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Major Determinants and Long-Term Outcomes of Successful Balloon Dilatation for the Pediatric Patients with Isolated Native Valvular Pulmonary Stenosis: A 10-Year Institutional Experience

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Purpose: We report herein major determinants and long-term outcomes of balloon dilatation (BD) for 27 pediatric patients with isolated native valvular pulmonary stenosis (VPS). **Materials and Methods:** From May 1997 to May 2003, 27 pediatric patients with VPS (pressure gradients ≧ 40 mmHg) were enrolled in this retrospective study. Single-balloon maneuver was applied in 26 patients, and double-balloon maneuver in 1. After BD, the pressure gradients were documented simultaneously by pullback maneuver by cardiac catheterization and echocardiography within 24 hours, at 1-month, 3-month, 1-year, and 4-to-10-year follow-ups. **Results:** Before BD, the echocardiographic gradients ranged from 40 to 101 mmHg (61 ± 19, 55), and from 40 to 144 mmHg (69 ± 32, 60) by pressure recordings. After BD, the gradients ranged from 12 to 70 mmHg (29 ± 13, 27) by pressure recording ($p < 0.001$), and from 11 to 64 mmHg (27 ± 12, 26) by echocardiography within 24 hrs ($p < 0.001$). The ratios of the systolic pressure of the right ventricle to those of the left ventricle were 55 to 157% (89 ± 28, 79%) before BD, and 30 to 79% (47 ± 13, 42%) after BD ($p < 0.001$). Follow-up (7.7 ± 5.7, 4.5 years) echocardiographic gradients ranged from 11 to 61 mmHg (25 ± 11, 24). Two patients did not have immediate success owing to infundibular spasm. Improved right ventricular compliance could be accounted for the ultimate success in these 2 patients. The ultimate successful rate was 100%. **Conclusion:** BD can achieve excellent long-term outcomes in the pediatric patients with isolated native VPS.

Key Words: Balloon dilatation, pediatric, valvular pulmonary stenosis

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INTRODUCTION

Balloon dilatation (BD) has emerged as the treatment of choice for patients with valvular pulmonary stenosis (VPS) since 1982.[1] We report herein a 10-year experience of long-term outcomes of BD for the pediatric patients with isolated native VPS in our institution, describe the major determinants of such interventional cardiac catheterization, and recommend an adjunctive treatment of inhaled nitric oxide for devastating pulmonary hypertension following BD.

MATERIALS AND METHODS

From May 1997 to May 2003, a total of 27 consecutive patients (12 male and 15 female and aged 2 days to 15.7 years) with isolated native VPS underwent BD at a tertiary medical institution in the Central Taiwan. Patients with pulmonary atresia and intact ventricular septum, supravalvular pulmonary stenosis and/or branch pulmonary artery stenosis associated with the Williams syndrome, supravalvular pulmonary stenosis *status post* arterial switch for the dextro-transposition of the great artery and Taussig-Bing anomaly, and VPS associated with other congenital heart diseases were excluded from this study. BD was recommended to the families as an alternative to surgery if the echocardiographic pressure gradient was ≧ 40 mmHg across the pulmonary valve. Informed consent was obtained from each

