Original Article

Outcomes of Aortic Balloon Valvuloplasty in Newborns: A Single-Centre Experience

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Abstract

Introduction: Critical or severe aortic stenosis in new-borns is a condition that requires rapid intervention. Aortic balloon valvuloplasty (ABV) is a method of choice that has been successfully performed since 1983. **Aims:** This study was conducted to explore the experiences of our centre. **Study Design:** The data of ABV performed on new-borns ($n = 52$) between 2007 and 2020 were retrospectively analysed to evaluate follow-up of the cases. **Materials and Methods:** Patients were divided into 4 groups according to procedural immediate results. **Results:** Left ventricular endocardial fibroelastosis and left ventricular systolic dysfunction were detected in 18 (34.6%) and 19 (36.5%) patients, respectively and there was a significant association between fibroelastosis and left ventricular dysfunction ($P < 0.05$). The preprocedural echocardiographic mean gradient was significantly lower in the unsuccessful group ($P < 0.41$). The mean hospital stay day was shorter in the group with optimal results without statistical significance ($P = 0.055$). Immediate inadequate results after the procedure were detected as a major risk for re-intervention. Re-intervention was required in one-fifth of the patients and the most common cause was aortic stenosis. The risk factors of mortality were found to be associated with the disease itself such as ventricular dysfunction, being critical aortic stenosis instead of procedural reasons. **Conclusion:** ABV is an effective method and as left ventricular dysfunction and critical aortic stenosis are risk factors of mortality, preprocedural evaluation, and quick intervention are essential.

Keywords: Aortic balloon valvuloplasty, critical aortic stenosis, new-borns

Introduction

Congenital valvular aortic stenosis constitutes 3%–6% of congenital heart diseases. It occurs more frequently in males than in females, by a ratio between 3:1 and 5:1. Of the patients, 15%–20% have accompanying patent ductus arteriosus, aortic coarctation, and ventricular septal defect.[1]

Critical aortic stenosis is defined as the condition in which there is dependence on the ductus arteriosus for the adequate continuation of the systemic circulation and prevention of low cardiac output syndrome. In the case of critical aortic stenosis, prostaglandin E1 infusion therapy should be initiated and palliative procedures should be performed as soon as possible.[2]

Palliation strategies consisting of aortic balloon valvuloplasty (ABV) or surgical valvotomy are equally effective in terms of survival. However, percutaneous ABV has been preferred by many centres since it was first carried out in 1983. In this procedure, through stiff guide-wires, low-pressure balloon catheters with a width of a maximal 90% of the

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aortic annulus are inflated. Subsequently, hemodynamic, angiographic, and echocardiographic evaluations are performed to assess the immediate result of the procedure. If it is necessary, the procedure has to be repeated with bigger balloons.[3] Determining factors of outcomes consist of aortic valve morphology, the severity of the stenosis, left ventricular structure and function, and the degree of regurgitation after valvuloplasty. The most common complication of the ABV is aortic regurgitation (AR) but a severe degree of regurgitation is rarely seen.[4]

ABV or surgical valvotomy decision varies according to the experience and preference of the centres as both methods have a similar effect in decreasing the aortic valve gradient. There was no statistically significant difference between these two methods in terms of the need for re-intervention.[5] Moreover, ABV procedure as a first-line palliative therapy has been shown to avoid or postpone aortic valve surgery.[6] In our institution, we have preferred to perform ABV since 2007. The current study aims to evaluate postprocedural outcomes and long-term follow-up of the cases.

Materials and Methods

In the current study, the medical records of new-borns with valvular aortic stenosis who were diagnosed in our hospital between 2007 and 2020 were retrospectively analysed ($n = 52$). Inclusion criteria comprised being younger than 1 month old and having critical or severe aortic valve stenosis. Those with additional congenital heart disease, except hemodynamically insignificant shunt lesions and patients who were not eligible for biventricular repair, were excluded.

