Early Outcome of Balloon Pulmonary Valvuloplasty for Pulmonary Valve Stenosis in Adolescents and Adults: Experience at A Tertiary Care Cardiac Institute

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ABSTRACT

Background: Balloon pulmonary valvuloplasty is the procedure of choice for pulmonary valve stenosis in any age group. The data on efficacy of the procedure in adolescent and adult population is scanty in Pakistan. **Objective:** To determine the early outcome of balloon pulmonary valvuloplasty in adolescents and adults. **Study Design:** Descriptive retrospective case series. **Settings:** Pediatric cardiology department of Faisalabad Institute of Cardiology, Faisalabad-Pakistan. **Duration:** Three years and Six months from 01-01-2016 to 30-06-2019. **Methodology:** All consecutive patients of age 10 years or above who underwent percutaneous balloon pulmonary valvuloplasty in the study period were enrolled. The outcome parameters including successfulness and complications of procedure recorded. The procedure was labelled successful if peak to peak pressure gradient across pulmonary valve reduced to less than 50% or more of the pre procedure value, suboptimal if gradient reduced by 25-49% and unsuccessful if gradient reduced by less than 25%. **Results:** A total of 41 patients underwent balloon pulmonary valvuloplasty procedure. Mean age was 22.2± 10.5 years while female to male ratio was 1.05:1. Majority of the patients (n=26, 63.4%) were symptomatic and dyspnea on exertion was the dominant symptom (n=16, 39%). Majority of the patients had doming pulmonary valve (n=37, 90.2%). Mean balloon to pulmonary valve annulus ratio was 1.24 ± 0.1 (range 1.1-1.43). The procedure was successful in all patients (n=41, 100%) as the mean peak to peak pressure gradient across pulmonary valve decreased from 121.9 ± 53.2 mmHg (pre valvuloplasty) to 30.1±11.9 mmHg (post valvuloplasty) irrespective of doming or dysplastic valve. There were no major complications. Transient self-limiting vaso-vagal syncope was noted in 7.3% of patients (n=3). On post procedure echocardiography there was not a single case of moderate or severe pulmonary valve regurgitation (PR) while mild PR was observed in 48.8% patients (n=20). **Conclusion:** Balloon pulmonary valvuloplasty in adolescent and adult patients is a very safe procedure with high success but very low complications rate.

Keywords: Pulmonary valve stenosis, Balloon pulmonary valvuloplasty, Adolescents, Pulmonary regurgitation

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Submitted for Publication: 15-07-2020 *Accepted for Publication: 14-09-2020*
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Citation: Mughal AR, Saeed MH, Ahmad M, Sadiq M. Early Outcome of Balloon Pulmonary Valvuloplasty For Pulmonary Valve Stenosis in Adolescents and Adults: Experience at A Tertiary Care Cardiac Institute. APMC 2020;14(3):200-4.
DOI: 10.29054/APMC/2020.965

INTRODUCTION

Congenital pulmonary valve stenosis accounts for 8 to 10 % of patients with congenital heart disease.[1] The reported incidence of PVS in adults is 0.12 per 1000 adults.[2] The age of presentation is variable depending upon the severity of PVS and symptoms. Those patients of PVS who present during adolescence or adult life, the decision about surgical valvotomy or non-surgical balloon pulmonary valvuloplasty treatment options is not easy.[3]

Per cutaneous trans-catheter balloon pulmonary valvuloplasty (BPV) is the treatment of choice for pulmonary valve stenosis since the introduction of this procedure in 1982 by Kan.[4] BPV has totally replaced the surgical pulmonary valvotomy and is the treatment of choice for moderate to severe valvular pulmonary stenosis in all age groups.[5]

BPV has excellent results because of least trauma to patients with limited clinical presentation.[6] Complications during and immediately after balloon valvuloplasty are usually minimal. Children and adolescent patients behave differently to balloon pulmonary valvuloplasty ranging from suicidal right ventricle (RV) physiology, reduction in gradients across pulmonary valve and re stenosis. During valvuloplasty transient bradycardia, premature beats and a fall in systemic pressure on balloon inflation are usually noted which return to normal after deflation of balloon. Transient blood loss, complete right bundle branch block, transient or permanent heart block, cerebrovascular accident, loss of consciousness, cardiac arrest, convulsions, balloon rupture at high balloon inflation pressures, rupture of tricuspid valve papillary muscle, and pulmonary artery tears, though rare have been reported.[7]

The early outcome and usefulness of balloon pulmonary valvuloplasty in adolescents and adults with pulmonary valve stenosis has not been studied much in resource limit developing countries like Pakistan resulting in scanty data. The objective of this study was to determine the early outcome of balloon pulmonary valvuloplasty in adolescents and adults at Faisalabad institute of cardiology (FIC).

