Balloon Dilation of the Aortic Valve: Studies in Normal Lambs and in Children With Aortic Stenosis

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To evaluate the risks of and optimal method for valve dilation in aortic stenosis, balloons of different sizes were used to dilate the normal aortic root in 16 lambs and then stenotic valves in 15 children. In the lambs, inflated balloon to aortic anulus diameter ratios ranged from 0.9 to 1.5. These hearts were examined immediately after the procedure. Ratios of 0.9 to 1.1 did not produce significant damage to the left ventricular outflow tract, whereas those of 1.2 to 1.5 produced tears or hematomas, or both, of the aortic valve leaflets (n = 3), mitral valve leaflets (n = 4) and interventricular septum (n = 4).

The 15 patients, aged 10 days to 15 years, underwent 16 balloon aortic valvotomy procedures. The balloon-aortic anulus ratio ranged from 0.67 to 1.1 (mean 0.90). The average pressure gradient decreased 69% and, overall, the peak systolic gradient decreased from 86 ± 21 to 28 ± 14 mm Hg (p < 0.01) and the aortic valve area increased from 0.44 ± 0.11 to 0.73 ± 0.22 cm²/m² (p < 0.01). Immediately after the procedure an increase in aortic regurgitation was noted in 8 (57%) of 14 patients, but was never >3+ and has been well tolerated. Other early complications encountered consisted of transient left bundle branch block in two patients, temporary femoral artery occlusion in three and femoral artery rupture requiring operative management in one infant.

Balloon valvotomy can reduce the transvalvular gradient in most patients with valvular aortic stenosis when a balloon less than 1.1 times the aortic root diameter is used. Although an increase in aortic regurgitation occurs in most, it appears well tolerated over short-term follow-up.

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Since the initial description of static balloon dilation of valvular pulmonary stenosis by Kan et al. (1), use of this technique has increased substantially. In addition to its application in this lesion, it has been utilized with some success in the management of other valvular obstructive lesions such as aortic and mitral stenosis (2–7). Whereas the balloon diameter sizes used have generally been similar to or less than the valve diameter, it has been shown in experimental and clinical studies, relative to the pulmonary valve, that balloon diameters 20 to 40% larger than the anulus are both safe and more effective than those smaller (8,9).

On the other hand, in the limited clinical reports concerning valvular aortic stenosis (2–4), balloon sizes used have been less than the anular diameter. The only data currently available relative to the use of large balloons are the observations of Waller et al. (5), which describe aortic wall damage in six infants with a normal heart studied at autopsy and in one infant with valvular aortic stenosis who underwent dilation before death. The purposes of the present study were 1) to evaluate the effects of balloons of various sizes on the aortic valve and paravalvular structures of normal live newborn lambs and 2) to report on our initial experience, using this information, with balloon dilation in 15 patients with valvular aortic stenosis.

Methods

During a 1 year period ending November 1985, at The Children's Hospital, Boston, 16 normal newborn lambs and 15 patients with valvular aortic stenosis underwent balloon dilation. The experimental lamb methods and results are presented first and are followed by our clinical data. Aortic

regurgitation was assessed angiographically using the following criteria as outlined by Hunt et al. (10): Grade 1: A whiff or jet of regurgitant contrast material was seen in the outflow tract of the left ventricle, but the ventricular cavity was never outlined, and all the contrast material was cleared from the ventricle in each systole. Grade 2: Faint but progressive opacification of the ventricle occurred in each diastole. The cavity was never clearly outlined, but the contrast material persisted during systole. Grade 3: The ventricular cavity was rapidly and clearly outlined. The density of the ventricular contrast material was always less than that of the aortic contrast material. Grade 4: The ventricular cavity was rapidly and clearly outlined. The density of the left ventricular contrast material equaled that of the aortic contrast material after more than three beats. Grade 5: The ventricular cavity was rapidly and clearly outlined. The density of ventricular contrast material equaled that of the aortic contrast material within three beats.

