Aortic Wall Injury as a Complication of Neonatal Aortic Valvuloplasty
Incidence and Risk Factors

David W. Brown, MD; Erin C. Chong, BA; Kimberlee Gauvreau ScD; John F. Keane, MD; James E. Lock, MD; Audrey C. Marshall, MD

Background—Transcatheter balloon aortic valvuloplasty for critical aortic stenosis in neonates is routinely performed without recognized complication. Aortic wall injury has rarely been observed after balloon aortic valvuloplasty, although the incidence of this complication is unstudied. We reviewed single-center data to determine the incidence of aortic injury during balloon aortic valvuloplasty and to identify risk factors.

Methods and Results—This retrospective study included all patients <2 months of age who underwent balloon aortic valvuloplasty at our institution from 1985 to 2007. We defined aortic wall injury as an intimal flap, dissection, or vessel rupture as diagnosed by angiography, echocardiography, or direct surgical or postmortem inspection. Primary imaging data were reviewed, as were all procedural and pathology reports, to identify cases of aortic wall injury. Patient and procedural variables were analyzed. Of 187 procedures performed, 28 procedures resulted in aortic wall injury (15%). Injury was recognized at the time of the procedure in only 16 cases (57%). Intimal flaps occurred most commonly in the distal ascending aorta (n=13), most often involving the greater curvature. In multivariate analysis, severe ventricular dysfunction at the time of the procedure (odds ratio, 2.8; P=0.02), greater number of balloon dilation attempts per procedure (odds ratio, 1.5; P=0.005), and novice interventional staff (odds ratio, 2.5; P=0.05) were associated with aortic injury. Incidence of injury was not different in the recent era compared with earlier experience.

Conclusions—Aortic wall injury, specifically creation of an intimal flap, is an underrecognized complication of neonatal balloon aortic valvuloplasty, occurring in 15% of cases even in the recent era. Only severe ventricular dysfunction, greater number of balloon dilations, and novice staff were associated with injury. The clinical sequelae of aortic wall injury remain incompletely understood. (Circ Cardiovasc Intervent. 2008;1:53-59.)

Key Words: heart defects, congenital ■ valvuloplasty ■ balloon ■ catheterization ■ complications

A

acute procedural complications after catheterization can go unrecognized when clinical sequelae are delayed, subtle, or nonspecific.1,2 When devices are involved, regulatory mandates with regard to postprocedural evaluation may facilitate the identification and tracking of these events. For other procedures, complications may not be investigated until a major clinical event occurs.

Clinical Perspective see p 59

Transcatheter balloon aortic valvuloplasty (BAVP) constitutes the primary approach to neonatal critical aortic stenosis at many centers. Outcomes of the interventional catheterization procedure are comparable to those of surgical valvotomy with regard to relief of aortic stenosis, improvement in left ventricular function, freedom from reintervention, and long-term survival.3-8 BAVP in infants is done exclusively with “off-label” use of balloon catheters because none have been approved for this purpose. Well-described acute procedural complications of BAVP include death, induction of aortic regurgitation, damage to the mitral valve, and vascular injury related to the access vessels.7,9,10 The procedural death rate, reported to be 12% in the early experience, appears to have decreased in the recent era.10-12 Femoral vascular injuries constitute the majority of procedural complications and range from thrombotic obstruction with diminution of distal pulses to catastrophic disruption of access vessels requiring surgical intervention.9,12-15

Although mentioned in animal experiments and in 2 early cases,16 aortic wall injury has gone almost unmentioned in subsequent series. When Egito et al13 noted aortic intimal flaps in 2 patients, they speculated that technical modifications would reduce or eliminate the potential for this complication. A recent case at our institution in which a large aortic intimal flap was raised in the ascending aorta prompted a review of all cases of neonatal aortic valvuloplasty. We sought to characterize aortic wall injury after BAVP, to
Determination of Aortic Injury

Patients with injury were identified either by review of the clinical documentation (diagnosed at injury) or by review of the primary echocardiographic or angiographic data (diagnosed at review). Clinical documentation included echocardiography reports, catheterization reports, operative notes, and autopsy reports. Injury diagnosed at review was defined as a mobile, linear structure in the lumen of the aorta, >3 mm in length, and visible by 2-dimensional echocardiography (Figure 1) or as a linear filling defect or extraluminal contrast visible by aortic angiography (Figure 2). All echocardiograms were reviewed by a staff echocardiographer (D.W.B.) blinded to the results of angiography or other clinical information to evaluate for evidence of aortic wall injury. All angiograms were independently reviewed by 2 separate angiographers (J.E.K., A.C.M.).

determine its incidence in neonates, to identify risk factors, and to ascertain any short- or long-term implications of this complication.

