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Gradient Reduction, Aortic Valve Regurgitation and Prolapse After Balloon Aortic Valvuloplasty in 32 Consecutive Patients With Congenital Aortic Stenosis

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From 1986 to 1988, balloon aortic valvuloplasty was performed in 32 patients with congenital valvular aortic stenosis. The patients ranged in age from 2 days to 28 years (mean ± SD 8.3 ± 5.9). One balloon was used in 17 patients and two balloons were used in 15 patients. Immediately after valvuloplasty, peak systolic pressure gradient across the aortic valve decreased significantly from 77 ± 27 to 23 ± 16 mm Hg ($p < 0.01$), a 70% reduction in gradient. At early follow-up study (4.1 ± 3.3 months after valvuloplasty), there was a 48 ± 20.5% reduction in gradient compared with that before valvuloplasty, and at late follow-up evaluation (19.2 ± 5.6 months), a reduction in gradient of 40 ± 29% persisted.

Echocardiography showed evidence of significantly increased aortic regurgitation in 10 patients (31%) and aortic valve prolapse in 7 patients (22%). There was no correlation between the balloon/anulus ratio and the subsequent development of aortic regurgitation or prolapse. In fact, no patient who showed a significant increase in aortic regurgitation had had a balloon/anulus ratio >100%.

It is concluded that balloon aortic valvuloplasty effectively reduces peak systolic pressure gradient across the aortic valve in patients with congenital aortic stenosis. However, subsequent aortic regurgitation and prolapse occur in a significant number of patients, even if appropriate technique and a balloon size no greater than that of the aortic anulus are used.

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Balloon aortic valvuloplasty is an increasingly popular method of treating congenital valvular aortic stenosis in infants and children with native and postsurgical stenosis (1–4). Complications from balloon aortic valvuloplasty include bleeding, arrhythmias, decreased femoral pulses, injury to the mitral valve, aortic regurgitation and death (1,2). In this study we reviewed our experience with the efficacy and complications of balloon aortic valvuloplasty in 32 consecutive patients with congenital aortic stenosis.

Methods

Study patients. From March 1986 to December 1988, we performed balloon aortic valvuloplasty in 32 patients with congenital valvular aortic stenosis. All patients had discrete stenosis with a peak systolic pressure gradient across the aortic valve ≥50 mm Hg as determined by direct measurement during cardiac catheterization, the absence of other associated cardiac anomalies except coarctation of the aorta and the absence of aortic regurgitation greater than grade 2 of 4 (0 to 4) grades. In all patients >1 year of age, the known potential risks and benefits of managing the aortic stenosis with either balloon aortic valvuloplasty or surgery were explained to the family, and the option of performing valvuloplasty instead of surgery was offered. The parents of all patients (n = 28) who met this criterion requested balloon aortic valvuloplasty. In addition, the parents of four patients <1 year of age with good left ventricular function and an adequate-sized aortic valve anulus were offered balloon aortic valvuloplasty and chose this form of treatment.

The 32 patients forming the study group ranged in age from 2 days to 28 years (mean ± SD 8.33 ± 5.9). Four patients were <1 year of age at the time of balloon aortic valvuloplasty and one was >16 years of age. Three patients had coarctation of the aorta; in one it had been surgically corrected during infancy, in one it was balloon-dilated at the time of balloon aortic valvuloplasty and in one it was

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considered to be so mild as not to require treatment. Six patients had undergone previous surgical aortic valvotomy.

Echocardiography. All patients had complete echocardiographic examination 1.5 ± 1.8 months before balloon aortic valvuloplasty, and the degree of aortic stenosis was estimated by pulsed and continuous wave Doppler ultrasound. The degree of aortic regurgitation was also determined by pulsed wave ultrasound and was graded on a scale of 0 to 4 (5). The echocardiographic presence of aortic valve prolapse was determined from the long-axis view as previously described by Mardelli et al. (6). We defined mild prolapse as occurring when aortic valve leaflet tissue was imaged inferior to the aortic valve ring toward the left ventricular outflow tract without displacement of the coaptation point of the valve. Severe prolapse was defined as occurring when the coaptation point of the valve leaflet was markedly displaced inferiorly into the left ventricular outflow tract. Moderate prolapse was defined as being between mild and severe.

