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ORIGINAL ARTICLE

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The effect of balloon valvuloplasty for bioprosthetic valve stenosis at pulmonary positions

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Abstract

Background: Balloon dilatation of a bioprosthetic valve in the pulmonary position could be performed to delay valve replacement. We proposed to identify the long-term effectiveness of such a procedure.

Methods: We reviewed the medical records of 49 patients who underwent balloon valvuloplasty between January 2000 and December 2015. The primary goal was to determine the time interval until the following surgical or catheter intervention.

Results: The mean age at bioprosthetic valve insertion was 5.7 years old, and the mean age for ballooning was 11.7 years. The mean interval after pulmonary valve replacement was 71.6 months. The mean ratio of balloon size to valve size was 0.94. The pressure gradient through the pulmonary valve after balloon valvuloplasty was significantly improved (55.3 ± 18.5 mm Hg vs 33.8 ± 21.5 mm Hg, $P < .001$). There were no significant changes in pulmonary regurgitation and no serious adverse events. Patients had a mean freedom from re-intervention of 30.6 months after balloon valvuloplasty. The interval of freedom from re-intervention was affected only by the pressure gradient before balloon valvuloplasty and the patient age at insertion. The mean interval to re-intervention in patients with pressure gradients less than 48.5 mm Hg before ballooning was 46.0 months, which was significantly longer than for those with a higher gradient (18.7 months).

Conclusion: The effectiveness of this process may depend on the pressure gradient before ballooning and the patient age at valve insertion. It is possible that earlier valvuloplasty at pressure gradient not over 48.5mm Hg may have a benefit to delaying re-operation.

KEYWORDS

balloon valvuloplasty, bioprosthesis, pulmonary valve stenosis, re-intervention

1 | INTRODUCTION

Following repair of complex cardiac defects, bioprosthetic pulmonary valves are often needed to maintain pulmonary valve function. Many patients with bioprosthetic pulmonary valves require reoperation due to inevitable valve failure. Balloon valvuloplasty is a highly effective and safe method for treating acute and chronic congenital pulmonary valvular stenosis.[1–4] However, bioprosthetic valve failure has a very different nature from congenital valve stenosis.[5,6] A few reports have explored balloon dilatation to treat bioprosthetic valve failure, mainly at aortic positions.[7–12] The efficacy and safety of this method have not been reported. Very few reports have explored balloon dilatation for bioprosthetic valves in the right heart.[13,14] A few case reports examined ballooning for tricuspid bioprosthetic valve stenoses. Despite promising immediate results, intermediate and long-term effects have not been reported.[9,15] Percutaneous pulmonary valve replacement has recently received attention, and successful implantations for failed prosthetic valves have been reported.[16,17] However, this method is not

All authors listed above meet authorship criteria according to the latest guidelines of the International Committee of Medical Journal Editors and all authors are in agreement with the manuscript.

yet popular in Korea. Therefore, surgical valve replacement or catheter-based dilatation is unique practices for our patients with prosthetic valve failure. We aimed to determine outcomes after balloon valvuloplasty of a prosthetic valve at the pulmonary position.

2 | METHODS

We reviewed the medical records of patients who underwent balloon valvuloplasty of a bioprosthetic pulmonary valve at the Samsung Medical Center and the Sejong Heart Center between January 2000 and December 2015. Patients with missing data or a lack of follow-up examinations were excluded.

Two-dimensional and Doppler echocardiography were performed prior to balloon valvuloplasty. We applied the indications of catheter-based balloon valvuloplasty in patients with a high-calculated peak pressure gradient over a prosthetic valve greater than 50 mm Hg or a high estimated right ventricular systolic pressure greater than two-thirds of the systemic systolic blood pressure based on Doppler echocardiography. The degree of pulmonary regurgitation was evaluated by pediatric cardiologists who had practiced for at least 3 years and was classified as mild (grade 1), moderate (grade 2) or severe (grade 3). Balloon valvuloplasty was performed under local anesthesia. Heparin (50–100 units/kg) was infused immediately after femoral artery puncture. The pressures at the right ventricle and the main pulmonary artery were measured before and after balloon valvuloplasty. The systolic peak-to-peak pressure gradient through the pulmonary valve was calculated. Descending aorta pressure was monitored during the procedure. The bioprosthetic valve diameter was measured by angiography at the inner margin of the valve struts or at the hinge point of the laterally projected valve leaflets. The balloon size was determined by considering the measured bioprosthetic valve diameter and the valve size written in the surgical record. Usually balloon size should not exceed the tissue valve size in the surgical record, but a little bigger than measured can be utilized to get the best results. Double balloon techniques were used when the available balloons were limited. The balloon catheters used in our patients were noncompliant high pressure 2 or 4 cm balloon catheters, such as the XXL (Boston Scientific, Natick, MA) or MAXI LD (Johnson and Johnson, New Brunswick, NJ). Balloon valvuloplasty was performed as described previously.[18,19] Balloon pressures applied were the nominal pressure, but rated burst pressure was occasionally applied in cases with high resistance to nominal pressure. Significant adverse events during the procedures were evaluated.

