PROSPECTIVE STUDY OF BALLOON AORTIC VALVOPLASTY FOR CONGENITAL AORTIC VALVE STENOSIS – RESULTS AND IMMEDIATE COMPLICATIONS

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ABSTRACT

Objective: The aim of study was to evaluate the results and complications of percutaneous balloon aortic valvuloplasty (BAV) in children with congenital aortic valve stenosis (AVS) at our setup.

Study Design: Quasi experimental study.

Place and Duration of Study: Pediatric cardiology department of Armed forces institute of cardiology / National institute of heart diseases (AFIC/NIHD) from 1st August 2010 to 31st July 2012.

Patients and Methods: We included 27 consecutive children including 21 (78%) male, who underwent BAV and procedural success was defined as if peak to peak pressure gradient (PG) across aortic valve was reduced to less than 50% of pre-procedural value with no more than grade II aortic regurgitation. Balloon to annulus ratio was kept under 0.9 and strictly followed in all cases.

Results: The mean age of study population was 7.7 ± 4.6 years and procedure was successful in 25 (92.6%) cases and in these cases mean pre-procedural PG was reduced from 80.1 ± 34 mmHg to 26.1 ± 16.9 mmHg. Procedure was considered unsuccessful in two children including one case, where PG reduced to 60% of pre-procedural value. In another patient, procedure was abandoned as aortic valve could not be crossed after multiple attempts and transseptal puncture was not feasible. Local vascular complications occurred in 07 (26%) children. There were no deaths, non fatal cardiac arrest, cardiac tamponade or requirement of emergency cardiac surgery in our study population.

Conclusion: BAV is an effective procedure with low complication rate in children.

Keywords: Congenital bicuspid aortic valve; Trans-septal puncture; aortic regurgitation.

INTRODUCTION

The incidence of left ventricle outflow tract obstruction (LVOTO) reported by Kitchiner D et al is around 0.6/1000 live births and aortic valve stenosis (AVS) comprised 71%[1] and most common cause is bicuspid aortic valve[1,2]. The children with congenital AVS usually have a progressive course and are at substantial risk of arrthymias, infective endocarditis and sudden death[3]. The clinical presentation varies from asymptomatic to syncope to sudden death and depends upon valve morphology, associated lesions and severity of LVOTO. Symptoms and echocardiographic derived peak instantaneous PG determines the timing of intervention. Percutaneous balloon aortic valvuloplasty (BAV) is the treatment of choice in children with AVS as their valves are pliable with little calcification and BAV is safer than aortic valve replacement[4-6]. General indication for BAV is peak instantaneous PG of 60-70 mmHg and we followed the same principle in our study. The general proposal for balloon to annulus ratio is 0.85 - 0.9 for BAV (balloon aortic valvuloplasty), as over sizing can cause AV regurgitate whereas under sizing results in suboptimal outcome[6-8]. Efficacy of BAV in children is well recognized in international literature[6,7,9] but such data is meagre in our country. The purpose of this study was to prospectively study the outcome and associated immediate problems of BAV at our setup over 24 months time period.

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PATIENTS AND METHODS

This quasi experimental study was carried out at paediatric cardiology department of Armed forces institute of cardiology / National institute of heart diseases Pakistan, from 1st

August 2010 to 31st July 2012 and included 27 cases who underwent BAV, after fulfilling the inclusion/exclusion criteria.

Inclusion criteria: age less than 18 years**,** isolated aortic valve stenosis with favourable morphology, peak instantaneous PG across aortic valve of > 60 mmHg (in presence of LV dysfunction due to AVS, lower gradient also acceptable), no associated heart diseases.

Exclusion criteria: calcified aortic valve**,** aortic valve surgery or balloon valvuloplasty in past.

Before procedure, detailed history, physical examination, complete blood counts, chest X-ray and detailed 2D-echocardiography/Doppler were performed. Basic demographic parameters like age, gender, clinical signs and symptoms, height, weight and family history were recorded. Echocardiography specifically was performed for determining severity of obstruction and morphology of the valve, aortic valve annulus, left ventricle (LV) dimensions & ejection fraction and any associated cardiac defects especially left sided obstructive lesions. All patients were admitted on the day of procedure and after informed consent, patients were subjected to BAV under general or local anaesthesia with or without sedation, depending upon patient's age. After establishing vascular access (femoral artery and vein), aortic root angiogram with pigtail catheter was done in moderate left anterior-oblique (LAO view) to define the valve morphology and direction of the jet (Fig 1). Catheter derived peak to peak pressure gradient across aortic valve was recorded.