Valvuloplasty technique. Cardiac catheterization was performed by standard techniques. Patients were sedated and given local anesthesia. The femoral artery and vein were entered percutaneously and heparin was administered intravenously (100 U/kg body weight). Care was taken to try to enter the femoral artery atraumatically through the anterior arterial wall. Complete right and left heart catheterization was performed, and peak systolic pressure gradient across the aortic valve was determined by withdrawal measurement using a pigtail catheter. Cineangiography was performed in the left ventricle, and the aortic valve anulus diameter was measured at the hinge points of the aortic valve leaflets. Calibration blocks were included at the isocenter of the anteroposterior and lateral imaging tubes for standardization of anulus measurement. A wire was then placed through the pigtail catheter, curled in the apex of the left ventricle and the pigtail catheter removed.

One or two balloon catheters with an estimated balloon size of 80% to 100% of the aortic valve anulus were then advanced along the wires and positioned across the aortic valve. The effective dilation diameter for two balloons was determined as previously described by Yeager (7). The balloons were then inflated by hand until the waist on the balloon or balloons caused by the stenotic aortic valve disappeared or maximal inflation pressure was attained (4 to 6 atm). A larger balloon size was used if the initial balloon size did not reduce the gradient across the valve to <30 mm Hg. Balloon inflations were repeated two to four times, with minor variations in the position of the balloon catheters to insure centering in the aortic anulus. After dilation, repeat pressure measurements were made with a pigtail catheter and all catheters were removed. The patients were then admitted to the hospital and monitored for complications, including decreased pulse or bleeding.

Follow-up. Early follow-up evaluation consisting of complete physical examination and echocardiography was performed at 4.1 ± 3.3 months (range 1 to 11) after balloon aortic valvuloplasty in 30 patients. Late follow-up study was performed at 19.2 ± 5.6 months (range 12 to 27) in 17 patients.

Data analysis. Values obtained before and after balloon aortic valvuloplasty were compared using a paired Student's *t* test. Differences between groups (for example, one balloon versus two balloons) were compared using an unpaired Student's *t* test or chi-square analysis. All data are expressed as mean values ± SD.

Results

Gradient reduction. The precatheterization Doppler-measured peak systolic pressure gradient across the aortic valve was 72 ± 18 mm Hg. There was no significant difference between the Doppler echocardiographic gradients and the peak systolic pressure gradients across the aortic valve measured directly at the time of cardiac catheterization (77 ± 27 mm Hg). Immediately after balloon aortic valvuloplasty, peak systolic pressure gradient across the aortic valve decreased significantly from 77 ± 27 to 23 ± 16 mm Hg ($p < 0.01$), a 70% reduction in gradient (Fig. 1). One balloon was used in 17 patients and two balloons were used in 15 patients. The mean balloon/anulus ratio was 100 ± 13% (range 80% to 147%). There was no correlation between the balloon/anulus ratio and the immediate reduction in gradient after balloon aortic valvuloplasty (Fig. 2). In 11 patients, because initial balloon aortic valvuloplasty did not reduce the peak systolic pressure gradient to <30 mm Hg, a larger balloon (or balloons) was used. The gradient was reduced to <30 mm Hg in 9 (82%) of these patients. Not surprisingly, the balloon/anulus ratio in these 11 patients was greater (110 ± 14%) than that in patients in whom only the initial balloon size was used (95 ± 9%) ($p < 0.001$).

At early follow-up evaluation, the Doppler gradient across the aortic valve was increased from the directly measured gradient immediately after balloon aortic valvuloplasty to 36 ± 12 mm Hg ($p < 0.01$) (Fig. 1). However, this represented a reduction in gradient of 48 ± 20.5% compared with the value before balloon aortic valvuloplasty. At late follow-up evaluation, echocardiograms showed no significant change in the peak systolic pressure gradient (43.5 ± 19 mm Hg) or in the reduction in gradient (40 ± 29%) compared with early follow-up echocardiograms (Fig. 1). Peak systolic pressure gradient was ≤50 mm Hg in 31 (97%) of the 32 patients immediately after balloon aortic valvuloplasty and persisted at ≤50 mm Hg in 27 (90%) of 30 patients at early and 10 (59%) of 17 patients at late follow-up evaluation. However, peak systolic pressure gradient was ≤30 mm Hg in 26 (81%) of the 32 patients immediately after balloon aortic valvuloplasty but persisted at ≤30 mm Hg in only 11

