Intermediate-term follow-up results of pulmonary balloon valvuloplasty in children

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Twenty-two patients (10 boys, 12 girls) with pulmonary valve stenosis whose mean age was 6.7 ± 4.1 years (range 1 to 14 years) at time of the procedure underwent balloon dilatation angioplasty. All patients had isolated pulmonary valve stenosis with no associated cardiac anomalies, and their pulmonary valvular gradients were greater than 50 mmHg. Diagnostic catheterization and balloon valvuloplasty were performed during the same procedure. The mean peak systolic pressure gradient before balloon dilation of 95.8 ± 29.5 mmHg (54-163 mmHg) was reduced to 30.2 ± 15.8 mmHg (7-64 mmHg) after balloon dilation ($p < 0.001$). A linear relation was found between the predilation pressure gradient and the pressure gradient drop ($r = 0,86$; SE: 28.94) ($y = 0.89x-12.11$). Following a successful valvuloplasty, the mean peak systolic pressure in the right ventricle decreased from 119.0 ± 30.4 mmHg (71-184 mmHg) to 55.2 ± 16.9 mmHg (29-97 mmHg) ($p < 0.001$). Continuous wave Doppler was used for follow-up. Pressure gradients were estimated in 14 patients between one and 29 months after the dilation 120 ± 7.1 months). The mean follow-up gradient was 19.0 ± 6.0 mmHg (11-32 mmHg). No important complication was noted in the immediate course or throughout the follow-up period, but four patients (28.6%) had minimal pulmonary insufficiency. In conclusion, these data confirm that balloon dilation in valvular pulmonary stenosis is safe and effective, and suggest that stenosis does not recur.

Key words: congenital heart disease (CHD), pulmonary valvular stenosis, balloon angioplasty.

Isolated pulmonary valve stenosis is a cardiovascular malformation accounting for seven to 15 percent of patients with congenital heart disease[1]. Pulmonary balloon valvuloplasty (PBV) as an alternative to surgical valvulotomy for treatment of isolated valvular pulmonary stenosis usually results in adequate reduction of the transvalvular gradient. This procedure has been performed several times since 1982 without a reported death or significant morbidity[2-5].

The present report describes the efficacy of this procedure and follow-up in our institution.

Material and Methods

Between June 1993 and March 1995, 22 consecutive patients (10 boys, 12 girls) with pulmonary valve stenosis underwent balloon dilatation angioplasty. Diagnosis was made by physical examination, chest-X-ray, electrocardiogram, and complete two-dimensional and Doppler echocardiographic examination.

All patients had isolated pulmonary valve stenosis with no associated cardiac abnormalities, and their pulmonary valvular gradients were greater than 50 mmHg. Before cardiac catheterization, balloon valvuloplasty was described to the patients and their families as an alternative to the surgical approach, and informed consent was obtained.

All patients underwent diagnostic catheterization and balloon valvuloplasty during the same procedure. Right heart hemodynamic data was obtained before and after (10 minutes or longer) valvuloplasty. The recorded data included right ventricular and main pulmonary artery pressures. Systolic blood pressure was determined with sphygmomanometer in the left upper arm in all

patients every five minutes. Right ventricular or right ventricular outflow tract angiocardiograms were performed using a angiocardiographic catheter, with posteroanterior and cranially angulated views. Accurate measurements of the valve annulus diameter were obtained from the fixed image on the video playback unit. The magnification factor of the cineangiogram was determined by comparing the angiographically determined diameter of the catheter to its actual diameter[2,4].

A balloon with an inflated diameter 30-40 percent greater than the dimension of the valve annulus was selected. Pulmonary balloon valvuloplasty was performed by the trefoil balloon technique using a 3 cm. Mansfield balloon (Boston Scientific Corp., Mansfield Division, Mansfield, MA). Total balloon size was calculated using a previously described formula[5,6].

Pulmonary balloon valvuloplasty has been described in detail in many publications[2-5,7,8-12] (Fig. 1).