In 24 cases, aortic valve was crossed in retrograde manner with 0.35 Terumo wire over Judkin right (JR) 5 or 6F and exchanged with 0.35 super stiff exchange wire, followed by BAV. To avoid melon seeding and to prevent valvular damage, we used rapid RV pacing or intravenous (IV) adenosine to reduce the cardiac output. Post procedural intravenous and aortic root angiogram were routinely performed to specifically look for valve regurgitation and peak to peak pressure gradient across LVOT was also recorded. In two cases, transseptal puncture was done as aortic valve could not be crossed in retrograde approach. Through femoral vein, we did trans-septal puncture and advanced the Mullin Sheath into LA over loopy wire. Multipurpose catheter was advanced into intravenous through the Mullin sheath and through it entered exchange length Terumo wire and crossed AV (Fig 02).

In one case, wire was snared through the arterial line and successful aortic valvuloplasty done. In other case, after septal puncture, wire was easily crossed from intravenous to aorta in the direction of flow and BAV done in antegrade manner. Post procedural care included monitoring of access site, pulse and BP along with review echocardiography after 06 & 24 hrs. Data collected regarding hemodynamic status, valve annulus, pre & post procedural PG across the valve, balloon size, no of inflations, immediate results, pre and post procedural intravenous pressures and any complication encountered during the procedure. Procedure was considered successful if PG reduced to less than 50% of initial value and unsatisfactory if PG reduced by less than 50%. Local access site vascular complications were managed as per hospital protocols. Intravenous heparin was started if limb pulse remained absent two hours after the procedure till return of the pulse. Intravenous streptokinase (SK) was used in selected cases, if limb was cold with Doppler evidence of ischemia at least 6-8 hours after the procedure. Data was entered in computer based statistical programme, SPSS 17 and descriptive analysis including frequencies with percentages, mean and standard deviations were done.

RESULTS

A total of 27 patients were included with median height of 113 cms and male to female ratio of 3.5:1; other demographic features of the study population are shown in table 1. Age ranged from 06 months to 15 years and 23 (85.2%) cases were done under general anaesthesia. Right femoral artery was accessed in 24 (89%) cases

(within one or two attempts in 86% of these cases). In 03 (11%) patients, left femoral artery was accessed after unsuccessful attempts on right side. Various sizes of arterial/delivery sheaths were used according to balloon sizes in & included 5F (4), 6F (6), 7 F (12), 8 F (5). The ratio of balloon to aortic valve annulus was strictly kept under 0.9:1. The mean balloon size used for BAV was 14.7 ± 2.6 (range 10-20 mm) in 26 cases (in one procedure was abandoned as AV could not be crossed).

Procedure was successful in 25/27 (92.6%) cases and in these cases mean pre-procedural angiographic PG was 80.1 ± 34 mmHg (mean echo derived PG 92 mmHg ± 30) and was reduced to 26.1 ± 16.9 mmHg after the procedure. In four of these 25 cases (16%), first inflation was followed by bigger balloon inflation to achieve the satisfactory results. Procedure was considered un-successful in 02 (7.4%) children including one, where PG reduced to around 60% of pre-procedural value, and second (higher size) balloon was not chosen as it was likely to result in significant AV regurgitation. In another patient, aortic valve could not be crossed in spite of multiple attempts and transseptal puncture was not feasible so the procedure was abandoned. RV pacing was used in 16 patients while in 5 cases, intravenous adenosine was used to prevent the melon seeding of the balloon during inflation and no venous line was accessed in these cases, whereas in five cases BAV done without RV pacing or intravenous adenosine as valvular stenosis was of moderate severity. Interestingly, there were 02 patients who also underwent satisfactory patent ductus arteriosus (PDA) device closure along with AVS (Fig-3). In both cases PDA was first closed with the device and subsequently, after confirming PG across AV, the BAV was successfully accomplished.