patient's parent(s) before BD. Fourteen infants ≦ 6 months old were pre-medicated with intramuscular injection of Meperidine HCl and Clemastine Fumarate. Other 13 patients > 6 months old were pre-medicated with intramuscular injection of Meperidine HCl, Clemastine Fumarate, and Chlorpromazine HCl. Hemodynamic data were obtained before BD to confirm the diagnosis and to rule out any additional cardiac malformations from the right heart and left heart catheterization through cannulation of the femoral vein and artery by the standard Seldinger technique. All these 27 patients were heparinized (100 units/kg) before BD. We did not prescribe intravenous or oral antibiotics for prophylaxis. After documentation of obstruction (≧ 40 mmHg) at the level of the pulmonary valve by pullback maneuver, right ventriculography was performed to visualize the pulmonary annulus in each patient, whose diameter could be measured by calipers after calibration. We performed BD in 26 patients by single-balloon technique, with a diameter 20% to 40% larger than that of the pulmonary annulus. Due to unavailability of the suitable single balloon catheter at that time, double-balloon technique was performed in 1 patient with a summated diameter 40% larger than the pulmonary annulus. We chose a superstiff wire (Medi-tech, Boston, MA, USA), which was anchored distally into the branch pulmonary artery in each of the 26 patients (21 left; 5 right) and into the descending aorta via the ductus in 1 patient, to offer a taut support to "rail" the balloon catheter crossing the stenotic pulmonary valve. Once the balloon catheter was placed in the stenotic lesion, we inflated the balloon 3 times at least and maintained under the recommended 3 - 3.5 atmospheres for no more than 10 seconds under fluoroscope to find out any indentation (waist) caused by the stenotic valve disappeared. After BD, the deflated balloon catheter was removed, and the pressure gradient was obtained by pullback maneuver in each patient. Finally, right ventriculogram was repeated in each patient to check the separation of the pulmonary valve. The whole procedures took from 1.5 to 3.5 hours (mean 2.2 hours), with a total fluoroscopic time from 30 to 55 minutes (mean 35 minutes). Doppler echocardiography was performed within 24 hours in each patient to check the immediate effectiveness of BD. Follow-up Doppler echocardiography was performed in each patient at varied time interval to recheck the ultimate successful rate. We defined successful BD as having 1) echocardiographic pressure gradient ≦ 40 mmHg across the pulmonary valve, and 2) ratio of the systolic pressure of the right ventricle over that of the left ventricle ≧ 80% by pressure tracings after BD.[2] Ineffective BD was defined as: 1) residual gradient ≦ 40 mmHg across the pulmonary valve by pullback pressure recording or by echocardiographic examination, or 2) persistence of symptoms that warranted surgery following BD. All 27 patients were followed up for 4 to 10 years (7.7 ± 5.7; median 4.5 years). We used the Wilcoxon Signed Rank Test to analyze statistical significance and expressed all hemodynamic data as mean ± SD and median in the pressure tracings of cardiac catheterization and echocardiography with color Doppler flow mapping before and after BD.

RESULTS

Chart recordings of clinical manifestations, plain chest films, electrocardiography, echocardiography, and hemodynamic data of the cardiac catheterization were all available for review in all these 27 patients. Their clinical profiles are summarized in Table 1. All 27 patients had a typical systolic ejection murmur over the left upper sternal border. Thirteen of 27 patients were symptomatic before BD (48%), including 9 infants with shortness of breath and prolonged feeding, and 4 children with exercise intolerance and exertional dyspnea. Fourteen patients were asymptomatic (52%). Two-dimensional echocardiography showed dome-shaped pulmonary valve and post-stenotic dilatation of the main pulmonary artery in 27 patients. However, there was no patient with dysplastic pulmonary valve. Doppler echocardiography showed turbulent flow across the pulmonary valve, with the pressure gradients ranging from 40 to 101 mmHg (61 ± 19, median 55 mmHg). At cardiac catheterization, the pressure gradients ranged from 40 to 144 mmHg (69 ± 32, median 60 mmHg) before BD, and ranged from 12 to 70 mmHg (29 ± 13, median 27 mHg) after BD (p <

Table 1. Clinical Profiles of 27 Pediatric Patients with Isolated Native Valvular Pulmonary Stenosis Who Underwent Balloon Dilatation