The data were obtained from patients' medical history records including age, gender, weight, the use of prostaglandin infusion therapy before the procedure, the presence of inotropic therapy, prepostprocedural serum lactate level, preprocedural PH value, duration of the intubation, neonatal intensive care unit stay, the reason and time of the reintervention and the early and late complications of the ABV.

Echocardiographic evaluations were performed using Philips IE33 colour ultrasound systems (Philips, Bothell, Seattle, WA, USA) with S8-3, and S5-1 sector array transducers were used for TTE examination. The probes had a frequency of 3–8 MHz, and 1–5 MHz, respectively. Through the echocardiography, aortic valve peak and mean gradient, aortic annulus diameter, valve morphology, the left ventricular systolic functions, the presence of the fibroelastosis and/or the left ventricular hypertrophy and prepost procedural valves regurgitations were recorded. The aortic annulus diameter was measured by two-dimensional echocardiography in early systole and angiography in the left ventricular mid-systolic phase. Patients with an ejection fraction of <58% were determined to have left ventricular systolic dysfunction**.** Aortic valve regurgitation was graded using the standard methods according to the American Society of Echocardiography as none/trace (0), mild (1), moderate (2), or severe (3).[7]

Ethical statement

The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national guidelines on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008. This study has been approved by the TUEK department (Decision date: August 26, 2021 and decision number: 2021/8-1). We declare that informed consent from each patient was provided.

The procedure

Cardiac catheterization was performed in patients who had transthoracic echocardiographic continuous flow doppler average gradient of ≥50 mmHg in the aortic valve, ST-T wave change in patients with gradient <50 mmHg and presence of left ventricular systolic dysfunction. The access way of ABV was either the femoral artery or femoral vein in case of the presence of patent foramen ovale. Prophylactic heparin (50–100 units/kg (intravenous) was given to all patients who underwent femoral artery intervention during the procedure. Tyshak (NuMED) low-profile balloon was used in all patients. The balloon valvuloplasty procedure was initiated with a balloon/annulus diameter ratio of 0.8–0.9. If necessary, the procedure was continued with the balloon diameter/annulus diameter ratio of 1–1.2, considering the residual transvalvular gradient and the grade of AR. The valvular aortic gradient was measured as a peak and mean gradient by continuous flow Doppler echocardiography and systolic valvular gradient during catheterization.

The patients were divided into 4 groups according to postprocedural results including invasive aortic valvular gradient and the presence and degree of the AR. The groups were determined as follows: Group 1, Optimal: gradient <35 mmHg, and no AR. Group 2, Adequate with mild AR: gradient <35 mmHg and trivial or mild AR. Group 3, Adequate with prominent AR: gradient <35 mmHg and moderate to severe AR. Group 4, Inadequate: gradient >35 mmHg with or without AR. The success criteria for aortic valvuloplasty were determined to be present in groups 1 and 2, specifically postprocedural gradient below 35 mmHg and no prominent AR.

Heparin and tissue plasminogen activator were used in the treatment of patients in which disturbed circulation of the femoral artery by doppler ultrasonography were detected. The loading dose of heparin was 50 units/kg (intravenous), and the maintenance dose was 20 units/kg/h. The dosage range of the tissue plasminogen activator was between 0.1 and 0.5 mg/kg/h.

Early hospital mortality was specified at up to 72 h postprocedure, while total mortality at up to the time of discharge (range 2–43 day). Long-term mortality was defined as any time after discharge.

Statistical analysis

Statistical evaluations were made using the "IBM SPSS Statistics for Windows, version 19 (IBM Corp., Armonk, N.Y., USA)" program. Independent-samples *t*-tests were

used for the comparison of normally distributed numerical data, and the Chi-square test and Fisher's Exact Test were used for the analysis of categorical data. The Pearson test was used for the analysis of normally distributed numerical data and the Spearman test was used for those that did not show normal distribution. As descriptive statistics, the mean, standard deviation of continuous variables, and percentages of discontinuous variables were specified. The Kruskal-Wallis test was used to identify differences between groups. The Kaplan-Meier method was used to estimate freedom from each of the specified endpoints, stratified by age, over the available follow-up time. Binary logistic regression analysis was used to detect mortality-related factors. The statistical significance limit was accepted as $P < 0.05$.

