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Effect of rapid right ventricular pacing on development of aortic valve regurgitation after stenotic aortic valve balloon valvoplasty

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ABSTRACT

INTRODUCTION: Balloon aortic valvuloplasty was used as an alternative method to surgical valvotomy in childhood for treatment of congenital aortic valve stenosis. However, acute complications after balloon dilation including aortic valve regurgitation or early death may occur due to balloon instability. There are many methods proposed to decrease these complications. Each has its uses and limitations.

OBJECTIVE: To describe the role of rapid right ventricular pacing in decreasing degree of aortic valve regurgitation by providing balloon stability during balloon dilation procedure for congenital aortic valve stenosis.

METHODS: A comparative clinical trial was conducted on 46 patients with severe or symptomatic congenital aortic valve stenosis who were referred for elective balloon dilation at Iraqi Centre For Heart Diseases in Baghdad, Iraq from December 2012 to August 2014. Patients were randomized into two groups: the first group underwent balloon valvoplasy with rapid pacing of right ventricle, the second group included patients underwent balloon valvoplasty alone. Effect of procedure on decreasing pressure gradient around aortic valve and development of significant aortic regurgitation were assessed post-operatively by echocardiography and cathiterization.

RESULTS: Forty six patients with congenital aortic valve stenosis that match the criteria for balloon aortic valvoplasty, of them 25 were males (54.3%) and 21 were females (45.7%). Twenty patients (43.4 %) were below the age of 5 years. Balloon valvoplasty with pacing is as effective as without as measured by reduction of pressure gradient across aortic valve. However, group with pacemaker are more prone to avoid development of aortic regurgitation. In group 1, from eight patients who had no aortic regurgitation before the procedure, 6 continued without regurgitation. In group 2, 12 patients had no aortic valve regurgitation perioperatively, while only one continued to have no aortic regurgitation after the procedure. Bicuspid aortic valve and age more than 10 years were found to increase risk of development of aortic regurgitation after balloon valvoplasty if pacing is not used to stabilize the Balloon.

CONCLUSION: Rapid right ventricular pacing are safe and effective method in decrease degree of aortic valve regurgitation by provide balloon stability during the procedure and prevent valvular damage so delay the time of valve replacement if needed

Key words: valvular aortic stenosis, balloon valvuloplasty, rapid right ventricular pacing, aortic regurgitation.

INTRODUCTION

Congenital aortic valve stenosis accounts for 5-6% of congenital heart diseases. It occurs more commonly in male.[1] Aortic valve balloon dilation has now become as an alternative to surgery in childhood. However, the residual stenosis and occurrence of aortic valve regurgitation are well known problems after balloon dilation as well as after surgical valvotomy.[2,3] Residual stenosis has little influence on future surgical option but the resulted aortic regurgitation during balloon valvoplasty which is often due to commissural avulsion, cusp dehiscence, and cusp tear or perforation that make the later surgical intervention more difficult.[4,5] The benefit from doing balloon aortic valvoplasty is to delay the artificial valve replacement until adulthood.[6,7]

Balloon stability appears to be an important issue during aortic valvoplasty because the movement of inflated balloon during procedure inside the valve interfering with proper positioning of balloon, thus leading to failure, suboptimal results for procedure, damage to great vessel or intraluminal structure[8] and even death.[9]

Only a few methods are known to avoid these problems. Extra stiff wires, long balloons, and long sheaths give additional support reducing the risk of displacement.[10] Temporary proximal balloon occlusion has found only limited use for some procedures such as coil occlusion of large ducts and collaterals.[11] Adenosine has been shown to be safe and effective in creating transient cardiac standstill and is used during balloon dilatation procedures[12] and implantation of stents and grafts.[13,14] However, there is a wide range of effective doses and significant variation in the time intervals from adenosine injection to asystole and duration of asystole.[15] Balloon dilatation of valvular aortic stenosis is an established procedure for children.[16,17,18]

The effect of rapid right ventricular pacing in such intervention is to reduce stroke volume and cardiac output that lead to reduce blood pressure and blood pressure amplitude so maintain balloon stability with less damage to valve during balloon inflation.[19]

The aim of this study was to evaluate the result of rapid right ventricular pacing during aortic valve balloon dilation to decrease the degree of aortic valve regurgitation during procedure in children.

METHODS

Setting of the study: Forty six children and adolescents with congenital aortic valve stenosis who referred for balloon valvoplasty were enrolled in this comparative clinical trial. The study was conducted at Iraqi centre for heart diseases in Baghdad/ Iraq from December 2012 to August 2014.

