

ORIGINAL ARTICLE

IMMEDIATE AND MIDTERM RESULTS OF BALLOON AORTIC VALVULOPLASTY IN CHILDREN WITH AORTIC VALVE STENOSIS WITH SPECIAL REFERENCE TO DYSPLASTIC AORTIC VALVE

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Background: This study was conducted to determine the immediate and midterm outcome of balloon aortic valvuloplasty in children from age 1 month to 16 years, with special reference to mean balloon to aortic valve ratio along with doming versus dysplastic valve. **Methods:** This was a retrospective cohort study. Patients who underwent balloon aortic valvuloplasty in a single tertiary care hospital were reviewed regarding immediate outcome, morphology of aortic valve, mean balloon to aortic valve ratio and complications during procedure from January 2006 till December 2016. **Results:** Of 171 patients, 80.11% had fall to good results while 73.1% had adequate outcome. Mean gradient fall of more than 50% or Peak systolic gradient decreased significantly post ballooning, which indicates good results. The age ranges from 1–92 months, 89.4% patients from age group less than 1 year had adequate outcome, ($p=0.017$). In terms of morphology, 55.6% cases had doming while 44.4% cases had dysplastic aortic valve. There was no significant difference between dysplastic and doming valves in terms of outcome ($p=0.224$). Only 6 patients (3.5%) developed significant aortic regurgitation. Regarding short-term and intermediate outcome 92% of the patients were free from a second intervention and there was no significant difference between complications regarding balloon to aortic valve ratio also. **Conclusion:** Our 10-year experience showed that balloon aortic valvuloplasty is a safe and effective therapy, irrespective of age groups. The complications rate is low and good outcome is achieved by keeping balloon to aortic valve ratio of ± 0.9 irrespective of morphology of valve.

Keywords: Children; Congenital aortic valve stenosis; Balloon aortic valvuloplasty

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INTRODUCTION

Congenital aortic valve stenosis comprises of about 5% of all congenital heart diseases. It is more common in males. Morphologically, the common valve type is functionally bicuspid 63%, unicuspid 14% and dysplastic 11%. Functionally bicuspid aortic valves have a better outcome in terms of freedom from a second intervention. Kevin Gao *et al* found that at neonatal age functionally unicuspid aortic valve had early presentation than as compared to non-neonatal age group.^{1–3}

Surgical valvotomy was the mainstay of treatment until 1983 when Lababidi *et al* introduced the procedure of balloon aortic valvuloplasty (BAV).³ Currently valvuloplasty holds good long-term results with 89% not requiring a re-intervention at 1 year, 72% at 5 years, 54% at 10 years and 27% at 20 years.⁴

Awasthy N *et al* showed that balloon valvuloplasty has good long-term outcome by comparing the results of BAV in various age groups and thus an acceptable initial option in the treatment of congenital aortic stenosis.^{5–9}

In Pakistan where congenital cardiac surgery facilities are limited, BAV is the preferred choice of

treatment irrespective of age and valve morphology, as evident by above mentioned data with minimal morbidity and mortality rates.¹⁰ There is however, limited data from Pakistan looking at the outcome of BAV irrespective of the morphology especially the dysplastic aortic valve as comparison with other morphologies of aortic valve stenosis. The purpose of selecting this study was to assess the benefits of BAV and its complications by mean balloon to aortic valve ratio in doming versus dysplastic valves.

MATERIAL AND METHODS

A retrospective study conducted at paediatric cardiology centre in The Children Hospital and the Institute of Child Health Lahore by reviewing previous records from January 2006 till December 2016 after institutional review board approval. The echocardiographic and angiography data was analysed through *proforma*.

