Intermediate-Term Effectiveness of Balloon Valvuloplasty for Congenital Aortic Stenosis

A Prospective Follow-up Study

Brian K. O'Connor, MD; Robert H. Beekman, MD; Albert P. Rocchini, MD; and Amnon Rosenthal, MD

**Background.** Percutaneous balloon valvuloplasty has proven to be acutely effective in the treatment of congenital valvar aortic stenosis; however, the intermediate- and long-term effectiveness of the procedure remain to be documented.

**Methods and Results.** To assess the intermediate-term effectiveness of balloon valvuloplasty, repeat catheterization was performed in 27 of 30 children 1.7±0.1 years after balloon valvuloplasty for congenital aortic stenosis (AS). In 33 children the peak AS gradient was reduced acutely by 55% from 77±4 to 35±3 mm Hg (p<0.001), and left ventricular systolic pressure was reduced from 176±4 to 138±4 mm Hg (p<0.001). Despite a technically adequate valvuloplasty procedure, three patients had inadequate relief of obstruction and required complex surgical intervention. Twenty-seven of the 30 patients available for late reevaluation (90%) enrolled in the follow-up study. The peak AS gradient remained significantly reduced compared with that present before valvuloplasty (29±3 versus 77±4 mm Hg, p<0.001). Furthermore, there was no difference in peak AS gradient at follow-up compared with that immediately after valvuloplasty. The greatest increase in gradient at reevaluation was 14 mm Hg. Twenty of 27 patients (74%) had no change in the degree of aortic insufficiency at follow-up compared with that present before valvuloplasty. At follow-up, 16 patients had no aortic insufficiency at all, and only two had moderate-to-severe (3–4+) insufficiency. Femoral artery injury was documented in four patients, three of whom were under 12 months of age at valvuloplasty.

**Conclusions.** Balloon aortic valvuloplasty provides safe and effective intermediate-term gradient relief without early restenosis in children and adolescents with congenital AS. (Circulation 1991;84:732–738)

Percutaneous balloon valvuloplasty has proven to be acutely effective in the treatment of congenital valvar aortic stenosis (AS)\(^1\)-\(^5\); however, the intermediate- and long-term effectiveness of the procedure remain to be documented. In contrast, numerous follow-up studies after balloon valvuloplasty in adults with calcific AS have demonstrated a high incidence of restenosis and late mortality.\(^6\)-\(^12\) Extrapolation of these data to congenital AS is unwarranted, however, as there are important differences in the morphological substrates underlying each lesion. While calcific AS is a progressive acquired lesion with deposition of calcium within normal or nearly normal valve leaflets,\(^13\) congenital AS is a defect in valve morphogenesis that leads to variable degrees of leaflet (commissural) fusion.\(^14\) All systematic follow-up studies published to date have addressed the outcome after balloon valvuloplasty for calcific AS only. Therefore, the present study was designed to prospectively evaluate the hemodynamic outcome at cardiac catheterization 1–3 years after percutaneous balloon aortic valve valvuloplasty (PBAV) in children and adolescents with congenital AS.

**Methods**

**Patient Selection**

At our institution, all patients with congenital AS undergoing PBAV have demonstrated stenosis warranting intervention based on the following criteria: a resting peak systolic AS gradient of 75 mm Hg or greater, or a gradient of 50 mm Hg or greater with associated symptoms (heart failure, chest pain, or...
syncope) and/or evidence of myocardial ischemia on resting or exercise electrocardiogram. Patients excluded from valvuloplasty are those with severe hypoplasia of the aortic annulus or left ventricle (annulus diameter less than 6 mm or left ventricular end-diastolic volume less than 20 ml/m²), those with moderate-to-severe aortic insufficiency (3+ or greater by angiographic criteria), and newborns with critical AS.

