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Article

Balloon Valvuloplasty in Congenital Critical Aortic Valve Stenosis—A Rescue Procedure for the Left Ventricle

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Abstract: Critical aortic valve stenosis (CAVS) is a life-threatening cardiac disease of the newborn requiring urgent treatment. First-line therapy is still controversial. The aim of our study was (1) to analyze retrospectively the patients of our institution who underwent balloon aortic valvuloplasty (BAV) due to CAVS, and (2) to describe techniques for improved feasibility of the intervention using microcatheters and retrieval loops. Twelve patients underwent 23 BAVs: 1 BAV was performed in 3 patients, 2 BAVs in 7 patients, and 3 BAVs in 2 patients. Trans-valvular pressure gradient (Δp) and left ventricular shortening fraction (LVSF) improved significantly in the first two interventions; first BAV: Δp from 73.7 ± 34.5 mmHg to 39.8 ± 11.9 mmHg ($p=0.003$) and LVSF from 22.3 ± 13.5 % to 31.6 ± 10.2 % ($p=0.001$); second BAV: Δp from 73.2 ± 33.3 mmHg to 35.0 ± 20.2 mmHg ($p<0.001$) and LVSF from 26.7 ± 9.6 % to 33.3 ± 7.4 % ($p=0.004$). Cardiac surgery during the neonatal period was avoided for all children; median time to valve surgery was 5.75 years. Few complications occurred: mild to moderate aortic regurgitation, one remediable air embolism, and one intimal injury of the ascending aorta. We conclude that BAV is a successful primary treatment for CAVS resulting in left ventricular relief, stabilization of the neonate, and a time gain until cardiac surgery.

Keywords: critical aortic valve stenosis; transcatheter balloon valvuloplasty; retrieval loop; neonate; cardiogenic shock; left ventricular dysfunction

1. Introduction

Aortic valve (AV) stenosis is a rare congenital cardiac malformation with a prevalence of 2.2 to 6 % [1,2]. "Critical" aortic valve stenosis (CAVS) implies a severe impairment of the left ventricle (LV) due to a high-grade stenosis and pressure overload of the LV. Of note, there is no standardised definition for CAVS [3]. AV dysplasia and hypoplasia of the aortic annulus are the main causes. In most cases, the AV has a unicuspid or bicuspid morphology [2,4] due to congenital commissural fusions. Additional cardiac malformations may exist as for example aortic hypoplasia or coarctation of the aorta.

CAVS results in LV pressure overload with severely reduced LV systolic function, LV enlargement and eccentric dilatation, mitral regurgitation, and consecutive low output heart failure. Endocardial fibroelastosis of the LV may occur as well [5]. Cardiomegaly and fetal hydrops may develop antenatally [6].

After birth, clinical manifestations vary from mild symptoms to cardiogenic shock. However, floppiness, pallor, nutritional disturbance, and failure to thrive are common initial symptoms. A typical systolic murmur may be missing especially in case of high-grade stenosis with low cardiac output.

Frequently, the definitive diagnosis is only made after clinical manifestation in the neonate or infant as the rate of prenatally diagnosed CAVS by fetal ultrasound is still low [7]. In case of (imminent) cardiogenic shock, intravenous prostaglandin application should be started immediately after birth respectively after diagnosis in order to maintain a sufficient systemic perfusion via a patent

ductus arteriosus. Inotropic medication, mechanical ventilation, and balloon atrioseptostomy may also be indicated [8,9].

The further therapeutic approach can be challenging. It should always be aimed at LV pressure relief by enlargement of the aortic valvular orifice. It is still controversially discussed, which technique – transcatheter balloon aortic valvulotomy (BAV) or cardiac surgery – is more beneficial [3,10–15]. Transcatheter BAV – first described by Labadibi et al.[16] – has become standard of care in most centres. The intention is to quickly reduce the stenosis and thus to achieve improvement of LV function, yet avoiding open-heart surgery and cardio-pulmonary bypass in a critically ill neonate. Both retrograde and antegrade trans-valvular access are performed depending on the feasibility of probing the stenotic valve.

The aim of this retrospective study was to analyse patients' characteristics, procedural parameters, effectiveness, complications, and outcome of transcatheter BAV in CAVS in our institution. Stable support for guidewires and valvuloplasty catheters is particularly challenging in CAVS due to the valvular dysplasia and the small anatomical features in the relevant age group. In this regard, we also present rarely described techniques for peri-interventional wire and catheter support.