A routine two-dimensional echocardiography was performed on all patients the day after the procedure to evaluate significant changes and adverse events. Pulmonary regurgitation was investigated in the same way. Regular echocardiographic follow-ups were maintained after discharge. The decision regarding balloon valvuloplasty was made after all cases were presented and discussed at a multidisciplinary conference with cardiologists and surgeons present. Re-intervention was defined as a subsequent surgical or catheter intervention on the same bioprosthetic pulmonary valve, such as valve replacement or balloon valvuloplasty. The final follow-up date was defined as the date of the last echocardiography or the most recent hospital visit in patients without a second intervention.

For statistical analysis, SPSS 23.0 (IBM Company, Chicago, IL) was used. The mean, median, standard deviation and range were calculated for continuous variables. Frequencies were calculated for nominal variables. Kaplan-Meier curves were obtained to examine freedom from re-intervention. Cox's proportional hazard model was used to identify risk factors for early re-intervention. Cutoff points were predicted using a receiver operating characteristics curve, and the log-rank method was used to compare the Kaplan-Meier curves of the two groups. A $P < .05$ was considered statistically significant.

The Institutional Review Board of Samsung Medical Center approved this study, and the requirement for consent from patients or parents was waived.

3 | RESULTS

Forty-nine balloon dilations were performed in 46 patients. Thirty-one of the 46 patients were male. The primary diagnoses of congenital heart disease included tetralogy of Fallot/double outlet right ventricle with pulmonary stenosis (17), pulmonary atresia with ventricular septal defect (17) and transposition of great artery and ventricular septal defect (4). Table 1 shows patient data before and after balloon valvuloplasty. The patients' mean age for the bioprosthetic valve insertion was 5.7 years. The bioprosthetic valves included 17 (34.7%) porcine tissue valves and 32 (65.3%) bovine tissue valves. The mean age at balloon valvuloplasty of bioprosthetic pulmonary valves was 11.7 years old, and the mean interval after pulmonary valve replacement was 71.6 months. The size of the bioprosthetic valves ranged from 14 mm to 25 mm. The mean balloon to valve size ratio was 0.94. The pressure

TABLE 1 Patient data before and after balloon valvuloplasty

	Before balloon valvuloplasty	After balloon valvuloplasty	*P*
Age of pulmonary valve replacement (year)	5.7 ± 4.0		
Age of balloon valvuloplasty (year)	11.7 ± 4.9		
Interval after pulmonary valve replacement (month)	71.6 ± 28.6		
Interval to next intervention (month)	20.7 ± 23.0		
Follow-up after intervention (month)	23.6 ± 22.2		
Valve size (mm)*	19 (14–25)		
Size ratio (balloon/valve)	0.94 ±0.11		
Pressure (right ventricle/aorta)	0.79 ±0.16	0.62 ±0.19	<.001
Pressure difference (mm Hg)	55.3 ±18.5	33.8 ±21.5	<.001
Pulmonary regurgitation	1.6 ± 1.2	1.8 ± 0.9	.859

Mean ± standard deviation, *median (lower-upper).

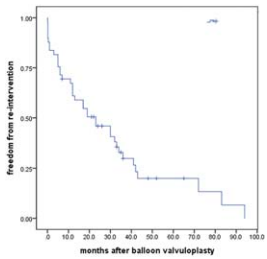

FIGURE 1 The cumulative curve of the time interval for freedom from re-intervention after balloon valvuloplasty

gradient through the pulmonary valve and the ratio of the right ventricle to aorta pressure after balloon valvuloplasty significantly improved without significant changes in pulmonary regurgitation (Table 1).

The double balloon technique was used in three cases. There were no adverse events during or immediately after balloon valvuloplasty except for balloon ruptures observed in two cases.