Study group. The study group consists of all 33 children and adolescents with congenital valvar AS who underwent PBAV at the C.S. Mott Children’s Hospital between July 1985 and June 1988. Children undergoing the procedure after June 1988 are not included, because the follow-up period in these patients was judged too short to warrant inclusion. During the 36-month period from July 1985 to June 1988, PBAV was offered as an investigational alternative to surgical valvotomy to all patients fulfilling the criteria outlined above. All patients chose PBAV as their mode of treatment during this interval. The protocols for the PBAV procedure and the follow-up evaluation were approved by the hospital institutional review board and informed consent was obtained before each study.

Valvuloplasty Procedure

PBAV was performed as described in detail previously. A complete right and left heart catheterization was performed, including at least three measurements of cardiac output by thermodilution technique. A left ventricular cineangiogram and an aortogram were performed before valvuloplasty. Valve dilation was performed using either a single- or double-balloon technique. Repeat hemodynamic measurements and an aortogram were performed after valvuloplasty.

Two patients were initially treated with undersized balloon catheters (balloon/annulus ratio 0.80 or less), resulting in suboptimal gradient relief. Repeat valvuloplasty using appropriate-sized balloons resulted in acutely effective gradient reduction in each individual. The intermediate-term results of the second, technically adequate procedures are included below in the follow-up study.

Follow-up Study

Of the patients in our study, three had suboptimal gradient relief despite adequate valvuloplasty technique, and each subsequently required complex surgical intervention. The remaining 30 patients were approached prospectively for enrollment in the follow-up hemodynamic study. Two patients refused repeat catheterization and one patient was lost to follow-up (Table 1, patients 28, 29, and 30). Thus, 27 of 30, or 90%, of the patients available for late follow-up evaluation were enrolled in the study.

The repeat hemodynamic evaluation was performed an average of 1.7±0.1 years after balloon valvuloplasty. The follow-up cardiac catheterization was performed in an identical manner to the initial study, with simultaneous measurements of left ventricular and aortic pressures, thermodilution cardiac output measurements, and quantitation of aortic valve insufficiency by angiography.

Data Analysis

Continuous data are expressed as mean±SEM. Changes in serial hemodynamic data obtained before valvuloplasty, after valvuloplasty, and at late follow-up are assessed using a repeated-measures ANOVA. The significance of differences between each time interval (before versus after valvuloplasty, before valvuloplasty versus follow-up, and after valvuloplasty versus follow-up) are assessed using Scheffe’s test to adjust conservatively for the effects of multiple pairwise comparisons. Serial aortic valve areas were calculated and compared only for those children with no aortic insufficiency at each time interval. Group comparisons were performed using a Student’s t test for continuous data and the Fisher exact test for categorical data. The influence of clinical and hemodynamic variables on late outcome after valvuloplasty (absolute gradient reduction) was assessed by stepwise multiple regression analysis. For this analysis, the balloon/annulus ratio in children undergoing a double-balloon valvuloplasty procedure was calculated as balloon diameter sum/(annulus×1.3); this ratio estimates the effective cross-sectional dilating area, or the effective balloon/annulus ratio.16,17 All analyses are two-tailed and statistical significance is defined as a value of p<0.05.

Results

Pertinent clinical and hemodynamic data characterizing the 33 children undergoing aortic valvuloplasty between July 1985 and June 1988 are presented in Table 1. At valvuloplasty the average age was 8.5±1.2 years (3 months to 21 years), and the average weight was 34±4.4 kilograms (5–75 kilograms). Sixteen patients underwent a single-balloon procedure with a balloon/annulus diameter ratio of 0.97±0.03 (0.87 to 1.18). In the remaining 17 patients, a double-balloon technique was used with an effective balloon/annulus diameter ratio of 1.0±0.03 (0.92 to 1.27), which corresponds to a summed balloon/annulus diameter ratio of 1.3±0.03 (1.2 to 1.65). Nine patients underwent PBAV for restenosis after surgical valvotomy.18 Before valvuloplasty the peak systolic AS gradient was 77±4 mm Hg (51–146 mm Hg), the left ventricular systolic pressure was 176±4 mm Hg (112–240 mm Hg), and the left ventricular end-diastolic pressure was 16±1.1 mm Hg (9–47 mm Hg). The aortic valve annulus ranged from 7 to 30 mm in diameter, and the mean cardiac index before valvuloplasty was 3.6±0.2 l/min/m².

