CODEN [USA]: IAJPBB ISSN : 2349-7750

INDO AMERICAN JOURNAL OF
PHARMACEUTICAL SCIENCES
SJIF Impact Factor: 7.187

Avalable online at: http://www.iajps.com *Research Article*

CRITICAL NEONATAL AORTIC VALVE STENOSIS, INTERMEDIATE AND IMMEDIATE RESULTS OF PERCUTANEOUS BALLOON VALVULOPLASTY

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Article Received: November 2020 **Accepted:** December 2020 **Published:** January 2021

Abstract:

Aim: *To evaluate immediate and midterm results after balloon valvuloplasty in an infant population with critical aortic stenosis, giving special consideration to relief of aortic stenosis, degree of aortic regurgitation (AR), left ventricular function, and duration of freedom from reintervention.*

Method: *It was a retrospective follow-up study held in the Pediatric Cardiac Surgery department of Bahawal Victoria Hospital, Bahawalpur for two-years duration from November 2018 to November 2020. A retrospective control study was performed on 25 newborns, in whom balloon aortic dilation was performed. We assessed clinical and echocardiographic outcomes for the degree of restenosis, LV function, AR, and the need for re-intervention.*

Result: *The median age at enlargement was 45 days (range 6 days to 120 days). The median body weight was 3.9 kg (1.9 kg-6.4 kg). Balloon valvuloplasty was performed with manual balloon inflation through the femoral artery. The mean aortic systolic pressure gradient decreased from 70 ± 7.23 mmHg to 40 mmHg ± 4.3 (p = 0.001). Mild aortic regurgitation occurred in 12 patients, while one patient had perforation of a non-coronary nodule leading to severe AR requiring surgery. There was one death during the procedure. There was no AR progression in the mean follow-up of 25 months (3.0 - 24 months). No patient required re-intervention for restenosis. LV function improved in 9 of 11 patients (82%), while 2 months after surgery there was one death due to persistent LV dysfunction.*

Conclusion: *Balloon valvuloplasty in infants with critical AS is a safe and effective therapeutic procedure. Mortality is 8%. Mild aortic regurgitation does not progress in the short to medium term. There is no restenosis in the intermediate period, and LV function improves in most patients.*

Keywords: *aortic stenosis, balloon valvuloplasty, left ventricular (LV) dysfunction, interventional procedures, aortic regurgitation*

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Please cite this article in press Hafiz Shahpal Arshad et al, ***Critical Neonatal Aortic Valve Stenosis, Intermediate And Immediate Results Of Percutaneous Balloon Valvuloplasty.,*** *Indo Am. J. P. Sci, 2021; 08(1).*

INTRODUCTION:

Critical congenital aortic stenosis (AS) is a serious and life-threatening condition in early childhood, mainly in newborns. The morphology of neonates with symptomatic aortic stenosis covers a wide spectrum of abnormalities and often includes patients with aortic ring hypoplasia, severe valvular dysplasia, left ventricular hypoplasia, mitral valve abnormalities, and endocardial fibrosis. Due to the increased afterload already present during the fetal circulation, these children often exhibit severe left ventricular (LV) myocardial dysfunction and even symptoms of myocardial infarction. Reduced mitral and LV flow may be at least partially responsible for the underdevelopment of the LV cavity, which is a prognostically unfavorable symptom of good therapeutic outcome. Nevertheless, early intervention is necessary to reduce the burden on LV stroke and prevent further damage to the heart muscle. In the past, different types of surgical approaches have been associated with high operative mortality (ranging from 21% to 86%), but recent reports suggest that surgical outcomes are improving. Balloon aortic valve surgery has been proposed as a less invasive option, and although it was initially associated with significant morbidity and mortality during procedures, especially in neonates, it is now generally considered a safe and effective technique. The patient tends to report late in our alignment, and this delayed presentation and diagnosis means these children are even sicker. We describe our experiences from a higher grade pediatric cardiac surgery center with short-term results.

PATIENTS AND METHODS:

It was a retrospective follow-up study held in the Pediatric Cardiac Surgery department of Bahawal Victoria Hospital, Bahawalpur for two-years duration from November 2018 to November 2020. Twenty-five more infants (20 men and 5 women) with critical aortic stenosis underwent balloon valvuloplasty. Of these 8 patients (32%) with severe congestive heart failure requiring inotropic support, (45%) required ventilation, and 4 (16%) started prostaglandin E1 treatment to improve cardiac output and saturation prior to surgery. The diagnosis was confirmed by clinical evaluation, ie low cardiac output, cardiogenic shock, congestive heart failure and liver enlargement. Echocardiographic criteria included morphological features of left ventricular hypertrophy with decreased left ventricular function, regardless of intervalvular gradient, good LV size and selected aortic ring value of -2 SD on the Z scale. All measurements were performed by Doppler echocardiography and reported as mean ± SD. Interventional data collection, echocardiographic reports and catheterization were reviewed. Post-valvuloplasty hemodynamic data were assessed by echocardiography in a catheterization laboratory in three newborns due to the critical condition. We defined early mortality as death during first hospitalization or within 30 days after surgery and late mortality as death thereafter. A good score was defined as a decrease in the gradient before and after to 50% with improvement in LV function and no more than a mild to moderate AR.