No	Age/Wt/Gender at BD	Symptoms and signs	PG (mmHg) before BD			PG (mmHg) after BD			Follow-up echo (mmHg) at 7.7 ± 5.7; 4.5 y
			Echo	Cath	sRV/sLV	Cath	sRV/sLV	Echo	
1	2 m/5 kg/M	SOB	96	104	119/106	28	43/108	26	20
2	13.6 y/47 kg/M	NS	55	65	79/108	30	47/112	30	21
3	2.8 y/14 kg/M	NS	46	50	64/103	28	43/110	26	25
4*1	6 y/30 kg/M	ED/EI	101	144	157/131	70	85/108	64	
4*2	9 y/45 kg/M		61	86	99/129	40	55/127	36	38
5	15.7 y/42 kg/M	ED/EI	100	130	148/94	36	56/118	33	30
6	3.7 y/15 kg/F	NS	55	69	82/108	40	55/106	35	20
7	12.5 y/29 kg/M	ED/EI VRD	98	101	115/129	50	66/127	46	26
8	1.1 y/8 kg/F	NS	44	48	58/81	23	33/72	24	23
9	1 m/4 kg/M	SOB	49	51	69/75	27	48/71	26	25
10	6 m/7 kg/F	NS	64	62	76/88	19	39/88	16	13
11	2 m/4 kg/F	SOB	65	60	84/91	40	64/90	24	22
12*1	14 y/73 kg/F	ED/EI	82	133	152/111	50	69/120	50	35
12*2	15.7 y/92 kg/F		55	50	74/112	36	60/120	36	
13	1.6 y/13 kg/M	NS	43	41	51/75	20	30/80	19	22
14	15.7 y/57 kg/F	NS	55	61	71/106	31	41/120	33	34
15	2.9 y/11 kg/F	NS	41	44	62/94	13	31/104	11	12
16	1.5 m/3 kg/F	NS	50	50	74/98	25	49/100	27	18
17	3 m/5 kg/F	NS	44	44	58/99	23	38/102	29	25
18	1 m/4 kg/M	SOB	75	86	97/99	18	40/97	19	15
19	1.5 m/4 kg/F	SOB	62	70	84/80	36	50/82	28	23
20	2 d/3 kg/M	SOB	56	55	75/69	13	47/66	15	14
21	7.5 m/7 kg/F	NS	43	44	58/106	24	39/103	27	27
22	3.5 m/5 kg/M	SOB	52	54	73/92	21	40/116	20	11
23	2.3 m/4 kg/M	NS	44	40	65/100	30	34/100	30	27
24	2.5 m/5 kg/F	SOB	71	119	132/85	20	34/95	16	15
25	6.5 m/10 kg/F	NS	40	40	65/83	16	31/90	14	12
26	4 m/5 kg/F	SOB	54	60	78/97	36	42/88	24	22
27	5 m/7 kg/F	NS	48	40	58/84	12	29/88	15	13

BD, balloon dilatation; Cath, catheter pullback pressure recording; Echo, echocardiography with color Doppler flow mapping; ED, exertional dyspnea; EI, exercise intolerance; NS, no specific symptoms and signs other than heart murmur; PG, pressure gradient across the pulmonary valve; SOB, shortness of breath; VRD, von Recklinghausen disease; M, male; F, female.
Patient 4 (*1, *2) and patient 12 (*1, *2) underwent gradational BD owing to infundibular spasm in each of them at the first try of BD.

0.001). The ratio of the systolic pressure of the right ventricle to that of the left ventricle ranged from 55 to 157% (89 ± 28, median 79%) before BD, and ranged from 30 to 79% (47 ± 13, median 42%) after BD ($p < 0.001$). Within 24 hrs after BD, the Doppler echocardiography showed significant drop of the pressure gradients, which ranged from 11 to 64 mmHg (27 ± 12, median 26 mmHg) ($p < 0.001$). The echocardiographic gradients were lower (11 - 61, 25 ± 11, median 24 mmHg) at the 3-month follow-up than those detected within 24 hrs (11 - 64, 27 ± 12, median 26 mmHg) after BD ($p = 0.03$).

The echocardiographic gradients in the long-term follow-ups, at an interval of 7.7 ± 5.7 years (median 4.5 years), were lower (22 ± 7, median 22 mmHg) than those documented within 24 hrs (27 ± 12, median 26 mmHg) after BD.

