The Immediate And Intermediate Results Of Percutaneous Balloon Aortic Valvuloplasty In Patients With Congenital Valvular Aortic Stenosis

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ABSTRACT

Background: Aortic valve stenosis results from minor to severe degrees of aortic valve maldevelopment. This stenosis causes mild to severe obstruction of the left ventricular outflow .

Objectives : to study the immediate and intermediate results of percutaneous balloon aortic valvuloplasty in patients with congenital valvular aortic stenosis .

Type of the study: A prospective study.

Methods: The study was done on thirty five patients with congenital valvular aortic stenosis who had percutaneous balloon aortic valvuloplasty in Ibn Al- Bitar Center for Cardiac Surgery from May 2009 to February 2011.

Results: Twenty seven patients were male (77.2%) and 8 patients were female (22.8%), male to female ratio 3.5/ 1, . The aortic valve was bicuspid in 18 patients (51.4%) while 17 patients (48.6%) had tricuspid aortic valve. Balloon aortic valvuloplasty was successful in 30 patients (85.7%),. Maximum peak instantaneous Doppler pressure gradient across the aortic valve 24 hours postprocedural echocardiography showed reduction which is statistically significant. New aortic regurgitation had occurred in 15 patients (42.8%), it was mild in 9 patients (25.6%), moderate in 5 patients (14.3%) and severe in 1 patient(2.9%) which is statistically significant. The follow up of 12.57 ± 3.88 (3- 22) months after intervention was done for all patients using echocardiography Doppler study, reveal the maximum peak instantaneous Doppler pressure gradient across the aortic valve was raised which is statistically significant. The aortic regurgitation was present in 18 patients (51.4%) , it was mild in 9 patients (25.7%) , moderate in 6 patients (17.1%) and severe in 3 patients (8.6%). No mortality had been reported during the procedure or on follow up.

Conclusion: Aortic balloon valvuloplasty is safe and effective procedure in the treatment of congenital valvular aortic stenosis but mild aortic regurgitation is the most common immediate complication of aortic balloon dilatation and progressive aortic regurgitation is a major problem during the intermediate follow up.

key words: Aortic valve, congenital stenosis, valvuloplasty, follow up.

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Aortic valve stenosis results from minor to severe degree of aortic valve maldevelopment. This stenosis causes mild to severe obstruction of the left ventricular outflow that may be associated with left heart obstructive lesions. Most commonly the valve is bicuspid with a single fused commisure and an eccentrically placed orifice. Less commonly, the valve is unicuspid and dome shaped, particularly in the neonate. Rarely, the valve has three unseperated cusps, with the stenosis being centrally located [(1)]. Males are affected more frequently than females, with the ratio reported to be in the range of 3: 1 to 5: 1[(2)]. Associated congenital heart defects occur in approximately 20% of patients with congenital aortic stenosis [(3)]. Pure aortic valve stenosis results in compensatory ventricular hypertrophy over time proportional to the degree of obstruction[(4)]. Chronic pressure overload typically results in concentric left ventricular hypertrophy with increased wall thickness and a normal chamber size[(5)]. Reduced coronary blood flow reserve may produce inadequate myocardial oxygenation in patients with severe aortic stenosis, even in the absence of coronary artery disease[(6)]. Most patients with congenital aortic valve stenosis are asymptomatic during childhood. angina or syncope are reported in <10% of patients even when peak-to-peak pressure gradients are >80 mm Hg. [(7)]. The apical impulse is usually normal in mild aortic stenosis, but with increasing severity of stenosis, the apical cardiac impulse become more forceful [(8)]. A suprasternal notch thrill is palpable in as 85% of patients with valvular aortic stenosis. The systolic crescendo-decrescendo systolic ejection murmur of aortic stenosis usually follows an early systolic ejection click, which is loudest at the left lower sternal border or apex. The ejection murmur is generally loudest at the upper right sternal border or in younger children at a upper left sternal border, and it radiates into the neck over the carotid arteries bilaterally. [(9)].The resting electrocardiogram usually demonstrates voltage criteria for left ventricular hypertrophy if the aortic stenosis is severe. Ventricular dysrhythmias may be demonstrated on 24-hour ambulatory electrocardiogram monitoring in asymptomatic patients. On chest radiography the heart is usually of normal size or slightly enlarged, with a rounding of the left ventricular border and apex[(10)] .Echocardiography remains the most common modality used to define anatomy and assess severity of aortic stenosis. The long-axis view of the left ventricular outflow tract demonstrates decreased valve