2. Material and Methods

After approval from the local ethics committee of the Saarland, Saarbruecken, Germany (file number 37/24), this single-centre retrospective observational cohort study was performed at the Saarland University Medical Center, Homburg/Saar, Germany.

We retrospectively analysed all patients with CAVS who underwent emergency transcatheter BAV as first-line therapy in our institution from January 2006 to December 2023. Criteria for the diagnosis of CAVS were depressed systolic LV-function and / or clinical symptoms of heart failure or cardiogenic shock. We reviewed the relevant patients' files as well as the echocardiographic and angiographic records in order to obtain the following data:

- patients' characteristics (sex, body weight, age at intervention),
- AV cuspidity and diameter of the AV annulus,
- balloon diameter and balloon / annulus ratio,
- direction of the AV access (i.e. antegrade or retrograde),
- left ventricular end-diastolic diameter (LVEDD, [mm]) before BAV,
- left ventricular shortening fraction (LVSF, [%]) before and after BAV,
- trans-valvular systolic pressure gradient [mmHg] before and after BAV,
- post-interventional aortic regurgitation and other BAV-related complications (cardio-vascular injuries, thrombosis, embolism, haemorrhage, mortality),
- time to AV surgery.

Z-scores were calculated according to Cantenotti et al. 2017 [17] for the AV annulus and according to Cantenotti et al. 2014 [18] for the LVEDD.

2.1. Statistics

The reduction of the trans-valvular pressure gradient as well as the improvement of the LVSF by BAV was evaluated using paired t-tests; the normality of data was assessed by Shapiro-Wilk test. A Kaplan-Meier analysis (time-to-event analysis) was performed to calculate the time to valvular surgery after BAV. IBM® SPSS 28.0 statistics software was used for statistical analyses.

2.2. Percutaneous Catheterization

Femoral venous and arterial access was chosen in all patients. 4 French introducer sheaths and 4 French angiographic catheters (Multipurpose A SPECIAL, Cordis®, Miami Lakes, FL, USA) were used. First, we aimed at trans-arterial retrograde probing of the AV using a coronary guidewire. If this was successful, it may still have been difficult to pass the severely stenotic AV orifice with the angiographic catheter. In these cases, a 2.7 French microcatheter (Rebar™ 18, ev3 Neurovascular,

Irvine, CA, USA) was introduced beforehand in order to provide more support for the angiographic catheter and thus to allow its trans-valvular passage. For retrograde BAV, the guidewire usually can be positioned stably within the LV (Figure 1).

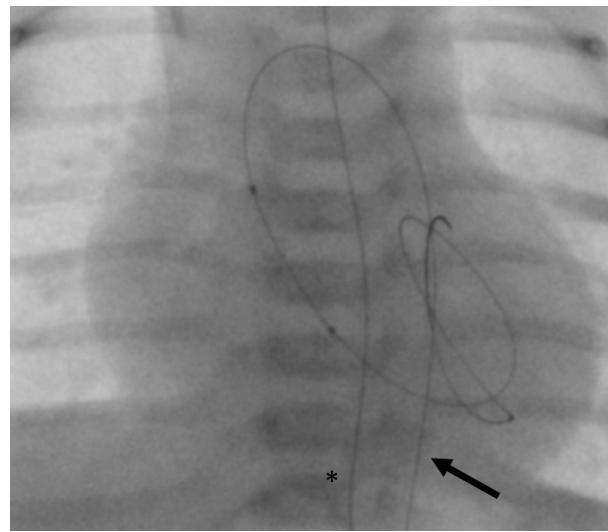


Figure 1. Angiography of balloon aortic valvulotomy (BAV) with retrograde access (posterior-anterior projection). A trans-aortic guidewire (arrow) is inserted deep into the LV to ensure stable balloon support during BAV. The asterisk marks a gastric tube.

If retrograde catheterization was not feasible, a trans-venous antegrade approach was accomplished via lower vena cava, right atrium, foramen ovale, left atrium, and LV. After passing the AV into the ascending aorta, the guidewire was caught using a retrieval loop (Multi-Snare®, pfm medical mepro gmbh, Nonnweiler-Otzenhausen, Germany, 5 or 10 mm diameter) that was inserted retrogradely into the aorta (Figure 2a). Then, it is possible to pull the wire into the descending aorta and fixate it stably during the BAV (Figure 2b).