Methods

All patients <2 months of age who underwent BAVP for valvar aortic stenosis at Children’s Hospital Boston from 1985 to 2007 were identified from the hospital’s cardiology database. For patients who had >1 procedure in the first 2 months of life, subsequent catheterizations were considered additional procedural encounters. Demographic information, including age, weight, height, and body surface area, was collected from the medical record. Follow-up clinical information was obtained from medical records, including surgical and autopsy reports when relevant. Procedural consent was given by the parent or guardian of the patient before intervention, and this retrospective review was approved by the Committee on Clinical Investigation of the Children’s Hospital Boston.

Valvuloplasty procedures were carried out with previously described techniques. Initial balloon sizes were chosen to approximate 80% of the aortic annular diameter, and serial dilations were performed with incremental increases in the effective dilating diameter applied. Aortic regurgitation was most commonly assessed by ascending aortography through a pigtail catheter, although a cutoff pigtail was substituted in some cases. Starting in approximately 1997, the guidewire (usually an 18-gauge floppy-tipped wire) was routinely preshaped to follow the curvature of the aortic arch. Right ventricular pacing was not used in any of these infants.

Figure 1. Aortic wall injury by echocardiogram. Two-dimensional echocardiogram image taken from high parasternal view shows a long-axis view of the aortic arch. A large circumferential flap injury is noted that originates in the distal ascending aorta and extends across the transverse arch.

Figure 2. Aortic wall injury by angiogram. Angiogram with a Berman angiographic catheter in the left ventricle demonstrates a prominent circumferential filling defect across the distal ascending aorta consistent with a large intimal flap.

Review of Echocardiograms and Catheterizations

Preprocedural and postprocedural echocardiogram reports were reviewed to determine aortic annulus dimension, ascending aorta diameter, and left ventricular function. Z scores for left-sided heart structures were derived from original measurements or repeat measurements in the case of missing information at the time of image acquisition. Ventricular function was graded by echocardiographic ejection fraction as normal (>55%), mildly depressed (45% to 55%), moderately depressed (35% to 44%), or severely depressed (<35%). For those few patients with missing preprocedural echocardiograms, ventricular function was graded by review of predilation left ventricular angiograms.

Catheterization reports were similarly evaluated for various procedural variables such as total length of procedure, number of dilation attempts, direction of balloon catheter approach (antegrade or retrograde), aortic stenosis gradient, type of angiographic catheter in the ascending aorta, maximum balloon dimension, and ratio of balloon to annulus. Performing staff interventionalists were categorized as novice if they had performed ≤5 neonatal BAVPs and were considered to be experienced if they had performed >5 neonatal BAVPs. All procedural complications were noted from review of catheterization reports and hospital records.

Data Analysis

Descriptive statistics were generated to compare patients with aortic injury as a complication of their procedure with those with no injury. Comparisons were performed with the Fisher exact test for categorical variables and the Wilcoxon rank-sum test for continuous variables. Multivariable analysis was performed by use of logistic regression analysis with outcome aortic injury and potential risk factors consisting of both patient- and procedure-level factors. The model accounted for the lack of independence between multiple procedures performed on the same patient.