Acute Effectiveness of Valvuloplasty

In this patient group, balloon valvuloplasty achieved a significant reduction in peak systolic AS gradient (F=116, p<0.001), left ventricular systolic pressure (F=60, p<0.001), and left ventricular end-diastolic pressure (F=7, p<0.01) and a significant
### Table 1. Acute Hemodynamic Data of 30 Children Undergoing Successful Balloon Aortic Valvuloplasty Between July 1985 and June 1988 With Late Hemodynamic Data in 27 (90%) Participating in the Follow-up Study

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**Mean:** 8.6 34.9 17 76 32 176 313 3.71 3.42 1.7 29 138 3.63  
**SEM:** 1.2 4.7 1 4 2 4 3 0.15 0.14 0.1 3 4 0.17

*Alcortic insufficiency; CI, cardiac index; Grad, peak systolic aortic stenosis gradient; LVS, left ventricular systolic pressure; NS, p>0.05 by Scheffé's test.*

**Versus post values.**

Increase in aortic valve area ($F=21, p<0.001$). There was no significant effect on cardiac index ($F=2, p=NS$). Immediately after valvuloplasty the peak AS gradient was reduced from 77±4 to 35±3 mm Hg, a 55% gradient reduction ($p<0.001$). The aortic valve area increased from 0.47±0.04 to 0.64±0.07 cm²/m² ($p<0.05$). Left ventricular systolic pressure was reduced from 176±4 to 138±4 mm Hg ($p<0.001$), and the left ventricular end-diastolic pressure was reduced from 16±1 to 12±1 mm Hg ($p<0.05$). In 27 of 33 patients valvuloplasty caused no acute increase in aortic insufficiency compared with that present before valvuloplasty. Of these 27, 18 had no aortic insufficiency immediately after valvuloplasty. Three patients experienced a 1+ increase in aortic insufficiency, and the remaining three had a 2+ increase in aortic insufficiency immediately after valvuloplasty.

Despite a technically adequate procedure, three patients had inadequate gradient relief after valvuloplasty and required complex surgical palliation. The first patient, a 16-year-old male with Noonan syndrome required aortic valve replacement because of annular hypoplasia. The second, a 2-year-old female with severe left ventricular dysfunction, ultimately required cardiac transplantation after unsuccessful surgical valvotomy. The third patient, a 4-year-old...
male with annular hypoplasia, required a Konno operation with left ventricular outflow reconstruction and aortic valve replacement.

**Follow-up Data**

Of the 30 children available for late reevaluation, 27 patients (90%) underwent a repeat hemodynamic evaluation an average of 1.7±0.1 years after balloon valvuloplasty (Table 1, patients 1–27). The follow-up study documented persistent gradient relief without significant restenosis in any child (see Figure 1). The peak systolic AS gradient remained significantly reduced at follow-up compared with that before valvuloplasty: 29±3 mm Hg versus 76±4 mm Hg (p<0.001). This represents a 62% decrease in the AS gradient at follow-up. Similarly, the aortic valve area was also significantly improved at follow-up compared with that before valvuloplasty: 0.81±0.09 versus 0.47±0.04 cm² (p<0.01). With respect to restenosis, there was no significant increase in systolic AS gradient at the follow-up study compared with that measured immediately after balloon valvuloplasty: 29±3 versus 31±2 mm Hg (p=NS). The greatest increase in gradient at follow-up was 14 mm Hg, documented in two patients 1.3 and 3.8 years after valvuloplasty, respectively. The aortic valve area (calculated for patients without aortic insufficiency) was somewhat greater at follow-up than that calculated acutely after valvuloplasty: 0.81±0.09 versus 0.64±0.07 cm² (p<0.05). Cardiac index at follow-up showed no significant difference compared with that before or immediately after valvuloplasty.