Experimental Data

Methods

Experimental procedure. Seventeen normal infant lambs aged 2 to 12 weeks (median 4 w) and weighing 4.0 to 11.0 kg (median 6.4) were sedated with intramuscular ketamine (2 mg/kg body weight). In the first three animals, attempts to pass the deflated balloon mounted on an 8F or 9F catheter by way of a carotid artery cutdown or femoral artery puncture resulted in vessel rupture. One of these animals died before balloon dilation could be carried out. Thus, the abdominal aorta, cannulated below the level of the renal arteries through a retroperitioneal approach, was subsequently used for vascular access in the remaining 16 lambs.

Balloon valvotomy. A 6F National Institutes of Health angiocatheter was first advanced to the aortic root and a single frame lateral aortogram was recorded during injection of 1 ml/kg of contrast material over 1.5 seconds. The diameter of the aortic valve anulus was measured directly from the angiogram at the aortic valve hinge points and corrected for magnification. The valve was then crossed with a 6F pigtail catheter, a 0.035 inch (0.889 cm) Teflon-coated guide wire was introduced, and a balloon valvotomy catheter (Mansfield Scientific) was advanced over the guide wire and positioned such that it straddled the aortic valve. In three animals the balloon was not inflated in order to determine if any damage occurred with transvalvular passage of such a large catheter. In the other 13 animals, the balloon was inflated with diluted contrast material to a pressure of 3 to 6 atm for 7 to 10 seconds and then rapidly deflated. A lead II electrocardiographic rhythm strip was recorded during the procedure in 12 of the 16 animals.

The valvotomy balloons were mounted on 8F or 9F polyethylene catheters, were 3 or 4 cm in length and had an

inflated diameter that ranged from 10% smaller to 50% larger than the aortic valve anulus. A second aortogram followed dilation in 10 animals, but was unsuccessful because of technical problems in the other 6. All animals were killed electively 30 minutes to 48 hours after the procedure using a lethal dose of pentobarbital and the hearts were then examined.

Statistical analysis of the data was not carried out. These studies were performed in accordance with the animal welfare regulations at The Children's Hospital and using the guiding principles of the American Physiological Society.

Results

Although inflation of the balloon acutely obstructed outflow, none of the lambs required or received ventilatory or hemodynamic support during the procedure. The 16 animals were divided into three groups.

Group 1 (n = 3). In these three lambs the balloon was not inflated, and the only electrocardiographic abnormality noted was transient brief ventricular tachycardia during catheter placement in one. The postdilation angiogram revealed 2+ aortic regurgitation in one. Pathologic examination was negative except for superficial scraping of the endocardium.

Group 2 (n = 6). In these six lambs the inflated balloon diameter was 0.9 to 1.1 times the measured aortic anulus size. During electrocardiographic monitoring in five of the six, sinus bradycardia occurred in one lamb, which progressed to second degree heart block and was followed by death within 30 minutes due to left ventricular performation (by the wire) and pericardial tamponade. Transient ST segment elevation occurred in two lambs immediately after the dilation, but resolved within 5 minutes in each. The postdilation aortogram (performed in three of the six animals) revealed no aortic regurgitation in two and 1+ regurgitation in the other.

Pathologic examination revealed no significant damage to the outflow tract in any lamb other than superficial endocardial scraping. The aortic valve leaflets and the coronary ostia were normal.

Group 3 (n = 7). In these seven lambs the inflated balloon diameter was 1.2 to 1.5 times the size of the aortic valve anulus. Electrocardiographic monitoring in six of the seven identified short runs of ventricular tachycardia in four during either wire placement or dilation. In five animals ST-T changes occurred during and immediately after the dilation and persisted in two until they were killed 45 to 60 minutes later. On aortography (in four of seven) after the procedure, aortic regurgitation was 4+ in two, 3+ in one and 2+ in the other.

Pathologic examination of the hearts demonstrated substantial damage in five of the seven lambs (Table 1). In the lamb in which the largest balloon was used (1.5 times the aortic anulus), persistent sinus bradycardia occurred, 4+

aortic regurgitation was evident angiographically and at postmortem a large transmural tear in the ascending aorta with dissection of blood into the vascular pedicle together with tears in the left coronary cusp and interventricular septum were present. Injuries among the other animals included interventicular septal tears in three (extensive in one), and torn aortic valve leaflets in two. The degree of cardiac trauma associated with the procedure appeared to be related to the size of the balloon.

