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Determinants of Successful Balloon Valvotomy in Infants With Critical Pulmonary Stenosis or Membranous Pulmonary Atresia With Intact Ventricular Septum

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Objectives. **This study reviewed our experience with percutaneous balloon valvotomy in infants with critical pulmonary stenosis or membranous pulmonary atresia with intact ventricular septum and defined the anatomic and hemodynamic characteristics of infants in whom this procedure is successful and provides definitive therapy.**

Background. **Unlike children with valvular pulmonary stenosis, the follow-up of infants with critical pulmonary stenosis undergoing percutaneous balloon valvotomy is limited.**

Methods. **Between December 1987 and August 1992, percutaneous balloon valvotomy was attempted in 12 infants with critical pulmonary stenosis (n = 10) or pulmonary atresia with intact ventricular septum (n = 2). Two outcome groups were identified: Group A patients are acyanotic, have mild residual pulmonary stenosis and have not required operation; Group B patients have required operation.**

Results. **Of the 12 infants, 11 had a successful balloon valvotomy procedure. Group A patients (n = 7) have a residual gradient of 22 ± 18.7 mm Hg (mean ± SD) at follow-up of 3.2 years (range 1.2 to 5.0). In Group B (n = 5), operation was required for inability to cross the pulmonary valve (n = 1) or persistent severe hypoxemia for ≥2 weeks after valvotomy (n = 4). Significant differences ($p \leq 0.01$) between the two groups (Group A vs. Group B) were identified in pulmonary valve annulus (Z value) 8.1 mm (−1.1) versus 5.5 mm (−3.4); tricuspid valve annulus (Z value) 14.0 mm (0.8) versus 8.8 mm (−1.8); right ventricular volume 65 versus 29 ml/m^2; and Lewis index 10.9 versus 8.9.**

Conclusions. **Percutaneous balloon valvotomy is effective and likely to provide definitive therapy in infants with critical pulmonary stenosis or membranous pulmonary atresia with intact ventricular septum who have a tricuspid valve annulus >11 mm, pulmonary valve annulus ≥7 mm and right ventricular volume >30 ml/m^2.**

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Percutaneous balloon valvotomy of the pulmonary valve was first described by Kan et al. in 1982 (1). It is now considered to be the treatment of choice for congenital valvular pulmonary stenosis (2–4). Follow-up studies of patients undergoing balloon valvotomy between 2 months and 20 years of age have documented long-term efficacy of the procedure (3,4), but follow-up of infants with critical pulmonary stenosis undergoing percutaneous balloon valvotomy has been limited. The purpose of this study was to review our experience with percutaneous balloon valvotomy in infants with critical pulmonary stenosis or membranous pulmonary atresia with intact ventricular septum. We further sought to define the anatomic and hemodynamic characteristics of those infants in whom percutaneous balloon valvotomy has been successful and the only intervention required.

Methods

Between December 1987 and August 1992, percutaneous balloon valvotomy was attempted in 12 infants with critical pulmonary stenosis (n = 10) or membranous pulmonary atresia with intact ventricular septum (n = 2) presenting to the Division of Pediatric Cardiology at C. S. Mott Children's Hospital. We have used the following definition of critical pulmonary stenosis: valvular pulmonic stenosis, suprasystemic right ventricular pressure and age <2 months. The majority also had a right-to-left atrial level shunt leading to systemic arterial hypoxemia.

