews of this technique in infants and children where PRGs of 48% to 65%, mean after-dilation pressures of 37 and 38 mm Hg, and mean after-dilation valve areas of 0.65 cm²/m² have been reported. Our patients, however, cover a much wider age range and include some subjects with significant additional morphological and anatomic problems. The wide range of patient characteristics and valve morphology thus allows assessment of the factors that may influence outcome.

Although age did not influence the overall results, the neonatal group should be considered separately. These patients are generally the sickest with the most unfavorable valve morphology (thick and unicommisural) and the highest incidence of associated medical problems such as left ventricular dysfunction or hypoplasia. Surgery has been associated with high mortality of 10–90% in these patients, particularly when they present at less than 7 days of age. The three deaths in this review were aged less than 1 week. In retrospect, however, the causes of death may have been partly related to remediable measures such as access site, erroneous wire course, or avoidance of a large BAR. With the need for catheter maneuverability, we now prefer to dilate neonates from the femoral artery. We also favor the initial use of a small BAR of 85–90% when a unicommisural valve is present because the primary objective of dilation is to improve the immediate patient condition. This may then allow for later valve maturation or attempts at redilation if necessary.

A BAR greater than 100% was the only technical factor that significantly affected outcome, with larger balloons being associated with more AR. These findings are consistent both with our experimental animal work and with some published clinical experience with newborn critical aortic stenosis reporting damage to the left ventricular outflow tract and aortic valve with oversized balloons. Surprisingly, the BAR in the range of this study did not influence PRG in contrast to our results from many other models and congenital lesions, in which progressively increasing balloon sizes were also used.

The use of two balloons rather than a single-balloon technique did not significantly influence outcome. We have preferred evaluation of effective dilation diameter of the two balloons based on the perimeter of the valve annulus subtended by both balloons and expressed as the diameter of a single balloon with the same perimeter area. This permits comparisons between techniques with proper consideration of differences in BAR. Echocardiographic evaluation of valve morphology suggested the mechanisms of valve dilation and features influencing outcome. This means of evaluation of congenital valvar aortic stenosis has been validated in other studies; however, the favorable outcome of dilation in this study precluded comparative surgical or pathological evaluation in virtually all cases. There was major fusion in one (bicommissural valve) or two (unicommissural valve) commissures. These observations correspond with both surgical and pathologic data. Obstruction is produced by limitation of orifice size by commissural fusion, although the lower PRG observed with thicker valves may represent additional "mass" obstruction of thick and less-mobile valve cusps and may be similar to observations in dysplastic pulmonary valves, which do not respond well to dilation.

Relief of obstruction was mostly associated with recognizable commissural division. Some limited two-dimensional echocardiographic evaluation in patients after pulmonary valve dilation and some intraoperative and postmortem studies in acquired aortic and mitral stenosis suggest that separation of fused commissures, in the absence of overlarge balloons, can be a means of stenosis relief. In contrast to our findings in congenital aortic stenosis in children, however, in adults with acquired calcific aortic stenosis, disruption of calcium deposits appears to be a major means of relieving obstruction. AR is the complication of dilation that most frequently causes concern. Immediately after dilation, when predilation candidates with no or mild AR are chosen, it is unlikely for a significant change in AR grade (64/75 with no more than a 1/5 increase in AR grade) to occur. However, in four patients, increases of more than three of five grades in AR were produced. Three had unicommisural valves, and in one of these, a large BAR was used. It appears that the risks of AR in a unicommisural valve may be increased, particularly in older patients in whom the presence of thick valve tissue and undeveloped commissures may predispose to valve tears rather than commissural division. This contrasts with the soft and "lumpy" valves of neonates, which may present a better substrate for commissural division or stretching of the orifice. Soft neonatal valves, however, may also be more prone to wire perforation, which when unrecog-
nized and followed by dilation can have disastrous consequences. Although these observations are based only on the unfavorable course of a few patients, the increased risks of producing AR in unicommissural valves have been previously recognized in the surgical literature. In one infant with a plant, thick bicommissural valve, who had had previous surgical valvotomy and in whom a BAR 107% was used, significant AR was produced by a partial separation of the left coronary cusp from the annulus.

Long-term evaluation of our patients will provide a better basis for comparison with the surgical alternatives. Despite carrying a mortality of less than 2% outside the neonatal period, surgery remains a palliative procedure with risks of significant after-surgery AR, inadequate stenosis relief, and need for reoperation. In patients who have undergone surgical valvotomy, there are reoperation rates of up to 40% at 10 years and a disturbing risk of late death of up to 22%. The immediate results of dilation are, so far, similar. Follow-up of our patients is limited, and the data are complicated by the heterogeneous techniques (Doppler and echocardiography vs. catheterization) used for evaluation of gradient and regurgitation. In particular, Doppler has not been specifically validated after balloon valvuloplasty, although there appears to be no reason to believe those data would differ from existing validation. Nevertheless, there seems to be no evidence of significant restenosis at short-term follow-up, with little change in the overall AR grade. The increase in AR noted at 2-year follow-up in one patient, however, emphasizes the need for careful follow-up.

These results suggest that valve morphology is a significant determinant of outcome after balloon dilation of congenital aortic stenosis. Patients with a unicommissural valve may be at increased risk of developing significant AR, while those with thick valves may have a less satisfactory PRG. The avoidance of a BAR greater than 100% will minimize chances of major increases in AR. While these factors are not at present, contraindications to an attempt at dilation, they should assist in the risk-benefit assessment of individual procedures.

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