

PROSPECTIVE STUDY OF PERCUTANEOUS BALLOON PULMONARY VALVULOPLASTY – IMMEDIATE RESULTS AND COMPLICATIONS

Mehboob Sultan, Maad Ullah, Nadeem Sadiq, Khurram Akhtar, Hajira Akbar

Armed Forces Institute of Cardiology & National Institute of Heart Diseases, Rawalpindi

ABSTRACT

Objective: To assess the results and immediate complications of percutaneous balloon pulmonary valvuloplasty at AFIC/NIHD.

Study design: Quasi experimental study

Place and duration of study: Paediatric cardiology department of Armed Forces Institute of Cardiology & National Institute of Heart Diseases (AFIC-NIHD) Pakistan from 01st October 2010 to 31st September 2013.

Patients and Methods: This study comprised 143 patients (74 male and 69 female) with pulmonary valve stenosis undergoing percutaneous balloon valvuloplasty. The procedure was classified as successful when the angiographic derived peak to peak pressure gradient (PG) across right ventricular outflow tract was reduced to less than 50% of pre-procedural value, suboptimal if reduction was 25-50% and unsuccessful if PG reduced by less than 25% of its initial value.

Results: The mean age of study population was 8.4 ± 10.3 years and procedure was successful in 133 (93%) cases. Mean PG was reduced from 85.6 ± 34.4 mmHg to 24.7 ± 14.5 mmHg ($p < 0.001$). Procedure was considered unsuccessful in one case, where PG across right ventricular outflow tract (RVOT) reduced from 70 to 60 mmHg, due to concomitant infundibular bands. In another nine patients, procedure considered suboptimal, as mean PG reduced from 81 ± 24.1 to 50 ± 16 mmHg. Among study population, 31 (21.7%) cases were considered as critical pulmonary stenosis. There were two deaths, two non fatal cardiac arrests, one life threatening arrhythmias and minor rhythm problems in five cases, but no cardiac tamponade or emergency cardiac surgery in our study population.

Conclusion: Percutaneous balloon valvuloplasty was effective and safe for the treatment of pulmonary valve stenosis with excellent short term results.

Keywords: Pulmonary valve stenosis, Percutaneous balloon pulmonary valvuloplasty, Infundibular bands.

INTRODUCTION

Congenital pulmonary valve stenosis (PVS) accounts for about 07-10% of congenital heart defects and the spectrum of its severity varies from mild to critical and valve morphology ranges from doming pulmonary valve to severely dysplastic valve¹. Extreme form is quite similar to pulmonary atresia with intact septum. The therapeutic options thus greatly depend on the clinical severity as well as valve morphology. In vast majority of the cases, balloon pulmonary valvuloplasty (BPV) is the treatment of choice for PVS in both children as well as adults with

documented efficacy and safety¹⁻⁵. Though there are number of studies from developed countries regarding efficacy and follow up of balloon pulmonary valvuloplasty (BPV)^{1,4-7}, the data from developing countries especially Pakistan is scanty. This prospective study had an aim of analysing the results and immediate complications of BPV.

MATERIALS AND METHODS

This quasi-experimental study was carried out at Armed forces institute of cardiology / National institute of heart diseases Pakistan, from 1st Oct 2010 to 31st Sep 2013. Patients with pulmonary valve stenosis with peak instantaneous PG across RVOT of more than 60 mmHg were included in the study. Patients with severe infundibular bands and those cases with history of previous cardiac surgery or pulmonary

Correspondence: Maj Mehboob Sultan, Consultant Paediatrician & Paediatric Cardiologist, AFIC/NIHD Rawalpindi.

Email: drmehboobsultan@gmail.com

Received: 3 Feb 2014; Accepted: 3 Mar 2014

valve ballooning. Total 143 consecutive cases that underwent attempted BPV were included in the study.

Pre-procedural assessment included detailed history, thorough physical examination; complete blood counts, chest X-ray and detailed 2D echocardiography / Doppler. Echocardiography specifically done for determining severity and morphology of the pulmonary valve, pulmonary valve annulus and presence of any associated cardiac defects. After informed consent, patients were subjected to BPV under general anaesthesia or local anaesthesia with or without sedation, depending upon the patient's age. After establishing vascular access, RV entered with NIH (pressure also recorded) and right ventricle (RV) angiogram done in AP and LAO 90 to visualize the pulmonary valve, infundibulum and RV cavity (Figure-1). In majority of the cases, pulmonary valve was crossed with 0.35 teromu wire over JR 5 or 6F and exchanged with 0.35 super stiff exchange wire followed by pulmonary ballooning (Figure-2). As per protocol, we kept balloon to annulus ratio to around 1:1.25 to achieve the desired results.