The procedure was fully explained to the parents whom their patients were eligible to be included in this study and their signed consent form was requested before doing the procedure.

Inclusion criteria: All Patients with severe congenital aortic stenosis and younger than 20 years who were referred to pediatric cardiac clinic at Iraqi center for heart diseases were selected in this study. The definition of severe aortic stenosis was as follows:

1. Peak pressure gradient across aortic valve > 70 mmHg regardless of symptom.
2. Pressure gradient more than 50mmHg with symptom, electrocardiographic ST-T changes suggestive of myocardial perfusion abnormality or hypotension in response to exercise test.

Exclusion Criteria: The followings had been excluded from the study:

1. Neonate and young infant because most of them had left ventricular dysfunction from severe aortic valve stenosis, a condition that preclude the use of pacing in such patients.
2. Associated moderate to severe degree of aortic valve regurgitation pre-intervention in order to avoid the interference of regurgitation on the result of this study.
3. Any patient with left ventricular systolic dysfunction.

Randomization: Patients were randomized into 2 groups. Group 1 which included 23 patients who were presented to our clinic during even days, and group 2 which included 23 patients who presented in odd days.Patients in group 1 have received balloon valvuplasty with pacing while those in group 2 have received balloon valvuplasty without pacing.

Procedure: Under general anesthesia, arterial and venous access were achieved, then (50-100 unit/kg) of heparin was administered intravenously. A 4, 5 or 6-F multipurpose or right coronary artery catheter was advanced into ascending aorta through J-tip guide wire (Cook, Bloomington, IN). The views used to assess aortic valve are 30 degrees right anterior oblique view and 60 degrees left anterior oblique view. Contrast material is injected and a cineaortography for stenosed aortic valve is done to be used as a road map. The size of the annulus which was preliminarily assessed by echocardiography is re-assessed angiographically. The type of balloon used in this procedure is Tayshak 2 (NuMed Canada) with a size of 90-100 % of that of the aortic valve annulus. Length of the balloon is chosen according to the age of the patients; 2, 3 and 4 cm in infants, young children, and older children and adolescent respectively.

Just before balloon inflation, temporary bipolar pacing catheter was introduced from femoral vein. The pacemaker wire is directed to the right ventricular apex and VVI mode is chosen. The tip of the guide wire is positioned in the left ventricular apex away from mitral valve apparatus.

Once we start inflating the balloon, the pacemaker is set on 180-200 beat /minute. Then after deflation of the balloon the pacemaker rate

is decreased to 80 beats/minute to mainta in backup for the normal heart rate. Pacing was terminated when the patient is hemodynamically stable. Usually we inflate the balloon 3-4 times for five seconds and five minutes apart. The aim is to abolish the waist created by stenosed valve. When the stability of balloonis not achieved at that paced heart rate the next inflation is made after increasing pacing to 220-240 beats/minuteprogressively. We regarded the procedure successful in both groups if previous pressure gradient decreased by 50% or more than the gradient before the procedure with no or little change in degree of aortic valve regurgitation than that before the intervention. Assessment of success is made by continues and pulsed Doppler echocardiography to measure the peak and mean pressure gradient between the aorta and left ventricle or by cardiac catheterization to measure the pull-back pressure gradient between left ventricle and aorta. The degree of aortic regurgitation is assessed by catheterization through magnitude of regurgitation jet in aortic valve ring, reveres flow after aortogram. Also it is measured by echo Doppler to measure aortic pressure half time. The degree of aortic valve regurgitation is classified as being non, trivial, mild, moderate and severe. This classification is made according to the recommendations for valvular regurgitation by European association of echocardiography 2010.[20]

Table 1: Shows distribution of patients with or without pacemaker according to some socio-demographic variables.

Socio-demographic variables		Group 1 *	Group 2†
Age (years)	Average	8.39± 5.37	8.67± 5.95
	Range	2-18	(2-19)
Weight (kg)	Average	25.52±17.14	23.02±15.29
	Range	9-65	9-55
Gender	Male	12 (52.2%)	13 (56.5%)
	Female	11 (47.8%)	10 (43.5%)
	Total	23 (100%)	23 (100%)
Type of valve	Bicuspid aortic valve	16 (69.6%)	15 (65.2%)
	Tricuspid aortic valve	7 (30.4%)	8 (34.8%)
	Total	23 (100%)	23 (100%)

* Include patients underwent balloon valvoplasty with rapid pacing.
† Included patients underwent balloon valvoplasty without rapid pacing.

