Pulmonary valve regurgitation following balloon valvuloplasty for pulmonary valve stenosis: Single center experience

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ABSTRACT

Background : **Pulmonary valve regurgitation following balloon valvuloplasty for moderate to severe pulmonary valve stenosis is a known late outcome of this procedure.**

Objective : **The aim of the study was to characterise the status of pulmonary regurgitation on follow up after pulmonary valve balloon dilatation (PVBD), and to study the determinant of the severity of PR.**

Materials and Methods : **We retrospectively reviewed 50 consecutive patients, aged 2 days to 18 years, with isolated pulmonary valve stenosis, who had undergone PVBD in 2004-2009 and were assessed with follow-up Doppler echocardiography. The impact of balloon to annulus ratio, age, and valve anatomy on the late development of moderate and severe pulmonary valve regurgitation following balloon valvuloplasty was analysed.**

Results : **Six patients (12%) had no pulmonary valve regurgitation; 32 (64%) had mild, 9 (18%) had moderate, and 3 (6%) had severe pulmonary valve regurgitation at a mean follow-up of 4 years. Balloon to annulus ratio, age, and valve anatomy were not statistically significant predictors for moderate and severe pulmonary valve regurgitation.**

Conclusions : **The majority of patients in our population had mild pulmonary valve regurgitation. Moderate to severe pulmonary valve regurgitation was well tolerated at midterm follow-up. Age, balloon to annulus ratio, and valve anatomy were not statistically significant predictors for the late development of moderate and severe valve regurgitation. Large and longer follow-up studies are needed to address this question.**

Keywords : Balloon valvuloplasty, dysplastic valve, pulmonary valve regurgitation

INTRODUCTION

Congenital pulmonary valve stenosis (PS) accounts for between 7.5 and 9% of all congenital heart malformations.[1] Balloon valvuloplasty is the accepted first-line treatment for all age groups with moderate to severe PS.[1-3] Mid- and long-term follow-up studies[4-9] have reported pulmonary valve regurgitation as a late outcome of balloon valvuloplasty. The degree of pulmonary valve regurgitation reported in these studies ranged from mild to moderate in majority of the cases, with a few cases developing severe pulmonary valve regurgitation. Berman[10] reported development of severe pulmonary valve regurgitation in six infants who underwent balloon valvuloplasty; one required valve replacement. Several studies[5,7,9-11] examined balloon to annulus ratio, age, high degree of obstruction, and more complex valve morphology as the risk factors for late development of severe pulmonary valve regurgitation, but these findings were not consistent in all these studies.[5,7,9-11] The aim of this study was to examine the rate and degree of pulmonary valve regurgitation in our population at midterm follow-up. We also examined the balloon to annulus ratio, age, and valve anatomy as the predictive factors of development for moderate and severe pulmonary valve regurgitation.

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MATERIALS AND METHODS

The records of patients who underwent balloon dilation of pulmonary valve at a single tertiary care center from 2004

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to 2009 were reviewed after obtaining the ethical approval of the hospital ethics committee at Royal Hospital, Oman. The procedure had been performed by five cardiologists during this time and all used the same technique as described by others.[2,12,13] We included all patients with isolated pulmonary valve stenosis, of age from 2 days up to 18 years. Patients with hemodynamically insignificant patent ductus arteriosus and secondum atrial septal defects were included as well. None of the patients had previous cardiac surgery. Interventional cardiac catheterization via right femoral venous route was performed under general anesthesia. Tyshak 2 and Z-Meditech balloons were used and, occasionally, coronary balloons were used for initial dilatation to assess advancement of bigger balloons across the pulmonary valve in neonates. The valve diameter was measured by echocardiography and confirmed by angiography at the hinge point of the valve leaflets in lateral projection. Dysplastic pulmonary valve was defined at catheterization and echocardiogram as very thick with poorly mobile leaflets.[14-16] Measurement of peak to peak pressure in the right and left ventricles during the procedure was used to assess the degree of obstruction before and after the balloon inflation. Doppler echocardiography was used at the last follow-up to assess the degree of pulmonary valve regurgitation as mild when the diastolic flow reversed midway between the valve and the bifurcation of the pulmonary trunk, as moderate when the reversal reached the level of the bifurcation, and as severe when flow reversal was seen within branch pulmonary arteries. All patients had clinical assessment during follow-up; in addition, right ventricular function and dilatation were assessed for all patients and reported if present.