A subsequent re-intervention in the form of either surgical valve replacement or second valvuloplasty was performed in 38 (77.6%) cases, and the mean interval between interventions was 20.7 months. The mean follow-up period after initial balloon valvuloplasty was 23.6 months. Figure 1 shows the time until re-intervention after balloon valvuloplasty of bioprosthetic pulmonary valves. The mean freedom from re-intervention was 30.6 months after balloon valvuloplasty. Cox proportional hazards analysis revealed that the time interval until re-intervention was only affected by the pressure gradient before balloon valvuloplasty and the patient age at valve insertion. The material of the valve leaflet, the interval from pulmonary valve replacement, and the ratio of balloon size to valve size did not affect the time interval until re-intervention (Table 2).

We observed a negative correlation between the interval to re-intervention and the pressure gradient before balloon valvuloplasty (Figure 2). The receiver operating characteristics curve 24 months after the initial dilatation showed high sensitivity and specificity ($P = .002$, 95% CI 0.619–0.896) for a 48.5 mm Hg pressure gradient before balloon valvuloplasty. Figure 3 shows significantly different freedom from re-intervention between the two groups based on a 48.5 mm Hg pressure gradient before balloon valvuloplasty. The mean interval to re-intervention in patients with pressure gradients lower than 48.5 mm

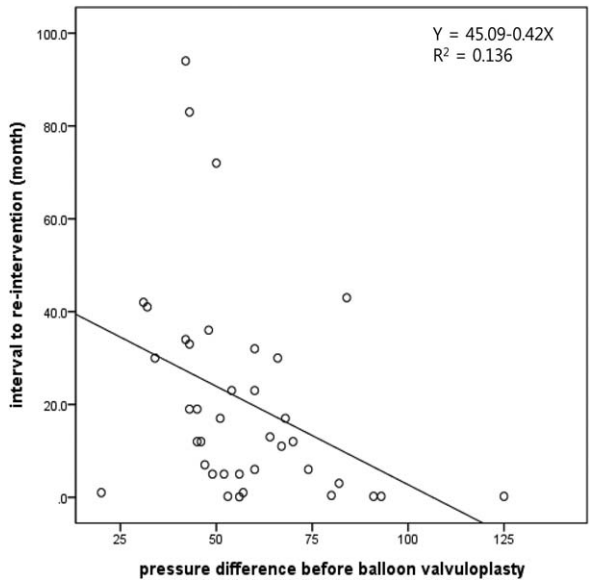

FIGURE 2 The negative correlation between the interval to re-intervention and the pressure difference before ballooning

Hg before ballooning was 46.0 months, which was significantly longer than in other patients (ie, 18.7 months).

4 | DISCUSSION

Balloon valvuloplasty of a stenotic, bioprosthetic pulmonary valve may be an effective palliative procedure for delaying future valve replacement. However, the effect of the balloon valvuloplasty was dependent on the pressure gradient of the stenosis before balloon valvuloplasty.

After reconstructing the right ventricular outflow tract in congenital heart disease, bioprosthetic valve insertion at a pulmonary position is typically performed at a suitable age. However, the degradation of the bioprosthetic valve requires a number of valve replacement procedures. Despite percutaneous pulmonary valve replacements which are increasingly performed worldwide, surgical replacement remains the conventional standard therapy.

The mechanisms of bioprosthetic valve failure are attributed to several processes, including intrinsic calcification, cuspal tearing, perforation and cuspal thrombosis.[5] Commissural fusion and a rigid stent

TABLE 2 Risk factors influencing freedom from re-intervention after balloon valvuloplasty by Cox proportional hazard analysis

				95.0% CI for Exp(B)	
	Wald	Sig	Exp(B)	Lower	Upper
Age of pulmonary valve replacement (year)	4.683	0.030	0.896	0.812	0.990
Pressure difference (mm Hg) before balloon valvuloplasty	7.545	0.006	1.035	1.010	1.060
Pressure (right ventricle/aorta) before balloon valvuloplasty	0.423	0.516	2.403	0.171	33.771
Valve type	0.023	0.878	1.071	0.445	2.579
Size ratio (balloon/valve)	0.973	0.324	0.173	0.005	5.635
Interval from pulmonary valve replacement (month)	1.319	0.251	1.008	0.994	1.023

Abbreviations: CI, confidence interval; Sig, significance.