The authors had full access to the data and take responsibility for the integrity of the data. All authors have read and agree to the manuscript as written.
Table 1. Neonatal BAVP: Comparison at Initial Procedure*

<table>
<thead>
<tr>
<th></th>
<th>Total Patients (n=173)</th>
<th>Aortic Wall Injury (n=28)</th>
<th>Controls (n=145)</th>
<th>P, Univariate Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, d</td>
<td>5 (0–59)</td>
<td>3 (0–58)</td>
<td>6 (0–59)</td>
<td>0.08</td>
</tr>
<tr>
<td>Weight, kg</td>
<td>3.5±0.9</td>
<td>3.4±0.7</td>
<td>3.5±0.9</td>
<td>0.40</td>
</tr>
<tr>
<td>Aortic annulus, mm</td>
<td>5.9±1.4</td>
<td>5.4±0.9</td>
<td>5.9±1.4</td>
<td>0.02</td>
</tr>
<tr>
<td>Aortic annulus Z score</td>
<td>−1.6±1.4</td>
<td>−2.1±1.0</td>
<td>−1.5±1.4</td>
<td>0.01</td>
</tr>
<tr>
<td>Ascending aorta, mm</td>
<td>9.2±2.4</td>
<td>8.6±2.5</td>
<td>9.2±2.3</td>
<td>0.38</td>
</tr>
<tr>
<td>Ascending aorta Z score</td>
<td>0.8±1.7</td>
<td>0.3±1.7</td>
<td>0.9±1.7</td>
<td>0.24</td>
</tr>
<tr>
<td>Predilation ventricular function, n (%)</td>
<td></td>
<td></td>
<td></td>
<td>0.004</td>
</tr>
<tr>
<td>Normal</td>
<td>60 (35)</td>
<td>3 (11)</td>
<td>57 (39)</td>
<td>...</td>
</tr>
<tr>
<td>Mild</td>
<td>24 (14)</td>
<td>3 (11)</td>
<td>21 (14)</td>
<td>...</td>
</tr>
<tr>
<td>Moderate</td>
<td>20 (12)</td>
<td>3 (11)</td>
<td>17 (12)</td>
<td>...</td>
</tr>
<tr>
<td>Severe</td>
<td>69 (40)</td>
<td>19 (68)</td>
<td>50 (34)</td>
<td>...</td>
</tr>
<tr>
<td>Early surgery (&lt;30 d after procedure), n (%)</td>
<td></td>
<td></td>
<td></td>
<td>0.42</td>
</tr>
<tr>
<td>None</td>
<td>134 (77)</td>
<td>20 (71)</td>
<td>114 (78)</td>
<td>...</td>
</tr>
<tr>
<td>Stage 1 palliation</td>
<td>20 (12)</td>
<td>5 (18)</td>
<td>15 (11)</td>
<td>...</td>
</tr>
<tr>
<td>Coarctation repair</td>
<td>8 (5)</td>
<td>0</td>
<td>8 (6)</td>
<td>...</td>
</tr>
<tr>
<td>Other</td>
<td>11 (6)</td>
<td>3 (11)</td>
<td>8 (5)</td>
<td>...</td>
</tr>
<tr>
<td>Early repeat BAVP (&lt;2 mo of age), n(%)</td>
<td></td>
<td></td>
<td></td>
<td>0.04</td>
</tr>
<tr>
<td>Yes</td>
<td>13 (8)</td>
<td>5 (18)</td>
<td>8 (6)</td>
<td>...</td>
</tr>
<tr>
<td>No</td>
<td>160 (92)</td>
<td>23 (82)</td>
<td>137 (94)</td>
<td>...</td>
</tr>
<tr>
<td>Era of balloon dilation, n(%)</td>
<td></td>
<td></td>
<td></td>
<td>0.54</td>
</tr>
<tr>
<td>1985–1995</td>
<td>85 (49)</td>
<td>12 (43)</td>
<td>73 (50)</td>
<td>...</td>
</tr>
<tr>
<td>1996–2006</td>
<td>88 (51)</td>
<td>16 (57)</td>
<td>72 (50)</td>
<td>...</td>
</tr>
</tbody>
</table>

*Values are mean±SD or median (range) when appropriate.

Patients

Between 1985 and 2007, 173 neonates <2 months of age (135 male, 38 female) underwent BAVP for aortic stenosis at Children’s Hospital Boston (Table 1). Of these, 13 patients underwent repeat BAVP within the first 2 months of life, and 1 patient had 3 procedures, for a total of 187 procedures, including 1 patient with aortic wall injury at the time of repeat procedure (28 total cases of injury).