Statistical analysis

Statistical analysis was performed using Stata 11 (StataCorp. 2011. Stata statistical software: Release 11. College station, TX, USA: StataCorp. LP). Mean standard deviation and ranges were calculated for continuous variables. Frequencies were determined for nominal and ordinal variables. Univariate and multivariate logistic regression analyses were used to examine the risk factors for the development of moderate and severe pulmonary valve regurgitation that included age, balloon to annulus ratio, and valve morphology. A $P<0.05$ was considered to be statistically significant.

RESULTS

We analyzed 50 consecutive patients who underwent balloon dilatation of pulmonary valve from 2004 to 2009. The patients' characteristics are shown in Table 1. The mean age at the time of intervention was 2.23 years (range: 2 days–18 years). There were 32 males and 18 females; 19 had dysplastic valve and 31 had non-dysplastic valve. The mean pre-dilatation peak right and left ventricles' systolic pressures were 90 mm Hg (range: 47-167 mm Hg) and 78 mm Hg (range: 43110 mm Hg), respectively. The mean post-dilatation peak right and left ventricles' systolic pressures were 47 mm Hg (range: 24-83 mm Hg) and 81 mm Hg (range: 35-125 mm Hg), respectively. The mean time of follow-up was 4 years (range: 2-6 years). The mean balloon to annulus ratio was 1.30 (range: 1–1.66). Six patients (12%) had no pulmonary valve regurgitation, 32 (64%) had mild pulmonary valve regurgitation, 9 (18%) had moderate pulmonary valve regurgitation, and 3 (6%) had severe pulmonary valve regurgitation, as shown in Figure 1. We performed univariable logistic regression using age, balloon to annulus ratio, and valve anatomy as the three variables predicting moderate and severe valve regurgitation. None were statistically significant. Similar results were seen in the multivariable logistic analysis also. Three patients developed severe pulmonary valve regurgitation with mild right ventricular dilatation at a mean follow-up of 4 years. The mean age at the time of intervention for this subgroup was 4 months; the mean pre- and post-dilatation peak right to left ventricular pressures were 108/74 and 58/95 mm Hg, respectively. The mean balloon to annulus ratio used in this group

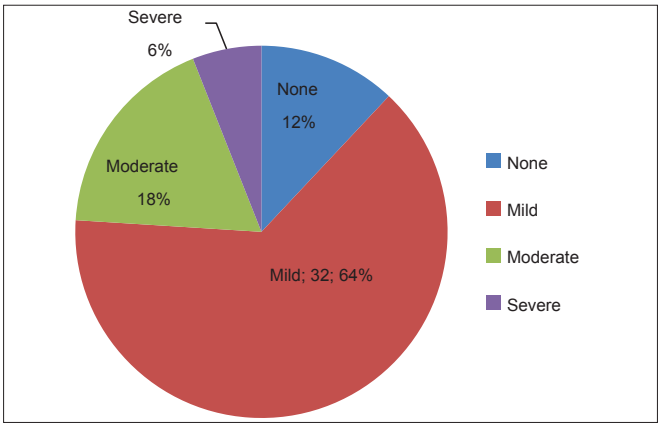

Figure 1: Frequency of pulmonary valve regurgitation at follow up among 50 patients