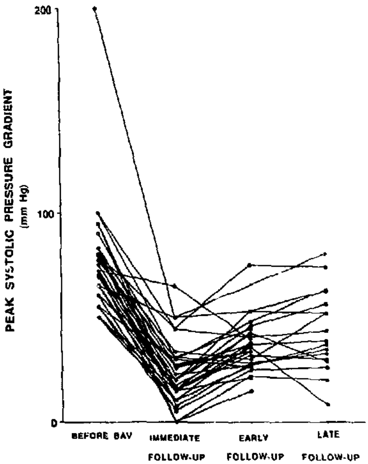

Figure 1. Peak systolic pressure gradient (mm Hg) across the aortic valve in 32 consecutive patients with congenital aortic stenosis before and immediately after balloon aortic valvuloplasty (BAV) and at early (4.1 ± 3.3 months) and late (19.2 ± 5.6 months) follow-up study.

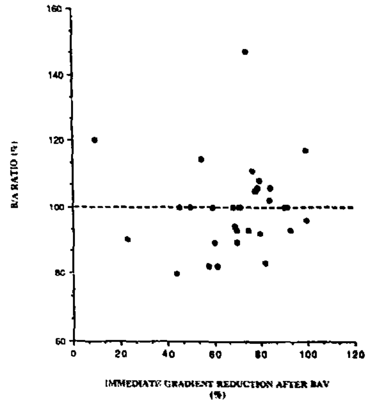

Figure 2. Relation of balloon/anulus (B/A) ratio (%) to immediate gradient reduction (%) after balloon aortic valvuloplasty (BAV).

(37%) of 30 patients at early and 5 (29%) of 17 at late follow-up study.

Aortic regurgitation and prolapse. At early follow-up study, echocardiographically determined aortic regurgitation had increased significantly (≥2 grades) in four patients. At late follow-up evaluation, 6 more patients had shown progression of aortic regurgitation, so that a total of 10 patients (31%) had a significantly increased degree of aortic regurgitation since balloon aortic valvuloplasty at late follow-up study. This incidence of patients with significantly increased aortic regurgitation (≥2 grades) was not significantly different whether balloon aortic valvuloplasty was performed with only the initial balloon or balloons (8 of 21 patients) or repeated with a larger balloon or balloons (2 of 11 patients). There was no correlation between the balloon/anulus ratio and the subsequent development of an increase in aortic regurgitation or aortic valve prolapse (Fig. 3). In fact, in no patient who showed a significant increase in aortic regurgitation was a balloon/anulus ratio >100% used. No patient has yet required surgical aortic valve replacement.

A total of seven patients (age 1.3 to 10.8 years at time of balloon aortic valvuloplasty) showed aortic valve prolapse on follow-up echocardiography (three mild, two moderate and two severe) (Fig. 4). Of these seven patients, four underwent balloon aortic valvuloplasty with two balloons and three with one balloon. The three patients with mild prolapse showed an increase in the degree of aortic regurgitation of grade 1, 2 and 4, respectively. The four patients with moderate and severe prolapse showed increases in aortic regurgitation of grade 2 (two patients) and 3 (two patients), respectively (Fig. 4). There were no significant differences between those patients who did and those who did not develop aortic regurgitation or prolapse after balloon aortic valvuloplasty with regard to age, weight, balloon/anulus ratio, previous surgery, prevalvuloplasty pressure gradient or preexisting aortic regurgitation. Therefore, on the basis of this study, we are unable to predict which patients are more likely to develop these complications.

Complications. Two patients had significant bleeding from the catheterization site after returning from the cardiac catheterization laboratory, and one required a blood transfusion for this reason. Five patients had a decreased femoral pulse at 24 h after balloon aortic valvuloplasty despite heparin therapy in three patients and urokinase therapy in one patient. Four of these five patients were <15 months of age and weighed <10 kg. Two patients (6%) continued to have a decreased femoral pulse at late follow-up study, and both of these patients were <1 year of age at the time of balloon aortic valvuloplasty.