Results

Patients

Between 1985 and 2007, 173 neonates <2 months of age (135 male, 38 female) underwent BAVP for aortic stenosis at Children’s Hospital Boston (Table 1). Of these, 13 patients underwent repeat BAVP within the first 2 months of life, and 1 patient had 3 procedures, for a total of 187 procedures, including 1 patient with aortic wall injury at the time of repeat procedure (28 total cases of injury).

And an additional 15 patients died ≤30 days after BAVP; most deaths (23 of 35 cases) occurred in the first decade of experience with the procedure (1985 to 1995).

Technical Details of BAVP

The majority of BAVPs were performed via a retrograde approach (n=162), with some 22 procedures performed via an antegrade approach; in 3 early cases, the approach could not be ascertained confidently by review of the available records (Table 2). The median size of the largest balloon used was 6 mm, with median ultimate balloon-to-annulus ratio of 0.95. The average number of dilations per case was 2 (range, 1 to 7), and the average case lasted 119 minutes (range, 35 to 353 minutes). Postdilation angiography was performed most often by pigtail catheter (112 procedures, 60%), with cutoff pigtail catheters used in 66 (35%) and end-hole catheters used in 6 procedures (3%). The angiographic catheter in the remaining 3 procedures (2%) could not be determined.

Injuries as a Result of BAVP

Of the 187 procedures performed, aortic injury was diagnosed in 28 cases (15%; Figures 1 and 2). Angiography was available for secondary review for 173 procedures (14 missing angiograms); echocardiography was available for 178 procedures (9 missing follow-up echocardiograms). Injury was infrequently diagnosed angiographically at the time of catheterization (n=8) but was evident on retrospective review.
Table 2. Neonatal BAVP Procedural Data (187 Procedures)

<table>
<thead>
<tr>
<th></th>
<th>Aortic Wall Injury (n=28)</th>
<th>Controls (n=159)</th>
<th>P, Univariate Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Predilation AS gradient, mm Hg</td>
<td>45 (23–83)</td>
<td>55 (8–140)</td>
<td>0.15</td>
</tr>
<tr>
<td>Dilation attempts, n</td>
<td>3.5 (1–7)</td>
<td>2 (1–7)</td>
<td>0.003</td>
</tr>
<tr>
<td>Maximum balloon size, mm</td>
<td>6 (2.5–7)</td>
<td>6 (3–9)</td>
<td>0.23</td>
</tr>
<tr>
<td>Balloon-to-annulus ratio</td>
<td>1.0 (0.63–1.23)</td>
<td>0.92 (0.6–2.0)</td>
<td>0.01</td>
</tr>
<tr>
<td>Case duration, min</td>
<td>131 (53–338)</td>
<td>115 (35–353)</td>
<td>0.10</td>
</tr>
<tr>
<td>Dilation approach, n (%)</td>
<td></td>
<td></td>
<td>0.05</td>
</tr>
<tr>
<td>Antegrade</td>
<td>0</td>
<td>22 (14)</td>
<td>0.05</td>
</tr>
<tr>
<td>Retrograde</td>
<td>28 (100)</td>
<td>134 (84)</td>
<td>0.05</td>
</tr>
<tr>
<td>Unknown</td>
<td>0</td>
<td>3 (2)</td>
<td>0.05</td>
</tr>
<tr>
<td>Angiographic catheter, n (%)</td>
<td></td>
<td></td>
<td>0.32</td>
</tr>
<tr>
<td>Pigtail</td>
<td>14 (50)</td>
<td>98 (62)</td>
<td>0.05</td>
</tr>
<tr>
<td>Cutoff pigtail</td>
<td>13 (46)</td>
<td>53 (33)</td>
<td>0.05</td>
</tr>
<tr>
<td>End hole</td>
<td>1 (4)</td>
<td>5 (3)</td>
<td>0.05</td>
</tr>
<tr>
<td>Unknown</td>
<td>0</td>
<td>3 (2)</td>
<td>0.05</td>
</tr>
<tr>
<td>Attending catheterizer, n (%)</td>
<td></td>
<td></td>
<td>0.03</td>
</tr>
<tr>
<td>Novice</td>
<td>12 (43)</td>
<td>36 (23)</td>
<td>0.03</td>
</tr>
<tr>
<td>Experienced</td>
<td>16 (57)</td>
<td>122 (77)</td>
<td>0.03</td>
</tr>
</tbody>
</table>

AS indicates aortic stenosis. Values are median (range) when appropriate.