mobility and systolic doming of the cusps. Short-axis imaging demonstrates the anatomy of the valve cusps and commissures.. Color Doppler and spectral pulsed wave and continuous wave Doppler are performed to confirm the localization of obstruction and to quantitate the degree of stenosis[11]. The mean age of death in patients with aortic stenosis was 35 years, with 40% mortality by age 30 and 60% mortality by age 40. More than half of the patients who died had sudden unexpected death, whereas most of the remaining deaths were due to progressive congestive heart failure[12]. Although mild aortic stenosis may remain stable for many years, ultimate progression is the rule [13]. In addition to the progression of aortic stenosis, many patients will develop significant and progressive aortic valve regurgitation over time, particularly if they have had surgical valvotomy or percutaneous balloon valvuloplasty [14].Medical therapy for congenital aortic valve stenosis in children and adolescents consists of bacterial endocarditis prophylaxis precautions, exercise restrictions according to the guidelines of the 36th Bethesda conference [15], and periodic follow-up evaluations to monitor the progression of valve dysfunction. The American College of Cardiology/American Heart Association guidelines for management of aortic stenosis [16] recommend that asymptomatic children and young adults with Doppler peak instantaneous gradients of ≥ 70mm Hg (peak velocity > 4.2m/s) be considered for cardiac catheterization and possible balloon valvuloplasty. Patients who desire to participate in competitive sports or are contemplating pregnancy and have Doppler peak gradients between 5o and 70 mm Hg should also be considered for catheterization and possible valvuloplasty. If the catheter measured peak-to-peak gradient is >60mm Hg, balloon valvuloplasty is indicated. If the patient desires to play competitive sports or become pregnant, balloon valvuloplasly is justified if the peak-to-peak gradient is >50mm Hg. Patients with symptoms (angina, syncope, dyspnea on exertion) or ischemic or depolarization changes on rest or exercise electrocardiography should have valvuloplasty if the peak-to-peak gradient is >50mm Hg.[16].

With a conservative dilation of the aortic valve, the gradient should be reducedby 60% to 70% or to a gradient ≤ 30 to 40 mmHg, this usually can be accomplished without inducing significant aortic insufficiency , no more than that seen after surgical valvotomy [17].Aortic valve replacement is usually required in patients who develop progressive aortic valve regurgitation or recurrent stenosis refractory to balloon valvuloplasty. Replacement with a mechanical prosthesis currently provides the most durable result, but the patient must be anticoagulated and there is no valve growth potential, both of which are very significant problems in small children[18]. Use of bioprosthetic valves, either homograft or heterograft, avoids the need for anticoagulation, but valve growth potential is still a major issue and longevity of these valves is frequently poor, particularly in small children. Percutaneous aortic valve implantation is a promising new technique that is currently being developed as an alternative to surgical valve replacement in adult patients who have severe aortic stenosis and are deemed inoperable [19].

Aim of the study:To study the immediate and intermediate results of percutaneous balloon aortic valvuloplasty in patients with congenital valvular aortic stenosis .

Methods

Study group (patients) : A prospective study done on thirty-five patients with congenital valvular aortic stenosis who required intervention in Ibn Al-Bitar Center For Cardiac Surgery from May 2009 to February 2011 .

Criteria for dilatation :

Inclusion criteria : Critical aortic stenosis was present, defined by clinical (presence of low cardiac output, cardiogenic shock, congestive heart failure) and echocardiographic criteria (morphological evidence of left ventricular hypertrophy, with depression of left ventricular function, irrespective of the transvalvular gradient) . A resting peak systolic aortic valve gradient of 70 mm Hg or greater, or a gradient of 50 mm Hg or greater with associated symptoms (exertional dyspnea, chest pain, or syncope) and /or evidence of myocardial ischemia on resting electrocardiogram .

Exclusion criteria : Balloon dilatation was not performed when aortic regurgitation was more than mild degree or if the patient had significant associated cardiac anomalies that require surgical treatment .

Methods : Balloon dilatation was performed retrogradely via the percutaneous femoral artery approach in all cases .All procedures were performed under general anesthesia. Before each procedure, the patients parent, signed a statement of informed consent . Patients were instructed to cease oral intake a minimum of six hours before the scheduled procedure .

