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Pulmonary valve balloon valvuloplasty compared across three age groups of children

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Abstract: The aim of this study was to investigate the characteristics and outcomes of treating pulmonary stenosis with percutaneous valvuloplasty, and to compare them among three childhood age groups. All children under 15 years of age who had undergone pulmonary valve balloon valvuloplasty in Madani Heart Center from 2005–2009 were enrolled in this study. Data were analyzed using IBM SPSS software (SPSS, Inc, Chicago, IL). Mean (± standard deviation) age of patients was 55.5 ± 47.4 months. Two-thirds of the subjects had moderate pulmonary valve stenosis. Balloon valvuloplasty failed in nearly one-fifth of the treated patients. There were 17 failures and two cases of mortality, descriptively less frequent among children >5 years; however, the observed difference was not statistically significant. Mild pulmonary valve insufficiency was a common finding.

Keywords: childhood cardiology, pulmonary stenosis, percutaneous valvuloplasty

Introduction

Patients with severe stenosis should undergo treatment even if it is well tolerated and is asymptomatic at the beginning. This is due to the possibility of dangerous complications that may emerge if timely treatment is not used.[1] Balloon valvuloplasty for pulmonary valve stenosis is the treatment of choice for isolated pulmonary stenosis in all childhood age groups.[2]

The balloon valvuloplasty procedure in treating pulmonary valve stenosis has its origins in the success of surgical valvotomy to relieve the pressure gradient developed across the stenotic pulmonary valve.[3] The first catheter attempts to relieve the gradient were described by Rubio and Limon Lason in 1954[4] and Semb et al in 1979.[5]

The short-term and long-term effects of this therapy are still an area of interest for interventional cardiologists as stronger evidence is needed from studies in different settings and populations.

The aim of this study was to investigate characteristics and outcomes of treating pulmonary stenosis with valvuloplasty, and to compare the results among three childhood age groups.

Methods

All children under 15 years of age who had undergone pulmonary valve balloon valvuloplasty in Madani Heart Center from 2005–2009 were enrolled in this study. Madani Heart Center is a referral subspecialty center belonging to Tabriz University of Medical Sciences and is located in Tabriz, northwest of Iran. A total of 87 children were studied.

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The diagnosis was based on two-dimensional echocardiography and peak-to-peak pressure gradient difference between the pulmonary artery and right ventricle.

Medical files of the patients were reviewed. The main variables investigated included: age, sex, coincident diseases, baseline right ventricle and pulmonary artery pressure gradient, pulmonary artery-right ventricle pressure gradient at baseline and after 24 hours, remaining residual pressure, annulus size, balloon size, complications, and mortality. Percutaneous balloon valvuloplasty was performed on a standard base for any patient with transvalvular gradient >40 mmHg. A catheter, with deflated balloon at a given size, was inserted through the skin into the vessel. The patient was heparinized. The gradient across the pulmonary outflow was measured and location of the valve was defined using fluoroscopy and a ventriculogram in the anteroposterior and lateral projections. After conducting valvuloplasty and all measurements, the results were compared among three age groups: infants, 1–5 years, and 5–15 years.

Data were entered into the computer and analyzed using IBM SPSS software (version 16.0; SPSS Inc, Chicago, IL). Descriptive of continuous variables were presented as mean ± standard deviation. Based on data distribution, independent *t*-test or Mann–Whitney *U* test were used to compare numeric variables. *P* values less than 0.05 were considered statistically significant.

Study protocol was approved by regional committee of ethics at Tabriz University of Medical Sciences.

Results

Mean age of the patients was 55.5 ± 47.4 months. The youngest patient undergoing valvuloplasty was 3-months-old. One-fifth of children were infants. Boys comprised 49.4% of participants.

Echocardiographic findings and cardiac involvement types are given in Figure 1.