Left ventricular systolic pressure (see Figure 2) remained significantly reduced at the follow-up study compared with that before valvuloplasty: 138±4 versus 176±4 mm Hg (p<0.001). Further, there was no significant change in left ventricular systolic pressure at follow-up compared with that immediately after valvuloplasty (p=NS). The left ventricular end-diastolic pressure at follow-up was not significantly different from that measured immediately after valvuloplasty (p=NS).

At the follow-up catheterization, 20 of 27 patients (74%) had no increase in aortic insufficiency compared with that present before valvuloplasty (see Figure 3). Of the seven patients with increased aortic insufficiency, two had a 1+ increase and five had a 2+ increase in aortic insufficiency at late follow-up. In four of these seven patients, the aortic insufficiency produced acutely after valvuloplasty had not progressed, whereas in three patients the insufficiency had increased at follow-up (a 1+ increase in two, a 2+ increase in one). Perhaps most important, an average of 1.7 years after valvuloplasty 16 patients had no aortic insufficiency at all, and only two had moderate-to-severe (3–4+) aortic insufficiency.

Stepwise multiple regression analysis identified effective balloon/annulus ratio and prevavalvuloplasty peak AS gradient as the only significant predictors of absolute gradient reduction at the follow-up evaluation ($Y = -69 + 63.6X_1 + 0.69X_2$, $r=0.82$, $F=25$; where $Y$ is gradient reduction in millimeters of mercury, $X_1$ is effective balloon/annulus ratio, and $X_2$ is AS gra-
occurred in three of five children under 12 months of age, but in only one of 22 patients older than 12 months of age at the time of valvuloplasty (Fisher exact, \( p=0.01 \)). Vessels in the remaining patients appeared to be intact, based on lack of symptoms, presence of symmetric, easily palpable pulses, and the ability to easily recannulate the arteries at the follow-up catheterization. Thus, femoral artery occlusion or stenosis occurred in 60% of infants undergoing valvuloplasty but in less than 5% of older patients. Since femoral arteriography was not performed in this study, it is possible that some arterial stenoses may have gone undetected.

**Discussion**

PBAV was originally described as treatment for congenital valvar AS in children.\(^1\)\(^-\)\(^5\) The excellent early outcome in this population led to application of the procedure in elderly patients with calcific AS. Due to the large patient population available, all systematic follow-up studies evaluating the late effectiveness of PBAV have been in the elderly population. Unfortunately, these follow-up studies have documented a high incidence of early restenosis and late mortality after PBAV in adults with calcific AS.\(^6\)\(^-\)\(^12\) It is unwarranted, however, to extrapolate these data to the pediatric population with congenital AS since different morphological substrates underlie each defect.

The present study is the first systematic, complete (90% follow-up), invasive evaluation of the intermediate-term effectiveness of PBAV in children with congenital valvar AS. It has documented substantial gradient relief without significant restenosis an average of 1.7 years after PBAV. The peak systolic AS gradient was reduced from 76±4 mm Hg before valvuloplasty to 29±3 mm Hg at intermediate follow-up, a 62% reduction. The greatest increase in gradient at follow-up was 14 mm Hg, occurring in two children. These data stand in marked contrast with the high incidence of restenosis reported in adults with calcific AS. They indicate that PBAV provides effective intermediate-term gradient relief, and that early restenosis is uncommon after PBAV in children and adolescents with congenital AS.