Clinical Data

Methods

Patients. Balloon valvotomy was attempted in 15 consecutive patients aged 10 days to 15 years (mean 8.8 ± 5.2 years) with valvular aortic stenosis. All patients had a peak systolic gradient of ≥50 mm Hg and none had fluoroscopic evidence of valve calcification. Aortic regurgitation was present before dilation in seven patients (1 + in six and 2 + in the other). The valvotomy procedure was undertaken after informed consent had been obtained; the clinical protocol was approved by the Committee on Clinical Investigation of The Children's Hospital.

Cardiac catheterization. Right and left heart catheterization was performed in all and included cardiac output determination when possible (12 patients). In the older children, peak systolic gradient (having corrected for standing wave effects) was recorded using a pigtail catheter in the ventricle introduced by way of a percutaneously placed right femoral artery sheath one French size larger than the catheter. All three infants had critical aortic stenosis; two of

them required intubation and inotropic support before and during the catheterization. In one of the latter, 10 days old, the arterial study was accomplished through an umbilical artery using a 4F pigtail catheter. In the other two infants, aged 6 weeks and 4 months, respectively, a 4F pigtail catheter was percutaneously inserted without a sheath into the right femoral artery. Biplane cineangiograms of the left ventricle and aortic root were recorded before dilation to allow measurement of the aortic valve anulus from the lateral projection (Fig. 1) and to evaluate the degree of aortic regurgitation.

Balloon valvotomy. The arterial sheath and pigtail catheter were then removed from the right femoral artery, leaving an exchange wire positioned across the aortic valve. A balloon valvotomy catheter was advanced over the wire and positioned across the left ventricular outflow tract. In the older children the balloon size (8 to 25 mm inflated diameter, mounted on an 8F or 9F shaft) was between 0.85 to 1.1 times the size of the aortic anulus (mean 0.90 ± 0.11) (Table 2). Among the infants, because it was considered that these 8F or 9F catheters would be too large, 4, 5 or 6 mm balloons mounted on a 4.5F shaft were utilized, the 5 mm balloon being passed by way of the umbilical artery in one (Case 11). In the three infants the balloon/anulus ratio was 0.67, 0.75 and 0.75, respectively, in each instance smaller than in the older patients. Once positioned, the balloon was inflated four to six times (until we were certain that the balloon straddled the valve during peak inflation) to pressures of 4 to 7 atm until the waist disappeared. It was then deflated rapidly and withdrawn to the descending aorta. Each inflation-deflation period lasted at most 15 seconds. Although the inflation pressure exceeded, by 2 atm

Table 1. Summary of Findings in the Seven Lambs in Group 3 (inflated balloon diameter 1.2 to 1.5 times aortic anulus size)

	Lamb No.						
	1	3	4	11	5	7	10
Balloon size (mm)	15	15	15	20	20	20	25
Balloon-aortic anulus ratio	1.2	1.2	1.3	1.3	1.4	1.4	1.5
Aortic valve leaflets	Normal	Normal	NCC tear	Normal	RCC tear	Normal	LCC tear
Mitral valve leaflets	Normal	Normal	AL hemorrhage	AL hemorrhage	AL hemorrhage	Normal	AL hemorrhage
Interventricular septal tear	Hemorrhage and 2 mm tear underneath aortic cusp	Normal	Hemorrhage and 2 mm tear underneath aortic cusp	12 mm lacerations on LV side, nearly transmural		Normal	2 mm tear on LV side
Ascending aorta	Normal	Normal	Normal	Normal	Normal	Hematoma on underside of aortic arch	Large tear and dissection
Aortic regurgitation	Not known	None	Not known	3 +	Not known	4 +	4 +