Balloon valvotomy. Percutaneous balloon valvotomy was performed after complete right and left heart catheterization and biplane right ventricular angiography (Fig. 1, A and B). The pulmonary and tricuspid valve annuli were measured from the valve hinge points in the frontal and lateral projections, with the larger diameter reported. Right ventricular end-diastolic volume was calculated by the biplane Simpson algorithm as described by Graham et al. (5). All angiographic

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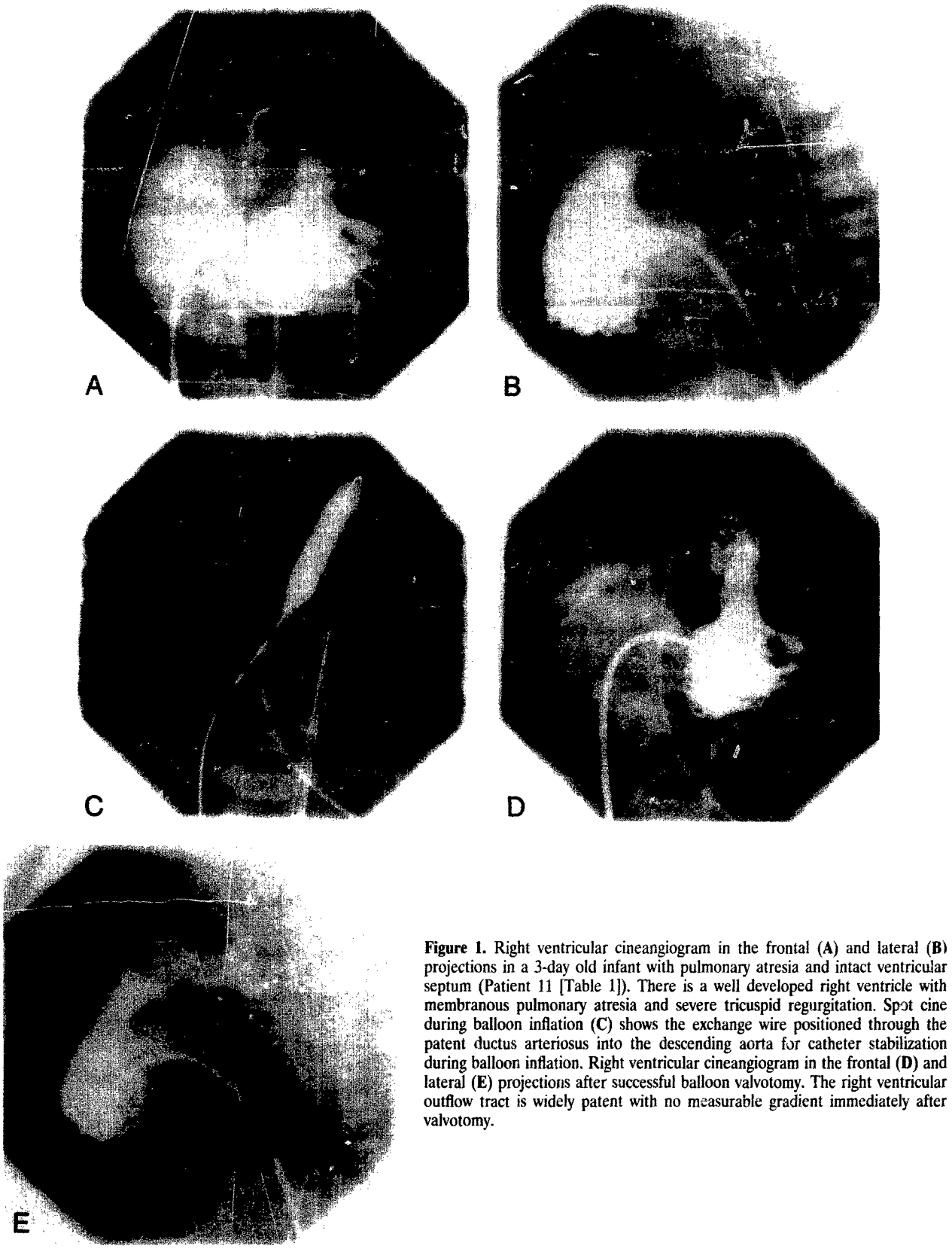

Figure 1. Right ventricular cineangiogram in the frontal (**A**) and lateral (**B**) projections in a 3-day old infant with pulmonary atresia and intact ventricular septum (Patient 11 [Table 1]). There is a well developed right ventricle with membranous pulmonary atresia and severe tricuspid regurgitation. Spot cine during balloon inflation (**C**) shows the exchange wire positioned through the patent ductus arteriosus into the descending aorta for catheter stabilization during balloon inflation. Right ventricular cineangiogram in the frontal (**D**) and lateral (**E**) projections after successful balloon valvotomy. The right ventricular outflow tract is widely patent with no measurable gradient immediately after valvotomy.

