SIX YEARS EXPERIENCE OF TRANSCATHETER RELIEF OF CONGENITAL AORTIC VALVE STENOSIS IN PAEDIATRIC POPULATION AT ARMED FORCES INSTITUTE OF CARDIOLOGY RAWALPINDI

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ABSTRACT

Objective: To determine the efficacy and safety of transcatheter balloon valvuloplasty in severe aortic stenosis in paediatric population.

Study Design: Observational study.

Place and Duration of Study: Catheterization lab at armed forces institute of cardiology, national institute of health Rawalpindi, from Jan 2011 to Dec 2016.

Material and Methods: All patients having age 1-12 years, who underwent balloon dilatation of severe aortic valve stenosis, were registered in the registry kept at catheterization laboratory. Complete patient profile, echocardiographic findings and pre and post balloon valvuloplasty findings were recorded. Procedure was considered successful if invasive gradient across aortic valve was reduced to less than 50% of original. The data was analyzed using SPSS version 23.

Results: A total of 75 patients undergone aortic balloon valvuloplasty during study period with mean age of 5.3 ± 3.3 years. All patients undergoing the procedure had severe aortic valve stenosis with the mean echo derived pressure gradient (PG) across the aortic valve of 70 ± 28 mmHg. The mean invasive PG across the aortic valve before and after balloon valvuloplasty was 71 ± 29 mmHg Vs. 22 ± 15 mm of Hg (*p*-value <0.001). Procedure was successful in 72 cases (96%) while three patients had suboptimal result. Post valvuloplasty 8 patients (10.6%) patient had mild AR. No patients developed sever AR, pericardial effusion and mortality was found to be zero percent.

Conclusion: We conclude that balloon valvuloplasty is a safe and effective procedure with minimum complications in patients with isolated severe aortic stenosis.

Keywords: Aortic stenosis, Pressure gradient, Valvuloplasty.

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INTRODUCTION

Aortic stenosis accounts for about 6% of congenital cardiac malformation in pediatric population. In one study the incidence was estimated to be 3.8/10,000 live births^{1,2}. Valvular aortic stenosis is the most common form of left ventricular outflow tract (LVOT) obstruction in children, accounting for as many as 71% to 86% of patients and it is more common in males^{3,4}. Based upon large retrospective autopsy studies, bicommissural aortic valve had been estimated to occur in 1 to 2 percent of the general population⁵.

Critical aortic stenosis is a form which presents in early infancy with left ventricular failure and low cardiac output.

Aortic stenosis is diagnosed through transthoracic echocardiography which identifies both the site and severity of obstruction besides the associated anomalies⁶. Treatment options for severe aortic valve stenosis in young children includes balloon valvuloplasty, surgical valvotomy & surgical Ross procedure. Surgical valve replacement is generally not feasible in young children due to small annulus size. At our center we generally prefer balloon valvuloplasty as first choice unless it's contraindicated. Left heart catheterization is performed in conjunction

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with aortic balloon valvuloplasty determines the magnitude of peak to peak pressure gradient from left ventricle to aorta. Balloon valvuloplasty is usually performed when peak to peak systolic pressure gradient between left ventricle and aorta exceeds 60 mmHg at rest⁷. Associated aortic valve regurgitation is usually considered as contraindication to balloon valvuloplasty⁸. The aim of our study was to evaluate the efficacy and short term results of balloon aortic valvuloplasty in children age 1-12 years.

MATERIAL AND METHODS

All patients aged between 1-12 years who had undergone Aortic balloon valvuloplasty were included in the study at AFIC-NIHD from January 2011 to December 2016. Infants were excluded as those cases are usually having critical aortic stenosis with some degree of left ventricular dysfunction.

Patients age less than 1-12 years, aortic valve stenosis with favorable morphology with no more than trivial regurgitation and peak instantaneous PG across aortic valve of >60 mmHg were included in the study.

The data of all these patients were entered in SPSS spread sheets at time of procedure. The data included name, date of birth, age, gender and date of procedure performed, diagnosis & relevant information. All patients were admitted on the day of procedure. After establishing vascular access, aortic root angiogram with pigtail catheter was done in left anterior-oblique to define the valve morphology and direction of the jet. In majority of cases, aortic valve was crossed in retrograde manner followed by BAV. Post procedural LV and aortic root angiogram routinely performed to specifically look for valve regurgitation and peak to peak pressure gradient across LVOT also recorded. Data before and after balloon valvuloplasty includes severity of aortic stenosis, anatomy of aortic valve, size of aortic annulus, mean PG across aortic valve, size of balloon used. It also included the immediate post catheterization complications like degree of aortic regurgitation, which is measures through post

catheterization echocardiography, loss of limb pulses after catheterization and their management and mortality after balloon valvuloplasty. The analysis of the data is the basis of this study. Data were analyzed through SPSS version 23.