The left heart catheterizations were done by the pigtail catheter passed retrogradly from femoral artery to the aorta and then to the left ventricular cavity . Systemic pressure was recorded and an angiogram in left anterior oblique view was done. A Judkin's right coronary catheter is used to cross the stenotic aortic valve by straight guide wire to the left ventricle when the pressure was recorded. The Judkin's right coronary catheter was replaced by pigtail catheter through an exchange guide wire . Left ventricular angiography was not routinely done especially if the left ventricular end diastolic pressure was elevated . Intravenous heparin (100 IU/kg) (maximum 5000IU) was administered routinely following femoral artery connulation and with the introduction of the balloon . Repeat hemodynamic measurements and an aortogram were performed after valvuloplasty for assessment of aortic regurgitation. All patient were followed up by echocardiography for 3-22 months (12.57±3.88months) after the intervention.

Definition of successful balloon aortic valvuloplasty : With preserved left ventricular function , success was defined as a gradient reduction of 60%- 70% or more, or a maximum residual gradient of 50 mm Hg or less . With impaired left ventricular function , it was defined as improvement of left ventricular function , irrespective of the gradient (because almost underestimated) , employing an adequate balloon to annulus ratio. Patient who did not require aortic valve surgery within the first seven days after the procedure . The procedure considered to be successful if the patient did not develop severe aortic regurgitation .

Statistical analysis : Data and results were expressed as numbers, percents, range and mean ± standard deviation (SD) . Association between different variables

was measured by using Chi-square test. Difference between pressure gradients before and after interventions was measured by using the paired-t-test. P value < 0.05 was taken as significant .

Age (years)	Male		Female		Total	
	No	%	No	%	No	%
<1 year	5	83.3	1	16.7	6	17.1
1--4	7	63.6	4	36.4	11	31.4
5--9	7	70.0	3	30.0	10	28.6
=>10	8	100.0	-	-	8	22.9
Age Mean±SD (Range)	7.20±5.54 (1m-16y)		4.19±2.56 (6m-8y)		6.51±5.14 (1m-16 y)	
Weight (Kg)Mean± SD (Range)	23.52±16.21 (4-60)		15.50±5.68 (7-23)		21.69±14.81 (4-60)	

Results :The studied group include 35 patients with congenital valvular aortic stenosis. Twenty seven

Table (1) : Sex , age and weight of the studied group

patients were male (77.2%) and 8 patients were female (22.8%) with a male: female ratio of 3.5:1. The patients ages ranged from 1 month - 16 years. (6.51 ± 5.14 years) and the patients weights ranged from 4-60 kg (21.69 ± 14.81 kg) (Table 1).

The aortic valve was bicuspid in 18 patients (51.4%) while 17 patients (48.6%) had tricuspid aortic valve. Balloon aortic valvuloplasty was completed in all cases and was successful in 30 patients (85.7%) .Peak to peak systolic aortic pressure gradient was reduced from 95.57 ± 24.58 (70-155) mm Hg to 34.00 ± 12.99 (5-60) mm Hg (P value of 0.0001), which is statistically significant. So the percent of reduction of pressure gradient was 63.23 ± 13.43 (29-94) mm Hg (Table 2).

Balloon aortic valvuloplasty achieved a significant reduction in left ventricular systolic pressure from 198.29 ± 29.60 (140-250) mm Hg to 137.86 ± 23.40 (80-200) mm Hg (P value of 0.0001) and a significant reduction in left ventricular diastolic pressure from 22.89 ± 10.54 (10-40) mm Hg to 19.71 ± 8.48 (8-35) mm Hg (P value of 0.0001) (Table3). Maximum peak instantaneous Doppler pressure gradient across the aortic valve 24 hours post procedural echocardiography showed a reduction in maximum pressure gradient from 86.94 ± 16.18 (70-140) mm Hg to 37.97 ± 12.27 (20-65) mm Hg after balloon aortic valvuloplasty which is statistically significant (Table4). Mild aortic regurgitation was present in 3 patients (8.6%) before balloon aortic valvuloplasty which did not progress after the procedure. New aortic regurgitation had occurred in 15 patients (42.8%), it was mild in 9 patients (25.6%), moderate in 5 patients (14.3%) and severe in 1 patient (2.9%) which is statistically significant (Table5).