One versus two balloon technique. When comparing results between patients in whom one balloon and two bal-

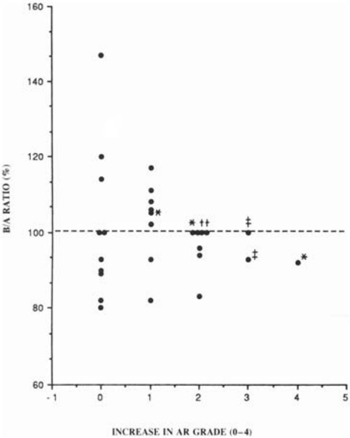

Figure 3. Relation of balloon/anulus (B/A) ratio (%) to degree of increase in grade of aortic regurgitation (AR) (grade 0 to 4) in patients after balloon aortic valvuloplasty. Patients with aortic valve prolapse are denoted as follows: *mild; †moderate; ‡severe.

loons were used, there were no significant differences between the age of patients or initial peak systolic pressure gradient across the aortic valve before balloon aortic valvuloplasty (Table 1). The balloon/anulus ratio was also similar between the two groups: (98 ± 11% versus 102 ± 16%). Immediately after balloon aortic valvuloplasty, the two groups were similar with regard to residual gradient, although the percent gradient reduction was significantly greater with the two balloon technique ($p < 0.05$). However, at early and late follow-up study, there were no significant differences between the two groups with regard to peak systolic pressure gradient, percent reduction in gradient or degree of aortic regurgitation. Similarly, there were no significant differences in gradient reduction, aortic regurgitation or prolapse between those patients with or without previous surgical aortic valvotomy.

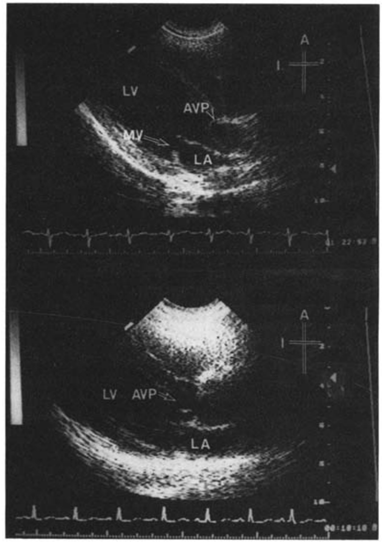

Figure 4. Echocardiographic parasternal long-axis view of the left ventricle in a patient with mild aortic valve prolapse (AVP) **(top)** and a patient with severe aortic valve prolapse **(bottom)** after balloon aortic valvuloplasty. A = anterior; I = inferior; LA = left atrium; LV = left ventricle; MV = mitral valve.

Discussion

Gradient reduction. Our results show that balloon aortic valvuloplasty immediately and effectively relieves aortic valve stenosis in patients with moderate to severe congenital valvular stenosis. The reduction in gradient in our patients was comparable to or greater than that in previously reported data (1–3). Furthermore, there was a continued significant reduction in gradient at both early and late follow-up study, indicating the continued long-term benefits from this procedure. The increase in gradient across the aortic valve from the period immediately after balloon aortic valvuloplasty to early follow-up evaluation may partially reflect different measurement techniques. Because there was no significant difference between peak systolic pressure gradient derived from Doppler ultrasound and direct catheterization measurement, we elected to use the catheterization measurement as our initial gradient for comparison. However, there are inherent problems in comparing immediate reduction in gradient with the patient sedated in the catheterization laboratory and follow-up Doppler-derived gradients with the patient awake in the echocardiographic laboratory. It is thus possible that the differences between these two measurements are overestimated and not truly representative of changes in the degree of aortic valve stenosis. However, the continued reduction in gradient of

Table 1. Summary of Results of Balloon Aortic Valvuloplasty in 32 Patients

		Before BAV	Immediate Follow-Up		Early Follow-Up		Late Follow-Up	
	Age (yr)	Pressure Gradient (mm Hg)	Pressure Gradient (mm Hg)	Gradient Reduction (%)	Pressure Gradient (mm Hg)	Gradient Reduction (%)	Pressure Gradient (mm Hg)	Gradient Reduction (%)
One balloon (n = 17)	7.3 ± 3.6	73 ± 15	27 ± 17	63 ± 23	41 ± 16	42 ± 23	41 ± 19	42 ± 30
Two balloons (n = 15)	9.4 ± 7.1	81 ± 36	18 ± 13	77 ± 13*	33.5 ± 10	50 ± 22	46 ± 20	38 ± 29

*$p < 0.05$ when compared with one balloon technique. BAV = balloon aortic valvuloplasty.

40% at long-term follow-up study is encouraging for good long-term results of this method.