AL = anterior leaflet; LCC = left coronary cusp; LV = left ventricular; NCC = noncoronary cusp; RCC = right coronary cusp.
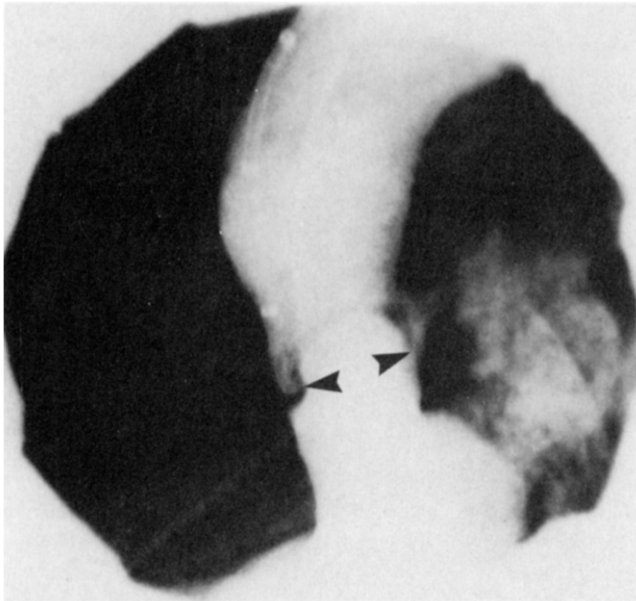
Figure 1. Hinge points (**arrows**) of aortic valve leaflets (long axial oblique projection) at the level at which anular diameter is measured.

at most, the manufacturer's recommended values (6.1 atm for the 4 mm to 2.7 atm for the 25 mm balloon), rupture of the balloon did not occur in any patient. In all but one patient (Case 4) the balloon dilation catheter was removed and a pigtail catheter was advanced over the wire to record the transvalvular gradient and for aortography. In the last four children we also used a second pigtail catheter from

the left femoral artery for pressure monitoring during dilation and for postdilation hemodynamic measurements and angiography. The aortic valve area was calculated when possible using the Gorlin formula (11). After the postdilation aortogram the catheters were removed and hemostasis was achieved. The first six patients were transported initially to the intensive care unit and subsequent patients were returned to the regular ward.

The Student t test was used to compare pressure gradients and valve area measurements before and after the valvotomy procedure.

Results

Peak systolic gradient and valve area measurements.
Pre- and postdilation gradient measurements were available in 14 of the 15 patients. Two pairs of observations were obtained in an infant whose valve was dilated on two separate occasions, such that a total of 15 sets of measurements were recorded (Table 2). The predilation peak systolic ejection gradient ranged from 58 to 130 mm Hg (mean 86 ± 21) and the balloon diameter to aortic anulus diameter ratio from 0.67 to 1.11 (mean 0.90 ± 0.12). The balloon diameters ranged from 4 mm in the infants (2 cm in length) to 25 mm in the oldest patient. After infancy, balloon lengths of 4 cm were used when available rather than those 3 cm in length. Pressures of 4 to 7 atm were required to fully inflate the balloon and to eliminate the waist (achieved in all), formed in the balloon by the narrow orifice of the aortic valve. It was quite striking that in the older children (that

Table 2. Summary of Findings in 15 Patients

Patient No.	Age (yr)	Balloon-Aortic Ratio	LVEF	Peak Systolic Gradient (mm Hg)				Aortic Regurgitation			Valve Area (cm²/m²)	
				Pre	Post	% Change	Late	Pre	Post	Late	Pre	Post
1 +	10.9	1.0	0.74	110	50	61	50	1 +	2 +	1 +	0.37	0.57
2	6.3	1.1	0.55	85	5	94	5	0	2 +	2 +	0.42	—
3	14.5	0.85	—	90	30	67	35	1 +	1 +	2 +	0.25	0.45
4	0.3	0.67	—	106	—	—	—	0	—	—	—	—
5	11.6	0.85	0.70	62	7	88	44	0	0	0	0.50	0.88
6a	0.2	0.75	0.29	68	35	49	94	0	0	0	—	—
6b	0.5	1.1	0.61	94	23	76	—	0	1 +	—	0.37	0.55
7	2.2	0.86	0.82	110	35	68	39	1 +	1 +	0	0.38	0.73
8	7.9	0.90	0.72	58	10	83	3	1 +	2 +	2 +	0.52	0.77
9	11.8	1.0	0.35	130	42	68	50	1 +	3 +	2 +	0.41	0.80
10	15.0	0.83	0.74	70	35	50	50	0	1 +	1 +	0.65	0.62
11	0.03	0.75	0.30	100	40	60	40	0	1 +	1 +	—	—
12 +	13.7	0.90	0.59	60	30	50	—	2 +	2 +	—	0.47	0.51
13	11.7	0.96	0.64	98	33	66	—	0	0	—	0.30	0.70
14	9.4	0.80	0.79	75	10	86	—	1 +	3 +	—	0.58	1.30
15 +	4.3	1.0	0.72	68	29	57	—	0	0	—	0.54	0.88
Mean	7.5	0.90		86	28	68	41				0.44	0.73
± SD	±5.5	±0.12		±21	±14	±14	±25				±0.11	±0.22