Table 3. Means of Diagnosis Aortic Wall Injury (n=28)

<table>
<thead>
<tr>
<th></th>
<th>Angiography Alone, n (%)</th>
<th>Echocardiography Alone, n (%)</th>
<th>Both Modalities, n (%)</th>
<th>Missed, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time of original study</td>
<td>1 (3)</td>
<td>8 (29)</td>
<td>7 (25)</td>
<td>12 (43)</td>
</tr>
<tr>
<td>Secondary review (n=26)*</td>
<td>4 (16)</td>
<td>11 (42)</td>
<td>11 (42)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

*Twenty-six cases had both angiographic and echocardiographic images available for secondary review. In the remaining 2 cases, 1 was diagnosed by angiography alone, and 1 was diagnosed by echocardiogram alone.

of angiography in 15 total cases (Table 3). Correlation between the 2 independent angiographic reviews was excellent (14 of 15 cases). Limited opacification of the aortic arch on ascending aortography, compounded by wash-in from ductal flow, probably contributed to underdiagnosis by angiography.

Echocardiograms at the time of injury detected only 15 of the total 28 cases in which aortic injury was found on secondary review. As noted above, postprocedure echocardiograms were available on nearly all patients (178 of 187 procedures). Of the 28 cases of aortic injury, 11 injuries were evident by both angiography and echocardiogram; 5 injuries were noted by angiography alone (missing echocardiogram in 1 patient) and 12 injuries by echocardiogram alone (missing angiogram in 1 patient; Table 3). Limited views of the thoracic aorta by echocardiogram contributed most often to failure to diagnose by echocardiogram.

Although aortic intimal flaps accounted for the large majority of injuries, we also noted limited circumferential dissections. Flaps occurred most commonly at the base of the innominate artery and along the transverse arch but were also observed more proximally and distally (Figure 3). Of the 26 injuries involving the ascending aorta and aortic arch, the majority (15 injuries, 58%) involved the greater curvature of the arch, 7 injuries (25%) were circumferential lesions involving both the greater and lesser curvature, and 4 (15%) involved only the lesser curvature.

Aortic injury was not associated with most baseline patient characteristics assessed in univariate analysis (including demographic variables such as age, sex, body surface area, or ascending aorta sizes), Z scores, predilation gradient, type of subsequent surgery necessary, or era of procedure; however, aortic annulus size (5.4 versus 5.9 mm in those uninjured; \( P = 0.02 \)), aortic annulus Z score (2.1 versus 1.5; \( P = 0.01 \)), and severe predilation ventricular dysfunction (68% versus 34%; \( P = 0.004 \)) were associated with aortic injury (Table 1). Patients undergoing repeat BAVP at 2 months of age also were more likely to have aortic injury (18% versus 6%; \( P = 0.04 \)). In multivariate analysis, the only baseline patient characteristic that remained significantly associated with aortic injury was the presence of severe ventricular dysfunction (odds ratio 2.8; \( P = 0.02 \); Table 4).

Procedural variables associated with aortic wall injury in univariate analysis included the number of balloon dilations performed (3.5 versus 2 in those uninjured; \( P = 0.003 \)), the ultimate balloon-to-annulus ratio (1.0 versus 0.92; \( P = 0.01 \)), dilation approach (100% retrograde versus 85% retrograde; \( P = 0.05 \)), and novice interventional staff (43% novice versus 23% in those uninjured; \( P = 0.03 \); Table 2). Other procedural variables, including maximum balloon dimension, angiography...
graphic catheter used, and case duration, were not associated with injury. In multivariate analysis, only number of balloon dilation attempts per procedure (odds ratio 1.5 for each additional inflation attempt; \( P = 0.005 \)) and novice interventional staff (odds ratio 2.5; \( P = 0.05 \)) remained significantly associated with aortic wall injury (Table 4).