Results

According to demographic characteristics, 17.3% of the patients were female and 82.7% were male. The average age and body weight of the patients at the time of the catheterization were 14.4 ± 18.1; 3.254 ± 0.6, respectively.

It was detected that 26.9% of the patients were intubated and 44, 3% were being given inotropic therapy and 28.8% of patients had acidosis before the procedure.

The mean of aortic valve maximal and average gradient were found 61.75 ± 18 and 34.3 ± 13.24 respectively in preprocedural echocardiographic evaluation. Aortic coarctation and aortic arch hypoplasia were seen in 17.4% and 3.8% of patients, respectively. Left ventricular endocardial fibroelastosis and left ventricular systolic dysfunction were detected in 18 (34.6%) and 19 (36.5%) patients, respectively. There was a significant association between fibroelastosis and left ventricular dysfunction ($P < 0.05$). While 8 (15, 4%) patients had mild preprocedural AR, moderate-severe AR was not detected in any of the patients. The preprocedural clinical and echocardiographic characteristics of the patients are given in Table 1.

Aortic valve morphology structure was shown normal only in 2 (3.8%) of the patients and dysplasia was seen in 21 (40.4%) of the patients. The most common aortic valve type was bicuspid. The types of overall aortic valves are shown in Figure 1.

The ABV success rate was 70%. Moderate to severe AR after the procedure was found in 8 (15.5%) of the patients. While 7 (13.5%) of them belonged to group 3, 1 (2%) was in group 4. ABV results by groups are given in Table 2.

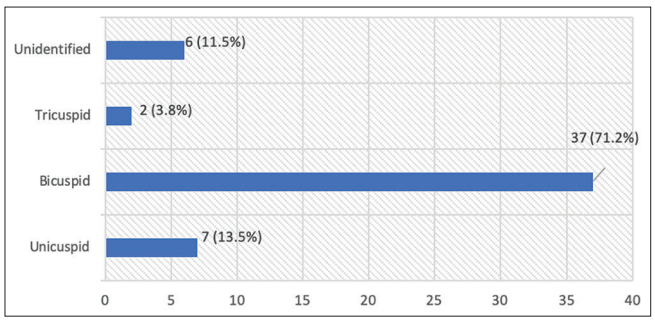

Figure 1: The type of aortic valve morphology (*n*, %)

In the current study, we found no statistically significant differences in procedural results in terms of valve morphology and dysplasia, left ventricular dysfunction, fibroelastosis, and the need for invasive ventilation. Likewise, there was no association between the balloon-to-annulus ratio and the decrease in the gradient ($P > 0.05$). Additionally, the groups were compared according to the mean of age, weight, mechanical ventilation duration, the length of stay in the intensive care unit, echocardiographic aortic average and maximal gradient, echocardiographic aortic annulus Z score, ejection fraction levels, echocardiographic and angiographic balloon to annulus ratio, angiographic peak to peak gradient and prepostprocedural left ventricular pressure. It was demonstrated that there were no differences in terms of the parameters listed above except for the echocardiographic mean gradient. The preprocedural echocardiographic mean gradient was significantly lower in group 4 than in group 3 ($P < 0.41$). Moreover, although it was not statistically significant, it was

Table 1: Preprocedural demographic, clinical and echocardiographic characteristics of the patients