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Table 1. Clinical, Hemodynamic and Anatomic Characteristics of 12 Infants Undergoing Attempted Pulmonary Balloon Valvotomy

			PVA		TVA			Gradient			Gradient		
Pt No./ Dx	Age (days)	Wt (kg)	Diameter (mm)	Z value	Diameter (mm)	Z value	RV vol (ml/m^2)	Pre (mm Hg)	Post (mm Hg)	PGE_1	F/U (mm Hg)	Surgery	Outcome
1/PS	1	3.5	8.7	−0.5	14	1.0	95	75	10	Yes	11	No	Alive
2/PS	2	3.6	4.1	−6.0	7.2	−3.5	22	—	—	No	—	Yes	Dead
3/PS	7	4.5	8.5	−1.0	17	2.0	78	63	16	No	22	No	Alive
4/PS	25	3.4	4.8	−5.0	7.8	−3.0	18	115	40	No	14	Yes	Alive
5/PS	7	3.5	7.6	−1.5	14.2	1.0	56	64	18	No	16	No	Alive
6/PS	2	3.7	8.7	−0.5	15	1.5	78	76	20	Yes	13	No	Alive
7/PS	11	3.2	7	−1.5	12	0.0	33	119	20	No	61	No	Alive
8/PS	1	2.9	4.7	−4.5	7.8	−2.0	45	69	5	Yes	0	Yes	Alive
9/PS	2	3.1	6.7	−2.0	10	−1.0	30	82	5	Yes	6	Yes	Alive
10/PS	38	4.3	7.5	−2.0	12.3	−0.5	50	112	30	No	13	No	Alive
11/PA	3	3.1	8.5	−0.5	13.6	1.0	62.5	—	0	Yes	9	No	Alive
12/PA	2	3.6	7.2	−2.0	11	−1.0	28	—	10	Yes	—	Yes	Alive
Mean	8.4	3.5	7.0	−2.25	11.8	−0.38	49.6	86.1	15.8		17.5		
SD	11.5	0.47	1.64	1.90	3.14	1.80	24.8	22.7	11.7		17.3		

Dx = diagnosis; F/U = follow-up; Gradient = gradient across the pulmonary valve; PA = pulmonary atresia with intact ventricular septum; PGE_1 = prostaglandin E_1; Pre (Post) = before (after) attempted pulmonary balloon valvotomy; PS = critical pulmonary stenosis; Pt = patient; PVA = pulmonary valve annulus; RV vol = right ventricular volume; Surgery = surgery for persistent cyanosis: TVA = tricuspid valve annulus; Wt = weight.

measurements were corrected for magnification by use of a 1-cm filmed grid.

After the diagnosis had been confirmed, balloon valvotomy was performed. A 4F or 5F end-hole catheter was positioned in the right ventricular outflow tract, and the pulmonary valve was crossed with a 0.018- to 0.021-in. guide wire. In cases of pulmonary atresia, the pulmonary valve membrane was perforated with a 0.021-in. guide wire (6). In infants with a patent ductus arteriosus, we prefer to position the distal wire in the descending aorta for maximal stabilization during catheter exchanges; otherwise, the distal wire tip was positioned in the right or left pulmonary artery. The balloon angioplasty catheter was advanced over the guide wire and inflated by hand until the waist created by the pulmonary valve was eliminated (Fig. 1C). A progressive dilation strategy was generally used, beginning with a 4- to 5-mm diameter balloon and increasing by 2- to 3-mm increments until a balloon/annulus diameter ratio of 1.2 to 1.3 was attained. After balloon valvotomy, repeat hemodynamic measurements were made. Right ventricular angiography was repeated in the two infants with pulmonary atresia and intact ventricular septum (Fig. 1, D and E) and in the infants with critical pulmonary stenosis at the operator's discretion. Prostaglandin E_1 was discontinued generally within the first 24 h after the procedure.