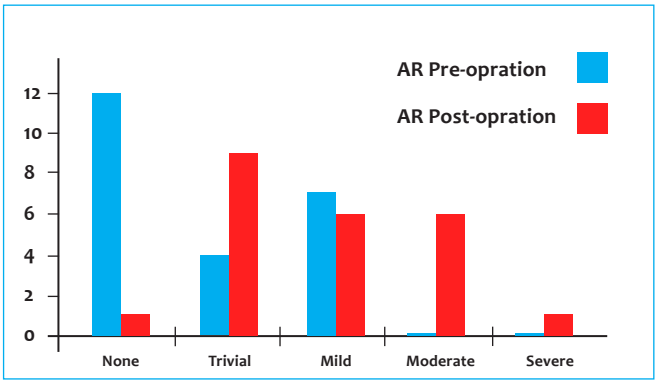

Figure 1: Distribution of patients without pacing according to degree of aortic regurgitations pre and post operation

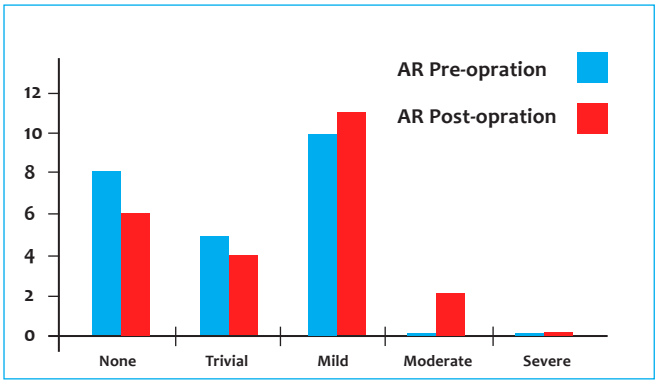

Figure 2: Distribution of patients with pacing according to degree of aortic regurgitations pre and post operation

Table 2: Degree of Development of aortic regurgitation after operation in both groups.

Aortic regurgitation	Group 1*	Group 2†	P Value
No regurgitation	6 (26.1)	1 (4.3)	
Trivial regurgitation	5 (21.7)	9 (39.2)	
Mild regurgitation	10 (43.5)	6 (26.1)	
Moderate to severe	2 (8.7)	7 (30.4)	0.038**
Total	23 (100)	23 (100)	

* Included patients underwent balloon valvoplasty with rapid pacing.
† Included patients underwent balloon valvoplasty without rapid pacing.
** Statistically significat

Statistical analysis: Statistical analysis was carried out using SPSS version 17. Categorical variables were presented as frequencies and percentages. Continuous variables were presented as (Mean±SD).Pearson's chi square(x2) and Fisher-exact test was used to find the association between categorical variables. Wilcoxon signed ranks test was used to compare medians between paired numerical readings when differences between those paired readings were none normally distributed.McNemar test was used to compare paired categorical readings. A p-value of ≤ 0.05 was considered as statistically significant.

Table 3: The comparison between pre and post-operative AR for patients with pacing or without pacing.

		Pre-operative (%)	Post-operative (%)	χ^2	P-value
Aortic Regurgitation	Group1*	15 (57.7)	17 (43.6)	1.241	0.265
	Group 2†	11 (42.3)	22 (95.6)		
	Total	26 (100.0)	39 (100.0)		
No Aortic Regurgitation	Group1*	8(40%)	6 (85.7%)	4.34	0.037**
	Group 2†	12 (60%)	1 (14.3%)		
	Total	26 (100.0)	39 (100.0)		

* Included patients underwent balloon valvoplasty with rapid pacing.
† Included patients underwent balloon valvoplasty without rapid pacing.
** Statistically signoficant

RESULTS

Forty six patients underwent aortic valve balloon dilation. Twenty-five were boys (54.3%) and 21 were girls (45.7%). We divided patients into three groups according to their age: Age < 5 years included 20 (43.4%) patients, age between 5-10 years included 9 (19.6%) patients and age > 10 years included 17 (37%) patients. The majority of patients have bicuspid aortic valve 32 patients (67.4%), while 14 patients (32.6%) had tricuspid aortic valve. The median age, weight, sex and types of valve in both groups has been shown in table 1.

Two patients only in group 1 (8.7 %) developed moderate to severe aortic regurgitation, while 7 patients (30.4 %) had aortic regurgitation in group 2 (Table 2). Fingure 1 and 2 show the degree of aortic regurgitation pre and post operatively for both groups.