METHODOLOGY

Study Design: Descriptive retrospective case series.

Settings: Pediatric cardiology department of Faisalabad Institute of Cardiology, Faisalabad-Pakistan.
Duration: Three years and Six months from 01-01-2016 to 30-06-2019.
Sample Technique: Non probability consecutive sampling technique was used.
Sample Size: All 41 patients who underwent BPV during the study period.
Inclusion Criteria: All the patients of age 10 years zero days or above and of any gender who underwent balloon pulmonary valvuloplasty, irrespective of doming or dysplastic valve, at FIC for moderate to severe isolated valvular PS from January 2016 to June 2019 were enrolled in the study.
Exclusion Criteria: Patients having multiple associated congenital heart defects but underwent BPV along with simultaneous other interventions, patients having history of congenital heart surgery but underwent the valvuloplasty procedure for pulmonary valve stenosis in the native valve, tissue bio prosthetic valve or right ventricle to pulmonary artery valve conduit and those with incomplete record of BPV were excluded from the study.
Data Collection Procedure: The approval from ethics committee of the hospital was taken. It is a routine of the institute to get informed written consent at time of admission and before start of every procedure. We retrieved the data of the patients from dedicated hospital database, including demographic profile and clinical data of the patients, bio-data (name, father name, residential address, contact number and hospital registration number for identification purpose only), age (in years), gender (male/ female/ transgender), weight in kilograms (Kg) or symptoms at presentation. Pre procedural findings of trans-thoracic echocardiography (TTE) including valve morphology (doming/ dysplastic), valve annulus, RV systolic function, color flow mapping, presence or absence of tricuspid valve regurgitation (TR), peak instantaneous pressure gradient across pulmonary valve (PIPG) in millimeter of mercury (mmHg) was also retrieved.
Similarly, the BPV procedure notes were re-evaluated for the procedural parameters like type of sedation given (Local anesthesia, conscious sedation or general anesthesia), femoral venous access site (right or left), RV pressure (RVP), pulmonary artery pressure (PAP) and severity of pulmonary valve stenosis (mild, moderate or severe). The shape (doming or dysplastic) and annulus of valve by RV angiogram at full lateral projection, presence or absence of TR, size of the balloon including length in centimeter (cm) and width in millimeter (mm) was also noted including balloon size to annulus ratio.
BPV Procedure: After careful history, clinical examination and informed written consent cardiac catheterization was performed through femoral venous access under local anesthesia in all the enrolled patients. NIH catheter was taken through the venous sheath to RV and then RV angiogram performed in full lateral projection (90^0) to confirm the valvular stenosis, morphology of valve and annulus. Hemodynamic data was assessed. A soft profile low pressure balloon (Tyshak II in all 41 cases), 20 - 50% greater in diameter than valve annulus, was selected and inflated across pulmonary valve over an extra stiff exchange length guide wire which already was anchored in a branch pulmonary artery by using a multipurpose catheter. One to three inflations were given in each case depending upon disappearance of waste and the inflation was not more than 3 seconds. Post-procedure right ventriculogram was performed in all cases to document an adequate valve opening. Post-procedure pulmonary artery to right ventricular outflow tract (RVOT) pull back gradient that is peak to peak pressure gradient (PPPG) across pulmonary valve was measured using an end-hole catheter, carefully excluding any right ventricular outflow obstruction gradient.
The Procedure was labelled as successful if peak to peak angiographic pressure gradient (PG) reduced to less than 50% of its initial value while it was considered suboptimal if PG reduced by 25-49% and unsuccessful if PG reduced by less than 25%. Procedural complications like syncope, arrhythmias, pericardial effusion, local bleeding / hematoma from femoral sheath site were recorded.
Findings of post procedural echocardiography done on day one were also retrieved for pulmonary valve instantaneous gradient and RV function, RVOT obstruction, pericardial effusion, TR (mild, moderate, severe) and Pulmonary regurgitation (mild, moderate, severe). The clinical stability of patients regarding blood pressure, pulse, temperature, local puncture site wound condition for inflammation and total hospital stay was noted.
Data Analysis: All the information was recorded in a proforma devised by the principal investigator. The patients or parents of patients were called for interview when and where required while confidentiality of the data was assured. The recorded data was entered in excel sheet and descriptive analysis done. Mean ± standard deviation (SD) calculated for all quantitative variables with normal distribution including age, weight, valve annulus size, pressure gradient across pulmonary valve, drop in gradient following balloon pulmonary valvuloplasty and residual gradient at day one. Frequencies and percentages were calculated for all categorical variables.