Aortic Injury Follow-Up

No patients with aortic injury were lost to follow-up (Table 5). Among those with aortic injury, 7 patients died, all within 4 months of initial BAVP. One death was procedural, with autopsy confirmation of flap injury of the aortic root obstructing the left main coronary artery; 1 patient with known injury had sudden, unexpected death at home 2 weeks after BAVP (autopsy not performed); and the remaining 5 patients died of progressive heart failure. Although deaths occurred more frequently in the aortic wall injury group (25% versus 19%), this was not statistically significant (\( P = 0.45 \)). Three patients with known aortic wall injury had it repaired with subsequent surgeries, with 1 repair occurring as late as 2 years after BAVP. Of the remaining 18 patients with aortic wall injury, 8 had subsequent surgeries (most commonly stage 1 palliation or surgical aortic valvotomy) with no evidence of aortic pathology described in the operative reports. For the 10 patients with aortic injury who did not have subsequent operations, the injury was still present on the most recent echocardiogram in 6 and not present in 4 patients on secondary review of the most recent echocardiograms. Other potential sequelae of aortic injury, such as stroke, occlusion of head or neck vessels, and subsequent aortic dissection, were not detected with retrospective chart review of clinical follow-up.

For the entire cohort, deaths were more common in the earlier era of experience (23 deaths from 1985 to 1995 versus 12 deaths from 1996 to 2007). Three deaths were procedural (including the aortic injury patient noted above). The most common cause of death in the cohort as a whole was progressive heart failure (15 of 35 cases), followed by postoperative complications, including stage 1 palliation, which resulted in an additional 12 deaths.

**Discussion**

Among 173 infants undergoing neonatal aortic valvuloplasty over a 20-year time span at our institution, aortic wall injury was detected in 15% of the procedures. Whereas intimal tears and/or flaps are an anticipated result of angioplasty procedures such as coarctation dilation (so-called “therapeutic tears”),17 their occurrence during valvuloplasty clearly has no therapeutic aspect; therefore, they can be categorized as adverse events, even in the absence of known clinical sequelae. Although previous reports of such injury are rare in the literature, the present study demonstrates that this complication is actually quite common.

Interestingly, although the study covered >20 years of transcatheter interventional procedures, with significant improvements in equipment such as more stable wires and

Table 4. Neonatal BAVP: Multivariate Analysis

<table>
<thead>
<tr>
<th></th>
<th>Odds Ratio</th>
<th>( P )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe ventricular dysfunction</td>
<td>2.8</td>
<td>0.02</td>
</tr>
<tr>
<td>Balloon dilation attempts</td>
<td>1.5</td>
<td>0.005</td>
</tr>
<tr>
<td>Novice interventionalist</td>
<td>2.5</td>
<td>0.05</td>
</tr>
</tbody>
</table>

Table 5. Neonatal BAVP: Aortic Wall Injury Follow-Up (All Injuries)

<table>
<thead>
<tr>
<th></th>
<th>Aortic Wall Injury (n=28)</th>
<th>Controls (n=145)</th>
<th>( P ) Univariate Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical follow-up, y</td>
<td>3.7 (0–18.3)</td>
<td>4.5 (0–22.6)</td>
<td>0.79</td>
</tr>
<tr>
<td>Lost to follow-up, n</td>
<td>0</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Deaths, n (%)</td>
<td>0</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Cause of death</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procedural</td>
<td>1</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Sudden/unexpected</td>
<td>1</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Heart failure</td>
<td>4</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>Postoperative stage 1</td>
<td>1</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Postoperative complications†</td>
<td>0</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Repeat BAVP procedures to date</td>
<td>10</td>
<td>44</td>
<td></td>
</tr>
</tbody>
</table>

Clinical follow-up is given as median (range).

*Two were repaired at surgery within 30 days of BAVP; 1 aortic injury was repaired 2 years later at surgery.