Table 3 showed statistically significant difference between the 2 groups in developing aortic regurgitation in those patient who had not got aortic regurgitation before the procedure.

The procedure was effective to relief of the obstruction of stenotic valve and reducing pressure gradient between aortic valve and left ventricle in both groups as in table 4.

Moderate to severe degree of aortic valve regurgitation that occurs in patients underwent aortic balloon dilation without pacing had statistically significant relation with patient's age of more than 10 years and presence of bicuspid aortic valve. Gender and body weight have not showed significant relation to the development of aortic regurgitation in patients in group 2 table 5.

Table 4: The mean differences of aortic stenosis pressure gradient in pre and post aortic valve dilation for the two studied groups.

	Mean ± SD		Z	P Value
	Pre-operative	Post operative		
Group 1*	102.78± 32.65	18.86± 7.14	-4.199	<0.001**
Group 2 †	96.17± 31.95	16.26 ± 8.14	-4.200	<0.001**

* Included patients underwent balloon valvoplasty with rapid pacing.
† Included patients underwent balloon valvoplasty without rapid pacing.
** Statistically significant.

DISCUSSION

The study was done at Iraqi centre for heart diseases on 46 patients with severe congenital aortic stenosis. There was mild male preponderance; 25 (54.3%) were males and 21 (45.7%) were females. Many studies have showed the same results but males are much involved than in our study. Vojislav et al[21] study found 74 % male and 26 % female, also Hala et al[22] study reported 81 % males and 19 % females. The mild male predominance in our study in comparison to others can be explained socially, as some Iraqi families reluctant to accept doing cardiac catheterization for their male offspring in order to save them the danger of death, as they believe. This behaviour was seen many times during our daily practice; however, we need a social study to find a real link.

The age of our patients ranges from 2-19 years. We excluded neonates and infants from our study. It is comparable to the range mentioned by Felipe et al study[23] in which neonates and infants have also been excluded. The reasons behind exclusion of neonates and infants in our study are many neonates with severe aortic valve stenosis present with left ventricular dysfunction that tends them intolerant to the

Table 5: Association between aortic regurgitation post operation and study variables for patients with or without pacing

		Degree of Aortic Regurgitation				
		No (%)	Trivial (%)	Mild (%)	Moderate or severe (%)	P-value
Group 1 (with pacing)						
Age (years)	< 5 years	4 (66.7)	3 (60.0)	3 (30.0)	0 (0.0)	0.302
	(5-10) years	0 (0.0)	1 (20.0)	4 (40.0)	0 (0.0)	
	≥ 10 years	2 (33.3)	1 (20.0)	3 (30.0)	2(100.0)	
Weight (Kg)	< 20 kg	4 (66.6)	4 (80.0)	4 (40.0)	0 (0.0)	0.094
	(20-40) kg	1 (16.7)	0 (0.0)	5 (50.0)	0 (0.0)	
	≥ 40 kg	1 (16.7)	1 (20.0)	1 (10.0)	2 (100.0)	
Gender	Male	4 (66.7)	2 (40.0)	4 (40.0)	2(100.0)	0.477
	Female	2 (33.3)	3 (60.0)	6 (60.0)	0 (0.0)	
Type of valve	BAV	6 (100.0)	3 (60.0)	6 (60.0)	1 (50.0)	0.295
	TAV	0 (0.0)	2 (40.0)	4 (40.0)	1 (50.0)	0.295
Group 2 (without pacing)						
Age (years)	< 5 years	1 (100)	5 (55.6)	4 (66.6)	0 (0.0)	0.04*
	(5-10) years	0 (0.0)	2 (22.2)	1 (16.7)	1 (14.3)	
	≥ 10 years	0 (0.0)	2 (22.2)	1 (16.7)	6 (85.7)	
Weight (Kg)	< 20 kg	1 (100)	6 (66.7)	5 (83.3)	2 (28.6)	0.062
	(20-40) kg	0 (0.0)	3 (33.3)	0 (0.0)	1 (14.3)	
	≥ 40 kg	0 (0.0)	0 (0.0)	1 (16.7)	4 (57.1)	
Gender	Male	1 (100)	5 (55.6)	2 (33.3)	5 (71.4)	0.477
	Female	0 (0.0)	4 (44.4)	4 (66.7)	2 (28.6)	
Type of valve	BAV	0 (0.0)	4 (44.4)	4 (66.7)	7 (100)	0.043*
	TAV	1 (100)	5 (55.6)	2 (33.3)	0 (0.0)	