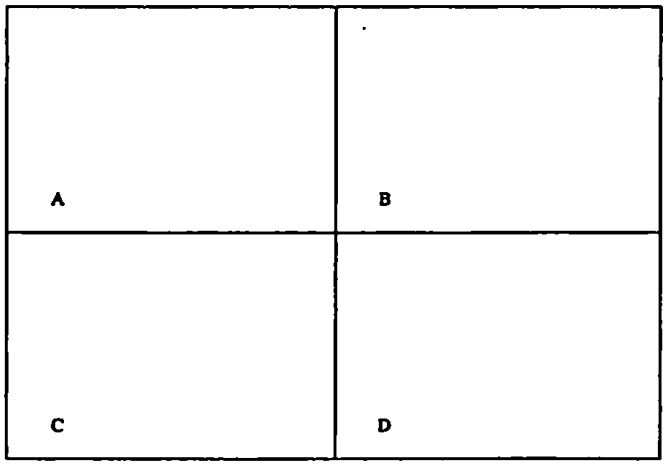

Fig. 1. Right ventricular angiograms of patient 17. A) Right anterior oblique position before PBV. B) "waist" effect with stenotic pulmonary valve. C) Maximum inflation of the balloon without any stenosis. D) Right anterior oblique position after PBV.

Once the operators were satisfied that maximum valve dilation had been achieved, the balloons were withdrawn over the wire and replaced with appropriately sized sheath/dilator sets. Postdilation hemodynamics and angiocardiograms were carried out using these sheaths. Beta blocking drugs were given to all patients (2 mg/kg/day propranolol) routinely. Since there were no complications, all patients were discharged home within 24 to 48 hours following the procedure.

Noninvasive modalities (auscultation, electrocardiogram, chest X-ray and two-dimensional and Doppler examination) were used for follow-up evaluation. Echocardiographic study was performed with Toshiba 160-A. Pulmonary valvar gradient was calculated using modified Bernoulli equation on Doppler echocardiography[13,14].

For statistical analysis, pressure data are presented as mean ± standard deviation. Student's t-test was used to compare paired data. The level of statistical significance was set at $p < 0.05$.

Results

The mean age of patients was 6.7 ± 4.1 years (range 1 to 14 years) at time of the procedure. The ages, pressure data of the patients and balloon sizes are shown in chronological order (according to timing of the procedure) in Table I. There were no complications in performing valvuloplasty in any of these patients.

The mean peak systolic pressure gradient before balloon dilation of 95.8 ± 29.5 mmHg (range 54-163 mmHg) was reduced to 30.2 ± 15.8 mmHg (range 7-64 mmHg) after balloon dilation. Significant reduction of transvalvular gradient occurred in every patient ($p < 0.001$) (Fig. 2).

A linear relation was found between the predilation pressure gradient and the pressure gradient drop ($r = 0.86$; SE: 28.94) ($y = 0.89x-12.11$) (Fig. 3).

Following a successful valvuloplasty, the mean peak systolic pressure in the right ventricle decreased from 119.9 ± 30.4 mmHg (71-184 mmHg) to 55.2 ± 16.9 mmHg (29.97 mmHg) ($p < 0.001$). The mean peak systolic pressures in the pulmonary artery were 23.4 ± 4.5 and 25.2 ± 4.2 mmHg before and after valvuloplasty, respectively, and the difference was not significant ($p > 0.05$) (Fig. 4).

Continuous wave Doppler was used for follow-up. Pressure gradients were estimated in 14 patients between one and 29 months after the dilation (mean 12 ± 7.1 months). In each patient the gradient at follow-up was lower when compared with the immediate post-valvuloplasty gradient. The mean follow-up gradient was 19 ± 6 mmHg (range 11-32 mmHg). No important complication was noted in the immediate course or throughout the follow-up period, but four patients (28.6%) had minimal pulmonary insufficiency (Fig. 5).