Characteristics	Results
Demographic and clinical findings	
Female/male, *n* (%)	9 (17.3)/43 (82.7)
Age at the time of the catheterization (days), mean±SD	14.4±18.1
Body weight (kg), mean±SD	3.254±0.6
Inotropic therapy, *n* (%)	23 (44.3)
Prostaglandin E 1 therapy, *n* (%)	15 (28.8)
Invasive ventilation, *n* (%)	14 (26.9)
Metabolic acidosis, *n* (%)	15 (28.8)
Systolic blood pressure (mmHg), mean±SD	68±12
Diastolic blood pressure (mmHg), mean±SD	41±8.9
Mean blood pressure (mmHg), mean±SD	51±10.7
Echocardiographic findings, mean±SD	
AoV maximal gradient (mmHg)	61.75±18
AoV average gradient (mmHg)	34.3±13.24
Aortic annulus diameter (mm)	5.92±1.03
Balloon-to-annulus ratio	1.01±0.15
Other heart diseases, *n* (%)	
Aortic coarctation	9 (17.4)
Aortic arch hypoplasia	2 (3.8)
Mitral valve stenosis	2 (3.8)
Left ventricular hypoplasia	2 (3.8)
Ventricular septal defect	4 (7.7)
Atrial septal defect	6 (11.6)
Endocardial fibroelastosis, *n* (%)	18 (34.6)
Left ventricular hypertrophy, *n* (%)	21 (40.4)
Left ventricular systolic dysfunction, *n* (%)	19 (36.5)
Mild AR, *n* (%)	8 (15.4)
Moderate-severe AR, *n* (%)	None
Ejection fraction, mean±SD	61.3±17.88
Fractional shortening, mean±SD	34.5±11.15

SD: Standard deviation, AR: Aortic regurgitation, AoV: Aortic valve

Table 2: Aortic balloon valvuloplasty results by groups

	Group 1	Group 2	Group 3	Group 4
n (%)	14 (26.9)	23 (44.2)	8 (15.4)	7 (13.5)
The mean of postprocedural invasive aortic gradient (mmHg)	22.14±9.69	19.96±8.99	25.63±10.48	38.0±1.67
Postprocedural AR, *n* (%)				
Trivial-mild	-	23 (44.2)	-	6
Moderate to severe	-	-	7 (13.5)	1 (2)
Total	52 (100)	52 (100)	52 (100)	52 (100)

AR: Aortic regurgitation

Table 3: Procedural details and outcomes of the study group

Characteristics	Results
Angiographic findings, mean±SD	
Preprocedural peak systolic gradient (mmHg)	68.57±20.52
Postprocedural peak systolic gradient (mmHg)	23.57±10.38
Aortic annulus diameter (mm)	6.7±0.97
Balloon diameter (mm)	5.9±0.97
Balloon to annulus ratio	0.84±0.11
The success of the procedure, *n* (%)	7 (13.5)
Re-intervention, *n* (%)	11 (21.2)
Mean re-intervention time (months), range	8.69±14.3 (0.3-46)
Mean follow-up time (years), range	5 (0.5-11.7)
Median intensive care length of stay (day), range	6 (2-43)
Peripheral arterial thrombosis, *n* (%)	9 (17.3)
Supraventricular tachycardia (adenosine responded), *n* (%)	1 (1.9)
AoV surgery types, *n* (%)	
AVR	1 (1.9)
AoV repair	2 (3.8)
Ross procedure	1 (1.9)
Sub-valvular resection	1 (1.9)
Mortality, *n* (%)	
Early hospital mortality	6 (11.5)
Total hospital mortality	11 (21.2)
Long-term mortality	0

SD: Standard deviation, AoV: Aortic valve, AVR: AoV replacement

seen that the mean length of stay in the intensive care unit was shorter in group 1 than in group 2 ($P = 0.055$).

The decrease in the patients' serum lactate level after the procedure as evidence of adequate perfusion was statistically significant ($P < 0.05$) [Figure 2]. The mean of neonatal intensive care unit stay was 9.5 ± 9.4 days and the intubation duration was 5.4 ± 6.3 h. Data related to procedure and follow-up are given in Table 2.