*Statistically significant

rapid heart rate induced by rapid pacing. Also-left ventricular dysfunction can lead to inaccurate aortic pressure gradient, and jet of aortic regurgitation due to impairment of pumping action of the heart. In addition, neonates and infants with severe aortic stenosis and preserved left ventricular function have a heart rate which is already rapid. So in such circumstances another method like stiff guidewires is enough to stabilize the balloon during inflation. Daehnert et al[8] has also excluded the neonate and infants from rapid pacing because he regarded that stiff guidewires are sufficient to ensure balloon stability. While Hala et al study[22] has used adenosine injection for neonates and infants instead of rapid right ventricular pacing to provide balloon stability.

In our study, 32 (67.4%) patients had bicuspid aortic valves, while 14 (32.6%) patients had tricuspid aortic valve.This result supports that of Balmer et al[24] study, which has found bicommisural aortic valve in 51 patients, and tricommisural valve in 17 patients, and two patients only had monocommisural valve. Also Carlos et al study[1] has found that 66% of congenital aortic stenotic valves were bicuspid. Our result contradict Hala's[22] who has reported that the majority of aortic stenotic valves were tricuspid 15 patients (71.5 %), while in 6 patients (28.5 %) the aortic valves were bicuspid. This controversy can be explained by the small size study of Hala.

The outcome of aortic valve balloon dilation in our patients is successful in reduction of pressure gradient across the aortic valve regardless whether we had used rapid pacing or not. This result is the same as Daehnert et al[8] and Hala et al[22] studies.

Regarding the degree of aortic valve regurgitation, our study found no significant change in development of aortic regurgitation after balloon dilation in group 1 (with Pacing), while in group 2 (without pacing) 26.1 % and 4.3% have developed moderate and severe aortic regurgi-

tation respectively. This is consistent with Felipe et al,[23] who has also used rapid right ventricular pacing during balloon dilation of stenotic aortic valve, the procedure was successful in reducing pressure gradient with no change in the degree of aortic valve regurgitation. Also Daehnert et al[8] study by comparing adenosine injection to rapid right ventricular pacing, has found no severe regurgitation but only 11 patients have mild aortic regurgitation in rapidly pacing patients. Vojislav et al[21] try to decrease of degree of aortic valve regurgitation by use another way to decrease degree of regurgitation by used balloon about 1-2 mm lower than aortic valve annulus but still eight patient develop aortic valve regurgitation four of them need surgery.

For patients enrolled in group 2 (without pacing), the degree of significant aortic valve regurgitation depends on their age at time of intervention and the morphology of valve. Patents older than 10 years and those with bicuspid aortic valves were more prone to have aortic regurgitation. Vojislav et al[21] has also found that aortic regurgitation is commonly found in older children and adolescents; however, Robert et al[25] study from 1986-1988 found no relation between age and degree of aortic valve regurgitation post balloon dilatation. In contradiction to our results, Hala et al[22] found no relation between valve morphology and degree of regurgitation. C Balmer et al[24] supports our study by finding that degree of post procedural aortic valve regurgitation is most likely related to valve morphology, however he stated that degree of aortic valve regurgitation is more in neonates and infants than in young children and adolescents, a note that contradict ours. Balmer has explained this by the fact that aortic valve leaflets of neonates and infants are more dysmorphic, myxomatous and thickened than young children and adolescents. Our explanation for finding high degree of aortic regurgitation in young adults and adolescents is that we already have excluded neonates and infants from our study. Also the heart rate of young children and adolescents is low which leads to increase stroke volume,[8] in addition long duration of aortic valve stenosis causes severe ventricular hypertrophy with consequent hyperdynamic ventricular contraction. All these factors causing rapid dancing movement of inflated balloon inside the valve which may injure the leaflet and valve commissures and increase degree of aortic regurgitation that can be decrease by rapid right ventricular pacing which cause rapid rate so decrease stroke volume and provide less balloon mobility during inflation so less damage. Bicuspid aortic valve has more chance to be thickened, fibrosed and calcified. These progressive degenerative changes make the valve more rigid and cusps more fused so the valve would be vulnerable for being damage during inflation of the balloon during valvoplasty.[21]

CONCLUSIONS

Rapid right ventricular pacing is safe and effective method to provide transient decrease in left ventricular cardiac output during aortic valve balloon dilation that provides balloon stability and reduce degree of aortic incompetence by decreasing valve damage.

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