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Long-term results of balloon pulmonary valvuloplasty in pediatric age group in surgical specialty teaching hospital/cardiac center/Hawler

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Abstract

Congenital valvular pulmonary stenosis accounts for 5-10% of all congenital heart disease. Balloon pulmonary valvuloplasty is a safe and effective method in reduction of moderate to severe valvular pulmonary stenosis. This retrospective study done in Hawler surgical specialty cardiac center on pediatric patients who had pulmonary valve stenosis (with echocardiographic peak gradient 2:50mmHg) and treated by balloon pulmonary valvuloplasty.

A total of 178 cases were involved, 93(52.25%) patient was male and 85 (47.75%) patients was female. 160 patient (89.89%) were treated with single balloon method 18 patient (10.11%) were managed by double balloon method technique. Follow up period of these patients range from 1 year to 10 years (mean of 5.5 year). In 153 patients (85.96%) pressure across pulmonary valve were below 36 mm Hg, while in 21 (11.80%) pressure gradient across pulmonary valve were (36-50 mm Hg). Four (2.24%) patients had pressure gradient across pulmonary valve more than 50 mm Hg. Forty patients (22.47%) developed mild pulmonary valve regurgitation, while 20 patient (11.24%) developed significant pulmonary valve regurgitation.

Balloon pulmonary valvuloplasty provides long-term relief of pulmonary valvular obstruction in the majority of pediatric patients. The long-term results are favorable.

Keywords: Congenital heart disease; Pulmonary stenosis; Valvuloplasty; Balloon pulmonary valvuloplasty

1. Introduction

Congenital cardiac abnormality occurs in approximately 0.8% of live births. Congenital heart defects remains the leading cause of death in children with congenital malformations[1].

Obstruction to the outflow from the right ventricle, whether within the body of the right ventricle, at the pulmonary valve, or in the pulmonary arteries, is described as pulmonary stenosis [2].

Pulmonary stenosis is a common congenital cardiac lesion. The incidence of valvar stenosis has been reported at 0.6 to 0.8 per 1000 live births. Balloon valvuloplasty is the procedure of choice for the valvular stenosis at all ages[3].

The aim of this study is to assess the long-term results of percutaneous balloon valvuloplasty at surgical specialty hospital/ cardiac center/ Hawler).

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2. Material and methods

This retrospective, single center, observational study involve pediatric patients (whom age range between one day up to 21 years) with history of pulmonary valve stenosis that treated by transcatheter pulmonary valve dilatation in surgical specialty teaching hospital/cardiac center/Hawler from 1st January 2007 to 31th December 2016.

The criterion for indicating percutaneous valvuloplasty was a peak pressure gradient 50 mmHg across the pulmonary valve with normal cardiac function and right ventricular/left ventricular pressure ratio> 0.8.

Exclusion criteria include patients whom been treated with surgical dilatation, presence of pulmonary stenosis at other levels (infundibular stenosis, supravalvular stenosis), and pulmonary stenosis in association with other congenital heart disease

Echo-Doppler examination usmg (VIVED E9) generation machine were performed on follow up. A 3MHz and 5 MHz probe were used for examination. A maximum peak instantaneous pressure gradient across RVOT was determined using the modified Bernoulli equation. Li P = 4(Vi- V12)

Immediate success is defined as a pulmonary gradient < 36 mmHg following the procedure, the effectiveness of the procedure was defined by immediate success and by a subsequent decrease in transvalvular gradient to < 36 mmHg. Restenosis was defined as an increase in pressure gradient increasing to 2: 36 mmHg after a successful procedure. 4

Patients' medical records were reviewed and the following procedural data were collected: age, weight at the time of valvuloplasty; clinical presentation; valve morphology, pre- and post valvuloplasty hemodynamic data (pulmonary transvalvular gradient, RV pressure, and right ventricular/left ventricular pressure ratio. Pulmonary regurgitation assessed by the ratio between the regurgitant jet and pulmonary annulus diameters, establishing 4 grades (grade I, ratio 10%; grade II, 11% to 25% grade III, 26% to 50% and grade IV> 50%) [2].

Finally, the length of follow-up was analyzed, defined as the time from valvuloplasty until final echocardiographic follow-up

Chi square Test were used for analyses. P value <0.05 was considered significant for all tests.

3. Results and discussion

A total of 178 cases were involved in the study; 93(52.25%) patient was male and 85 (47.75%) patients was female, male to female ratio was 1.1/1.