Echocardiography was performed on a VIVID-7-dimension machine by consultant cardiologist. The main parameters focused were:

- 1- Aortic valve morphology (unicuspid, bicuspid, tricuspid),

- 2- Valve annulus size measured both on echo (at hinge point), and angiography
- 3- Maximum peak-to-peak gradient at the valve measured in apical four chambers and suprasternal view or right upper parasternal view.
- 4- Aortic valve regurgitation grade and assessment for any accompanying cardiac malformation. It was graded as, mild: when the colour jet do not exceed the tip of anterior mitral valve leaflet (AML), the width of the jet was less than 30% of the left ventricular outflow tract (LVOT) width, a pressure half time (PHT) of more than 600msec, and end diastolic flow in descending aorta of less than 20cm/sec, moderate AR as: jet length distal to AML, jet width more than 30% of LVOT, PHT less than 600msec, and end diastolic retrograde flow in descending aorta of 20–40 cm/sec and dilated left ventricle, severe AR was defined as: jet length, jet width and pressure half time as same for moderate, plus retrograde flow in descending aorta of more than 40cm/sec and moderate to severely dilated left ventricle.^{11–15}
- 5- Doming valve was described as thin pliant valve that domed during systole,
- 6- Dysplastic valve was described as thick non-pliant valve that moved like a board.

Angiographically AR was categorized as, none/trivial: No contrast or a tiny jet entering LVOT, mild: small amount of contrast seen in LV during diastole and clears with systole, moderate: more contrast seen in LV during diastole with faint opacification LV, severe: complete opacification of LV and LV is densely opacified than ascending aorta.¹⁵

The interventional balloon aortic valvuloplasty was done under general anaesthesia. Antibiotic was given as infective endocarditis prophylaxis. Femoral artery was used as arterial access and a single stat bolus of heparin 75-100IU/kg was given.

Aortograms were obtained in left anterior oblique or right anterior oblique and hemodynamic was recorded and valve annulus measured. The initial balloon selected was 80–100% of valve ring or with balloon annulus ratio less than equal to 1 with variable balloon lengths according to patient age and weight.

In older patients, the right ventricle was paced at a high rate through temporary pacemaker wire passed through femoral vein to help stabilize the balloon. Each inflation was not more than 10sec. Post procedure haemostasis was secured by manual pressure and echocardiography performed.

Outcome was defined as adequate if gradient was less than 35mmHg with no or trivial AR or $\geq 50\%$ reduction in peak systolic gradient, inadequate: gradient more than 35mmHg or moderate to severe AR.^{16,17}

Analysis of the data was done by using SPSS program (version 21). Mean, median, standard deviation and ranges were used for quantitative data. While frequencies and percentages were used for categorical data. For comparing mean in two groups, independent sample test was applied. While for comparison of mean in more than two groups ANOVA test was used. For comparison of categorical data, Chi square test was applied. *p*-value of ≤ 0.05 was taken as significant.

RESULTS

A total of 171 cases with a mean age of 55.8 ± 53.8 months. There were 131 males and 40 females. The mean aortic valve annulus on Echo (mm) was 12.4 ± 4.1 (Z-score = ± 5) while on angiography, the mean measurement was 12.8 ± 4.3 (Z-score = ± 5). According to valve morphology 55.6% cases had doming while 44.4% cases had dysplastic aortic valve. A total of 1.2% (n=02) cases had monocuspid, 93.6% (n=160) had bicuspid and 5.3% (n=09) cases had tricuspid leaflets.

The mean peak echo gradient and Peak to peak angiographic gradient (mmHg) were 86.7 ± 29.4 and 78.7 ± 31.4 respectively. The mean EF% before procedure was 66.6 ± 15.4 . 87.7% cases had normal LV function (EF: $> 60\%$), 1.2% had moderate LV dysfunction (EF: 45–60%) and 11.1% had severe dysfunction (EF: $< 35\%$).

Of these 73.1% (n=127) cases had no residual gradient or were with adequate outcome and (n=137) patients had a fall of gradient $\geq 50\%$ (*p*=0.00). In terms of adequate outcome 39.2% were doming and 35.1% were dysplastic aortic valve. While 26.9% (n=46) had significant residual gradient among which 16.4% were doming and 9.4% were dysplastic valves, (*p*=0.224).