Follow-up data. Hospital records were reviewed for any surgical procedures and to determine the most recent echocardiographic or catheter estimate of pulmonary stenosis and insufficiency as well as the most recent arterial oxygen saturation. The systolic gradient across the pulmonary valve during follow-up was identified by Doppler echocardiography (n = 11) and by repeat cardiac catheterization in some patients (n = 4). On the basis of follow-up data, the patients were classified into two outcome groups: Group A patients are acyanotic, have mild residual pulmonary stenosis and have required no surgical procedures; Group B patients have required surgical intervention for inadequate pulmonary blood flow despite attempted balloon valvotomy.

At our institution, infants with critical pulmonary stenosis or pulmonary atresia with an intact ventricular septum whose systemic arterial oxygen saturation remains <65% for ≥2 weeks after balloon valvotomy have undergone a modified Blalock-Taussig shunt or right ventricular outflow patch.

Analysis of data and statistics. The right ventricular index was calculated as described by Lewis et al. (7): (Tricuspid valve annulus + Right ventricular inlet + Right ventricular outlet) ÷ (Diameter of the descending aorta at the level of the diaphragm). The *Z* values of the tricuspid and pulmonary valve annuli were obtained using the nomogram of Hanley et al. (8). The *Z* value is defined as follows: (Measured diameter − Mean normal diameter) ÷ (Standard deviation of the mean normal diameter). Data are presented as mean value ± SD. Comparisons of data obtained before and after balloon valvotomy were made using paired Student *t* tests. The clinical and anatomic characteristics of Groups A and B were compared using group *t* tests. Statistical significance was defined as a two-tailed p value <0.01 to correct for multiple comparisons.

Results

The clinical, hemodynamic and anatomic characteristics of the 12 infants are shown in Table 1 (mean [±SD] age 8.4 ± 11.5 days, range 1 to 38; mean weight 3.5 ± 0.5 kg, range 2.9 to 4.5). Before balloon valvotomy, the ratio of right ventricular to aortic systolic pressure was 165 ± 37% (range 110% to 222%). The pulmonary valve annulus diameter ranged from 4.1 to 8.7 mm (mean 7.0 ± 1.6), and its *Z* value ranged from −6.0 to −0.5 (mean −2.25 ± 1.9). The tricuspid valve annulus diameter ranged from 7.2 to 17 mm (mean 11.8 ± 3.1), and its

Z value ranged from −3.5 to 2.0 (mean −0.38 ± 1.8). Right ventricular end-diastolic volume ranged from 18 to 95 ml/m^2 (mean 49.6 ± 24.8). Mean right ventricular index (7) was 10.0 ± 1.4 (range 7.4 to 12.8). Before balloon valvotomy, systemic arterial oxygen saturation ranged from 78% to 100% (mean 94 ± 6%), and six infants were receiving a prostaglandin E_1 infusion at the time of the procedure. The mean fluoroscopic time was 65 ± 29 min (range 26 to 119).

Immediate results. Of the 10 infants with critical pulmonary stenosis, 9 underwent a successful balloon valvotomy procedure and had an immediate decrease in pulmonary valve systolic gradient from 86 ± 23 mm Hg (range 63 to 119) to 18 ± 12 mm Hg (range 0 to 40, $p \leq 0.0005$). Right ventricular systolic pressure decreased from 165 ± 37% of systemic levels before dilation to 69 ± 13% of systemic levels after dilation ($p < 0.0005$). In the tenth patient (Patient 2 [Table 1]), who had a very diminutive right ventricle, neither a wire nor a catheter could be passed across the pulmonary valve.