†Patient deaths within 30 days of operative procedure other than stage 1 palliation.
lower-profile, more sophisticated balloon catheters, the rate of aortic wall injury was relatively constant over the 2 eras evaluated. This finding is in marked contrast to the incidence of complications related to access of vessels, which have shown steady improvement over a similar time period.\(^\text{13}\)

Given the location of most of the injuries across the transverse arch (Figure 3), it is likely that the passage of the catheters or the presence of stabilizing wires, rather than trauma from an inflated angioplasty balloon, is the most likely cause of injury. Our finding that the number of dilation attempts was associated with the occurrence of injury supports this hypothesis; multiple dilations with incrementally larger balloons require multiple catheter exchanges. In some cases, the relatively stiff shaft of the dilation catheter can be difficult to advance around the arch and will frequently carry the guidewire against the anterior/superior surface of the distal ascending aorta. This mechanism of injury is consistent with the location of many of our flaps. In addition, mismatch between the lumen of a stiff balloon catheter and the guidewire could result in a “shoveling” injury of the intima as the balloon is advanced retrograde around the aortic arch. Because of the large variety of both balloon catheters and wires used over the time period of this study, indeed at times during a single case, an analysis to evaluate specifically for catheter-to-wire mismatch was not possible, but it remains a plausible mechanism for aortic wall injury.

In further support of this hypothesis, aortic injury was found exclusively in patients with a retrograde approach to the aortic valve, although only a small number of procedures (22) were performed with an antegrade approach. With a retrograde approach to BAVP, the force of ventricular ejection is directed along the wire against the distal ascending aorta and greater curvature of the arch, which could result in shearing injury to the intima and media similar to the flap-type injuries observed. This is supported by the location of most of the aortic wall injuries (Figure 3).

If the inflated angioplasty balloon itself were responsible for aortic injury, one might expect that forceful ventricular contraction leading to ejection of the balloon could increase the risk of aortic injury. However, we found the opposite, that aortic wall injury was much more common in those with severe ventricular dysfunction. In the setting of severe dysfunction, the force of ejection transmitted along the wire with balloon inflation would be less than in those with normal ventricular function. Severe dysfunction, a hallmark of more extensive aortic valve disease, may be a surrogate marker for more diffuse involvement of the ascending aorta, resulting in a predisposition to vascular trauma. Severe dysfunction also may be a marker for more technically complex cases (eg, smaller effective valve orifice) that required more extensive catheter manipulation or perhaps more critically ill infants in whom the intervention was done with less attention to technical detail. Our study has no other markers for the presenting clinical status of the patient; thus, severe ventricular dysfunction may be a surrogate measure.

Another possible explanation for the aortic wall injuries observed would be damage from the angiographic catheter in the ascending aorta rather than the balloon dilation catheter or stabilizing wires. The use of manually modified “cutoff” catheters, in which a portion of the distal catheter (most commonly a “pigtail” catheter) is cut off by the interventionalist, is relatively common in our laboratory (30% of cases in this cohort). We hypothesized that increased mismatch between the guidewire and the end hole of a cutoff catheter might predispose to a “shoveling” injury of the intima on the outer curvature of the aortic wall. However, our analysis did not find a significant association with the type of angiographic catheter used, and this mechanism would not explain the occurrence of circumferential lesions and lesions involving only the lesser curvature of the arch.

The experience of the interventionalist performing the BAVP was associated with aortic injury, with the patients of novice interventionists (defined in our study as having performed ≤5 BAVP procedures) 2.5 times more likely to have aortic wall injury as a complication of the procedure. The relationship between procedural complications and clinical experience, while intuitively seemingly closely correlated, has been virtually unstudied in pediatric interventional cardiology. Although our definition of novice versus experienced is somewhat arbitrary in this case, this distinction demonstrates that there are technical aspects to successful, uncomplicated BAVP that improve with increasing interventionalist experience and are independent of patient characteristics or other procedural factors. Whether this association holds true for other transcatheter procedures and how that effect might be best mitigated merit further investigation and study.

The late consequences of aortic wall injury in these patients are only partly defined by this study, and the follow-up available in this retrospective review offers little insight. Patients with bicuspid aortic valves have associated ascending aortic dilation and pathological arterial wall abnormalities. Whether intimal disruption in the neonatal period or even more extensive aortic wall injury may have any detrimental effect on the integrity of the aortic wall in these abnormal vessels later in life is an area for further investigation. In addition to these local vessel wall concerns, dissection and thromboembolic complication are potential risks, although no overt cases of this were found in this retrospective review.