Table I. Ages and Pressure Data of the Patients and Balloon Properties

			Before Valvuloplasty							After Valvuloplasty							
			Mean PA			Right Ventricle				Mean PA			Right Ventricle				
No.	Age (year)	Sex	S	D	M	S	D	ED	PGI	S	D	M	S	D	ED	PG2	Bal.
1	5	F	25	15	19	98	0	9	73	22	12	17	29	0	6	7	3x10
2	11	M	19	7	12	84	0	8	65	21	12	17	43	0	8	22	3x15
3*	7	M	28	12	19	160	0	16	132	26	5	11	61	0	6	35	3x12
4	12	F	15	8	11	107	0	3	92	24	11	14	83	0	7	59	3x15
5	9	M	17	7	10	71	0	6	54	21	8	13	45	0	5	24	3x15
6*	9	F	20	9	15	161	0	9	141	25	11	17	60	0	13	35	3x12
7*	13	M	26	8	17	81	0	7	63	25	8	16	59	0	9	34	3x16
8*	4	F	21	8	13	75	0	3	54	25	6	16	46	0	7	21	3x9
9	4	F	27	13	18	129	0	8	102	30	15	21	55	0	18	25	3x10
10*	1	F	22	13	18	100	0	12	78	28	15	20	75	0	4	47	3x8
11*	12	M	24	9	16	122	0	8	98	26	9	14	65	0	5	38	3x15
12	4	M	32	19	24	111	0	18	79	23	17	18	61	0	11	38	3x12
13	3.5	M	20	12	16	150	0	20	130	25	15	20	60	0	10	35	3x12
14	6	F	29	18	21	114	0	11	85	31	13	20	47	0	7	16	3x8
15*	2	F	31	16	19	141	0	5	110	33	21	24	97	0	4	64	3x10
16	3	F	24	8	17	103	0	11	79	25	9	13	43	0	7	18	3x8
17	4	M	27	14	20	116	0	16	89	21	11	13	29	0	3	8	3x12
18	2	F	22	11	17	96	0	10	74	20	5	11	32	0	3	12	3x12
19*	2	F	17	14	11	130	0	9	113	36	11	13	33	0	5	3	3x10
20	12	F	25	18	21	166	0	19	141	26	14	19	65	0	8	39	3x15
21	14	M	26	10	18	118	0	9	92	24	11	16	62	0	9	38	3x16
22	5	M	21	9	13	184	0	12	163	18	7	12	64	0	6	46	3x10
Mean	6.7	10 M	23.5	11.7	16.6	119.0	0	10.4	95.8	25.2	11.2	16.1	55.2	0	7.3	30.2	
SD	4.1	11 F	4.5	3.7	3.6	30.4	0	4.7	29.5	4.2	3.9	3.5	16.9	0	3.4	15.8	

PA: Pulmonary artery, S: Systolic (mmHg), D: Diastolic (mmHg), M: Mean (mmHg), ED: End diastolic (mmHg), PGI: Pressure gradient before valvuloplasty, PG2: Pressure gradient after valvuloplasty, Bal: properties of balloons, *: Follow-up data not available.

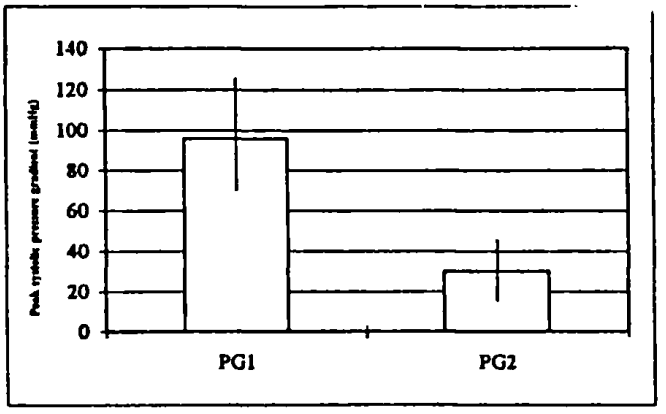

Fig. 2. The mean peak systolic pressure gradient before and after valvuloplasty.

PG1 : The mean peak systolic pressure gradient before valvuloplasty;

PG2 : The mean peak systolic pressure gradient after valvuloplasty (n = 22; p < 0.001).