Post procedural RV angiogram routinely performed and pressure recorded in both PA and RV to document the peak to peak pressure gradient across RVOT. Post procedural care included monitoring of access site, pulse and BP along with review echocardiography after 04 & 24 hours. Data collected regarding age, hemodynamic status, gender, pulmonary valve annulus, PG across pulmonary valve, balloon size, no of inflations, immediate results, pre and post procedural RV and LV pressures and any complication encountered during the procedure. Procedure considered successful if PG reduced to less than 50% of initial value, suboptimal if PG reduced by 25-49% and unsatisfactory if PG reduced by less than 25%. The records of early follow up were also recorded data also analysed by making various groups according to age, valve morphology and severity of pulmonary stenosis. All the data had been analyzed through SPSS 17. Descriptive statistics were used to

describe the results. Paired sample t test was used to compare quantitative variables in various groups. A p-value < 0.05 was considered as

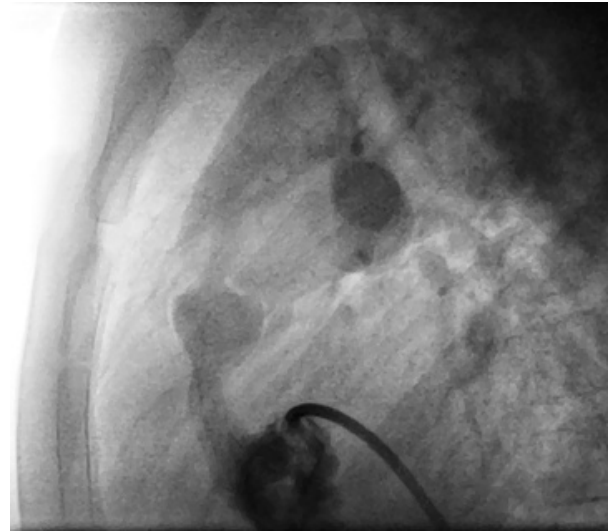


Figure-1: Right Ventricle angiogram (LAO 90) showing tight valvular pulmonary stenosis with post stenotic dilatation.

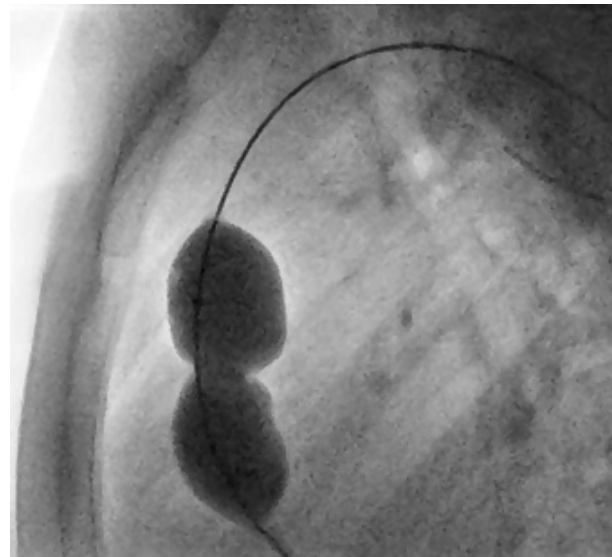


Figure-2: Balloon pulmonary valvuloplasty: Balloon with waist at pulmonary valve.

RESULTS

Total 143 consecutive patients underwent BPV for PVS at our institution during the study period. Age ranged from 01 month to 55 years

with mean age of 8.4 ± 10.2 years. Study population included 74 (52%) males and 69 (48%) female. Mean height was 104.5 ± 35.4 cms, mean weight was 21.7 ± 18.3 kgs, mean procedural time was 40.7 ± 21.1 minutes and mean fluoroscopic time was 10.6 ± 10.4 minutes. Ninety seven (67.8%) cases were done under general anaesthesia. Pre-procedural assessment revealed that 31 (22%) cases were critical (with central cyanosis) while concomitant subvalvular / infundibular stenosis was present in 10 (07%) patients. Mean pulmonary valve (PV) annulus size on echocardiography was 12.6 ± 3.4 mm (range 06-25) and on angiographic assessment it was 13.4 ± 3.8 mm.