In the two patients with membranous pulmonary atresia and intact ventricular septum (Patients 11 and 12 [Table 1]), right ventricular systolic pressure decreased from 110 to 70 mm Hg (range 122% to 78% systemic) and from 85 to 40 mm Hg (range 177% to 77% systemic). The gradient across the pulmonary valve immediately after valvotomy was 10 and 0 mm Hg, respectively.

Immediate complications. Guide wire perforation of the right ventricular outflow tract occurred in two patients. In one of these infants (Patient 2 [Table 1]), whose diagnosis was critical pulmonary stenosis, the wire was never successfully advanced across the pulmonary valve. The patient tolerated the guide wire perforation well and underwent operation for placement of a modified Blalock–Taussig shunt and pulmonary valvotomy. In the other infant, who had pulmonary atresia with an intact ventricular septum, perforation of the right ventricular outflow tract with the 0.021-in. guide wire required no therapy, and the balloon valvotomy was successfully completed. Minor complications noted during the procedures included mild metabolic acidosis (n = 1), supraventricular tachycardia requiring cardioversion (n = 1), transient ventricular tachycardia (n = 1) and variable atrioventricular block (n = 1). There were no deaths as a result of the procedure.

Outcome: Group A. Group A comprises the seven patients who required no additional intervention after balloon valvotomy and includes one of the two neonates with pulmonary atresia and intact ventricular septum (Patient 11 [Table 1]). In these seven children the peak systolic gradient across the pulmonary valve was reduced immediately from 85 ± 10 to 16 ± 3 mm Hg ($p = 0.0006$), and right ventricular systolic pressure was reduced from 107 ± 7 to 48 ± 4 mm Hg ($p < 0.0001$). Mean fluoroscopic time was 57 ± 23 min (range 31 to 97). The patients in Group A have been followed up for a mean 3.2 years (range 1.2 to 5.0). The most recent oxygen saturation was 98% (range 95 to 100%). All seven children have remained clinically well. Peak instantaneous pressure gradient by Doppler echocardiography across the pulmonary valve was 22 ± 18.7 mmHG (range 9 to 61). One patient had trace pulmonary regurgitation; three had mild pulmonary regurgitation; and three had moderate pulmonary regurgitation by echocardiographic criteria. Follow-up cardiac catheterization in the child with the Doppler gradient of 61 mm Hg documented a catheter peak gradient of 40 mm Hg.

Outcome: Group B. Group B includes the five patients who required surgical intervention after attempted balloon pulmonary valvotomy. In the four children in this group with successful balloon dilation, including one neonate with membranous pulmonary atresia with intact ventricular septum (Patient 12 [Table 1]), the pulmonary valve gradient decreased immediately from 89 ± 14 to 14 ± 13 mm Hg ($p = 0.003$). Right ventricular systolic pressure was reduced from 119 ± 2 to 54 ± 5 mm Hg ($p = 0.0055$). Mean fluoroscopic time was 74 ± 35 min (range 26 to 119). During catheterization of the first patient to require surgery (Patient 2 [Table 1]), the wire could not be advanced across the pulmonary valve, but it did perforate the right ventricular infundibulum. At operation, the patient received a modified Blalock-Taussig shunt was well as a pulmonary valvotomy. This patient subsequently died at 18 months of age at the time of a Fontan procedure. The second patient to require operation (Patient 4 [Table 1]) underwent a right ventricular outflow tract patch 27 months after balloon valvotomy for moderate persistent hypoxemia (systemic arterial oxygen saturation 87%).