In patients who developed moderate and severe aortic regurgitation (no.=6) the dilatation was done with a balloon/aortic annulus ratio of ≥ 109%.

The aortic valve annulus was 12.74 ± 3.60 (7-22) mm in diameter, balloon size was 12.91 ± 3.29 (8-20) mm in diameter so the mean balloon to aortic annulus ratio was 102.35 ± 9.54% (83.3-120%) (Table 6).

On follow up of the patients by echocardiography for 12.57 ± 3.88 (3-22) months after intervention, the maximum peak instantaneous Doppler pressure gradient across the aortic valve was raised from 37.97 ± 12.27 (20-65) mm Hg to 42.71 ± 13.95 (25-90) mm Hg which is statistically significant from pre percutaneous balloon aortic valuloplasty (Table 4) . Of the 35 patients, only 5 patients (14.28%) had significant pressure gradient (> 70 mm Hg) on follow up that need reintervention . On follow up, 3 patients with mild aortic regurgitation progress to moderate and patients with moderate progress to severe aortic regurgitation. The final results were 9 patients (25.7%) had mild aortic regurgitation, 6 patients (17.1%) had moderate and 3 patients (8.6%) had severe aortic regurgitation which is statistically significant from pre percutaneous balloon aortic valuloplasty (Table 5). No mortality had been reported during the procedure or on follow up.

Table (2) : Pressure gradient (mm Hg) a cross the aortic valve pre and post percutaneous balloon aortic valuloplasty (PBAV) with the percentage of reduction

	Pre PBAV	Post PBAV	P value
	Mean±SD (Range)	Mean±SD (Range)	
Pressure gradient across the aortic valve (mm Hg)	95.57±24.58 (70.0-155.0)	34.00±12.99 (5.0-60.0)	0.0001*
% of reduction of Pressure gradient	63.23±13.43 (29.0-94.0)		

*Significant using paired-t-test for difference between dependent means at 0.05 level of significance

Table (3) : Left ventricular systolic and diastolic pressure assessed by cardiac catheterization pre and post PBAV

Table (4) : The echocardiographic data of the patients before , 24 hours and on follow up after PBAV .

	Pre PBAV	Post PBAV	P value
	Mean±SD (Range)	Mean±SD (Range)	
Left ventricular systolic pressure	198.29±29.60 (140.0-250.0)	137.86±23.40 (80.0-200.0)	0.0001*
Left ventricular diastolic pressure	22.89±10.54 (10.0-40.0)	19.71±8.48 (8.0-35.0)	0.0001*

*Significant using paired-t-test for difference between dependent means at 0.05 level of significance

Table (5) : Aortic regurgitation pre PBAV , post PBAV and on follow up.

	Pre PBAV	24 hours Post PBAV	Follow up (12.57± 3.88)
	Mean ± SD (Range)	Mean ± SD (Range)	Mean ± SD (Range)
PG (mm Hg)	86.94±16.18 (70.0-140.0)	37.97±12.27* (20.0-65.0)	42.71± 13.95* (25.0-90.0)

*Significant difference from Pre PBAV using paired-t-test for difference between dependent means at 0.05 level of significance

#Significant difference from Post PBAV using paired-t-test for difference between dependent means at 0.05 level of significance

*Significant using Pearson Chi-square test for difference of proportions from pre PBAV at 0.05 level of significance

Aortic regurgitation	Pre PBAV		Post PBAV*		Follow up* (12.57±3.88)	
	No	%	No	%	No	%
No AR	32	91.4	17	48.6	17	48.6
Mild AR	3	8.6	12	34.3	9	25.7
Moderate AR	-	-	5	14.3	6	17.1
Severe AR	-	-	1	2.9	3	8.6

Table (6) : The annulus & balloon sizes with balloon/annulus ratio of the studied group

	Mean ± SD (Range)
Annulus size (mm)	12.74±3.60 (7.0-22.0)
Balloon size (mm)	12.91±3.29 (8.0-20.0)
Balloon / Annulus ratio (%)	102.35±9.54 (83.3-120.0)

Discussion: The age and sex of the patients were analyzed that showed male: female ratio of 3.5:1, which is consistent with the Frank et al [3]. The age distribution of the patients is wide (1 month-16 years) which is similar to many other previous studies like Balmer et al [20] (number of patients was 49 and the age ranged between m 3 months – 16.4 years). A successful immediate outcome was achieved in 85.7% of the patients, in accordance with the data that reported by Moore et al [21] and Gatzoulis et al [22], confirming that