The mean balloon to aortic valve annulus ratio on Echocardiography where there was no residual AS was 0.98 ± 0.12 , while in significant residual gradient the mean Balloon to aortic valve annulus ratio was 0.96 ± 0.11 . The mean balloon to aortic valve annulus ratio on angiography was 1.05 ± 1.09 in cases where there was no residual gradient and 0.93 ± 0.12 in cases who had significant residual gradient. The mean Balloon to aortic valve annulus ratio on Echo and Angiography was statistically same in terms of residual gradient. (*p* < 0.05). (Table-1)

In post balloon valvuloplasty complications, there were 37 cases that had aortic regurgitation in

which 19 cases were doming and 18 were dysplastic valves. Among degree of AR, 18.2% (n=31) had mild AR, 2.9% (n=5) had moderate AR and 0.6 (n=1) had severe AR. (Table-2)

There were total of 92.1% (n=159) cases with no complications, 2.9% (n=5) cases had arrhythmias mainly VT and 3.5% (n=6) patients had significant AR, while one patient went into cardiac arrest after VT and survived. Among complications, arrhythmias were mostly seen in age group <1 year while significant AR was mostly seen in age group 1–12 years with 5 moderate, 1 severe and rest were mild aortic regurgitation, (p=0.294). (Table-3)

There were 7% cases, which required a re-intervention, among which 5.3% had doming and 9.2% were dysplastic valve (p=0.374). The mean duration of re intervention was 38.5±26.8 months. A re intervention was more common in age group 1–12 years that was 9.9% (n=11) and only 7.7% (n=1) between 12–15-year age group. (Table-4)

In comparison of the three age groups, the highest adequate outcome was found in patients with age group less than 1year, i.e., 89.4% followed by 1 to 12-year of age group i.e. 67.7%, and in age group 12–15 years, 61.5% (p= 0.017). There were 12 (7%) cases in which valvoplasty was re done with a mean duration of re intervention of 38.50±26.82 months.

Table-1: Comparison of balloon aortic valve ratio on Echocardiography vs. Angiography

		No. of cases	Mean	Minimum	Maximum	p-value ^a
Balloon to aortic valve annulus ratio (Echo)	No residual	100	0.98	.75	1.60	0.693
	Significant residual	29	0.96	.72	1.29	
	Total	170	0.98	.72	1.60	
Balloon to aortic valve annulus ratio (Angio)	No residual	100	1.05	.70	11.80	0.588
	Significant residual	29	0.93	.61	1.15	

a. ANOVA test was applied

Table-2: Degree of aortic regurgitation vs. valve morphology of Aortic Valve

Degree of Regurgitation	Valve morphology		Total
	Doming	Dysplastic	
None	76	57	133
Mild	16	15	31
Moderate	3	2	5
Severe	0	1	1
Total	95	75	170

Table-3: Age groups comparison in Complications

Complication	Age groups			Total
	<1 year	1–12 year	12.1–15 years	
None	43	105	12	160
Arrhythmia	3	1	1	5
Significant AR	0	5	0	5
Cardiac arrest	1	0	0	1
Total	47	111	13	171

Table-4: Age groups comparison in outcome

Residual gradient	Age groups			Total
	<1 year	1–12 year	12.1–15 years	
no residual	42	75	8	125
significant residual	5	36	5	46
Total	47	111	13	171

DISCUSSION

The initial treatment of congenital aortic valve stenosis can be balloon valvuloplasty or surgical valvotomy. Both of the procedures are of palliative nature as it postpones the ultimate treatment as Ross procedure or Aortic valve replacement.¹⁸ Now with the introduction of better techniques and better profile balloons, the outcome of BAV has improved with low morbidity and mortality rates and good mid and long-term outcomes in children of different age groups with an advantage in neonates and young

infants of not requiring cardiopulmonary bypass, especially those with depressed LV functions.^{5,8,19-21}