RESULTS

A total of 75 patients (58 male and 17 female) underwent aortic balloon valvuloplasty during study period. The mean age of patients undergoing balloon valvuloplasty was 5.3 ± 3.3 years. Mean height was 102 ± 21 cm and mean weight was 16 ± 7 Kg. All patients undergoing the procedure had severe aortic valve stenosis with the mean echo derived pressure gradient (PG) across the aortic valve of 70 ± 28 mmHg (fig-1).

Mean aortic valve annular size determined on echocardiography was 14.6 \pm 2.5 mm. The

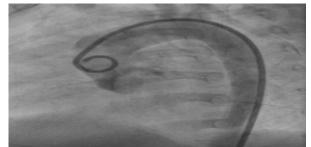


Figure-1: Aortogram in LAO view with pigtail catheter showed severe stenosisof aortic valve with small forward flow jet.

mean diameter of balloon used was 13 ± 2.4 mm (fig-2). The mean invasive PG across the aortic valve before and after balloon valvuloplasty was 71 ± 29 mmHg Vs. 22 ± 15 mm of Hg and *p*-value was <0.001. Mean procedural time was 44 ± 15 minutes while fluoroscopy time was 11 ± 7.5 min. Procedure was successful in 72 cases (96.0%) while three patients had suboptimal result. The three cases where result was suboptimal the PG reduced from 80mmHg to 55, 73 to 40 and in last one PG reduced from 60 to 44mmHg. Larger balloon was not used as it was anticipated to worsen the AR. In two case there was small PDA as well so was occluded with PDA occlude 8/6

device. Post valvuloplasty, eight patients (10.6%) patient had some degree of aortic regurgitation (AR) but none of them required any surgical intervention immediately. No patients developed severe AR, pericardial effusion or required emergency surgery and mortality was found to be 0%. Transient lower limb pulses were lost in 15% of cases, out of which 10% required heparin infusion and 05% were given streptokinase infusion, to achieve normal pulse & perfusion at discharge.

DISCUSSION

Balloon valvuloplasty is indicated for moderate to severe aortic stenosis to prevent progressive left ventricular hypertrophy & dysfunction and risk of syncope or sudden death⁹. The long-term results of percutaneous aortic valvuloplasty for congenital aortic valve stenosis in pediatric patients and its efficacy in preventing or postponing aortic valve surgery are good¹⁰. Its reported that about two thirds of the patients are free from aortic valve surgery 10 years after balloon valvuloplasty¹¹. In neonates Balloon valvuloplasty of aortic stenosis is generally revered as palliative procedure and carries high frequency of re-intervention but with good midterm survival is encouraging¹².

Surgical aortic valvuloplasty (SAV) and balloon aortic valvuloplasty (BAV) for congenital critical aortic stenosis have near similar outcomes¹³. There is a greater likelihood of important aortic regurgitation with BAV and of residual stenosis with SAV14. There is no statistical difference in the long-term outcome in the adults and adolescents as compared to the children; in many centers BAV is considered as the treatment of choice with good long-term outcome¹⁵. A study carried out by Soulatges on 93 patients aged 1 day to 18 years, treated with BAV as first-line therapy for congenital aortic valve stenosis with mean age at procedure time was 2.4 years; 37 patients underwent BAV at age ≤ 30 days (neonates), 29 patients at age ≥ 1 month and < 1 year (infants), and 27 patients were older than 1 year (children).

The invasive BAV peak-to-peak aortic valve gradient (mean $59 \pm 22 \text{ mmHg}$) was immediately reduced (mean $24 \pm 12 \text{ mmHg}$). The observed diminution of gradient was similar for each age group. Freedom from surgery after BAV at 5, 10,

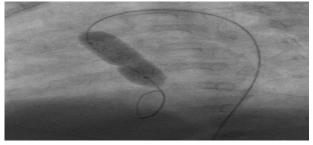


Figure-2: Inflated balloon across aortic valve with central waist.

and 20 years, respectively, was 82, 72, and 66%. The study confirms BAV as primary treatment for congenital AS is an efficient and low-risk procedure in infants and children. Compared to this study, our study showed mean peak systolic pressure gradient across the aortic valve as 71 \pm 29 mmHg Vs. 22 \pm 15 mm of Hg before and after valvuloplasty with *p*-valve <0.001.

In neonates, the prognosis is more severe and clearly related to "borderline LV"¹⁶. A study carried out by Torres A in 373 patients with aortic stenosis with median systolic pressure was 59 (50-71) mm of Hg before balloon valvuloplasty and 22 (15-30) after the procedure. Procedural success was achieved in 71 percent and 20 complication. percent had severe Overall complications observed in our study were 10 percent with no mortality¹⁷. A study carried out by AI Marshafawy H included 21 patients; 17 males, and 4 females. Their age ranged from the neonatal period to 10 years (mean age 5.6 ± 3.7 After the procedure, aortic valve years). regurgitation up to grade I were included. Significant reduction in pressure gradient was achieved (mean 66.7 ± 9.8 mmHg to 20.65 ± 2.99 mmHg) (*p*=0.001). Nine patients (42.8%) developed grade I AR, 2 patients (9.5%) developed grade II AR and 1 patient (4.8%) developed grade III AR. Two early deaths (9.5%); one died due to heart failure caused by grade IV

AR and a neonate died because of severely compromised LV function. One patient (4.8%) had femoral artery occlusion necessitating anticoagulation. Patients remained free from reintervention during follow up¹⁸. Compared to this study, our study shows that 10 percent developed some degree of AR but none developed severe AR. Femoral artery occlusion in our study was 15 percent, 10% requiring heparin and 05% patients requiring thrombolytic therapy.