The invasively measured peak to peak systolic aortic pressure gradient was reduced from 95.57 ± 24.58 mm Hg to 34.00 ±12.99 mm Hg (P value < 0.0001) after balloon aortic valvuloplasty which is more than that reported by Balmer et al [20] (where pressure gradient decrease from 68 ±27 mm Hg to 29 ±13 mm Hg (P value < 0.001)), Galal et al [23] (pressure gradient decline from 66 mm Hg to 32 mm Hg) and David et al [24], (median decrease of pressure gradient was 35 mm Hg). This can be explained by the fact of using a large balloon / annulus ratio in our study (102.35 ±9.54%, range 83.3 – 120%) in comparison to Balmer et al study (the balloon / annulus ratio was selected at a mean of 90%, range 67 – 100%). The left ventricular systolic pressure was reduced from 198.29 ±29.60 mm Hg to 137.86 ±23.40 mm Hg after balloon aortic valvuloplasty which is more than that reported by O'connor et al [25] (decrease from 176 ±4 to 138 ±4 mm Hg and Galal et al [23] (decrease from 159 to 122 mm Hg.The left ventricular end diastolic pressure was reduced from 22.89 ±10.54 mm Hg to 19.71 ±8.48 mm Hg (P value of 0.0001) which is not so different to that reported by Galal et al [23] as left ventricular end diastolic pressure was reduced from 13.5 mm Hg to 8.8 mm Hg (P value < 0.001).The maximal Doppler pressure gradient declined from 86.94 ±16.18 mm Hg to 37.97 ±12.27 mm Hg after balloon aortic valvuloplasty which is more than that reported by Balmer et al [20] as the maximal Doppler pressure gradient decreased from 88 ±23 mm Hg to 52 ±17 mm Hg. This can be explained by the fact of using a large balloon / annulus ratio in our study.Acute post dilation aortic regurgitation was moderate or severe in 17.2 % of patients which is higher than that reported by David et al [24] (14%) and Balmer et al [20] (10.2%), this results is also due to a large balloon /annulus ratio.We did not find any correlation between the valve morphology (Tricuspid or bicuspid) and aortic regurgitation, this is a in agreement with that reported by Balmer et al [20] .In all the patients who developed moderate and severe aortic regurgitation, the dilatation was done with large size balloon (balloon / aortic annulus ratio of ≥ 109%) confirming the relation between oversized balloons and an increased incidence of post dilation aortic regurgitation and this result agree with that reported by Moore et al [21], while Balmer et al [20] found no relationship between the balloon / annulus ratio and occurrence of aortic regurgitation (this results explained by the use of smaller balloon with balloon / annulus ratio of 67 – 100%). On follow up of the patients (12.57 ±3.88 months) after intervention, maximum peak instantaneous Doppler pressure gradient across the aortic valve was raised from 37.97 ±12.27 mm Hg 24 hours post intervention to 42.71 ±13.95 mm Hg which is nearly comparable with that reported by Balmer et al [20] which raised from 52 ±17 mm Hg immediately post intervention to 55 ±23 mm Hg (median follow up time of 19.8 months).

On the same period of follow up, moderate and severe aortic regurgitation were present in 25.7% of patients which is slightly less than that reported by Balmer et al [20] (29% after 1 year follow up). The acceptable explanation is that blood flow through the aortic valve leads to a constant haemodynamic trauma of the valve tissue which may result in progressive

tearing, scarring, retraction, and calcification of the valve, even in the absence of major residual stenosis **Conclusions :** Aortic balloon valvuloplasty is safe and effective procedure in the treatment of congenital valvular aortic stenosis and provides effective immediate and intermediate –term pressure gradient reduction in infants, children and adolescents with congenital valvular aortic stenosis . Mild aortic regurgitation is the most common immediate complication of aortic balloon dilation .There is a correlation between the use of oversized balloons and increased incidence of post interventional aortic regurgitation .The valve morphology (Tricuspid or bicuspid) had no correlation with occurrence of aortic regurgitation. Progressive aortic regurgitation, appears to be a major problem during the intermediate follow up of patients who underwent aortic balloon valvuloplasty . Restenosis is not a major outcome of the aortic balloon valvuloplasty during the intermediate follow up of the patients

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