Interventions: Percutaneous balloon valvuloplasty was performed with a mean (SD) balloon-to-ring ratio of 0.8-1. Retrograde approach was used in 24 patients, while one was given an ante approach. As for the assessment, one child developed from a femoral vein due to the lack of an arterial line. The aortogram was recorded at 450 LAOs. The aortic ring was also measured by angiography and has always correlated with the echo measurement. The mean diameter of the aortic annulus was 6.5 mm (5.30 - 8.22 mm) and the balloon-to-annulus ratio was 0.9- ± 0.04. A Tyshak balloon (Numed USA) was used in all patients.

Main Outcome Measures: Restenosis = 70 mmHg, Grade 2-3 aortic regurgitation, nodule rupture or perforation, surgery, valvuloplasty, LV function improvement, and death.

Follow-up: up to 24 months + 14.7 (median 6 months) follow-up. We compare percutaneous aortic balloon valvuloplasty in terms of early and intermediate survival, relief of aortic stenosis, degree of aortic insufficiency, left ventricular function, and lack of re-intervention.

Statistical analyzes: Measured and calculated data are expressed as mean ± SD. A p value of less than 0.05 was considered significant. A special statistical software, SPSS for Windows, version 15, was used for data analysis.

RESULTS:

The median age for balloon valvuloplasty is 45 days (6 days - 120 days). At the time of surgery, there were 11 newborns - aged less than 30 days (44%), while 14 infants (56%) underwent surgery over 30 days of age. The procedure was performed under general anesthesia in all patients. Of the 25 patients, 5 were female and 20 were male. Regarding the body weight of patients, 2 had a body weight of less than 2 kg, 6 had a body weight of 2-3 kg and 17 had a body weight of 3-6.5 kg. The median body weight was 3.6 kg (1.9 - 6.4 kg). The basic features are presented in (Table 1)

TABLE 1: Characteristics of patients undergoing aortic valvuloplasty

Characteristics	Numbers	Percentage
Age		
<30 days	11	44.0
30-120 days	14	56.0
Sex		
Male	20	80.0
Female	05	20.0
Weight		
<2kg	02	08.0
2-3 kg	06	24.0
3-6.5 kg	17	68.0
Access		
Antegrade	01	04.0
Retrograde	24	96.0
LV Function		
Normal	16	64.0
Dysfunction	09	36.0
Aortic Regurgitation (Preprocedure)		
No AR	14	56.0
AR (mild)	11	44.0

The mean aortic systolic pressure gradient decreased from 70 ± 7.23 mmHg to 40 ± 4.3 mmHg (p = 0.001). The immediate results are shown in Fig. 1.

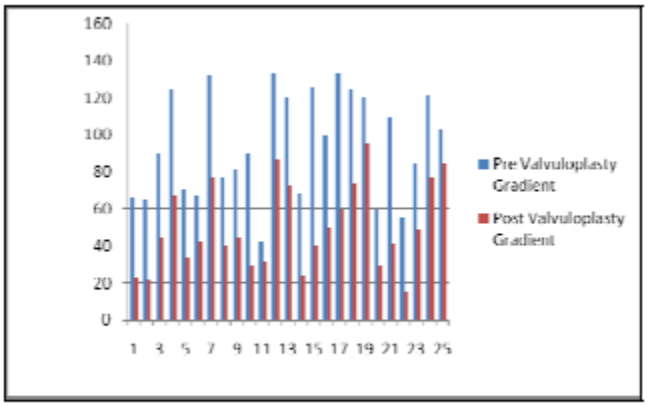

Fig1: Gradient relief in all 25 patients where data was complete in cath lab

Despite technically appropriate valvuloplasty, 6 (24%) children had insufficient relief of obstruction due to dysplastic valve but LV function improved and still did not require surgical intervention until 24 months of follow-up. Concerning complications out of 25 infants, 12 (24%) infants developed trivial AR immediately after surgery. One (8%) child developed severe AR due to a sliding wire perforation that required surgical repair 3 days later. There was one death during the procedure, resulting in ventricular tachycardia and cardiac arrest. During the procedure, one child developed ventricular tachycardia, which was later stabilized by cardioversion (Table 2).