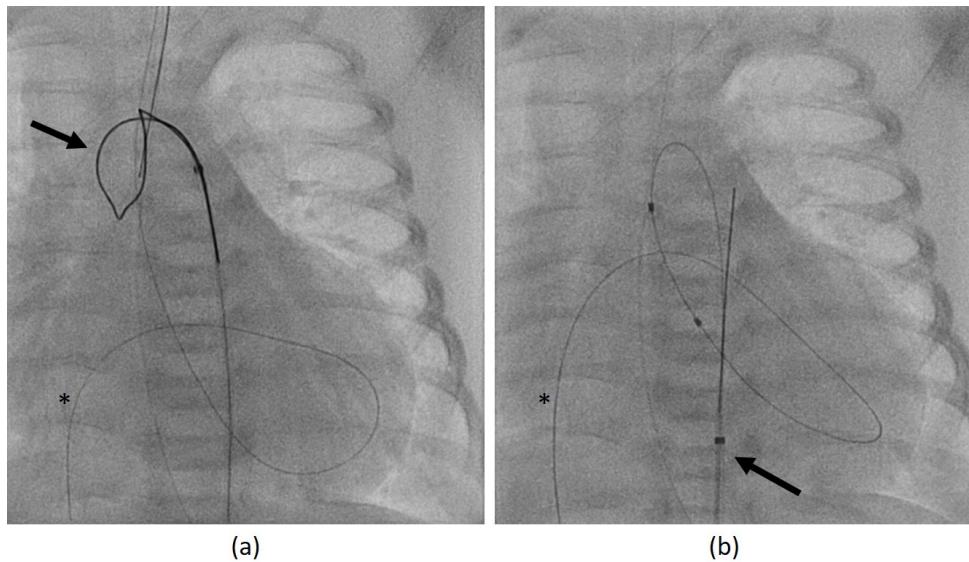


Figure 2. Angiography of balloon aortic valvulotomy (BAV) with antegrade access (posterior-anterior projection). (a) A coronary guidewire (asterisk) is positioned trans-venously up to the ascending aorta where it is snared by a trans-aortic inserted loop (arrow); (b) After catching of the guidewire (asterisk), it is attached by the snare catheter (arrow) in the descending aorta to ensure stable balloon support during BAV.

Laevocardiology was conducted in order to localize and to measure the diameter of the aortic annulus in all cases. For aortic valvuloplasty, we used either coronary balloon catheters or valvuloplasty catheters (Tyshak mini®, NuMED, Inc., Hopkinton, NY, USA) that were introduced over the guidewire. BAV was conducted stepwise with gradually increasing balloon diameters. We administered Heparin (100 IU per kg body weight) and antibiotic prophylaxis during the procedure.

3. Results

3.1. Patients' Characteristics, Cardiac Parameters, and Procedural Parameters

For underlying CAVS, BAV had been performed in 12 patients (83.3 % male) of whom 9 patients underwent a second procedure, and 2 patients underwent a third procedure. In total, 23 BAV had been performed. Renewed increase of the pressure gradient and / or worsening of the left ventricular systolic function were indications for re-intervention.

A unicusp AV was present in 9/12 patients (75 %), a bicuspid AV in 3/12 (25 %). At the time of the first BAV, median z-score for AV annulus was -1.25 (range: -4.1 to +2.8), and median z-score for LVEDD was +1.8 (range: -2.0 to +6.2). Retrograde BAV could be achieved in 6/12 (50 %) patients in the first intervention, in 6/9 (66.7 %) patients in the second, and 2/2 (100 %) patients in the third BAV. Antegrade BAV was performed for all other procedures. The balloon / AV annulus ratio for the first BAV was in median 0.90 (range: 0.7 – 1.1), for the second BAV in median 1.0 (range: 0.84 – 1.16), and for the third BAV 1.23 in both interventions.

The patients' characteristics, morphological and functional cardiac parameters, as well as procedural parameters are summarised in Table 1 and described case-based in Table 2.

Table 1. Overall patients' characteristics, AV cuspidity, access direction.