The third patient (Patient 8 [Table 1]) required a modified right Blalock-Taussig shunt and atrial septectomy because of severe persistent hypoxemia (systemic arterial oxygen saturation <60%) 14 days after balloon valvotomy. At 14.5 months of age, the atrial septal defect was closed, and the right Blalock-Taussig shunt was divided. The patient had no residual pulmonary valve stenosis, but because of right pulmonary artery stenosis at the site of the shunt and severe pulmonary regurgitation, pulmonary artery angioplasty and placement of a right ventricle/pulmonary artery conduit was performed 4 months later.

The fourth patient (Patient 9 [Table 1]) also required a modified Blalock-Taussig shunt secondary to severe persistent hypoxemia after balloon valvotomy. At follow-up catheterization 8 months later, the right ventricular outflow tract gradient was 5 mm Hg, and the right ventricular systolic pressure was 31 mm Hg; therefore, the Blalock-Taussig shunt was coil occluded, and the patient has done well.

In the fifth patient (Patient 12 [Table 1]), one of the neonates with membranous pulmonary atresia and intact ventricular septum, a modified Blalock-Taussig shunt was placed because of severe persistent hypoxemia despite a technically successfully balloon valvotomy procedure. Follow-up catheterization at age 6 months revealed severe pulmonary regurgitation, a hypoplastic right ventricle and tricuspid valve and moderate to severe tricuspid regurgitation. The patient underwent a bidirectional Glenn shunt followed by a Fontan procedure.

Clinical and hemodynamic predictors of outcome. The clinical and hemodynamic data shown in Table 2 were considered potential predictors of outcome group assignment. The

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Table 2. Clinical and Hemodynamic Characteristics

	Group A	Group B	p Value
Age (days)	9.9 ± 6	6.8 ± 6	0.69
Wt (kg)	3.7 ± 0.2	3.4 ± 0.2	0.20
Balloon size (mm)	9.1 ± 1	9.5 ± 1	0.50
Gradient pre (mm Hg)	85 ± 10	89 ± 14	0.83
Gradient post (mm Hg)	16.3 ± 3	13.8 ± 13	0.67
RVSP Pre (mm Hg)	107.3 ± 7	118.8 ± 2	0.33
RVSP Post (mm Hg)	48.6 ± 4	54 ± 5	0.90

Data presented are mean value ± SD. RVSP = right ventricular systolic pressure; other abbreviations as in Table 1.

groups did not differ significantly with regard to age, weight or balloon size utilized. Gradients across the right ventricular outflow tract both before and after balloon valvotomy were not significantly different, and in each group, balloon valvotomy achieved at least an 80% decrease in gradient. Right ventricular systolic pressures were not significantly different before and after balloon valvotomy, with both groups achieving a 50% to 60% decrease in right ventricular systolic pressure.

Anatomic predictors of outcome. The anatomic characteristics summarized in Table 3 revealed significant differences between outcome Groups A and B. Patients in Group A (no surgical intervention required) had significantly larger right heart anatomy. The pulmonary valve annulus diameter in Group A was 8.2 ± 0.3 versus 5.5 ± 0.5 mm in Group B ($p = 0.001$). The Z value of the pulmonary valve annulus was −1.1 ± 0.6 in Group A versus −3.4 ± 1.6 in Group B ($p = 0.01$). At follow-up, the pulmonary valve annulus Z value for Group A was −0.7 ± 0.9 (range −2 to 0.5, $p = 0.19$ compared with predilation value). The tricuspid valve annulus was 14.0 ± 0.7 mm in Group A versus 8.8 ± 0.6 mm in Group B ($p = 0.001$). The Z value of the tricuspid valve annulus in Group A was 0.8 ± 0.9 versus −1.8 ± 1.0 in Group B ($p = 0.003$). At follow-up, the tricuspid valve annulus Z value for Group A was 1.1 ± 1.4 (range −1.0 to 2.0, $p = 0.37$, compared with predilation value). Right ventricular end-diastolic volume was 65 ± 6 ml/m^2 in Group A versus 29 ± 6 ml/m^2 in Group B ($p = 0.003$), and the Lewis index was 10.9 ± 1.0 in Group A versus 8.9 ± 1.1 in Group B ($p = 0.01$).