a = first procedure; b = second procedure; LVEF = left ventricular angiographic ejection fraction before dilation; post = after dilation; pre = before dilation; + = postoperative patients.

is, those with the most poststenotic dilation of the ascending aorta and often the innominate artery), considerable difficulty was encountered maintaining a stable inflated balloon position in the valve orifice. Frequently the balloon was forcibly ejected into the ascending aorta and the catheter shaft would loop in the innominate artery. Relative to this observation was the finding that the angiographic left ventricular ejection fraction, when available, was only 0.29 and 0.30 respectively, in two infants at initial dilation whereas it exceeded 0.70 in 6 of 10 older patients. Overall, the balloon position appeared to be most stable when inflation was carried out using a 4 cm long balloon with the guide wire looped in the ventricle after advancement of the catheter to straddle the valve rather than advancing it into the left ventricle and then withdrawing it to straddle the valve. The peak systolic gradient after dilation was 5 to 50 mm Hg (mean 28 ± 14, p < 0.01) (Fig. 2), this representing a decrease of 49 to 94% (mean 68 ± 14%). The aortic valve area increased from 0.44 ± 0.11 to 0.73 ± 0.22 cm^2/m^2 (p < 0.01) (Fig. 3).

Postoperative patients. Three patients (aged 10.9, 13.7 and 4.3 years, respectively) had previously undergone four surgical valvotomy procedures consisting of two performed under inflow occlusion during infancy (Cases 1 and 12) and two using cardiopulmonary bypass at age 2 years (Cases 12 and 15). In Patient 1 a peak gradient of 48 mm Hg at age 4 had increased to 110 mm Hg by 10.9 years and was reduced by the dilation to 43 mm Hg (by 61%) whereas aortic regurgitation increased from 1 + to 2 +. In Patients 12 and 15, the gradient decreased from 60 and 68 to 30 and 29 mm Hg, respectively, and aortic regurgitation remained unchanged in one and absent in the other. A third patient (Case 4) underwent repair of an interrupted aortic arch and closure of a ventricular septal defect at 3 days of age, and
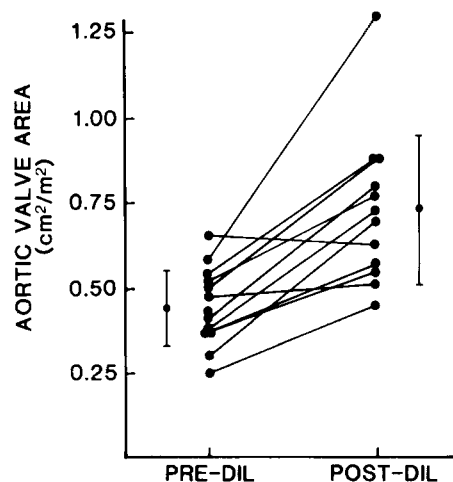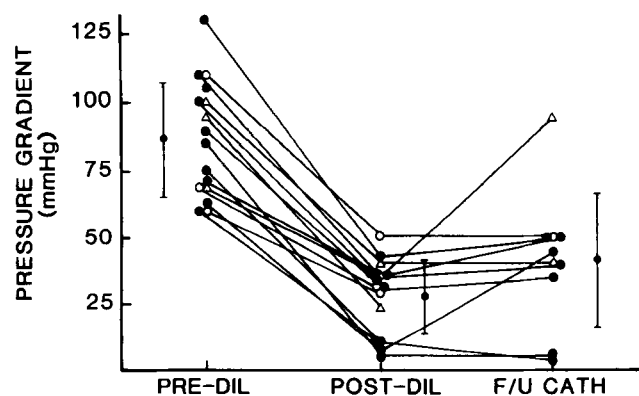
Figure 3. Changes in aortic valve areas before and after dilation (DIL) in 12 patients, together with mean ± SD.