Nearly two-thirds of the patients suffered moderate pulmonary valve stenosis. Noncardiac coincident diseases included two cases of bilateral tonsillar hypertrophy, one congenital cataract, one case of undescended testis, one hemophilia case, and one case of left sided inguinal hernia. Mean right ventricular pressure was 95.9 ± 35 mmHg at the first visit and mean pulmonary artery pressure was 26.2 ± 14.7 mmHg. Mean difference between the pulmonary artery and right ventricular pressure was 77 ± 35 mmHg. Mean frequency of balloons used was 1.2. Valvuloplasty complications were recorded in five patients. Pulmonary valve insufficiency was observed in 52 (59.8%) patients, 36 patients having mild pulmonary valve insufficiency. Stenosis remained in 56 patients leading to a mean pressure of 40 ± 26.4 mmHg. Two children died under treatment, one of whom was a 3.5-month-old infant who died after 3 days in intensive care unit, suffering from multiple cardiac anomalies. The therapeutic procedure failed in 17 patients needing a subsequent surgery. Table 1 provides a comparison of results and cardiac measurements among three age groups.

Discussion

Balloon valvuloplasty failed in nearly one-fifth of patients in this study leading to a surgical alternative treatment. Although balloon dilatation mortality and morbidity is reported to be greater than after surgery and the recurrence rate is higher following balloon dilatation, the comparison can be problematic

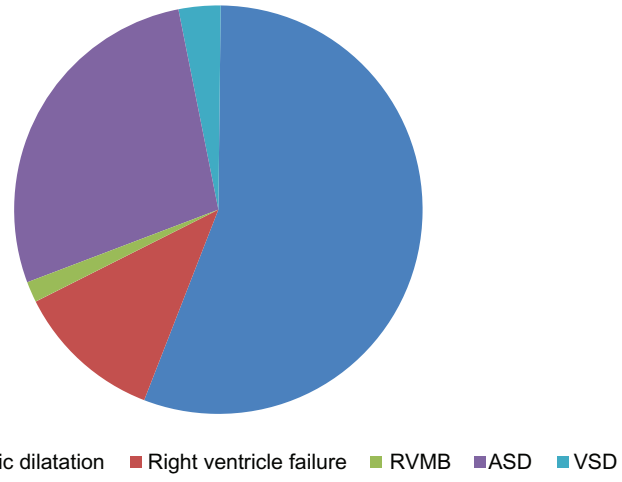

Figure 1 Distribution of echocardiographic cardiac involvements.
Abbreviations: ASD, atrial septal defect; RVB, right ventricular muscle bundles; VSD, ventricular septal defect.

Table 1 Comparison of results and cardiac measurements among three age groups of patients undergoing balloon valvuloplasty

Measures	Age groups		
	Infants	**1–5 years**	**>5 years**
PS severity (count)	Moderate (2)	Moderate (16)	Moderate (12)
	Severe (4)	Severe (3)	Severe (7)
Mean baseline RV pressure (mmHg)	90	85	92.4 (SD 37.2)
Mean baseline PA pressure (mmHg)	22	23	28.3 (SD 19.1)
Mean baseline RV-PA gradient pressure (mmHg)	59	70.5 (SD 35.4)	68.3 (SD 34.5)
Mean annulus size (mm)	9	15.1 (SD 7.1)	19.6 (SD 8.9)
Mean balloon diameter/annulus size ratio	1.5	1.4 (SD 4)	1.2 (SD 0.3)
Mean balloon frequency	1	1.2 (SD 0.4)	1.2 (SD 0.4)
Repeated valvuloplasty (count of events)	1	10	5
Largest balloon size	13.5	19.2 (SD 4.7)	20.7 (SD 5.9)
RV-PA gradient pressure (24 hours)	35	36.9 (SD 22)	35.8 (SD 24.3)
Sixth month RV-PA gradient pressure	–	29.9 (SD 32.6)	11 (SD 8.5)
Stenosis remained (count of events)	6	28	22
Mean residual stenosis gradient (mmHg)	42.5	37.8 (SD 22.7)	39.6 (SD 28.8)
Mean hospitalization times	1	1.4 (SD 1)	1.5 (SD 1.4)
Complications (count of events)	1	2	2
Failure	4	7	6
Hemorrhage (count of events)	1	1	0
Death (count of events)	1	1	0
Total number of patients	18	39	30