Table 1: Baseline characteristics

Characteristics	Mean and SD	Range/percentage
Age at the time of intervention (years)	2.23 (3.7)	2 days-18 years
Gender		
Male/Female		32 (64)/18 (36)
Follow-up Doppler echocardiography (years)	4	2-6
Pre-dilatation RVSP (mm Hg)	90 (2.8)	47-167
Pre-dilatation LVSP (mm Hg)	78 (1.81)	43-110
Post-dilatation RVSP (mm Hg)	47 (1.5)	24-83
Post-dilatation LVSP (mm Hg)	81 (2.2)	35-125
Balloon to annulus ratio	1.30 (0.16)	1-1.66
Valve anatomy		
Dysplastic		19 (38)
Non-dysplastic		31 (62)

RVSP: Right ventricle systolic pressure, LVSP: Left ventricle systolic pressure

was 1.46. Two of three patients who developed severe pulmonary valve regurgitation had dysplastic valve. All the three patients with severe pulmonary valve regurgitation were asymptomatic and reported no effort limitations. In our cohort of patients, balloon to annulus ratio of 1.5 and above was used in five patients, and only one patient with dysplastic valve developed moderate pulmonary valve regurgitation at 3 years of follow-up without right ventricular dilatation, with the rest of the group having only mild regurgitation. This group of patients had less degree of obstruction compared to those who developed severe pulmonary valve regurgitation, with the pre-dilatation peak right to left ventricular pressures of 64/80 mm Hg versus 108/74 mm Hg.

DISCUSSION

This study shows that pulmonary valve regurgitation is a common late finding after balloon valvuloplasty in our population and is well tolerated at midterm follow-up. Our finding is comparable to what have been reported by others.[4,6,11] Although pulmonary valve regurgitation is a common finding after balloon valvuloplasty, it is documented that moderate to severe pulmonary valve regurgitation progresses during follow-up.[3,9,11] Berman *et al.*,[10] reported 107 patients who underwent balloon valvuloplasty with a follow-up time of 0.5–10 years (mean 7.2). Six out of 107 patients developed severe pulmonary regurgitation with right ventricular dilatation; one required valve replacement and the others were expected to have valve replacement. These patients were younger than 2 months, had more severe obstruction, and underwent dilatation with oversized balloon (range: 1.33-1.5). In our analysis, we failed to demonstrate statistically significant relation between balloon to annulus ratio, age, and valve anatomy, and the development of moderate to severe pulmonary valve regurgitation. The failure to detect this relation is in part due to small sample size and low events per variable rate.[17] Furthermore, in our population, we used oversized balloon of 1.5 and above in five cases and did not observe the development of severe pulmonary valve regurgitation at follow-up. We noticed that those who developed severe pulmonary valve regurgitation had more severe degree of obstruction. It appears that the relation between balloon to annulus ratio is more relevant in typical valve anatomy where the leaflets fused centrally the splitting induced by balloon valvuloplasty does not extend beyond the valve commissures. However, in more complex anatomy where they induce higher degree of obstruction, balloon valvuloplasty may lead to a non-uniform tear which may extend to the valve annulus,[18] and in those patients, oversized balloon may cause more significant late pulmonary valve regurgitation. Oversized balloon above 1.4 had been previously used without causing severe degree of pulmonary valve regurgitation,[11,19] although balloon to annulus ratio above 1.4 is not recommended[20] because of the damage it causes to the right ventricle as demonstrated in animal models. Subsequent analysis by Rao[1] suggested a ratio of 1.2–1.25 as the most appropriate to prevent late development of pulmonary regurgitation.

Limitations of the study: The small sample size and small number of patients with moderate and severe pulmonary valve regurgitation render this study underpowered to detect the risk factors for the occurrence of pulmonary valve regurgitation. We did not compare the degree of pulmonary regurgitation immediately after PVBD to the degree on follow up. The follow up period is relatively small and we could not assess the impact on right ventricle function by cardiac MRI due to non availability. Neverthless, the study provides the data on the degree of PR after PVBD on follow up.

CONCLUSION

Pulmonary valve regurgitation is a common finding in midterm follow-up after balloon valvuloplasty, and the majority of the patients have mild pulmonary regurgitation. Moderate to severe pulmonary regurgitation is well tolerated at midterm follow-up and perhaps not related to age, balloon size, or valve anatomy. Larger studies with longer follow up data are required.

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