The patient population reported in this study represents all children and adolescents requiring intervention for congenital valvar AS at our institution between July 1985 and June 1988. During this interval, all patients chose to undergo balloon valvuloplasty rather than surgical valvotomy. The study group is therefore likely to be a representative sample of children with significant valvar AS. A second strength of the study is the nearly complete inclusion (90%) of all children available for intermediate follow-up evaluation. No clinical or acute hemodynamic factors differentiate the three children not enrolling in the follow-up study from the other 27 patients (see Table 1). Thus, it is unlikely that sampling bias has significantly affected the follow-up hemodynamic findings. Finally, the hemodynamic measurements in

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**Figure 3.** Pie chart showing increase in aortic insufficiency at follow-up compared with that present before valvuloplasty in 27 children undergoing follow-up cardiac catheterization. In 74% of patients, valvuloplasty caused no change in the degree of aortic insufficiency. Aortic insufficiency was evaluated on a 0–4+ scale.\(^\text{15}\)

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dient before valvuloplasty). Factors found not to be significant predictors of intermediate-term gradient reduction included age and weight at valvuloplasty, left ventricular systolic pressure before valvuloplasty, annulus diameter, previous surgical valvotomy, follow-up interval, and balloon number. The degree of gradient reduction differed acutely between the patients undergoing single- versus double-balloon valvuloplasty as previously reported\(^\text{17}\); however, this difference did not persist at intermediate-term follow-up. In this series, the incidence of valvuloplasty-induced aortic insufficiency did not relate to the balloon/annulus ratio. Aortic insufficiency increased in four of 17 children in whom the effective balloon/annulus ratio was 1.0 or less and in three of 10 children in whom the balloon/annulus ratio exceeded 1.0 (Fisher exact, \( p=1.00 \)).

**Complications**

The major complications associated with PBAV included the development of moderate-to-severe aortic insufficiency in two patients and femoral artery injury in four patients. There were no deaths and no cerebrovascular embolic complications in this series. Both patients who developed moderate-to-severe (3–4+) aortic insufficiency had aortic annulus diameters that were normal for body surface area. A single-balloon technique was used in the first patient (Table 1, patient 15) with a balloon/annulus ratio of 0.90, whereas a double-balloon technique with an effective balloon/annulus ratio of 0.92 was used in the second patient (Table 1, patient 12). Neither patient required surgical intervention or had a change in heart size on chest roentgenogram, but one experienced a subjective decrease in exercise tolerance. In each patient, the follow-up catheterization (1.5 and 3.2 years after valvuloplasty) documented a stable left ventricular diastolic volume and a normal left ventricular ejection fraction.

Femoral artery injury, either occlusion or stenosis, was observed at follow-up in four of 27 patients. This
this study were obtained using consistent methods over a follow-up interval of almost 2 years. At each study, the peak AS gradient was measured directly from simultaneous left ventricular and aortic pressure tracings, cardiac output was measured by thermodilution technique, and aortic insufficiency was quantified angiographically.

Several previous reports of balloon valvuloplasty in children with AS have included short or intermediate-term follow-up data on some patients.1-5,19,20 As follow-up studies, however, these reports are incomplete because they have presented late hemodynamic data in only a minority of their patients. Vogel and colleagues, for example, provided intermediate-term hemodynamic data on nine of 25 children after PBAV.19 In these children the Doppler-estimated AS gradient was 41 mm Hg immediately after valvuloplasty and 30 mm Hg an average of 9 months later, suggesting no early restenosis in the group sampled. Other studies have used inconsistent methods of gradient assessment, making it difficult to determine the true degree of restenosis that may have occurred. The report by Shaddy, presenting data in 17 of 32 patients with congenital AS, suggested that early restenosis may have occurred.20 The catheter-measured peak systolic AS gradient decreased acutely by 70% after valvuloplasty, but follow-up Doppler studies later documented a gradient reduction of only 40%. Direct comparison of catheter peak-to-peak and Doppler peak instantaneous gradients to assess late effectiveness may be misleading, however, since the two gradients may differ substantially in patients with aortic stenosis.21,22 The present study employs only serial catheter-determined peak AS gradients.