Re-intervention was required in 11 patients (21.2%) at follow-up. The mean of re-intervention time was 8.69 ± 14.3 months (range 0.3-46). The Kaplan-Meier estimates are shown in Figure 3. The re-intervention cause was aortic stenosis in 10 patients. The second ABV procedure was performed on all 11 patients as an interventional method. However, five of these patients (9.6%) required further surgical procedures. The types of surgery were as follows: one patient

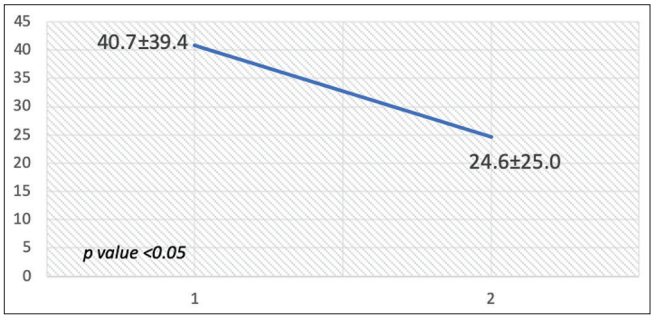

Figure 2: The mean of the pre-and postprocedural serum lactate level (mg/dl)

underwent aortic valve replacement, 2 patients underwent aortic arch repair, one patient underwent Ross procedure, and one patient underwent sub-valvular resection for additional discrete membrane. The data relating to the procedures and follow-up are given in Table 3.

According to Cox regression analysis, the re-intervention rate was found to be associated with early results of ABV. Group 4 (inadequate results with the gradient >35 mmHg) was found to have a significantly high rate of re-intervention ($P = 0.045$) [Figure 4]. However, there was no association between valve morphology or dysplasia and the re-intervention rate.

Peripheral arterial thrombosis was seen in 9 (17.3%) of the patients in those who underwent arterial intervention. Furthermore, serious complications that occurred during hospitalization in the neonatal intensive care unit were as follows: 5 patients had initial renal failure followed by multi-organ failure, 3 had heart failure, 2 had a pulmonary haemorrhage, 1 had sepsis, 1 had thrombocytopenia and intracranial haemorrhage.

The early and total hospital mortality rate was 11.5 and 21.2%, respectively. We did not have long-term mortality. Left ventricular dysfunction, the presence of fibroelastosis, and critical aortic valve stenosis were risk factors for mortality [Table 4].

Discussion

Critical congenital heart disease including critical aortic stenosis is the most common reason for acute cardiac failure in new-borns and is responsible for up to 25% of fatalities

of new-born infants.[2] Approximately one-third of the aortic valve stenosis requiring intervention in the new-born period is critical aortic stenosis.[4,5] In our study, the rate of 28.8%, or approximately one-third of the patients was corresponding to the definition of critical aortic stenosis similar to the literature.

When diagnosing valvular aortic stenosis by echocardiography, other accompanying lesions should be kept in mind such as aortic coarctation, aortic arch hypoplasia, mitral valve stenosis, and left ventricular hypoplasia. In accordance with the literature, the most common obstructive lesion associated with valvular aortic stenosis was aortic coarctation in the current study. Additionally, determining whether fibroelastosis is present or not is substantial because there was a significant association between fibroelastosis and left ventricular dysfunction ($P < 0.05$) similar to the literature.[4,8,9]

In the current era, ABV is the method of choice for treating congenital valvular aortic stenosis by evolving with the development of new technologies and procedural techniques.[6] Since the 1980s, the procedure's technical factors and associated outcomes have been studied and through them, balloon-to-aortic annulus ratio >1, younger age, and unicuspidal or thickened valve morphology were assigned as risk factors. Additionally, new-borns who underwent ABV were found to have higher rates of complications and mortality.[10-14]

The association between valve morphology and acute procedural outcomes has been extensively studied in medical research. It was postulated that the radial dilating force exerted by the inflation of the balloon usually tears the weakest part of the valve. While in the bicuspid aortic valve, the balloon dilatation tears the fused commissures with adequate relief of obstruction and some valvular regurgitation, in the unicuspid valve, balloon dilatation tends to split the leaflet opposite the patent commissure with only partial relief of obstruction and significant valvular regurgitation.[1] However, studies have shown different results regarding this association. In a study, compared with other valve morphologies, patients with bicuspid aortic valves experienced diminished freedom from re-intervention, death, or transplant.[11] Another study found no significant association between valve morphology and postprocedural diminished gradient, the presence and degree of AR, and the need for re-intervention.[4] Vergnat *et al*.[3] reported that valve morphology determined the need for reintervention and replacement in older children. In