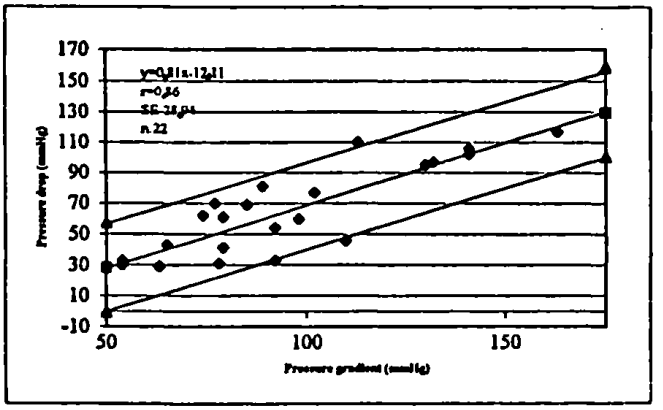

Fig. 3. A linear relation between the predilation pressure gradient and the pressure gradient drop.

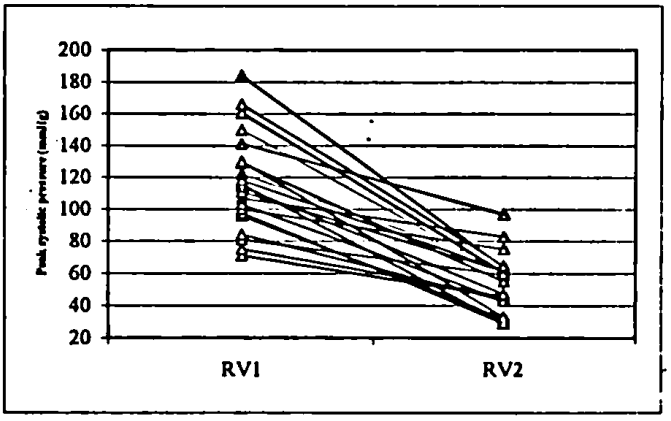

Fig. 4. The right ventricular peak systolic pressure drop after valvuloplasty.

RV1 : The right ventricular peak systolic pressure before valvuloplasty;

RV2 : The right ventricular peak systolic pressure after valvuloplasty.

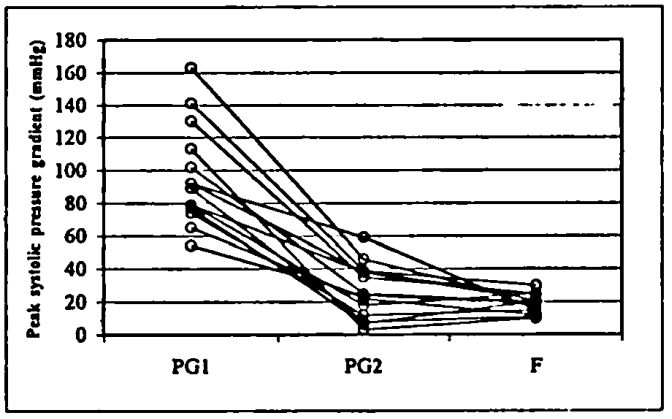

Fig. 5. Pressure gradient data of 14 patients. before, immediately after valvuloplasty, and during follow-up.

PG1 : Before valvuloplasty pressure gradient data;

PG2 : Immediately after valvuloplasty pressure gradient data;

F : Echocardiographic follow-up pressure gradient data.

Discussion

Pulmonary valve stenosis is one of the most common congenital heart disases. Diagnosis is usually established during childhood and treated when the pressure gradient at rest exceeds 50 mmHg. In recent years surgical valvuloplasty has been largely replaced by PBV[2-5].

Although the balloon valvuloplasty is used most frequently in children, it has also been used successfully in neonates[14-18] and in adults[19-24].

Rao et al.[25] recommended that the indications for balloon valvuloplasty be the same as those used for surgical valvuloplasty, and that balloon dilatation should not be performed in patients with peak pulmonary valvular gradients less than 50 mmHg. Wang et al.[26] concluded that asymptomatic patients with a gradient above 50 mmHg should be considered for balloon valvuloplasty, which could provide improvement both in transvalvular gradient and in right ventricular pressure, and that symptomatic patients should also be considered for valvuloplasty, regardless of gradient. Asymptomatic patients with a gradient between 40 to 50 mmHg could also be considered for valvuloplasty, but regular clinical and echocardiographic follow-up is another option. The mean peak systolic valvular gradient of our patients was greater than 50 mmHg.