Aortic regurgitation. The most concerning complications that we saw in our patients were the increase in aortic regurgitation and the development of aortic valve prolapse. The 31% incidence rate of a significant increase in aortic regurgitation after balloon aortic valvuloplasty in our patients is comparable with previously described incidence rates of 15% to 33% (1–3,8). Although others (1,9) have found a correlation between the use of a balloon/anulus ratio >100% and the development of significant aortic regurgitation, we found no such correlation. In fact, although we used balloon/anulus ratios >100% in 10 patients, none of these patients developed a significant increase in aortic regurgitation (Fig. 3), but 1 did have mild aortic valve prolapse by echocardiography (balloon/anulus ratio 106%). Thus, the significant increases in aortic regurgitation occurred in patients in whom the balloon/anulus ratio was ≤100%. This shows that a significant increase in aortic regurgitation can occur after balloon aortic valvuloplasty even if balloons no larger than the aortic valve anulus are used.

All patients at our institution during the period of this study who were >1 year of age with significant aortic stenosis underwent balloon aortic valvuloplasty. Therefore, we have no surgical group during this time with which to compare the efficacy and complications of balloon aortic valvuloplasty versus surgical valvotomy. However, aortic regurgitation is not an infrequent complication after surgical aortic valvotomy, as evidenced by the fact that aortic regurgitation is the indication for reoperation after surgical valvotomy in 30% to 36% of patients who require reoperation (8).

Aortic valve prolapse. We found a 22% incidence of aortic valve prolapse after percutaneous balloon aortic valvuloplasty. Although previously described (10) in adolescents and young adults after balloon aortic valvuloplasty, this complication has been rarely reported. We do not believe that this complication is attributable to variations in technique because the sizes and types of balloons that we used are comparable with those described in other reports. Pathologically, aortic valve prolapse occurs in association with a ruptured valve cusp and loss of commissural support. Aortic valve prolapse has also been described (11) in the presence of intact cusps associated with "floppy valve syndrome," fraying of the cusp, bicuspid aortic valve and mitral valve prolapse. Partial and complete detachment of the right coronary cusp from the aortic ring was reported (12) in two infants with critical aortic stenosis who had intraoperative balloon dilation of a dysplastic aortic valve. These infants died, presumably from severe aortic regurgitation secondary to valve detachment. After balloon aortic valvuloplasty, the development of aortic valve prolapse is probably secondary to tearing of the valve cusp itself or the valve raphe or, possibly, partial detachment of the valve from the valve ring. This kind of tear may then undermine the support mechanism of the valve and, thus, cause prolapse of the valve during diastole.

Although the natural history of aortic valve prolapse is unknown, two of our patients with prolapse have shown significant progression of aortic regurgitation over time and will probably require aortic valve replacement at some point. In our study, the three patients with the greatest increase in the degree of aortic regurgitation all showed some degree of prolapse (one mild, two severe). Thus, it is possible that the presence of aortic valve prolapse after balloon aortic valvuloplasty is predictive of more rapid progression of aortic regurgitation and the subsequent need for therapy.

One versus two balloon technique. There was a significantly greater immediate reduction in gradient when two balloons rather than one balloon were used. This finding is similar to the results of Beekman et al. (2), who compared single versus double balloon techniques for balloon aortic valvuloplasty. However, this difference was not present in our patients at early or late follow-up study, suggesting that this potential benefit is short lived. Also, because the use of one or two balloons was arbitrarily decided and not randomly assigned, the importance of this finding is questionable. The minor complications of bleeding and temporary decrease in femoral pulse occurred infrequently. In two patients, there was a long-term decrease in femoral pulse. Our finding of an increased incidence of decreased femoral pulse after balloon aortic valvuloplasty in patients <2 years of age is comparable to that in previous studies (1,9). Although the patients are asymptomatic at this time, the long-term impact of this problem is not known.

Conclusions. Balloon aortic valvuloplasty effectively reduces peak systolic pressure gradient across the aortic valve in a group of patients with congenital valvular aortic stenosis. Furthermore, aortic regurgitation occurs in approximately 33% of these patients and may ultimately require surgery in some. Aortic valve prolapse also occurs in a significant number of these patients. Those patients who develop aortic regurgitation or aortic valve prolapse cannot be identified by valvuloplasty technique, the presence of aortic regurgitation before the procedure or the preexisting gradient. Retrospectively, these results appear similar to results from surgery and can be obtained at a decreased overall cost and risk. In this study, data are lacking for an accurate comparison with surgery and as to whether there are certain anatomic substrates that have better results with balloon aortic valvuloplasty or with surgery. Until these data are available, we continue to recommend balloon aortic valvuloplasty as initial therapy in the treatment of congenital aortic valve stenosis in pediatric patients, outside of infancy, who require treatment. The use of balloon aortic valvuloplasty in infants and small children should be individualized.

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