at 4 months postoperatively (weight 4.6 kg) severe valvular aortic stenosis with a peak gradient of 106 mm Hg was identified. Associated with the aortic stenosis was marked diffuse narrowing of the ascending aorta which we thought would make cannulation for operative valvotomy difficult. We first used a 5 mm balloon, but no waist was seen during inflation. During an attempt to place a 7F sheath, to allow passage of a 6 mm balloon, which could not be introduced percutaneously, the right femoral artery ruptured. The femoral artery ends were ligated at emergency operation without subsequent difficulties; this is the patient in whom no postdilation gradient was obtained.

Complications. In addition to the femoral artery rupture noted, in two patients transient left bundle branch block developed during the procedure, resolving spontaneously within 24 hours. Femoral artery occlusion manifested by loss of pulse occurred in three patients. Pulses returned after 48 to 72 hours of therapy with heparin alone in two, and after treatment with streptokinase in the third patient. However, in one of these patients, the vessel was found to be very stenotic at catheterization 7 months later.

Before the valvotomy procedure eight patients had no aortic regurgitation, six had 1 + and one had 2 + regurgitation. Four of the eight patients without regurgitation developed 1 + to 2 + regurgitation and among the seven patients with regurgitation before the procedure, an increase was noted in four, the maximal degree being 3 +. Aortic regurgitation due to valve dilation was not obviously related to age, balloon size or previous operation. When change in aortic regurgitation was related to gradient relief, it seemed that increased aortic regurgitation was more likely with a greater degree of gradient relief (r = 0.59, p < 0.05).

Clinical course. Eleven patients were discharged within 48 hours of balloon valvotomy. The three infants required longer convalescence (5 to 10 days) although dramatic clin-

Figure 2. Peak ejection gradient before and after dilation (DIL) in 15 patients and at follow-up (F/U) catheterization in 10 patients together with mean ± SD. **Open circles** represent the three patients (Cases 1, 12 and 15) who had a previous surgical valvotomy; **triangles** represent the three pairs of observations in two infants (Cases 6 and 11).

ical improvement was seen in those two who had a successful balloon valvotomy. At the follow-up study, the femoral artery into which the balloon catheter had been previously inserted was used to measure the residual gradient in all but one patient (Case 8). Among the 10 patients recatheterized 6 weeks to 6 months after balloon valvotomy, no significant gradient increase was evident in 7, including 1 infant (Case 11). Significant increases occurred in two of the other three, from 7 to 44 mm Hg in patient 5 and from 23 to 94 mm Hg in the infant (Case 6) who underwent valve dilation at age 6 weeks. In this baby, a second dilation, using a 10 mm balloon, reduced the gradient to 23 mm Hg. Overall, the gradient was ≥35 mm in eight patients. Aortic regurgitation remained unchanged in six, was decreased in three and increased in the other.

Discussion

Balloon/anulus ratio. In valvular pulmonary stenosis, the use of balloon/anulus ratios >1 has been found to produce improved gradient reduction without apparent hazard (9). In addition, it has been shown in newborn lambs that balloons 20 to 40% larger than the pulmonary anulus do not result in extensive cardiac damage (8). In contrast, our experimental lamb data indicated that considerable damage to the normal aortic valve or paravalvular structures occurred frequently when balloon/anulus ratios of ≥120% were used. Furthermore, in the report of Waller et al. (5) an extensive transverse aortic arch wall tear was identified in a newborn infant with aortic stenosis after rupture of a balloon of similar diameter as the aorta. In addition, among six normal infant hearts studied at autopsy, aortic wall tears occurred in two after rupture of balloons of similar size and in another two after dilation without rupture using larger diameter balloons. On the basis of these data, it seems reasonable to suggest that use of balloon/anulus ratios of ≥120% or more in valvular aortic stenosis is dangerous, especially if balloon rupture occurs.