Variable	1 st valvuloplasty n = 12	2 nd valvuloplasty n = 9	3 rd valvuloplasty n = 2
Age at procedure – days	3 (1 – 55)	34 (4 – 83)	49 and 104
Female – n [%]	2 (16.7)	1 (11.1)	0
Male – n [%]	10 (83.3)	8 (88.9)	2 (100)
Body weight – kg	3.2 (2.6 – 5.1)	3.9 (2.7 – 5.1)	3.4 and 5.7
Unicuspid AV – n [%]	9 (75.0)	8 (88.9)	2 (100)
Bicuspid AV – n [%]	3 (25.0)	1 (11.1)	0
Antegrade BAV – n [%]	6 (50.0)	3 (32.3)	0
Retrograde BAV – n [%]	6 (50.0)	6 (66.7)	2 (100)

Data are illustrated as absolute numbers, and percentage respectively median and range. AV = aortic valve; BAV = balloon aortic valvuloplasty.

Table 2. Case-based description of cardiac and procedural parameters.

Case	sex	Valve cuspidity	Number of interventions	Age [d]	Weight [Kg]	LVEDD [mm] (z-score)	AV annulus [mm] (z-score)	Maximum balloon diameter [mm]	Balloon / annulus ratio	Antegrade (A) or retrograde (R) BAV	LVSF before BAV [%]	LVSF following BAV [%]	Maximal Δp before BAV [mmHg]	Maximal Δp following BAV [mmHg]	AR following BAV (grade 0-4)
1	m	UVC	1/2	3	3.6	30 (+5.4)	6.0 (-2.3)	5.5	0.91	R	13	23	37	20	0
			2/2	7	3.6	30 (+5.4)	6.0 (-2.3)	7.0	1.16	R	22	31	42	18	1
2	m	UCV	1/3	1	2.7	25 (+3.7)	5.5 (-2.4)	4.5	0.81	A	12	23	50	50	0
			2/3	4	2.7	26 (+4.2)	5.5 (-2.4)	6.0	1.09	A	21	30	60	36	1
			3/3	49	3.4	25 (+3.0)	6.5 (-1.5)	8.0	1.23	R	18	28	52	16	2
3	m	UCV	1/2	55	5.1	35 (+6.2)	9.0 (+0.9)	7.0	0.77	R	4	20	60	45	0
			2/2	70	5.1	34 (+5.8)	9.0 (+0.8)	8.0	0.88	R	15	23	50	21	1
4	m	UCV	1/2	29	3.9	25 (+2.8)	9.5 (+2.5)	7.0	0.73	R	15	27	90	50	1
			2/2	34	3.9	25 (+2.8)	9.5 (+2.5)	8.0	0.84	R	20	34	70	25	1
5	m	UCV	1/3	6	3.0	21 (+1.4)	6.0 (-1.9)	6.0	1.00	A	11	n.a.	55	36	1
			2/3	9	2.8	21 (+1.5)	6.0 (-1.7)	7.0	1.16	A	n.a.	n.a.	62	30	1
			3/3	104	5.7	19 (-1.4)	6.5 (-3.1)	8.0	1.23	R	33	36	81	40	1
6	m	UCV	1/2	1	3.4	21 (+1.3)	7.5 (+0.5)	7.0	0.93	R	44	50	130	50	0
			2/2	21	3.7	21 (+1.1)	7.5 (+0.2)	7.0	0.93	R	45	48	50	15	0
7	m	UCV	1/2	32	3.5	24 (+2.6)	7.0 (-0.6)	6.0	0.85	A	25	25	104	50	0
			2/2	83	4.9	24 (+0.5)	8.0 (-1.5)	8.0	1.00	R	33	39	130	40	2
8	f	BCV	1/1	7	2.9	21 (+1.6)	5.5 (-2.6)	5.0	0.90	R	41	43	85	45	2
9	f	UCV	1/2	2	3.2	15 (-2.0)	5.0 (-4.0)	5.0	1.00	A	38	37	50	30	0
			2/2	78	4.1	17 (-1.6)	5.5 (-3.9)	5.0	0.90	A	33	32	65	50	0
10	m	BCV	1/1	3	2.6	20 (+1.4)	8.5 (+2.8)	6.0	0.70	A	25	44	125	25	1
11	m	BCV	1/2	2	2.6	21 (+2.0)	6.5 (-0.1)	6.0	0.92	R	20	31	80	52	0
			2/2	55	4.6	28 (+3.7)	7.5 (-0.7)	8.0	1.06	R	25	30	130	80	0
12	m	UCV	1/1	2	3.2	21 (+1.3)	5.0 (-4.1)	5.5	1.10	A	9	25	19	25	1

Data are illustrated as absolute numbers respectively percentage. A = antegrade; AR = aortic regurgitation; AV = aortic valve; BCV = bicuspid aortic valve; LVEDD = left ventricular end-diastolic diameter; LVSF = left ventricular shortening fraction; R = retrograde; UCV = unicuspид aortic valve; Δp = trans-valvular pressure gradient. n.a. = not applicable due to left ventricular dyssynchrony.