Mean pre-procedural PG across the pulmonary valve was 85.6 ± 34.4 mmHg whereas mean post-procedural PG across the pulmonary valve was 24.7 ± 14.4 mmHg ($p < 0.001$). The mean balloon size used for BPV was 16.3 ± 4.8 mm (range 8-30). In 80 (56%) cases, one or two balloon inflations were considered sufficient. Overall, procedure was considered successful in 93% (133) of the total cases.

There were 09 (06%) patients with additional cardiac defects treated percutaneously in same setting including seven (05%) patient with ASD (closed with 08-28 mm ASD device occluders) and two patients with PDA (closed with 5/7 and 8/6 duct occluders). One (0.7%) patient had dextrocardia and BPV was accomplished with success.

Procedure was considered unsuccessful in only one (0.7%) case, where PG across RVOT reduced from 70 to 60 mmHg, due to concomitant infundibular bands. In another nine (06%) patients, procedure considered suboptimal, as mean PG reduced from 81 ± 24.1 to 50 ± 16 mmHg and main reason was again presence of infundibular element. The other complications encountered were divided into two groups, major and minor. Major complications included two (1.4%) deaths and two (1.4%) non-fatal cardiac arrests and one (0.7%) episode of life threatening arrhythmias. Minor issues include minor rhythm

problems in five (3.5%) cases. Two (1.4%) infants with critical pulmonary valve stenosis, aged 01 and 4 months, died as a direct complication of BPV. Both had prolonged procedural time, though eventually ballooning was successful, but needed to be ventilated after valvuloplasty and could not be survived and died after 6 and 20 hrs post procedure, in spite of all possible efforts.

DISCUSSION

The efficacy of BPV is time tested and is safe in experienced hands^{1,2,4-8}. Our experience of 143 BPVs also proved efficacious with 93% success and about 3.5% major complication rate. Congenital PVS is a common heart defect and is quite prevalent in our country, Pakistan, with more than 18 million people. In majority of the cases, severity of PVS increases with time and it carries significant morbidity especially exercise intolerance, if left untreated. The general protocol for the treatment of PVS is BPV in all age groups with moderate or more valvular stenosis or in symptomatic cases^{4,5,9}. We stated the BPVs after about one decade of first reported BPV by Kan et al in 1882¹⁰. With passage of time, the technique has improved and remains safe and effective. The most difficult cases are of neonates with critical Pulmonary stenosis (PS) and carries risk of major complications. Mean age in our study population was 8.4 years. No significant gender distribution difference was present in our study, which is in concordance to other reports⁶. In our study, the ratio of valvuloplasty balloon diameter to pulmonary annulus was kept around 1.25:1 as recommended by most of the literature⁴. Maostafa BA et al reported success of 83% in their 60 cases, whereas we achieved 93% success⁶. In another report from Iran, Ahmedi A et al reported 85% success in their 37 cases, whereas from USA the reported success was 91%^{2,11}. Pre-procedural echocardiographic assessment is of paramount importance and it should include determination of severity of PVS, valve morphology, valve annulus size and exclusion of other defects. Echocardiographer needs to specifically determine the infundibular contribution in the degree of RVOT obstruction,

as it is important contributing factor in valvuloplasty failure or suboptimal results. Pulmonary valve annulus size was not significantly different when measured by echocardiography or angiographically.