Age of the patients rage from 17 days old to 21 years, with mean age of (4.06 ±4.7) years old. Pressure gradient across the pulmonary valve range from 50mm Hg to 179m m Hg with mean pressure of (98.98±24.63). Follow up period of these patients range from 1 year to 10 years (mean of 5.5 year), (table l).

Table 1 Characters of patients who involve in the study

Parameter		
Age	0-21 years	4.06 ±4.7
Pressure gradient	50-179 mm Hg	98.98±24.63
Period of follow up	1-10 years	4.5±2.7
Females	85 (47.75%)	
Males	93 (52.25%)	

The morphology of the pulmonary valve prior to transcatheter intervention was varied between domed valve found in 127(71.35%) case, dysplastic valve in 42 (23.60) cases, while the remaining 9 (5.05%) cases were have more complex valve morphology (table 2).

Table 2 Morphology of the pulmonary valve prior to transcatheter intervention

Morphology	No.	%
Domed	127	71.35
Dysplastic	42	23.60
Complex	9	5.05
Total	178	100

Regarding treatment modality, it was recorded that 18 patient (10.11%) were managed by double balloon method technique, the remaining 160 patient (89.89%) were treated with single balloon method, (table 3).

Table 3 Methods of balloon dilatation used in pulmonary valvuloplasty

No. of patients		%
Single balloon	160	89.89
Double balloon	18	10.11
Total	178	100

Studied group were divided into two subgroups according to the early result of the balloon valvuloplasty, In 155 patient (87.08%); the immediate post valvuloplasty decrement in the pressure gradient across pulmonary valve were below 36 mm Hg and these patient had successful balloon dilatation(group one). In 23 patient (12.92%); balloon dilatation were only partially successful (pressure gradient across the pulmonary valve were decrease between 36-50 mm Hg)(group two) as shown in table (4).

Table 4 Immediate results of post transcatheter pulmonary valve dilatation

Results of intervention	No.	%
Successful (group one)	155	87.08
Partially successful (group two)	23	I 12.92
Total	178	100

Regarding the results of long term follow up (table 5), it was found that among the patients of group one, (137 patients 88.39%) still has transvalvular pressure gradient less than 36 mm Hg across pulmonary valve, while the pressure gradient remain more than 36 mm Hg in 18 patients (11.61%). Regarding patients in group two, sixteen patients (69.56%), show decline in the pressure gradient across the pulmonary valve (transvalvular pressure less than 36 mm Hg), while pressure gradient remain between (36-50 mm Hg) in three patients (13.04%). In the remaining 4 patients (21.74%) severe stenosis that demand surgical intervention to relieve transvalvular obstruction.

Table 5 Long term results of balloon pulmonary valvuloplasty-pressure gradient across pulmonary valve

Transvalvular pulmonary pressure	Group one	Group two	Total
Less than 36 mm Hg	137 (88.39%)	16 (69.56%)	153 (85.96%)
36-50 mm Hg	18 (11.61%)	3 (13.04%)	21 (11.80%)

'P value< 0.05

Grade 4 pulmonary valve regurgitation (Table 6) was found 17 (10.96%) patients of group one, while 53 (22.58%) patients found to have grade 2-3 pulmonary regurgitation. Regarding group two; 3 (12.5%) developed significant (grade 4) regurgitation, while Grade 2-3 pulmonary valve regurgitation found in 5 (20.8%) patient in group two.

Table 6 Long term results of balloon pulmonary valvuloplasty- pulmonary valve regurgitation

	Group one	**Group two**	**Total**
Mild (Grade 2-3) regurgitation	35 (22.58%)	5 (20.8%)	40 (22.47%)
Significant (grade 4) regurgitation	17 (10.96%)	3 (12.5%)	20 (11.24%)
Total	52 (33.54%)	8 (32.33%)	60 (33.71%)

'P value> 0.05

Percutaneous balloon pulmonary valvuloplasty (BPV) represents a maJor milestone in the field of interventional cardiology, regardless of the patient's age and valve morphology; BPV has replaced surgery as the initial treatment of choice for patients with moderate to severe pulmonary valve stenosis [5].

In this study, 18 patient (10.11%) were managed by double balloon method technique, the remaining 160 patient (89.89%) were treated with single balloon method. In a similar study that included 118 patients with congenital valvular pulmonary stenosis at Jipmer tertiary care hospital in India from 1988 to 2011, Ezhumalai, et al [7]found that double balloon technique was used in only I patient (0.9%) 6. Simultaneous double balloon dilation has the advantage of smaller profiles that minimize sheath requirements and potential vascular injury, although they require multiple sites of vascular entry. There are limited data evaluating the unequal distribution of wall stresses that may occur with this technique although no untoward clinical effects have been reported.