3.2. Effectiveness of the BAV

In the first BAV, the maximal pressure gradient could be reduced from 73.7 ± 34.5 mmHg to 39.8 ± 11.9 mmHg, whereas the mean LVSF increased from 22.3 ± 13.5 % to 31.6 ± 10.2 % (Figure 3).

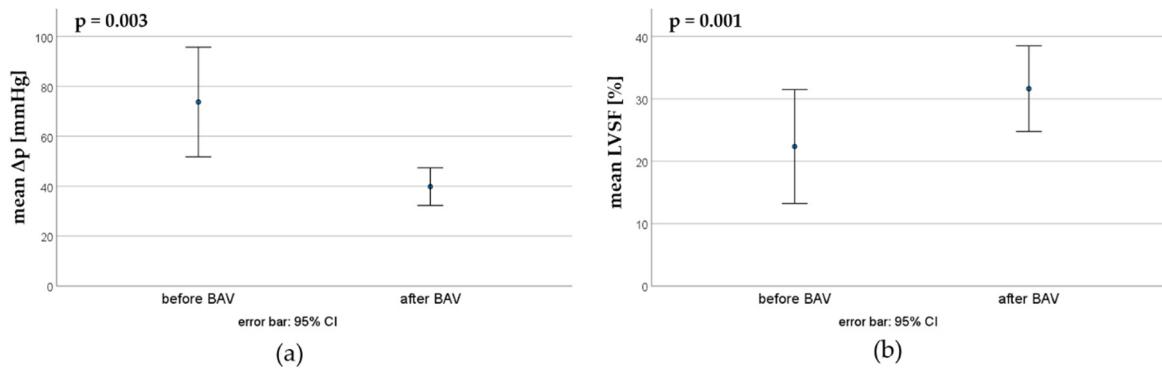


Figure 3. Paired t-tests. (a) Reduction of the trans-valvular pressure gradient (Δp), and (b) increase of the left ventricular shortening fraction (LVSF) by the first BAV.

3.2.2. Second BAV

Nine patients underwent a second BAV. Here, the mean pressure gradient could be reduced from 73.2 ± 33.3 mmHg to 35.0 ± 20.2 mmHg, whereas the mean LVSF increased from 26.7 ± 9.6 % to 33.3 ± 7.4 % (Figure 4).

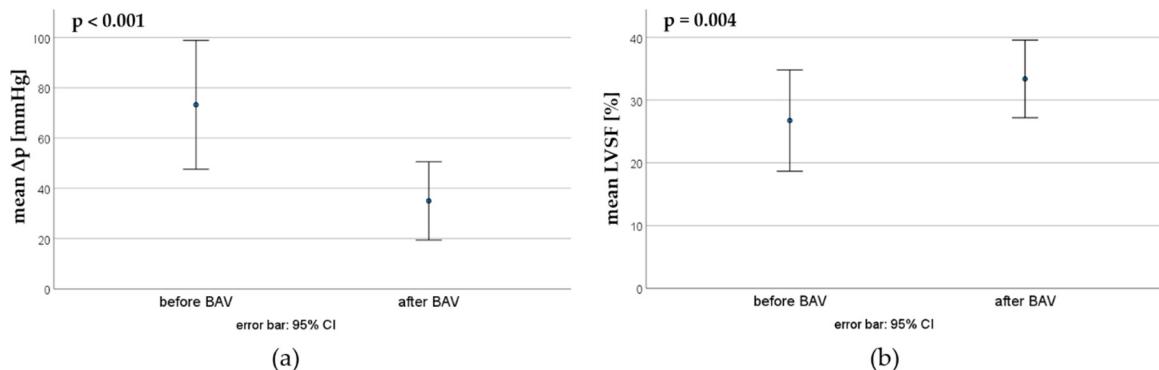


Figure 4. Paired t-tests. (a) Reduction of the trans-valvular pressure gradient (Δp), and (b) increase of the left ventricular shortening fraction (LVSF) by the first BAV.

3.2.3. Third BAV

A third BAV was performed in only two patients (cases 2 and 5, Table 2). A reduction of the pressure gradient and an increase of the LVSF were achieved in both interventions (Figure 5).