TABLE 2: Complications

	Number	Percentage
Early (0-30 days):		
• VT needing cardioversion	1	4.0
• Moderate AR	1	4.0
• Rupture of aortic cusp leading to severe AR (needing surgery)	1	4.0
• Death on day 5 post procedure (sepsis)	1	4.0
Late (1month-48 months)		
• Death (Severe LV dysfunction) 2nd month	1	4.0

After a mean follow-up of 24 months, 7 (28%) children with severe LV dysfunction and 2 (8%) children with biventricular dysfunction, 1 child at mid-follow-up still had mild impairment, while 7 showed improvement in LV function after 24 months of follow-up. There is one late death as one child died after 2 months of surgery due to persistent LV dysfunction despite improvement in the gradient. In 12 patients with mild AR, AR did not progress until 24 months of follow-up. During the observation, we lost two sightings and one death later. (Table 3)

TABLE 3: Serial follow up of patients with reference to various complications

No. of Pts	Months	AR +	AR ++	AR +++	Restenosis	Reintervention	LV Dysfunction
23	06	11	0	1	0	0	9
22	12	11	0	0	0	0	7
22	24	11	0	0	0	0	1
22	36	11	0	0	0	0	1
22	48	11	0	0	0	0	1

AR=aortic regurgitation,(+ = Mild AR,++ = Moderate AR, +++ =Severe AR) LV = left ventricle .

DISCUSSION:

Infants with severe congenital aortic stenosis in the first three months of life present a difficult clinical problem. They are mostly neonates with critical aortic stenosis and often with severe congestive heart failure resistant to treatment and requiring urgent intervention. Advances in anesthesia, intensive care and surgical techniques have reduced operative mortality in recent years, while balloon valvuloplasty is a good alternative treatment option. Recent studies, including an inter-institutional study, have documented better short-term outcomes, although data on the long-term prognosis of these infants is limited. In Pakistan, there are only a limited number of tertiary care centers where this treatment option is available. Resources are limited and there is a significant shortage of trained pediatric cardiologists. This would be especially true for neonatal and infant cardiac surgery, which requires even more setup and resources. Another issue is delayed presentation due to the lack of primary and secondary care services. These babies will arrive late in a much more severe condition and will require stabilization prior to intervention. Since critical AS in neonates is equally lethal without treatment, various surgical and catheter-based approaches have been proposed for treating critical AS. In 1955, Marquis and Logan made direct surgical access to the aortic valve using a trans-ventricular dilation. Trinkle and colleagues also proposed the CTV in 1974. In 1956, the first open surgical valvotomy with surface cooling and closure of the inflow was performed. These surgeries remained the only treatment options until 1983, when Lababidi reported the use of a balloon aortic valvotomy. In the early 1990s, McKay and colleagues examined the morphology of the ventricular arterial junction in critical AS in 21 patients at necropsy. These authors suggested that early aortic root replacement with pulmonary autograft may be the best way to achieve a biventricular correction. There have been reports of occasional aortic valve replacement with pulmonary autograft or the Ross-Konno approach performed in early childhood due to critical AS. Our first-of-its-kind study from Pakistan shows that the immediate and intermediate results for those who survived a critical aortic stenosis intervention in early infancy

are excellent in terms of survival and functional status. Our study found that out of 25 children, 12 (24%) children developed mild or mild aortic regurgitation immediately after surgery. This may be due to natural selection (only those suitable for tertiary care survive) and meticulous attention to detail, especially the decision about the size of the balloon (cost implications). Regarding aortic regurgitation (AR), 11 children still have mild AR up to 24 months of follow-up. Good thing there is no progression in aortic regurgitation (AR). In one child who developed severe aortic regurgitation during surgery due to perforation due to a straight sliding wire (0.018 terumo), early surgery led to a good outcome. One death occurred on the 5th day of surgery due to aortic sepsis and regurgitation (AR). While another child died after two months of surgery from persistent LV dysfunction. Low mortality (8%) compared to other centers of the world, which is 37% and 43%, results from the selection of only those children who are suitable only for balloon angioplasty. Children with a small aortic ring or left heart underdevelopment (according to the Z scale) were excluded from the study.

CONCLUSIONS:

Balloon aortic valvuloplasty is safe and effective for critical aortic stenosis in early childhood. Mortality is low (8%), while the incidence of severe AR is 4%. The AR is not progressing in the short- and medium-term follow-up. Most (82%) of the patients recovered LV function.

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