RESULTS

A total of forty-one consecutive patients who underwent balloon pulmonary valvuloplasty at our institute from January 2016 to June 2019 were enrolled in the study according to inclusion criteria and results analyzed.
Females were slightly dominant to male with female to male ratio 1.05:1. Minimum age of the patients was 10 years while maximum age was 53 years with a mean age 22.2± 10.5 years. Minimum weight of the patients was 18kg, maximum weight 70kg, while mean weight was 46.4±14.4kg. All patients had severe valvular PS on echocardiography (n=41, 100%). Majority of the patients (n=26, 63.4%) were symptomatic and dyspnea on exertion was the dominant symptom (n=16, 39%). Majority of the patients had doming pulmonary valve (n=37, 90.2%). Table 1 describes base line demographics and clinical characteristics.

Table 1: Baseline demographics and clinical characteristics

Demographics and Clinical Characteristics		Number (%)
Gender	Female	21 (51.2)
	Male	20 (48.8)
Age	10-18 years	17 (41.5)
	>18 years	24 (58.5)
Weight (Kg)	18-50 Kg	24 (58.5)
	>50 Kg	17 (41.5)
Severity of PS	Severe valvular PS	41 (100)
Symptomatology	Symptomatic Chest Pain Dyspnea on Exertion	26 (63.4) 16 (39%) 10 (24.4)
	Asymptomatic	15 (36.6)
Valve Morphology	Doming valve	37 (90.2)
	Dysplastic valve	4 (9.8)

Mean pulmonary valve annulus was 16.8 ± 2.6 mm (range 10.2-23mm) while mean balloon diameter was 20.8 ± 2.8 mm (range 14-25mm). In all cases Tyshak-II soft profile balloon was used with balloon to pulmonary valve annulus ratio of 1.24 ± 0.1 (range 1.1-1.43). As regard outcome of the procedure, it was successful in all patients (n=41, 100%). The mean peak to peak pressure gradient across pulmonary valve decreased from 121.9 ± 53.2 mmHg (pre valvuloplasty) to 30.1±11.9 mmHg (post valvuloplasty) irrespective of doming or dysplastic valve thus resulting in 100% success rate of the procedure. The minimum (min) and maximum (max) values of hemodynamic parameters before, during and after catheterization including RV pressure (RVP), pulmonary artery pressure (PAP), peak to peak pressure gradient (PPPG) across pulmonary valve, peak instantaneous pressure gradient (PIPG) at pulmonary valve in millimeter of mercury (mmHg) are described in Table 2.

Table 2: Pre and post valvuloplasty hemodynamic parameters

Parameters (mmHg)	Pre Valvuloplasty-Values			Post Valvuloplasty Values		
	Min	Max	Mean ± SD	Min	Max	Mean ± SD
RVP	60	287	145.2 ± 52.8	25	85	55.9 ± 13.2
PAP	13	40	23 ± 5.8	15	43	26.8 ± 6.6
PPPG	42	261	121.9 ± 53.2	9	68	30.1±11.9
PIPG	68	200	122.9 ± 39.3	6	58	27.3 ± 11.4

During the procedure of balloon inflation and deflation across the valve three patients (7.3%) developed transient self-limited vasovagal syncope along with sinus bradycardia. There was not a single case of cardiac arrest, arrhythmia, pericardial effusion, venous injury/ thromboembolic event or death. Echocardiography was done on next day of procedure to look for peak instantaneous gradient across pulmonary valve, tricuspid valve regurgitation (TR), pulmonary valve regurgitation (PR), RV function, pericardial effusion and tamponade. All the patients were discharged on next day. The morbidity parameters are described in Table 3.