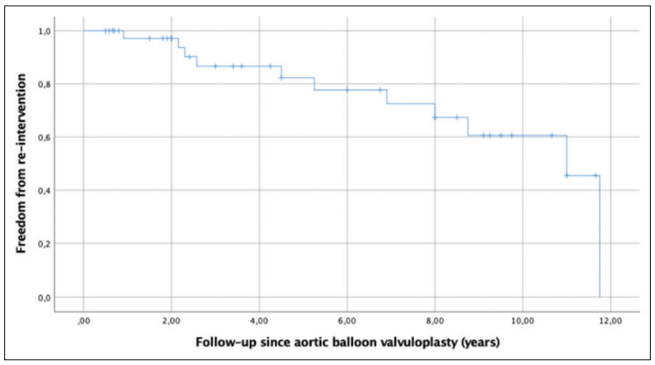

Figure 3: Kaplan Meier freedom from re-intervention is 73, 2% at 12 years after ABV. ABV: Aortic balloon valvuloplasty

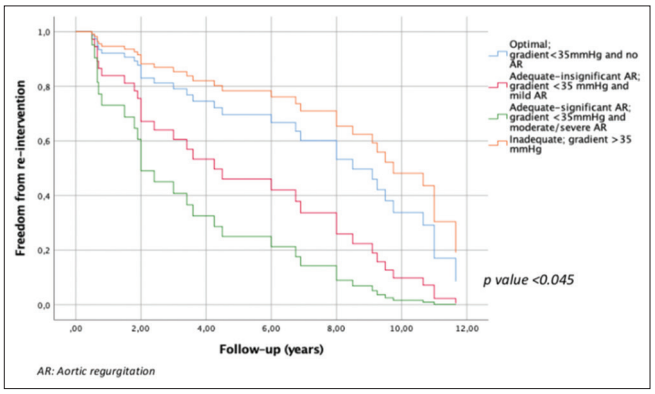

Figure 4: The re-intervention rate according to groups

Table 4: Logistic regression analysis of risk factors for mortality

	β	SEβ	Wald's χ^2	df	*P*	eβ (OR)
Age at the time of catheterization	−0.157	0.101	2.411	1	0.120	0.854
Weight at the time of catheterization	0.000	0.001	0.431	1	0.511	1000
Left ventricular dysfunction	3.571	1.115	10.265	1	0.001	35.556
Fibroelastosis	1.560	0.719	4.724	1	0.030	4.773
Dysplastic valve	0.069	0.669	0.011	1	0.918	1.071
Prostaglandin use (critical aortic stenosis)	3.268	0.898	13.242	1	0.000	26.250
Preprocedural echocardiographic AoV peak gradient	−0.002	0.019	0.013	1	0.908	0.998
Preprocedural echocardiographic AoV mean gradient	−0.024	0.028	0.707	1	0.401	0.976
Maximum balloon-to-aortic ratio	−0.521	0.407	1.636	1	0.201	0.594
Postprocedural immediate results, grouped						
Optimal	−0.642	0.808	0.631	1	0.427	0.526
Adequate-insignificant AR	−0.182	1.008	0.033	1	0.857	0.833
Adequate-significant AR	0.000	1.025	0.000	1	1.000	1.000
Inadequate	−0.916	0.592	2.399	1	0.121	0.400

AR: Aortic regurgitation, SEβ: Standard error of β, OR: Odds ratio, AoV: Aortic valve

the current study, we did not demonstrate any association between valve morphology with neither postprocedural success rates nor re-intervention.