The single oversized balloon technique worked well when the pulmonary annulus was less than 20 mm in diameter, and the double-balloon technique was necessary to provide adequate relief of obstruction in individuals with a pulmonary annulus diameter greater than 20 mm.[3] Double-balloon technique was used in the patient 7, in whom the pressure gradient across the pulmonary valve was 50 mmHg, obtained by pull-back pressure recording. The pressure gradients were 46 mmHg within 24 hrs, and 27 mmHg at the 1-month follow-up, measured by Doppler echocardiography. The patient 20 suffered from cyanosis 6 days after BD, due to a combination of ductal closure, poor compliance of the right ventricle with severe tricuspid regurgitation, and interatrial right-to-left shunting via incompetent patent foramen ovale, which were documented by Doppler echocardiography and a bubble contrast test. A medical emergency mimicking persistent pulmonary hypertension of newborn intervened and regressed gradually in 10 days after inhalation of nitric oxide. The patient 26 had mild VPS (13 mmHg) when she was born prematurely (at the 31st gestational age). The pressure gradient stepped up to 54 mmHg 4 months later. Post-prandial shortness of breath, which was found at the time of diagnosis, regressed after BD. Nine (56%) out of sixteen infants had shortness of breath and prolonged feeding, and 2 (50%) out of 4 children with exertional dyspnea were free of symptoms after BD. The patients 4 and 12 each underwent a second procedure due to infundibular spasm at the first try of BD. The pressure gradients dropped from 70 to 40 mmHg in the patient 4, and from 50 to 36 mmHg in the patient 12 after a second try of BD plus administration of propranolol. They were asymptomatic in the follow-up of 6.4 years and 5 year after the second procedure, respectively. The immediate successful rate of BD was 25 out of 27 patients (93%). The patients 4 and 12 did not achieve immediate success due to severe infundibular spasm after BD. Improved right ventricular compliance could be accounted for the ultimate success of the repeated BD in these 2 patients, with the aid of propranolol. In the long-term follow-ups of 4 to 10 years, the ultimate successful rate reached 100% in these 27 pediatric patients. In addition, there was no significant pulmonary and/or tricuspid regurgitation causing dilatation of the right ventricle and the right atrium, and engorgement of the superior vena cava and the inferior vena cava in the long-term follow-ups, evidenced by Doppler echocardiography.

DISCUSSION

To effectively perform BD for the VPS, we first recommend accurate measurement of the pulmonary annulus, by caliper calibration on the lateral projection of the right ventriculogram, to which a suitable balloon catheter can accordingly be selected. From our experience, we fully agree with the notion that a balloon catheter with its balloon diameter 20% to 40% larger than that of the pulmonary annulus is the best choice for BD in patients with isolated valvular pulmonary stenosis.[4] However, the large-profile balloon catheters of 4.0 cm in length or longer, which could cause trauma to the pulmonary artery or tricuspid valve, infundibular spasm, and arrhythmia in the neonates,[5] infants, and small young children at performing BD, should not be used. The low-profile balloon catheters of no more than 2.0 cm in length are highly recommended for BD in neonates and infants with severe to critical valvular pulmonary stenosis.[6] Another advantage of low-profile balloon catheter is that it could be "railed" to cross the stenotic pulmonary valve on a superstiff wire anchored in the left pulmonary artery or in the descending aorta,[6] Thus, how to overcome the difficulty in manipulating a superstiff wire into the branch pulmonary artery or the descending aorta is important in attempting BD.

It is not difficult to rail a balloon catheter to cross the stenotic pulmonary valve and the ductus along a guidewire into the descending aorta by the maneuver of transductal guidewire "rail".[7] However, experience has taught us that manipulation of guidewire or balloon catheter in the ductus can result in severe ductal constriction or even

closure that may be refractory to high doses of prostaglandins.[2] We did encounter a neonate, after radiofrequency valvulotomy and balloon valvuloplasty for pulmonary atresia and intact ventricular septum,[8] presenting intractable cyanosis due to a constellation of ductal constriction, poor compliance of the right ventricle, and interatrial right-to-left shunt via the incompetent patent foramen ovale, pathogenesis of which was very similar to that occurred in the patient 20, to whom nitric oxide was inhaled to relieve post-procedure cyanosis. Inhalation of nitric oxide could be used as an adjunctive treatment in some patients who present a medical emergency mimicking persistent pulmonary hypertension of newborn after BD.[8] Thus, it is better to leave the patent ductus arteriosus alone in neonates with critical stenosis of the pulmonary valve, unless congestive heart failure intervenes due to increased pulmonary blood flow. Nevertheless, successful transaortic balloon valvuloplasty for the critical pulmonary stenosis via the patent ductus arteriosus have been reported by Wang et al.,[6] and Coe et al.[9]