Major complications occurred in 2 (7.4%) cases (procedural failure), but there was no fatal or non-fatal cardiac arrest, life threatening arrhythmias, heart perforation or cardiac tamponade. Minor complications were encountered in nine cases (33%) and included mild to moderate aortic regurgitation (AR) in two cases and seven cases with local access site vascular complications. The local vascular

Figure-1: Aortogram showing aortic valve stenosis with central jet and bicuspid aortic valve.

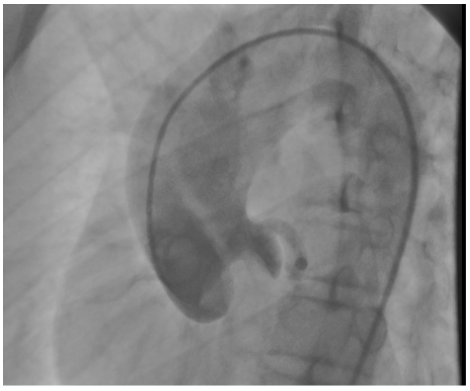


Figure-2: Aortic valve crossed from antegrade approach.

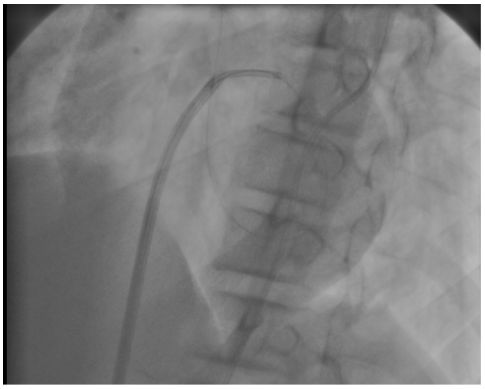
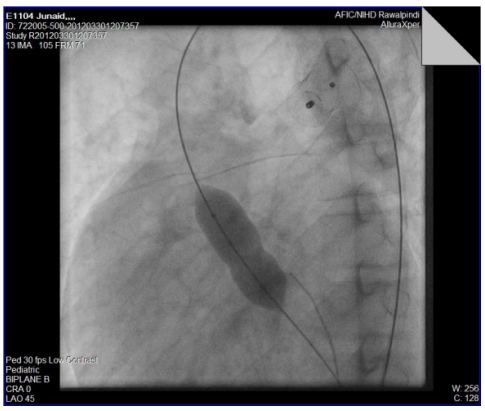


Figure-3: Balloon aortic valvuloplasty (BAV) with waist at point of aortic valve stenosis along with PDA device in place.



complications included, 05 cases where absence of limb pulse required intravenous heparin (for less than six hours in 04 cases, 01 case required heparin for 15 hours) and additional two cases where intravenous streptokinase was (within 12-18 hours of procedure) used to restore peripheral circulation. No other local vascular complication like bleeding, hematoma or AV fistula was encountered.

DISCUSSION

AVS mandates prompt diagnosis and well-timed treatment to avoid the complications and risk of possible sudden death[3]. The choice of treatment in children is evidently percutaneous aortic ballooning as AV leaflets are pliable, as opposed to the adults where calcific valves are less like to respond[4,6,10]. In our study, the mean age was 7.7 years with more than 92% success rate, quite similar to 83% from Valvuloplasty and Angioplasty of Congenital Anomalies (VACA) registry with median age of 6.8 years[11]. Male clearly out numbered females and the same is being reported in other studies as well[7,9]. It's worth mentioning here that in children valve replacement is less feasible due to non-availability of appropriate sized valves and the complications of prosthetic valves. The reported efficacy and long term results of BAV in children is encouraging as it buys sufficient time in most cases before aortic valve replacement (AVR) can easily be done[4,6]. In recent retrospective comparison of BAV with surgical valvotomy by Brown JW et al revealed 10 year freedom from AVR in 75% cases[12]. Moore P et al reported 87% success in 148 children who underwent valvotomy with 0.7% mortality and 95% survival rate at 8 years[10]. In our study the smallest case by weight was of 05 kgs with severe AVS who underwent successful BAV, confirming the efficacy of BAV in young infant as advocated by Mc Elhinney et al[13]. In recent times, even in older patients BAV is being used as a bridge therapy to percutaneous or surgical AVR[14,15]. Before proceeding for ballooning, a detailed transthoracic or transesophageal echocardiography is mandatory. We did detailed transthoracic echocardiography in our cases and peak instantaneous pressure gradient, valve annulus, ejection fraction and LV dimension were recorded. The general indication for BAV includes peak instantaneous pressure gradient of 60 mmHg or more across aortic valve[3,7]. General recommendation in selecting the size of balloon is to keep under 90% of valve annuls size and we strictly followed the same principle[7]. Valve annulus size was closely related when echocardiographically measured annulus was compared with angiographic measured annulus (15.8 vs 16.3 mm respectively).