Results of double balloon valvuloplasty are excellent but not superior to single balloon valvuloplasty, double balloon valvuloplasty should be used if the pulmonary valve annulus is too large to dilate with a single balloon. There is no need for double balloon valvuloplasty if the pulmonary valve can be dilated with a commercially available single balloon [8].

Regarding long term outcome of the percutaneous pulmonary valve dilatation Overall successfulness in this study was 153 (85.96%), these patients shows pressure gradient across pulmonary valve below 36 mm Hg taken by doppler echocardiography, and in 21 (11.80%) patient found to have pressure gradient between (36-50 mm Hg). also its found that immediate post dilatation results have a great influence on the expected long term outcome since statistically significant difference in the rate of success exist between those who shows full successfulness and those who shows only partial successfulness (88.39% Vs 69.56%). In a study done at The Johns Hopkins Hospital in Between June 1981 and December 1986, initial BPV was attempted in 49 patients. 44 patients in whom immediate result fall below 36 mmHg Only, 2 patients (4.55%) shows pressure gradient over 36 mm Hg. the remaining 42 patients (94.45%) shows pressure gradient below 36 mmHg. in another 5 patient (10.2%) involved in the mentioned study; pressure gradient after immediate post catheterization period fail to decline below 36 mm Hg; long term study of this group shows that one patient (20%) undergone surgical dilatation, one patient (20%) did re catheterization dilatation, and in 3 (60%) patients pressure gradient decline below 36 mm Hg. [9]. In Ezhumalai, et al. [10] study, 6 the long term success rate (2:6 years after valvuloplasty) was 99(91.7%), and 2(1.9%) patient developed significant restenosis. Raquel Merino study 53 patients diagnosed with pulmonary valve stenosis who underwent percutaneous balloon pulmonary valvuloplasty between December 1985 and December 2000 in Virgen del Roci'o tertiary care Hospital, Seville, Spain center, occurrence of long-term restenosis in 1 patient (2.1%).

Although the result of all these studies appeared to be encouraging, differences in the success rate may partially related to time of presentation of the patient, availability of catheterization equipment (including proper balloon size, and regular follow up regimen).

Regarding pulmonary insufficiency, 40 patients (22.35%) have grade 2-3 pulmonary, and in 20 patients (11.17%) echocardiographic study shows grade (grade 4) insufficiency. No statistical differences found in the degree of pulmonary regurgitation between patients that shows full immediate successfulness and those with partial successfulness after balloon dilatation. A study done by Garty et al. [11] in the Cardiac Catheterization Laboratories, Department of Cardiology, Hospital for Sick Children, in Toronto Canada, included 150 children who had PBD between 1984 and 1992 were reviewed. Moderate or severe PR found in 85 patients (57%) of children on long term follow-up.

In a similar study done in kingdom of Saudi, results showed that 26 of 35 (74%) patients with successful balloon pulmonary valvuloplasty developed pulmonary insufficiency on long- term follow-up. This is understandable, because the balloon valvuloplasty produces commissural splitting and tearing or avulsion of valve leaflets [12].

In a study done in Tunisia, at Fattouma Bourguiba University Hospital from April 1987 to April 1996, included 66 patients underwent percutaneous BPV in catheterization laboratory for relief of isolated pulmonary valve stenosis. Mild to moderate pulmonary regurgitation was present in 39% of patients [13].

In a study conducted in Iran Shahid Sadoughi University of Medical Sciences, From June 1998 to January 2012 sixty consecutive patients (33 females, 27 males) with moderate to severe valvar pulmonary stenosis Pulmonary insufficiency was demonstrated in 17 (32%) at late follow up. A second valvuloplasty was performed in two (3.8%) patients presenting with re-stenosis [14].

Although the result of all studies are good enough to consider balloon pulmonary valvuloplasty as a gold standard of treatment in congenital pulmonary stenosis, the deference in the long term follow up probably due to the slandered of the centers in which the catheterization carried in, together with the accumulative experience of the physician that did the catheterization, since the studies are done over deferent time.

4. Conclusion

The long-term results of balloon valvuloplasty for pulmonary stenosis appear encouraging. Repeat catheterization and echo doppler data suggest persistent relief of pulmonary stenosis. Less than moderate pulmonary regurgitation develops in most cases, but rarely requires surgical treatment.

Compliance with ethical standards

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Disclosure of conflict of interest

The authors declared no conflict of interest.

Statement of informed consent

Adequate and appropriate information about research and researchers were provided.

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