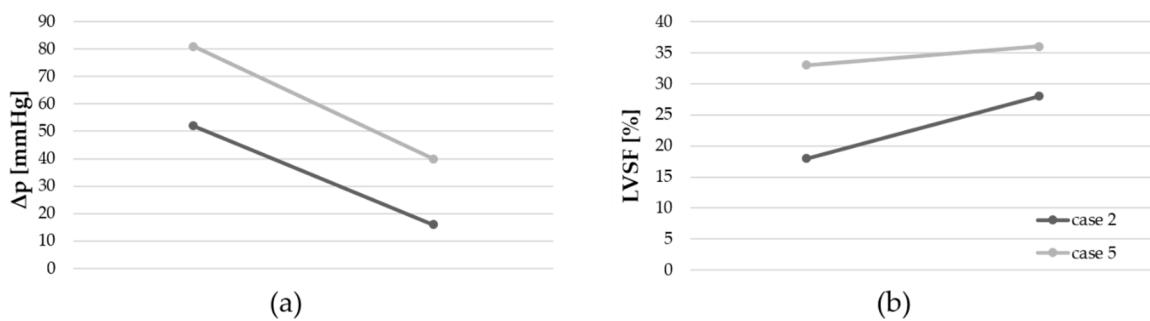


Figure 5. Third BAV. (a) reduction of the trans-valvular pressure gradient, and (b) increase of the left ventricular shortening fraction (LVSF).

3.3. Complications

3.3.1. Aortic Regurgitation

Echocardiographic assessment following the most recent BAV revealed no or only mild aortic regurgitation in 9/12 (75 %) patients; 3/12 (25 %) patients had moderate aortic regurgitation (Table 2, Figure 6). High-grade regurgitation did not occur.

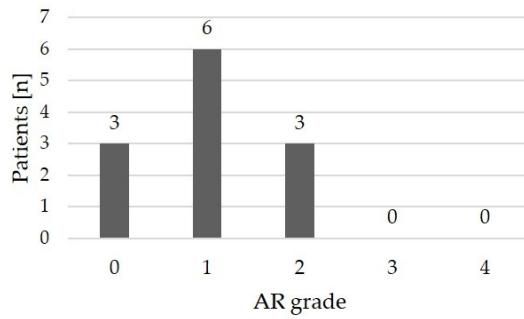


Figure 6. Grading of the aortic regurgitation (AR) immediately following balloon aortic valvulotomy.

3.3.2. Miscellaneous Complications

- In case 2, there was an air embolism into the left ventricle during the patient's first catheterization. Due to the depressed LV function with low contractility, the air bubble remained ventrally in the LV (Figure 7) where we managed to extract it by the catheter.

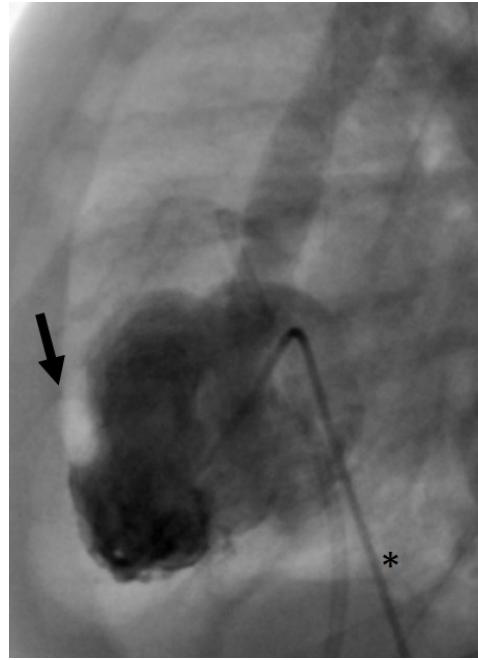


Figure 7. Angiographic image, lateral view. Air bubble (arrow) ventrally in the left ventricle during catheterization. The asterisk marks an angiographic catheter.

- In the same patient, an aortic wall injury resulting in a constriction of the intima following the second BAV occurred (Figure 8). However, this constriction was without significant stenosis, and was corrected at the time of necessary aortic valve repair.