Surgical results. The standard treatment of severe valvular aortic stenosis in children is surgical valvotomy under direct vision using cardiopulmonary bypass. It is clear that this approach is palliative in many patients. In the recent natural history study cooperative report (12), at a mean follow-up interval of 6.5 years among 130 postoperative patients, 18% had a peak gradient of ≥80 mm Hg and 50% a gradient between 25 and 79 mm Hg. Only 32% had a gradient <25 mm Hg and overall 6% had severe aortic regurgitation. Similar results have been reported by other investigators (13–17).

Balloon dilation results. The clinical experience with balloon dilation of valvular aortic stenosis is to date quite limited, and follow-up information is limited to only months in contrast to years in relation to surgical data. In 1984,

among 23 children so treated by Lababidi et al. (2), the predilation mean gradient of 113 ± 48 mm Hg was reduced at the conclusion of the procedure to 32 ± 15 mm Hg (being <25 mm Hg in 6 [26%]) and was similar at follow-up study in 6 at 38 ± 32 mm Hg. The balloons used were at least 1 mm smaller than the valve anulus and very high inflation pressures (to 120 psi) were used with balloon rupture occurring in eight without incident. Although 45% of patients had aortic regurgitation after the procedure, this was acquired in only four (17%), being 2+ at most, and no arterial complications were noted. In a study of three infants (4), the gradient was reduced with a small 4.2 mm balloon by approximately 50% without clinical evidence of regurgitation, with femoral pulses being described as diminished in two for several days. In another study (3), a gradient of 106 mm Hg in an 8 month old infant was reduced to 40 mm Hg using a 10 mm balloon (anulus 11 mm) without inducing regurgitation. In the study by Waller et al. (5), a gradient of 70 mm Hg in a 2 day old infant was reduced to 40 mm Hg using a 5 mm balloon (similar to the aortic diameter) which ruptured and an extensive aortic arch tear was evident at autopsy.

In our own experience, the immediate gradient reduction results are similar to those reported, with 33% of patients initially having a gradient <25 mm Hg, although at follow-up the gradient exceeded this value in 8 of 10 patients. Aortic regurgitation, however, was evident after balloon valvuloplasty in 73% of our 15 patients as compared with 44% before the procedure. In most it was ≤2+ and to date has been well tolerated in all. Transient pulse loss and left bundle branch block have occurred in three and two patients, respectively, whereas femoral artery rupture and severe stenosis have occurred on one occasion each. It is of interest that satisfactory gradient reductions, without significant regurgitation, have been achieved, albeit early, in three postoperative children and in another who had a balloon valvuloplasty 6 months earlier at age 6 weeks.

Technical considerations. It seems likely that the balloons currently available for use in infants may be too small when only one is used. This may explain our finding of a 94 mm Hg peak gradient at age 6 months in the infant whose valve was initially dilated at age 6 weeks with a 5 mm balloon and an anulus of 8 mm. Attempts to use larger devices (with diameters of 8F or more) are probably dangerous in infants weighing <6 kg as evidenced by our observation of femoral artery rupture using a 7F sheath in a 4.6 kg infant. Thus it seems that use of small balloons in infants with critical aortic stenosis may produce only temporary gradient reduction but enough to allow the infant to improve dramatically. In our experience balloon position during the inflation has been stable in infants and younger children, particularly those with a decreased ejection fraction. However, in most patients over 10 years this has been difficult to maintain until the waist produced by the stenotic

valve is abolished when using 3 to 4 cm long balloons and a retrograde approach.

Conclusions. Our data indicate that in the newborn normal lamb, aortic valve dilation with balloon sizes less than 120% the size of the aortic anulus is not associated with sustained arrhythmias or damage to left ventricular outflow tract structures. In children with valvular aortic stenosis, this technique will significantly reduce the valve gradient, at least over the short term. In most patients, the degree of aortic regurgitation will increase, although severe aortic regurgitation (greater than 3+) has not been encountered. In addition, use of small balloons is initially effective in some infants with critical obstruction, but an increase in valve gradient with recovery of ventricular function may occur. Although this procedure cannot now be considered the treatment of choice for valvular aortic stenosis in the young, our results and those of others suggest that further trials of this procedure, together with technologic improvements, are warranted. At the present time at our own institution, balloon dilation is being performed as an investigational procedure. It is carried out in patients who have an aortic valve peak gradient of 50 mm Hg or more and in whom aortic regurgitation is mild at most.

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