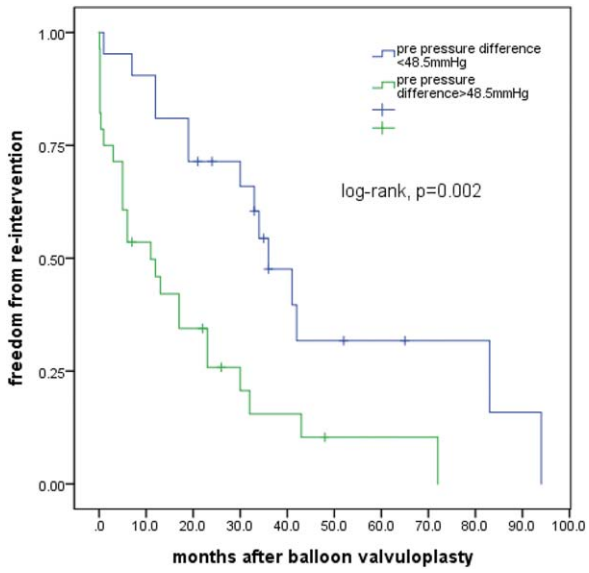

FIGURE 3 The difference in freedom from re-intervention between the two groups based on a 48.5 mm Hg pressure gradient before ballooning

frame may be favorable factors for balloon valvuloplasty, whereas cuspal calcification and tearing may be undesirable factors.[6,20] Nevertheless, balloon valvuloplasty of bioprosthetic valves at pulmonary positions has rarely been performed. There have been a few cases reporting successful dilatations and subsequent clinical improvements.[8,21]

Our data, such as the pressure gradient and the pressure ratio of the right ventricle to the aorta, showed that balloon valvuloplasty resulted in improved hemodynamics. A balloon valvuloplasty for congenital pulmonary stenosis was indicated when the pressure gradient was over 50 mm Hg and the ratio of the right ventricle pressure to the systemic pressure was over 50%.[22,23] However, no definite criteria exist for intervening with bioprosthetic valve stenoses at pulmonary positions, especially in asymptomatic patients. Instead, our criteria for balloon intervention were dependent on the operators. Typically, focal stenoses were common indications.

The pressure gradient and patient age at valve insertion were significant risk factors. A higher pressure gradient and a younger age resulted in higher risks for re-intervention. Previously, Lee et al. reported that a younger age at valve insertion was a risk factor for earlier valve failure.[24] Therefore, bioprosthetic valve stenoses in patients with early age valve insertions should be frequently evaluated; early balloon valvuloplasty could be more helpful. Severe bioprosthetic valve stenoses may indicate severe degradation. Therefore, balloon valvuloplasty of severely degraded valves has a limited effect. However, it should be emphasized that our goal was not to enhance the effectiveness of dilatation but to delay reoperation after balloon valvuloplasty. Unfortunately, effectiveness cannot be accurately defined for balloon valvuloplasty of bioprosthetic valve stenoses. In congenital stenosis of the pulmonary valve, residual gradients less than 30 mm Hg have been defined as effective.[11] Delaying valve replacement should be the main goal of our procedure.

In our study, the valve leaflet, balloon size and interval from valve insertion were not significant factors that effectively delayed reoperation. A balloon with an equal size to the prosthetic valve is typically recommended for the dilatation of stenotic bioprosthetic valves.[8] Bruce et al. described the mechanism of action after an in vitro balloon valvuloplasty of a bioprosthetic valve, which was a porcine valve and stent.[6] However, our study showed that the presence of a stent and the type of tissue did not lead to any differences.

The balloon valvuloplasty of a bioprosthetic pulmonary valve is straightforward and is similar to that for a native pulmonary valve. In an in vitro experiment,[6] cuspal tearing, embolization of calcified fragments, and thrombus could occur during dilatation. Cuspal tearing could result in pulmonary regurgitation; we did not observe significantly aggravated pulmonary regurgitation. However, evaluation may inaccurately underestimate pulmonary regurgitation in failed prosthetic valves. In general, pulmonary regurgitation is difficult to measure in a stenotic bioprosthetic valve and would be minor in effect compared with residual stenosis.

We also did not see pulmonary embolism on the day after balloon valvuloplasty. Balloon rupture due to severe calcification is a more severe issue in the balloon valvuloplasty of a bioprosthetic valve. In some cases, balloon valvuloplasty was avoided due to heightened precautions against balloon rupture. As a result, only two ruptures occurred. There were no serious problems due to balloon rupture.

Our study was limited by its retrospective design and the small number of patients. Balloon valvuloplasty was performed without consistent criteria; therefore, there may have been selection bias. The interval to the next re-intervention does not always reflect effectiveness. There were several non-hemodynamic social factors that affected this interval.

5 | CONCLUSIONS

The effectiveness of balloon valvuloplasty of a bioprosthetic valve at a pulmonary position remains unclear. However, earlier balloon valvuloplasty when the peak pressure gradient was not over 48.5 mm Hg may have a benefit to delaying the next intervention. Additional studies are needed to determine the appropriate cutoff for intervention.

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CONFLICT OF INTEREST

None.

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