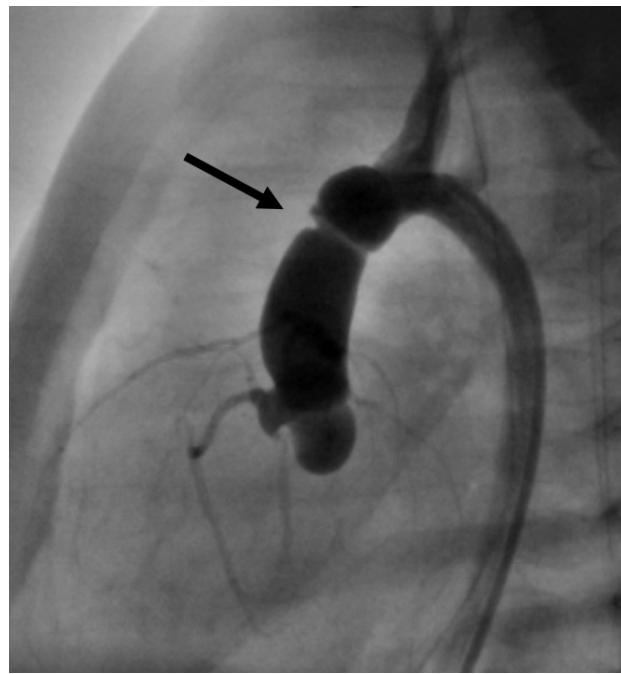


Figure 8. Angiographical image, lateral view. Intimal lesion with consecutive constriction in the ascending aorta (arrow).

- Further complications did not occur; there was no mortality.

3.4. Follow Up

To date, 9/12 patients (75.0 %) had to undergo a surgical AV reconstruction due to progressive aortic regurgitation, aortic re-stenosis, or combined stenosis and regurgitation. The earliest time for an operation was after 3 months. Median time to surgery (Kaplan Meier estimator) was 5.75 years (Figure 9).

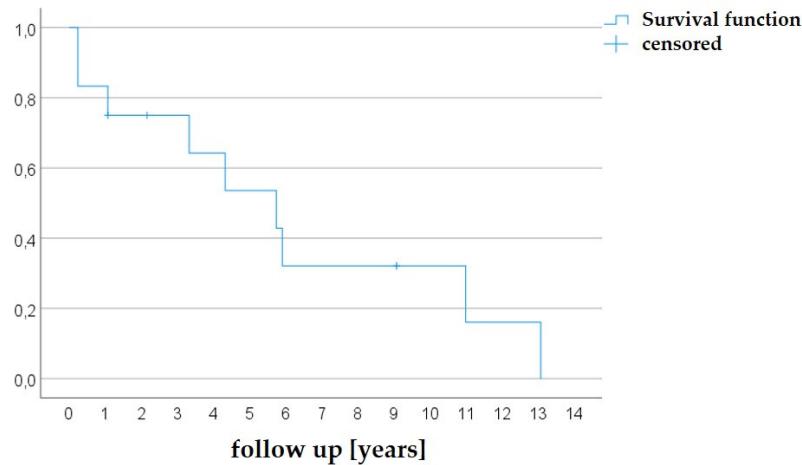


Figure 9. Kaplan Meier analysis. Freedom from AV surgery after BAV. The Kaplan Meier estimator was 5.75 years.

4. Discussion

In case of CAVS, high-grade LV dysfunction with diminished contractility and consecutive low cardiac output usually lead to rapid clinical deterioration up to cardiogenic shock of the neonate [9,19]. Therefore, urgent intervention is indicated. Regarding the further prognosis, saving the depressed LV has the topmost priority. Both open heart surgery and transcatheter BAV are possible

approaches for initial treatment [10]. Nevertheless, the optimal first-line therapy is still controversial [3].

In the present study, we analyzed a case series of 12 children with CAVS who underwent BAV. In all patients, aortic valve dysplasia in terms of either unicuspид or bicuspid AV was diagnosed. At the time of the first BAV, the median age was 3 days. In a recent study, Sylwestrzak et al. demonstrated that the best outcome is achieved if CAVS is diagnosed prenatally and postnatal BAV is performed within the first days of life [20].