We defined success as, if peak to peak PG across RVOT reduced to less than 50% of initial value, considered as suboptimal if PG reduced by 25-49% and labelled as unsuccessful / failed if PG reduced by less than 25%. Our success rate of 93% was in whereas other reported success rate of 78%⁴. This difference is primarily due to cut-off limit to define success, as we taken the 50% reduction than initial PG while other kept this limit to < 36 mmHg⁴. One large study reported reduction in PG from 71 to 33 in 784 pressures recorded BPVs⁵ and is comparable to our results of 59 mmHg reduction after ballooning. Another way to assess efficacy is to compare the RV pressure with aortic pressure as reported by Werynski W et al¹. The results of PBVs are dependent upon valve morphology and presence of subvalvular muscle bands and failure rate is high in dysplastic pulmonary valves⁵. The best results are expected in moderate to severe cases with doming pulmonary valve. The majority of complications encountered in young infants with critical PS where it was difficult to cross PV, but these problems are well documented. We had two deaths (both young infants with critical PVS) and two non-fatal cardiac arrests in our study population. As a word of caution, operator needs to be very careful while dealing with critical PS especially in neonates and young infants, as these patients' collapses quickly when RVOT is manipulated by catheter and in worst cases can go into cardiac arrest which is non-responsive to cardiopulmonary resuscitation (CPR) until successful BPV is achieved. The principle is to go quick with ballooning, once pulmonary valve is crossed. In the results of the VACA study published by McCrindle, residual moderate pulmonary regurgitation was detected in 7% of the patient¹².

In our study no case of moderate or severe pulmonary insufficiency was detected. It may be due to balloon annulus ration was kept around 1.25:1 and success was defined as 50% reduction in PG across pulmonary valve. Behjati-Ardakani M et al used balloon to annulus ratio of 1.45:1 with similar success as of ours⁷. Our study is having limitations of being done at single center with no randomization or follow-up, yet the efficacy and safety of the BPV are acceptable.

CONCLUSION

Our study confirms the safety and efficacy of BPV in isolated PVS in moderate to severe cases. Most complications are encountered in critical cases especially in young infants.

REFERENCES

1. Werynski P, Rudzinski A, Krol-Jawien W, Kuzma J. Percutaneous balloon valvuloplasty for the treatment of pulmonary valve stenosis in children – a single center experience. *Kardiologia* 2009;67:369-75
2. Holzer RJ, Gauvreau K, Kreutzer J, Trucco SM, Torres A, Shahanavaz S et al. Safety and efficacy of balloon pulmonary valvuloplasty: a multicenter experience. *Catheter Cardiovasc Interv*. 2012;80:663-72
3. Taggart NW, Cetta F, Cabalka AK, Hagler DJ. Outcomes for balloon pulmonary valvuloplasty in adults: Comparison with a concurrent pediatric cohort. *Catheter Cardiovasc Interv* 2013;82:811-5
4. Hatem DM, Castro I, Haertel JC, Rossi RI, Zielinsky P, Leboutte FC et al. [Short- and long- term results of percutaneous balloon valvuloplasty in pulmonary valve stenosis]. *Arq Bras Cardiol*. 2004;82:221-7
5. Stanger P, Cassidy SC, Girod DA, Kan JS, Lababidi Z, Shapiro SR. Balloon pulmonary valvuloplasty: Results of the valvuloplasty and angioplasty of congenital anomalies registry. *Am J Cardiol* 1990;65:775-83
6. Maostafa BA, Seyed-Hossien M, Shahrokh R. Long-term results of balloon pulmonary valvuloplasty in children with congenital pulmonary valve stenosis. *Iran J Pediatr*. 2013; 23: 32-6.
7. Behjati-Ardakani M, Forouzannia SK, Abdollahi MH, Sarebanhassanabadi M. Immediate, short, intermediate and long-term results of balloon valvuloplasty in congenital pulmonary valve stenosis. *Acta Med Iran*. 2013; 51:324-8.
8. Sharieff S, Shah-e-Zaman K, Faruqui AM. Short- and intermediate-term follow-up results of percutaneous transluminal balloon valvuloplasty in adolescents and young adults with congenital pulmonary valve stenosis. *J Invasive Cardiol*. 2003;15(9):484-7
9. Freund MW, Schouten T, Lemmers P, Schroer C, Strengers J. Successful percutaneous balloon valvuloplasty in a preterm infant weighing 1500 g with critical pulmonary valve stenosis. *Neth Heart J* 2008;16:264-6
10. Kan JS, White Jr RI, Mitchell SE, Anderson JH, Gardner TJ. Percutaneous balloon valvuloplasty: A new method for treating congenital pulmonary-valve stenosis. *N Engl J Med* 1982;307:540-2
11. Ahmadi A, Sabri M. Percutaneous balloon valvuloplasty inpatients with pulmonary valve stenosis: a single center experiment. *J Pak Med Assoc*. 2012;62:S58-61.
12. McCrindle BW. Independent predictors of long-term results after balloon pulmonary valvuloplasty. *Circulation* 1994;89:1751-9.