There was no hospital mortality pertaining to the procedure in our study as mostly the patients were optimized well before going on to the procedure specially in patients with LV dysfunction.^{2,22-24}

Although the majority of the patients had bicuspid aortic valve in our study, the number of patients with valve morphology was comparable to other studies.^{1,2} In correlation of valve morphology with LV function, we found 13.2% (n=21) patients

with bicuspid aortic valve had moderate to severe dysfunction, among these 21 patients 8.09% ($n=14$) were dysplastic and 4.01% ($n=7$) were doming valves. As it is evident by many studies that unicuspid aortic valves are correlated with poor LV function and that unicuspid aortic valves are more common in neonatal age which was excluded from our study population and hence functionally unicuspid valves were uncommon in our study.^{1,2,13}

The outcome in our study with adequate results were 73.1%, while 80.11% had a fall in pressure gradient $\geq 50\%$, making BAV an acceptable and efficient mode of treatment as seen and compared with many other studies. There was no clear statistical advantage of doming vs. dysplastic valve in their outcome results in our study. As doming valve slightly predominates in significant residual group 28 vs. 18, because these valves usually have higher gradients as compared to other valve types.¹³ We compared balloon aortic valve ratio on echocardiography vs. angiography to know their effect on outcome, but statistically both were same in their outcomes.²⁵⁻²⁸

In comparison of the three age groups in our study, we examined that patients with age <1 year had a better outcome ($p=0.017$) as compared to the other two age groups. Second intervention was more common in the second group 1-12 years followed by third group >12 years. The patients who required a second valvuloplasty, the initial residual gradient was high, which is in itself is a documented risk factor for reintervention as shown by Brown *et al.*⁴ Similar was the findings in the study by Parezanović *et al* who showed good results in infants less than 3 months and a second intervention in patients with higher follow up residual gradients of >50 mmHg in ages 8.5 years and above.⁸ While on the other hand factors predicting the need for a re intervention were valve thickness and peak systolic gradient, some authors have documented age <3 years as well as predictor of reintervention.²⁵ Regarding complication in our study 21.8% ($n=37$) patients had AR of which significant AR (moderate to severe) was only found in 6 cases which were among age 1-12 years group which correlates with the of Brown *et al*, they documented that AR was more likely to occur in older patients age >10 years ($p=<0.001$). Among these 6 cases doming and dysplastic were equal in numbers among them; however, none of them required any surgical intervention. In our study only 6 patients had significant AR and the mean balloon aortic ratio on echocardiography was 0.98 and on angiography was 1.05 and hence AR cannot be correlated with the balloon size, or residual gradient or valve morphology a finding which is inconsistent with recent studies.^{4,5,28-32}

We think that AR in our study might be secondary to technique and the to and fro dancing movement of the balloon during inflation and can be minimized by following ways, properly centering the balloon across the valve, temporary RV pacing or use of adenosine for stabilization of the balloon during inflation and use of extra stiff wires with large ventricular loops.^{23,33,34}

Freedom from a second intervention was 92%. Patients who required a second intervention were those with higher residual gradients after first intervention despite adequate size of balloon aortic valve ratio. Hence higher the residual gradient, the earlier will the patient requires a second intervention with recent studies advocating to achieve the residual gradient less than 35mmHg even at the expense of mild aortic regurgitation.^{4,8,25}

CONCLUSION

We found that BAV is a good, effective and a low-cost option especially in a limited resources country with acceptable immediate and midterm results.

Conflict of interest: There was no conflict of interest in this study.

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Pitfall: This is single institute study and need other institutional involvement.

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AUTHORS' CONTRIBUTION

HD: Conceived design and manuscript writing. AUQ: Statistical analysis. SNH & MS: Literature review, manuscript writing.

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