Nine patients (75.0 %) underwent a second BAV, two patients (16.7 %) needed a third one. Previous studies also described frequent need for re-intervention after successful first BAV, especially the younger the children are [13,21]. In our patients, both significant improvement of the LV function and significant reduction of the trans-aortic pressure gradient could be achieved. Petit et al. suggest that BAV is particularly successful in case of high-grade stenosis due to small valve orifice areas and unicuspид AVs [22], which is typical for CAVS. Repeated BAV may be required because AV stenosis tends to recur following the initial BAV due to the recovery of the LV function and consecutively increasing LV output. The development of scar tissue may as well promote re-stenosis. Moreover, it is advisable to start with low balloon / annulus ratios using coronary balloon catheters to prevent AV injury and high-grade aortic regurgitation. The balloon diameters can then be increased gradually in order to achieve a stepwise enlargement of the AV orifice area. Usually recommended balloon / annulus ratios are 0.7 – 1.0. Nevertheless, higher ratios might be required for an effective dilatation due to the rigidity of severely dysplastic AVs [8,10,14,23]. In our analysis, maximum balloon / annulus ratio was 1.23.

By applying an interventional method as rescue procedure, cardiac surgery including cardio-pulmonary bypass could be avoided in neonates who are a particularly vulnerable cohort with high perioperative mortality [24] that is even higher in case of cardiogenic shock. In our study, the estimated time to AV surgery was 5.75 years. Among others, severe left ventricular dysfunction is a risk factor for AV surgery following neonatal BAV according to Kido et al. [25]. However, the gain of time until first surgery is worthwhile because patients with congenital AV stenosis are exposed to a high life-time risk for multiple AV operations including AV reconstruction, Ross procedure or AV prosthesis [26–30]. Thus, future perioperative risks due to typical intrathoracic adhesions [31,32] might be reduced by postponing surgery to later childhood. On the other hand, there are data that valve replacement cannot be postponed by BAV [33]. Moreover, some authors generally perform primary cardiac surgery [34] because it offers a precise AV commissurotomy and reconstruction in contrast to arbitrary valve dilatation [11] and a longer freedom of re-intervention [35]. Hill et al. described no differences in long-term outcome for both, primary BAV and a surgical approach but a higher rate for re-interventions after BAV [15]. However, both are palliative approaches and AV surgery will be necessary in most cases anyway. Our data support the hypothesis of rescue interventional procedure to improve the survival in critically ill neonates with primarily diminished LV contractility.

When performing BAV, probing of highly restrictive AVs by catheter often is challenging. We describe a technique to provide more support for the angiographic catheter by inserting it via guide wire and an additional microcatheter. If a retrograde approach is unfeasible, trans-venous antegrade catheterization should be considered which provides equally effective results [36]. Here, a stable and safe positioning of the balloon during BAV can be technically delicate. For this purpose, it is useful to fixate the guiding wire in the descending aorta using a retrieval loop as first described by Rao et al. [37] in a trans-umbilical approach. The antegrade approach is associated with mitral valve injury whereas there is risk for arterial thrombosis in retrograde catheterization [36,38]. Both did not occur in our population. In our study, few BAV-associated complications occurred. The greatest risk exists for the development of aortic regurgitation especially in repeated BAV [21]. In 75.0 % of our patients, no or mild aortic regurgitation was detectable, and in 25.0 % moderate regurgitation. There was no case of severe aortic valve insufficiency which usually only increases over time according to Rao [39]. Another adverse event was an air embolism into the LV. Due to the poor LV function with a significantly reduced contractility, the air remained in the LV without embolization into systemic

arteries. Therefore, the bubble could be aspirated by catheter. The most remarkable complication was an intimal injury of the distal ascending aorta which was also described as typical in a study by Brown et al. [40]. In our case, the lesion was electively corrected in combination with the surgical AV reconstruction. There was no mortality peri-interventionally or in the follow-up in our study.

Limitations of our study are the retrospective approach as well as the limited number of patients which is based on either the low incidence of CAVS and the single center analysis.

5. Conclusions

In critical aortic valve stenosis, balloon valvuloplasty is a successful primary treatment resulting in prompt left ventricular relief and stabilization of the critically ill neonate. Thereby, cardiac surgery can be avoided during the neonatal period and postponed until later childhood. No mortality was observed in our cohort. Thus, transcatheter approach represents an effective emergency, yet palliative rescue procedure for the LV with an acceptable low rate of complications. Nevertheless, it seems advisable to choose the first-line therapy according to the experience of the respective treatment team.

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Institutional Review Board Statement: The study was conducted in accordance with the Declaration of Helsinki, and approved on 6 March 2024 by the local ethics committee of the Saarland, Saarbruecken, Germany (file number 37/24).

Informed Consent Statement: Informed consent for BAV was obtained from all subjects involved in the study.

Data Availability Statement: The data underlying the present study are available on request (corresponding author).

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Conflicts of Interest: The authors declare no conflicts of interest

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