Table 3. Anatomic Characteristics

	Group A	Group B	p Value
PVA Diameter (mm)	8.1 ± 0.3 (7–8.7)	5.5 ± 0.5 (4.1–7.2)	0.001
Z value	−1.1 ± 0.6 (−2 to −0.5)	−3.4 ± 1.6 (−6 to −2)	0.01
TVA Diameter (mm)	14.0 ± 0.7 (12–17)	8.8 ± 0.6 (7.2–11)	0.001
Z value	0.8 ± 0.9 (−0.5 to 2)	−1.8 ± 1.0 (−3.5 to −1)	0.003
RV vol (ml/m^2)	65 ± 6.0 (33–95)	29 ± 6.0 (18–45)	0.003
Lewis index	10.9 ± 1.0 (10.2–12.8)	8.9 ± 1.1 (7.4–10.2)	0.01

Data presented are mean value ± SD (range). Abbreviations as in Table 1.

Discussion

Present study. The present study has documented that percutaneous balloon valvotomy provides effective therapy for many infants with critical pulmonary stenosis or pulmonary atresia with intact ventricular septum. Furthermore, we identified three anatomic characteristics that appear to relate to the clinical success of percutaneous balloon valvotomy: pulmonary valve annulus diameter, tricuspid valve annulus diameter and indexed right ventricular volume (Table 3). There was minimal overlap between Groups A and B regarding these anatomic features. Percutaneous balloon valvotomy was the only intervention required in infants with a pulmonary valve annulus ≥7 mm, tricuspid valve anulus >11 mm and right ventricular end-diastolic volume >30 ml/m^2. All seven infants with a tricuspid valve annulus >11 mm had a successful balloon valvotomy procedure without the need for further therapy. The Z values of the tricuspid and pulmonary valve annuli in the two outcome groups are in agreement with these findings. All patients with a tricuspid valve annulus Z value of −0.5 or more or a pulmonary valve annulus Z value of −1.5 or more have had a clinically successful balloon valvotomy procedure without subsequent surgical intervention. All patients with a tricuspid valve annulus Z value of −1.0 or less, and five of the six patients with a pulmonary valve annulus Z value of −2.0 or less, have required surgical intervention.

Previous studies. The overall success rate of this procedure was 58%, with success defined as percutaneous balloon valvotomy being the only intervention needed. These data are comparable to the experience reported by Caspi et al. (9), in which the success rate in neonates with critical pulmonary stenosis was 55%. However, these investigators attributed failure of balloon valvotomy to the inability to advance a catheter across the pulmonary valve and to right ventricular hypoplasia (not quantitated). Our experience is also similar to the recent study by Talsma et al. (10), which reported a success rate of 56%. That study also noted a statistically significant difference in the pulmonary valve annulus size in infants with and without a successful percutaneous balloon valvotomy. However, they found no relation between right ventricular size using the Lewis index or tricuspid valve annulus diameter and clinical outcome. The initial report by Lewis et al. (7) in 1983 suggested that a Lewis index ≥11 is sufficient to sustain adequate pulmonary flow in patients with pulmonary atresia with intact ventricular septum after surgical valvotomy alone. In our study, the children in Group A had an average Lewis index of 10.9, whereas in Group B the Lewis index was 8.9 ($p = 0.01$). Only one patient in the present study with a Lewis index >10 required surgical intervention (Lewis index in this patient was 10.2).

Conclusions. From our experience we conclude that balloon valvotomy is likely to be the only procedure necessary for

infants with critical pulmonary stenosis or membranous pulmonary atresia with intact ventricular septum who have a tricuspid valve annulus >11 mm, pulmonary valve annulus ≥7 mm and right ventricular volume >30 ml/m^2. Infants with more severe right heart hypoplasia will most likely require surgical intervention, but percutaneous balloon valvotomy may still provide substantial clinical palliation.

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