Table 3: Morbidity during or post procedure

Morbidity Parameters		Number (%)
Complications during Procedure	Vaso-vagal syncope (self-limiting)	3 (7.3)
Post Procedure Echocardiography	Tricuspid regurgitation Trivial Mild	 2 (4.9) 1(2.4)
	Pulmonary regurgitation Nil Trivial Mild	 10 (24.4) 11 (26.8) 20 (48.8)
	Residual peak instantaneous gradient 29mmHg or below 30-45mmHg 45-59mmHg 60mmHg or above	 29 (70.7) 10(24.4) 2(4.9) 0

DISCUSSION

Balloon pulmonary valvuloplasty is a commonly performed procedure in many centers around the world as well as in Pakistan. We are performing this procedure in all age groups of patients with moderate to severe pulmonary valve stenosis at our tertiary care cardiac institute since 2015. The data on balloon pulmonary valvuloplasty in adolescent and adult population is scanty in our part of the world. This study was performed to analyze early outcome of balloon pulmonary valvuloplasty.

The success rate of procedure in our study was 100%. The peak to peak pressure gradient across pulmonary valve reduced from pre procedure value of 121.9±53.2 mmHg to post procedure value of 30.1±11.9 mmHg which is quite a significant reduction and this successfulness of the procedure is comparable to different studies from recent and past around the world.[8,9] Taguart N et al[10] in their comparative study described a significant drop in pressure gradient across pulmonary valve in adults as compared to children. In a study conducted in Lahore by Sehar T et al on BPV, it was seen if the pre valvuloplasty gradient is less and the valve is doming the success rate of BPV is 96.7% as compared to dysplastic valve or high gradient before the procedure.[11] In our study population the high success could be due to natural selection of patients presenting with doming valve (90.2%) which developed severe PS over a period of time from mild to moderate and then severe as they presented. Selection of appropriate size balloon is the key for the success of procedure. Use of smaller diameter balloon may result in significant residual PS while the oversized balloon may not warranty good long-term results without complications. Balloon to annulus ratio of 1.2: 1.25 has been

attributed to a good long term outcome of BPV.[12] This ratio is also an important factor in immediate post procedure outcome.[13] The good out come in our study can also be attributed to appropriate balloon to pulmonary valve annulus ratio which was 1.24 ± 0.1 which is consistent with the Qian X et al[14] and Rao PS[7] studies.

The BPV is a very safe procedure with low incidence of complications. Stanger P et al[9] in VACA registry of 26 institutions reported only 0.35 % major complications rate while 0.24 % death rate from total 822 cases of balloon pulmonary valvuloplasty. There has been a high incidence of complications of the procedure in neonates, infants and children[15,16] while most of the studies describe no major complications of BPV in children, adolescents or adult population.[17,18,3] Similarly Ezhumalai B et al[19] in his study in India reported 12% complications including major (3.7%) and minor complication (8.3%). In our study self-limited vasovagal syncope as a minor complication was noted in 7.3% of patients but our total study subjects were only 41. There was not a single case of arrhythmia, pericardial effusion, significant residual PS, venous injury, thromboembolic phenomenon or death.

Sievert H et al [20] in early era of interventions, reported that post BPV significant pulmonary valve regurgitation is rare and more commonly seen in surgical pulmonary valvotomy. A study from Iran[21] showed 57 % of patients had mild pulmonary regurgitation in the immediate post BPV period. Similarly, mild PR was noted in 55% of patients in Idrizi S et al study[22] while 34% patients developed mild PR in Qian X et al study.[14] The incidence of mild pulmonary valve regurgitation in immediate post BPV period was 48.8% in our study while there was not a single case of moderate or severe regurgitation. This shows that the incidence of PR after BPV is variable and depends on different factors like age, balloon annulus ratio and morphology of pulmonary valve. The success of the procedure in our case is due to use of appropriate size balloon with an adequate balloon annulus ratio which is in accordance to other studies in available literature.

CONCLUSION

We conclude that balloon pulmonary valvuloplasty is a very safe procedure in adolescent and adult patients of severe valvular pulmonary stenosis with a high success but very low complications rate.

LIMITATIONS

The sample size was quite low (n=41) in the study period but the reason could be the patients of age 10 years or above present through natural selection only, as most of the patients in early childhood having severe valvular pulmonary stenosis undergo the valvuloplasty before 10 years of age.

SUGGESTIONS / RECOMMENDATIONS

The diagnosis of pulmonary valve stenosis is usually missed in childhood resulting in delayed presentation so early diagnosis can result in better outcome. Appropriate balloon to annulus ratio is the hallmark of the successful procedure, so appropriate balloon selection is the rule for such grown up patients of PS.

CONFLICT OF INTEREST / DISCLOSURE

There was no conflict of interest.

ACKNOWLEDGEMENTS

We acknowledge hospital administration for provision of the disposables smoothly and help in retrieval of the data.

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