What is clear is that this complication caused death in 1 patient, with direct autopsy confirmation of aortic wall injury as the cause of death in that case; in a second case, there was a high clinical degree of suspicion that aortic injury was the likely cause of demise (autopsy was not performed). Overall, although a higher percentage of patients with identified aortic injury died (25%, versus 19% for those without injury), there was no statistically detectable increase in death. Three injuries were significant enough to prompt surgical repair. Other possible sequelae, such as occlusion of head and neck vessels or thromboembolic events, were not observed but not specifically assessed. Evidence of aortic injury persists in 4 other patients who did not have surgery at the most recent follow-up.

**Limitations**

As a retrospective review, this study is limited by ascertainment bias. Fourteen angiograms were missing (all in the early era of experience before digital image acquisition), and some patients with aortic injury may not have been diagnosed. In
addition, the transverse arch was not extensively imaged in some patients by both angiography and postprocedure echocardiogram, which also may have resulted in missed diagnoses. However, all of these factors would result in a higher rate of aortic injury, not a lower one. Another weakness of this study as a retrospective review is the quite limited follow-up information available in those with aortic injury, including more thorough assessment of possible associated morbidity such as occlusion of head and neck vessels or subclinical thromboembolic events.

Conclusions
Aortic wall injury, specifically creation of an intimal flap, is an underrecognized complication of neonatal balloon valvuloplasty, occurring in 15% of cases even in the recent era. This complication is frequently missed, and careful evaluation of the aorta after BAVP is indicated to specifically evaluate for aortic wall injury. Most injuries were noted in the transverse aortic arch. Severely depressed ventricular function, a greater number of balloon dilation attempts per procedure, and the degree of experience of the performing interventionalist were factors associated with aortic wall injury. Aortic injury contributed to death in at least 1 case, and although many injuries appeared to resolve on subsequent studies, the precise late effects of such aortic injuries remain uncertain and deserve further study.

Source of Funding
This work was supported by the generosity of the Annie Gorman Fund.

Disclosures
None.

References

CLINICAL PERSPECTIVE
Aortic wall injury after neonatal balloon aortic valvuloplasty for congenital aortic stenosis has rarely been described in the literature. This retrospective, single-center study evaluated all patients who underwent this procedure at <2 months of age over a 22-year period, including secondary review of all imaging studies, specifically to evaluate for this complication. Aortic wall injury was found in 28 of 187 procedures (15%) and was recognized at the time of the procedure in only 16 patients. The incidence of injury was not different in the recent era compared with earlier experience. Most injuries were noted in the transverse aortic arch, typically involving the greater curvature. In multivariate analysis, severely depressed ventricular function, a greater number of balloon dilation attempts per procedure, and the degree of experience of the performing interventionalist were factors associated with injury. Aortic wall injury, specifically creation of an intimal flap, is an underrecognized complication of neonatal balloon aortic valvuloplasty, occurring in 15% of cases even in the recent era. This complication is frequently missed, and careful evaluation of the aorta is indicated to evaluate for aortic wall injury after this procedure. Aortic injury contributed to death in at least 1 case in this series, and although many injuries appeared to resolve on subsequent studies, the precise late effects of such aortic injuries remain uncertain and deserve further study.
Aortic Wall Injury as a Complication of Neonatal Aortic Valvuloplasty: Incidence and Risk Factors

doi: 10.1161/CIRCINTERVENTIONS.108.777623
Circulation: Cardiovascular Interventions is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
Copyright © 2008 American Heart Association, Inc. All rights reserved.
Print ISSN: 1941-7640. Online ISSN: 1941-7632

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://circinterventions.ahajournals.org/content/1/1/53

Permissions: Requests for permissions to reproduce figures, tables, or portions of articles originally published in Circulation: Cardiovascular Interventions can be obtained via RightsLink, a service of the Copyright Clearance Center, not the Editorial Office. Once the online version of the published article for which permission is being requested is located, click Request Permissions in the middle column of the Web page under Services. Further information about this process is available in the Permissions and Rights Question and Answer document.

Reprints: Information about reprints can be found online at:
http://www.lww.com/reprints

Subscriptions: Information about subscribing to Circulation: Cardiovascular Interventions is online at:
http://circinterventions.ahajournals.org/subscriptions/