Table-1: Demographic features of study population (n=27).

Variables	Mean ± SD
Age	7.7 ± 4.6 years
Weight	23.2 ± 13 kgs.
AV annulus – echocardiographic derived	15.8 ± 2.9 mm
Angiographic AV annulus	16.3 ± 3.1 mm
Procedural time	60 ± 34.5 minutes
Fluoroscopic time	16.7 ± 14.2 minutes

BAV is traditionally done from retrograde approach through the arterial line, but transvenous antegrade approach is also being used as it avoids the placement of large arterial sheaths[16]. In our series, two cases needed septal puncture after retrograde approach was unsuccessful in crossing the valve. Two patients also had concomitant PDA which was occluded with the device in the same setting. The combined interventional procedures are well recognized and reduce the risks of repeated catheterizations and financial burdens[17]. In one of these cases, there was large PDA along with severe AVS, so PDA was first occluded with balloon to document the drop in pulmonary artery pressure and after PDA device closure; the same balloon was used for BAV. This manoeuvre not only proved economic but also safe. In a developing country, where financial constraint needs to be looked after by health professional,

we tried to economize the catheterization studies. In the same context, we tried to accurately measure the annulus, so only one optimal balloon used, and in four cases only second bigger sized balloon was used. Rapid RV pacing was used in 16 cases and rest of cases were managed with or without intravenous adenosine. Effectiveness of intravenous adenosine in BAV is reported in literature[18], in one of our case adenosine was not effective at optimal dosage so rapid RV pacing was employed. Rapid RV pacing during BAV is well established[19] but needs additional cost in comparison to intravenous adenosine.

Total two cases were considered as procedural failure, including one child where procedure was abandoned after failure to cross AV senosis. In the other patient, though inflation with appropriate sized balloon was done PG reduction was around 60%, further inflation at that stage was considered risky as it might have proved counterproductive in terms of AV regurgitation[8]. We had no mortality in our small study population, though a larger study reported 1.9% mortality in 630 ballooning with median age of 6.8 years[11]. However, 09 children experienced minor complication and all were managed with no residua. Similar observations were made from Switzerland in 2004[6]. Absence of limb pulse was encountered in 26% cases (we included all cases where limb pulse was absent after 02 hours of procedure) and were managed according to hospital protocol with normal pulse at discharge. Meticulous care was taken in arterial puncture with minimum number of attempts and placing smallest possible arterial sheaths along with intra-arterial heparin (50 units/kg) at the time of arterial cannulation. The low volume pulses in severe AVS can sometimes contribute to multiple attempts needed to establish arterial access. Patients who had a pulseless extremity 02 hours after catheterization continued to receive heparin therapy until pulse returned. If the extremity continued to have no palpable pulse with limb temperature lower than contralateral limb (and doppler evidence of ischemia) after 6-12 hours of heparin infusion, intravenous was streptokinase administered at a dose of 1000 units/kg/hour. Two children in our study required intravenous SK with restoration of circulation within 2-3 hours with no significant bleeding. Marcon F et al reported femoral artery thrombosis in 25% of their cases, quite similar to our observation[20]. Although AR is a recognized and fearsome complication[6,8], we had no case where emergency AVR was needed. Only two cases had mild to moderate AR, may be due to strict principle of keeping balloon around 90% of annulus size and using rapid RV pacing in most cases. Our study reinforce the safety and efficacy of BAV in children in contrast to adult[21], though with limitation of having small study population.

CONCLUSION

BAV is an effective and safe procedure in children for aortic valve stenosis with lower major complication rate, though with substantial local vascular complications.

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