The degree of intermediate-term gradient relief documented in the current study closely resembles that previously reported after surgical valvotomy,23-27 In the “Natural History Study”22 and the follow-up study of Jones and coworkers,24 a combined total of 60 children were systematically reevaluated 1-2 years after surgical aortic valvotomy. At cardiac catheterization the residual peak systolic AS gradient averaged 28 mm Hg. Twenty-five of the 34 patients reevaluated by Jones had aortic insufficiency, with moderate-to-severe insufficiency described in 15 of these 34 patients (44%). Comparison of these published data with those of the current follow-up study indicates that the intermediate-term gradient reduction and risk of aortic insufficiency after balloon valvuloplasty are similar to those of surgical valvotomy. With PBAV, however, the inherent risks of anesthesia, thoracotomy, and cardiopulmonary bypass are eliminated.

The major complications in this series were the development of moderate-to-severe aortic insufficiency and femoral artery injury. Moderate-to-severe aortic insufficiency (3-4+) developed in only two of 27 patients (Table 1, patients 12 and 15). In these two patients the effective balloon/annulus ratio was 0.90 and 0.92. The data in our study did not reveal a relation between the balloon/annulus ratio and the development of new aortic insufficiency after valvuloplasty. However, in the larger registry study,28 which evaluated the acute effectiveness of PBAV in 204 children with congenital AS, aortic insufficiency was found to develop more commonly when the balloon/annulus ratio exceeded 1.0. This difference in findings may be attributable to the smaller sample size of the current study. Other factors, in addition to balloon/annulus ratio, may contribute to the risk of new aortic insufficiency after balloon valvuloplasty. Sholler and associates29 have postulated that valve morphology, specifically commissural development and leaflet thickness, influence the occurrence of valvuloplasty-induced aortic insufficiency. These variables, however, were not evaluated in the current study and warrant further investigation.

Femoral artery injury was noted more commonly in children under 12 months of age at valvuloplasty (incidence, 60%; 90% confidence intervals, 27-86%). The infant population is at a higher risk of arterial injury because the ratio of catheter diameter to vessel lumen is large. During the study period, PBAV was attempted in two additional infants but could not be performed because of lack of suitable arterial access for the large valvuloplasty catheters used at that time. The development of smaller catheters may reduce the incidence of femoral artery injury in infants undergoing valvuloplasty in the future. Further studies using quantitative methods to evaluate femoral artery injury after valvuloplasty are necessary, particularly in infants undergoing valvuloplasty within the first year of life.

Conclusions and Recommendations

Balloon valvuloplasty provides effective intermediate-term gradient reduction in children and adolescents with congenital valvar AS. This is in marked contrast with the high incidence of early restenosis after valvuloplasty in adults with acquired calcific AS. The current study has shown that gradient reduction persists at an average follow-up of 1.7 years, without significant restenosis and without severe aortic insufficiency in the majority of children. Furthermore, the residual AS gradient and the risk of aortic insufficiency after PBAV appear remarkably similar to that described after surgical valvotomy. Since PBAV does not require general anesthesia, thoracotomy, or cardiopulmonary bypass and is associated with a shorter hospital stay compared with surgery, it should replace surgical valvotomy as the treatment of choice for children and adolescents with congenital valvar AS.

Acknowledgments

The authors wish to thank Kim Le Veque for invaluable aid in the preparation of the manuscript and Cathy Brown, RN, for assistance in coordinating patient administrative matters.

References


KEY WORDS • aortic stenosis • congenital heart disease • balloon valvuloplasty • children
B K O'Connor, R H Beekman, A P Rocchini and A Rosenthal

Circulation. 1991;84:732-738
doi: 10.1161/01.CIR.84.2.732

Circulation is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
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Print ISSN: 0009-7322. Online ISSN: 1524-4539

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://circ.ahajournals.org/content/84/2/732

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