Angiography has been traditionally used for the measurement of the aortic valve annulus before the procedure. However, it should be kept in mind that angiographic methods may be more problematic than echocardiography due to possible overestimation. Therefore, using both echocardiographic and angiographic measurements of the aortic valve annulus is recommended. The balloon-to-aortic annulus ratio of >1.1 measured by echocardiography is associated with a greater proportion of significant AR development.[14] In the current study, the echocardiographic mean balloon to-annulus ratio was detected at 1.01 ± 0.15 in line with the literature. Additionally, recent studies reported that balloon to aortic ratio was not associated with AR when considering the maximum ratio, similar to our study.[4,15] We measured both echocardiographic and angiographic aortic annulus and did not exceed the maximum balloon aortic ratio.

The criteria for determining the success of the procedure differ in studies. Our success rate of the ABV was 71% and optimal, adequate, and inadequate results were 27%, 59%, and 14%, respectively. In a study conducted by Boe *et al*.[6], patients were divided into 3 groups by ABV results; optimal; gradient <35 mmHg and no AR, adequate; gradient <35 mmHg and mild AR and inadequate; gradient >35 mmHg. According to this classification, the rate of optimal, adequate, and inadequate results were found 34.5%, 35.5%, and 30% respectively and the procedural success rate was reported as 70%. Varan *et al*.[4] considered that moderate and less AR after ABV were successful and with reference to this the success rate was detected to be 90%. In the current study, there was only one case that had severe AR in the adequate-significant AR group. If the patients who belong in the inadequate group are excluded, the success rate can be considered 86%. Vergnat *et al*.[3] defined the inadequate results as >50 mm Hg echocardiographic peak gradient and/or greater than mild regurgitation and their success rate was 80%. In another study conducted by Torres *et al*.[16], it was demonstrated that acute procedural success of ABV was evenly distributed, with one-third optimal, one-third adequate, and one-third inadequate results.

In the current study, there were no factors affecting the procedural results. Similarly, Boe *et al*.[6] reported that there were no significant factors associated with unsuccessful ABV in patients with critical aortic stenosis when compared to noncritical aortic stenosis patients. However, prior cardiac catheterization, preprocedural higher peak systolic gradient, preprocedural valve regurgitation, the number of balloon inflations, and trainee presence were found to be factors significantly associated with ineffective results in noncritical aortic stenosis. Varan *et al*.[4] also detected that the annulus diameter, valve morphology, balloon/annulus diameter ratio, reduction in gradient with valvuloplasty procedure, and aortic annulus Z-score were not significantly different between the procedure related to mild-to-moderate AR and severe AR patients. However, Reich *et al*.[17] demonstrated that a functional bicuspid aortic valve was an independent risk factor for the appearance of AR after valvuloplasty. Since our study group was limited to babies under 2 months, it can be suggested that valve structure does not affect the success of the procedure so early. Furthermore, as seen in the studies above, the studies that found factors affecting the procedure were those with noncritical aortic stenosis.

We found that the preprocedural echocardiographic mean gradient was lower in group 4 than in group 3. As known, patients with left ventricular dysfunction cannot create an adequate aortic valve gradient. This difference between group 3 and group 4 was thought to be due to the increasing gradient because of the improvement in left ventricular contraction when the stenosis was resolved after the procedure.

The incidence of moderate and severe AR is reported in the literature as 2.2%–29%.[8,11,16,18] Furthermore, it was determined that this complication was more frequent in the neonates after ABV.[8] Our results were similar to the literature with a rate of 15%.

In our study, the median intensive care length of stay was 6 days (range 2–43). In other studies, it was reported that the median hospital stay was 2.5 days (range 0–70)[3] and the mean 16.9 day.[6] Differences between studies may be related to postprocedural care.