The effectiveness of BD for critical valvular pulmonary stenosis ranged from 43% to 94%.[6] BD can be the definitive therapy for critical pulmonary stenosis or pulmonary atresia with intact ventricle septum in infants, with tricuspid valve annulus > 11 mm, right ventricular volume > 30 mL/m^2, or pulmonary valve annulus $\geqq$ 7 mm.[10] There was no instance of dysplasia or severe hypoplasia of tricuspid valve, pulmonary valve, and right ventricle in our study. This may be the reason of why we could achieve a successful rate of 100% in these 27 patients. We encountered 2 neonates with ductus-dependent pulmonary atresia and intact ventricular septum, and radiofrequency valvulotomy and gradational balloon dilatations were performed. One of them, with Z value of tricuspid valve < - 3 and > - 4, required surgical shunts and inhaled nitric oxide to wean off prostaglandin infusion and ventilator support.[8] It is the anatomic morphology of the tricuspid valve, the right ventricle, and the pulmonary valve to account for the different outcomes of critical VPS which underwent BD at different institutions.[6,10,11] Gradational BD was unnecessary in the present study, because of the absence of dysplasia of the tricuspid valve, the right ventricle, and the pulmonary valve, which are frequently seen in cases of pulmonary atresia with intact ventricular septum.

With improvement of transcatheter technique and equipments, either a single balloon catheter of low profile (better with a balloon diameter 20% to 40% greater than that of the pulmonary annulus),[6,11-13] or more balloon catheters of different sizes (with gradational dilatation) can be used to dilate the pulmonary valve.[5,6,12-16] In our patients with isolated native VPS, we used single-balloon maneuver in 26 patients and double-balloon maneuver in one patient to dilate the pulmonary valve by at least 3 inflations.

Determinants for unsuccessful BD for severe to critical pulmonary stenosis in neonates and infants $\leqq$ 6 months are smaller pulmonary valve annuli and severe tricuspid regurgitation, rather than the right ventricular size and right-to-left ventricular pressure ratio.[13] It is not farfetched to state that smaller pulmonary annulus demands more balloon catheters to gradationally dilate the pulmonary valve. However, a single balloon catheter of small profile can also be used to rail a superstiff wire to cross the stenotic pulmonary valve and to effectively perform BD at one time. This all-inclusive technique deserves a far wider range of attention and practice in cases of nonductus-dependent critical pulmonary stenosis.

Finally, propranolol can be used to reverse infundibular spasm which complicates BD.[17] This kind of functional infundibular stenosis may resolve with time by itself.[6,18] In this study, the echocardiographic gradients at the 3-month follow-up were lower (11 - 61, 25 ± 11, median 24 mmHg) than those detected within 24 hrs (11 - 64, 27 ± 12, median 26.0 mmHg) after BD. This implies that impingement on the infundibulum, causing undesirable spasm, may well occur in patients during and after BD, and most of them regress spontaneously.[18] Perforation of the right ventricular outflow tract is a major complication commonly encountered in patients with critical pulmonary stenosis undergoing BD,[2,11,12,19-22] which accounts for a mortality rate of 3% to 8%.[2,12,13,20-22]

In summary, 1) accurate measurement of the pulmonary annulus, 2) selection of small low-profile balloon catheter with inflated diameter 20% to 40% larger than that of the pulmonary

annulus, 3) successful anchorage of a superstiff wire onto the peripheral left pulmonary artery or onto the descending aorta as a rail for balloon catheter, and 4) absence of dysplasia of the tricuspid valve, right ventricle, and pulmonary valve are the four major determinants of successful BD for pediatric patients with isolated native VPS, especially in neonates and infants with critical VPS.

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