Our method of pulmonary angioplasty is similar to that described by Kan[12] and others[2-5,9-11]. We used trefoil balloon in all patients and the balloon diameter was 30-40 percent greater than the pulmonary valve annulus. It is generally agreed that a balloon/annulus ratio of greater than 1.0 is associated with better results than a balloon/annulus ratio of less than 1.0, and there is some evidence that a balloon/annulus ratio greater than 1.5 is associated with higher risk of complications[27]. Rao et al.[5,6,25], Melgares et al.[8], and Narang et al.[27] showed that balloon-annulus ratios between 1.2 and 1.5 were more appropriate for pulmonary valvuloplasty for relief of isolated valvar pulmonic stenosis.

Rao and coworkers[25] concluded that when immediate post-valvuloplasty pulmonary valvular gradient is > 30 mmHg, the chance of recurrence of stenosis is high and, therefore, it may be advisable to use larger balloons and reduce the valve gradient to < 30 mmHg. There were 12 patients whose peak systolic pressure gradients were greater than 30 mmHg (4 of these were > 40 mmHg) immediately after valvuloplasty. No follow-up data were available in six of these 12 patients. Because transvalvular gradient on Doppler follow-up was < 30 mmHg in the remaining six patients, secondary pulmonary balloon valvuloplasty procedure was not done.

A linear correlation between the pressure gradient drop and the predilation valvular gradient was found ($r = 0.86$; SE: 28.94) ($y = 0.89x-12.11$) (Fig. 3). This equation may be useful for the cardiologist in predicting the pressure drop after the procedure[4].

The mean peak systolic pressure in the right ventricle decreased from 119.0 ± 30.4 mmHg (71-184 mmHg) to 55.2 ± 16.9 mmHg (29.97 mmHg) after valvuloplasty ($p < 0.001$).

Although some reports showed that the mean peak systolic pressure in the pulmonary artery significantly increased immediately after the valvuloplasty. the mean peak systolic presures in the pulmonary artery in our series were 23.5 ± 4.5 and 25.2 ± 4.2 mmHg before and after valvuloplasty, respectively, and the difference was not significant ($p > 0.05$)[5,7].

Complete right bundle-branch block, transient or permanent complete heart block, cerebrovascular accident, loss of conciousness, cardiac arrest, convulsions, balloon rupture at high inflation pressures, tricuspid valve papillary muscle rupture, and severe infundibular obstruction requiring propranolol administration and/or surgical intervention have been reported. Complications have been remarkably minimal during and immediately after balloon pulmonary valvuloplasty. Transient bradycardia, premature beats, and a fall in systemic pressure during balloon inflation have been noted by all authors as seen in our patients. Although blood loss requiring transfusion has been reported in many studies, our patients did not need any transfusion[5,7,27,29].

Echo-Doppler follow-up studies were possible in 14 children for 12 ± 7.1 months (range 1 to 29 months) following valvuloplasty. The mean peak systolic pressure gradient decreased from 96 ± 31 mmHg (range 54-163 mmHg) to 27 ± 16 mmHg (range 30-117 mmHg) immediately following balloon dilation ($p < 0.001$), which on Doppler follow-up was 19 ± 6.2 mmHg ($p > 0.05$) in these patients. Our follow-up results showed that the mean pressure gradient one year after valvuloplasty was lower than that observed immediately after valvuloplasty.

In conclusion, these data confirm that balloon dilation in valvular pulmonary stenosis is safe and effective, and suggest that stenosis does not recur. We believe that the balloon dilation procedure will decrease the morbidity of pulmonary valve stenosis relief compared to the surgical approach. Two-dimensional and Doppler echocardiographic examination are preferred for noninvasive follow-up and can accurately access the severity of residual pulmonary stenosis.

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