The risk factors for re-intervention have been discussed in a multitude of studies. In the current study, the re-intervention rate was detected to be 17, 3% and it is associated with immediate outcomes of the procedure. Singh[1] reported that being under 3 months of age and having immediate postprocedural peak gradient >30 mmHg are considered predictors of restenosis. According to a study conducted by Sullivan PM *et al*.[8], neonatal age, additional left heart lesions, and preintervention aortic valve gradient were not associated with the risk of aortic valve replacement. These variables are associated with the risk of left ventricular outflow tract re-intervention. In accordance with previous studies, severe AR and recurrent aortic valve stenosis were the most important reasons for late surgical intervention in our study.[4,8]

In case of inadequate results, it can be difficult to decide whether to continue the procedure or not. Sullivan *et al*.[8] reported that patients with moderate or severe acute AR and a residual aortic stenosis gradient <30 mmHg after valvuloplasty had an approximately three times greater risk of requiring aortic valve replacement compared to those patients with a residual aortic stenosis gradient ≥30 mmHg and mild or no AR. In addition, they all underwent aortic valve replacement at 15 years of follow-up while aortic valve replacement was not required in 52% of cases with high residual gradient and mild or no AR. Varan *et al*.[4] detected that aortic valve replacement was done in 45% and 6.2% of patients with

residual gradient <45 mmHg with moderate-severe AR and ≥40 mmHg with mild or no AR respectively. We detected that one patient who had moderate AR underwent aortic valve replacement in the follow-up at 8, 8 years. However, a higher number of cases and longer follow-up periods are needed to better determine what the physicians should do.

According to the literature, ABV has a significant risk in terms of valve dysfunction and aortic valve replacement in the long-term.[8,11] In a study conducted with new-borns, Sullivan *et al*.[8] reported that aortic valve replacement was not required in 45% of the patients in the 15th year of follow-up after ABV. Maskatia *et al*.[11] also reported that aortic valve replacement was not required in 70% and 61% of patients at 10 and 15 years of follow-up after ABV, respectively. In a study conducted by Soulatges *et al*.[18], freedom from surgical intervention and transcatheter intervention were 72.9% and 54%, respectively in 37 new-borns at a mean follow-up of 11 years. Varan *et al*.[4] detected that freedom from reintervention after valvuloplasty was 71.7% in the 1st year, 58.8% in the 3rd year, 53.1% in the 5th year, and 26.9% in the 10th year of follow-up. In our study freedom from re-intervention after valvuloplasty was 77.7% at a mean follow-up of 5 years.

We detected that our mean re-intervention time was 8.69 ± 14.3 months of age (range 0.3-46). In a study conducted by Varan *et al*.[4], the mean re-intervention time was reported as 27.2 ± 45.8 months of age (range: 5 days-13 years).

Boe *et al*.[6] reported that hospital mortality in critical aortic stenosis was 10%. Neonatal ABV mortality in an intermediate-term follow-up has been reported as 9.3% and 12% in other studies.[1,4] There were no intraprocedural deaths in the current study, however, the hospital mortality was 21.2%. We noticed that most of the patients who did not survive (64%) were patients who had an ABV between the years 2007 and 2012 which may be due to the lack of experience and equipment or postprocedural care.

Mortality related to aortic stenosis for which ABV was performed is reported in critical aortic valve stenosis because of severe left ventricular systolic dysfunction and/or accompanying complex anomalies.[19,20] Varan *et al*.[4] reported left ventricular systolic dysfunction, borderline left ventricular structure, and endocardial fibroelastosis as important risk factors for mortality. In the current study, left ventricular dysfunction, the presence of fibroelastosis and critical aortic valve stenosis were detected as risk factors for mortality.

Conclusion

In a retrospective, single-centre study, our results indicate that ABV is an effective method in new-borns with severe or critical valvular aortic stenosis. Becoming aware of endocardial fibroelastosis in echocardiographic evaluation is important due to its association with left ventricular dysfunction. Inadequate results after the procedure are a major risk for re-intervention. Although AR was the most common complication of the procedure, severe regurgitation was rarely seen. Left ventricular dysfunction and critical aortic stenosis were risk factors for mortality, therefore preprocedural accurate evaluation and rapid intervention are essential.

Study limitations

This study is a retrospective study. Therefore, there is limited available data.

We compared no surgical cases with the ABV procedure because in our clinic we generally opt for ABV in neonatal critical or severe aortic stenosis cases.

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Conflicts of interest

There are no conflicts of interest.

Declaration of patient consent

Written informed consent was obtained from the patients' legal guardians.

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