Abbreviations: PA, pulmonary artery; PS, pulmonary stenosis; RV, right ventricle; SD, standard deviation.

due to methodological issues.[6] However, since the first report by Kan et al,[7] many studies have confirmed the safety and efficacy of pulmonary balloon valvuloplasty in infants, children, and adolescents with pulmonary valve stenosis, and it has gained much popularity. Indications for intervention in this age group include the prevention of progression of right ventricular outflow tract obstruction, right ventricular hypertrophy, and right ventricular fibrosis.

Outcome results in this study, as consistent with others, pose the idea of hemodynamic mechanisms being affected after pulmonary balloon valvuloplasty. In a study by Alyan et al, it was found that sympathetic overactivity and increased probrain natriuretic peptide levels were associated with the symptomatic status of patients with pulmonary stenosis and associated with a decrease in atrial pressure and probrain natriuretic peptide levels; pulmonary balloon valvuloplasty yielded a decrease in adrenergic overactivity in the patients with pulmonary stenosis.[8]

Although not statistically significant, there were 17 failures and two cases of mortality, descriptively less frequent among children >5 years. Failure, mortality, and complication are an inevitable part of cardiothoracic interventions.[9–11] The presence of complications is proportional to age and such complications are mostly found in infants. Although younger patients have shown poorer prognosis after valvuloplasty, interestingly the method has been used even for a 700-g neonate with pulmonary stenosis.[12]

Using an appropriate ratio of balloon to valve hinge point diameter is shown to optimize the chance of long-term success.[13] Mean balloon diameter/annulus size ratio in the present study varied from 1.2 in older age group to 1.5 among infants. The disruption of the annulus of the pulmonary valve may lead to hemorrhage into the pericardial sac and subsequent tamponade, which is why the choice of the right diameter of balloon is so important. It is best to choose the balloon according to data obtained from echocardiography and angiocardiography.[14] Werynski et al studied 137 children with isolated pulmonary stenosis who underwent valvuloplasty. The balloon diameter to pulmonary valve annulus ratio was 1.3 in their study and complications were seen in 3.6% of the patients, including one case of a balloon being lodged in the iliac vein.

Mild pulmonary valve insufficiency was a common finding in the patients of the present study. Moderate pulmonary valve insufficiency can also be considered as one of the procedure complications. It is associated with the diameter of balloons used during the intervention. According to literature, the occurrence of this problem ranges 10%–50% of patients with pulmonary valve stenosis who underwent surgical treatment or balloon valvuloplasty. For many years, there was a belief that this state should be well tolerated by patients. The summary data suggest that in long-term observation, serious insufficiency is not well tolerated. In a Polish study, none of patients needed reintervention and

in the long-term observation there was no insufficiency of the pulmonary valve >II°. But all the patients undergoing balloon valvuloplasty in that study had isolated pulmonary stenosis. New mild pulmonary insufficiency was noted in 28% after pulmonary balloon valvuloplasty in a long-term assessment by Fawzy et al.[15]

Like the present study, most studies have used echocardiographic assessments. However, Doppler echocardiography tends to overestimate the transvalvular gradient of systolic pressure in mild cases of pulmonary valve stenosis, in comparison to hemodynamic assessment. This needs to be taken into account when interpreting results. Nevertheless, echocardiographic diagnostics generally play a key role.

Conclusion

The study reveals that balloon valvuloplasty can be a useful and effective treatment for pulmonary stenosis in all childhood age groups. It was found that failure may not be uncommon and can lead to a subsequent surgery. Also, recurrences of the stenosis should be expected and repeated valvuloplasty may be inevitable.

Disclosure

The authors report no conflicts of interest in this work.

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