CONCLUSION

Aortic balloon valvuloplasty is a safe and effective procedure for aortic stenosis win pediatric population. It has a very low morbidity and mortality so may be considered as the first line therapy for congenital aortic stenosis especially where Ross surgery is not very feasible due to lack of homograft conduits.

CONFLICT OF INTEREST

This study has no conflict of interest to declare by any author.

REFERENCES

- Hoffman JI, Kaplan S. The incidence of congenital heart disease. Journal of the American college of cardiology 2002; 39(12): 1890-900.
- Kitchiner D, Jackson M, Malaiya N, Walsh K, Peart I, Arnold R. Incidence and prognosis of obstruction of the left ventricular outflow tract in Liverpool (1960-91): a study of 313 patients. British heart journal 1994; 71(6): 588-95.
- Liu CW, Hwang B, Lee BC, Lu JH, Meng LC. Aortic stenosis in children: 19-year experience. Zhonghua yi xue za zhi= Chinese medical journal; Free China ed 1997; 59(2): 107-13.
- 4. Keane JF, Fyler DC. Aortic outflow abnormalities. Nadas' pediatric cardiology. Philadelphia, PA: Saunders 2006: 581-602.
- Roberts WC, Ko JM. Frequency by decades of unicuspid, bicuspid, and tricuspid aortic valves in adults having isolated aortic valve replacement for aortic stenosis, with or without associated aortic regurgitation. Circulation 2005; 111(7): 920-5.
- 6. Alizadehasl A, Sadeghpour A. Congenital aortic valve stenosis.

in comprehensive approach to adult congenital heart disease. Springer London 2014; 275-79.

- Feltes TF, Bacha E, Beekman RH, Cheatham JP, Feinstein JA, Gomes AS, et al. Indications for cardiac catheterization and intervention in pediatric cardiac disease. Circulation. 2011; 123 (22): 2607-52.
- 8. Feldman T. Balloon valvuloplasty. In Cardiology Procedures 2017 (pp. 295-305). Springer London.
- Czarny MJ, Resar JR. Diagnosis and management of valvular aortic stenosis. Clinical Medicine Insights. Cardiology 2014; 8(Suppl 1): 15.
- O'connor BK, Beekman RH, Rocchini AP, Rosenthal A. Intermediate-term effectiveness of balloon valvuloplasty for congenital aortic stenosis. A prospective follow-up study. Circulation 1991; 84(2): 732-8.
- Fratz S, Gildein HP, Balling G, Sebening W, Genz T, Eicken A, et al. Aortic Valvuloplasty in Pediatric Patients Substantially Postpones the Need for Aortic Valve Surgery A Single-Center Experience of 188 Patients After up to 17.5 Years of Follow-Up. Circulation 2008; 117(9): 1201-6.
- 12. Egito ES, Moore P, O'Sullivan J, Colan S, Perry SB, Lock JE, Keane JF. Transvascular balloon dilation for neonatal critical aortic stenosis: early and midterm results. Journal of the American College of Cardiology 1997; 29(2): 442-7.
- McCrindle BW, Blackstone EH, Williams WG, Sittiwangkul R, Spray TL, Azakie A, et al Are outcomes of surgical versus transcatheter balloon valvotomy equivalent in neonatal critical aortic stenosis?. Circulation 2001; 104 (suppl 1): I-152.
- Awasthy N, Garg R, Radhakrishnan S, Shrivastava S. Long-term results of percutaneous balloon valvuloplasty of congenital aortic stenosis in adolescents and young adults. Indian Heart J 2016; 68(5):604-11.
- Soulatges C, Momeni M, Zarrouk N, Moniotte S, Carbonez K, Barrea C, et al. Long-term results of balloon valvuloplasty as primary treatment for congenital aortic valve stenosis: a 20-year review. Pediatric cardiology 2015; 36(6): 1145-52.
- Torres A, Vincent JA, Everett A, Lim S, Foerster SR, Marshall AC, et al. Balloon valvuloplasty for congenital aortic stenosis: Multi center safety and efficacy outcome assessment. Catheterization and Cardiovascular Interventions 2015; 86(5): 808-20.
- Al Marshafawy H, Al Sawah GA, Hafez M, Matter M, El Gamal A, Sheishaa AG, et al. Balloon Valvuloplasty of aortic valve stenosis in childhood: midterm results in a children's Hospital, Mansoura University, egypt. Clinical Medicine Insights. Cardiology 2012; 6: 57.

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