Cardiology in the Young

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Immediate results of primary balloon dilation for congenital aortic valve stenosis predict the mid-term outcome

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Abstract

Background: Balloon valvuloplasty is the primary treatment for congenital aortic valve stenosis in our centre. We sought to determine independent predictors of reintervention (surgical repair or repeated balloon dilation) after primary valvuloplasty. *Methods:* We retrospectively studied patients with congenital aortic valve stenosis who underwent balloon valvuloplasty during 2004–2018. The following risk factors were analysed: aortic valve insufficiency after balloon valvuloplasty >+1/4, post-procedural gradient across the aortic valve ≥35 mmHg, pre-interventional gradient across the valve, annulus size, use of rapid pacing, and balloon/annulus ratio. Primary outcome was aortic valve reintervention. *Results:* In total, 99 patients (median age 4 years, range 1 day to 26 years) underwent balloon valvuloplasty for congenital aortic valve stenosis. After a mean follow-up of 4.0 years, 30% had reintervention. Adjusted risks for reintervention were significantly increased in patients with post-procedural aortic insufficiency grade >+1/4 and/or residual gradient ≥35 mmHg (HR 2.55, 95% CI 1.13–5.75, p = 0.024). Pre-interventional gradient, annulus size, rapid pacing, and balloon/annulus ratio were not associated with outcome. *Conclusion:* Post-procedural aortic valve insufficiency grade >+1/4 and/or residual gradient ≥35 mmHg in patients undergoing balloon valvuloplasty for congenital aortic valve stenosis confers an increased risk for reintervention in mid-term follow-up.

Congenital aortic valve stenosis is a fairly common disease comprising 2–7% of all congenital heart anomalies.[1–3] The disease spectrum varies from mild and asymptomatic to severe aortic stenosis, with mortality rates up to 15% if left untreated.[2] Since its introduction by Lababidi some 35 years ago, transcatheter balloon aortic valvuloplasty has become a standard first-line treatment in the majority of centres.[4] Balloon aortic valvuloplasty is associated with a low mortality rate and significantly delays or even obviates the need for later surgical aortic valve repair. Main advantages of balloon aortic valvuloplasty over surgical aortic valve repair are its minimal invasiveness, avoidance of bypass, and much lower rate of admission to the ICU.[5–10] Of note, in a recent meta-analysis by Hill et al., balloon aortic valvuloplasty and valve surgery proved to be equally effective in the treatment of congenital aortic valve stenosis.[11]

However, despite acute success rate of 89%, as reported by Sullivan et al., balloon aortic valvuloplasty shows lower freedom from reintervention when compared with surgical approach (46% versus 78%) in a 10-year follow-up.[11,12] In addition, there is a compelling evidence of multiple risk factors contributing to adverse outcomes in patients undergoing balloon aortic valvuloplasty for congenital aortic valve stenosis. In a study by Hochstasser and colleagues, residual peak end-systolic gradient >30 mmHg, as assessed by echocardiography, was independently associated with higher rates of reintervention, while post-procedural aortic regurgitation grade >+1/4 was shown to double the risk of adverse events.[2] Conversely, in a single-centre retrospective study, Maskatia et al. demonstrated nine times lower risk for repeat valvuloplasty and surgical aortic valve repair in patients with functionally bicuspid aortic valves, while in another study by the same group of investigators, worse outcomes after balloon aortic valvuloplasty during the follow-up were present in neonates and patients with low left ventricular systolic function at baseline.[8,13]

Given the background from the literature, it is clear that there are numerous aspects of balloon aortic valvuloplasty influencing the outcome in this group of patients. Therefore, it is crucial to identify independent risk factors affecting the results of primary balloon aortic

valvuloplasty during the follow-up, in order to devise further management strategies for these patients. Thus, we aimed to determine independent predictors for reintervention (surgical repair or repeated balloon dilation) in a contemporary group of patients with congenital aortic valve stenosis that underwent primary balloon aortic valvuloplasty.

Materials and methods

Study design and population

This was a retrospective cohort study which included consecutive paediatric and young adult patients (age range 1 day to 26 years) with congenital aortic valve stenosis who had undergone primary balloon aortic valvuloplasty. The patient data were retrieved from an electronic database of a high-volume catheterisation laboratory of a tertiary referral centre from 2004 to 2018. Exclusion criteria were as follows: previous valvular or other cardiac surgery involving left ventricular outflow tract; concomitant congenital aortic disease; sub-valvular or supravalvular aortic stenosis; patients planned for univentricular palliation; death within 30 days of intervention. If present, patent ductus arteriosus in newborns, as well as foramen ovale, were not regarded as associated cardiovascular anomalies. Exclusion criteria were chosen to prevent the inclusion of any comorbidity which could affect the congenital aortic valve stenosis hemodynamically. The study has been conducted in accordance with 1975 declaration of Helsinki. The Institutional review board approved the study protocol and informed consent was waived.

Baseline clinical assessment

Congenital aortic valve stenosis was defined as an inborn abnormality of the aortic valve with a flow velocity of at least 3 m/second across it and/or significantly decreased aortic valve area on echocardiography.[14–17] Medical history, demographic, and anthropometric characteristics were obtained on admission. Standard two-dimensional and Doppler transthoracic echocardiography with assessment of the aortic valve anatomy and hemodynamics, as well as left ventricular systolic function (assessed by left ventricular shortening fraction), was performed the day before and the day after the balloon aortic valvuloplasty, as well as at regular check-ups in the follow-up. Echocardiographic dimensions were standardised using the corresponding Z-scores.[18] Measurements of the left ventricular size and function were performed in the parasternal long-axis view, at the level of the tip of the mitral valve leaflets, using the M-mode technique. Morphometric analysis of the aortic valve and the aortic valve annulus has been conducted in the parasternal long- and short-axis view.[14,16] The peak end-systolic gradient between the left ventricle and the aorta was obtained using continuous wave Doppler.

Interventional characteristics

Transcatheter balloon aortic valvuloplasty was indicated in concordance with contemporary guidelines.[19] In all patients, retrograde transfemoral approach was used. Pressure gradients were estimated before and after crossing the valve, prior to and after the balloon aortic valvuloplasty. Aortic valve insufficiency was assessed by aortography prior to and after the balloon aortic valvuloplasty:[6,9]

- None;
- +1, mild; a small amount of contrast enters the left ventricle, clearing with each cardiac cycle;
- +2, moderate regurgitation; contrast enters the left ventricle, discretely opacifying the entire left ventricle in diastole;
- +3 moderately severe; clear opacification of the left ventricle, equal in density with the aorta;
- +4 severe; complete, dense opacification of the entire left ventricle during cardiac cycle.

In most patients, dilation was initiated with a balloon diameter 90% of that of the aortic annulus, gradually increasing in size at the discretion of the operator, until the adequate result was achieved. Procedure was considered successful if the immediate, residual gradient after balloon dilatation was <35 mmHg and aortic valve insufficiency ≤+1/4.[20–23]

Follow-up and outcomes

All patients had a regular follow-up at 6- to 12-month intervals, for a period of at least 2 years. All patients underwent detailed echocardiography assessment at follow-up visits, which included left ventricle end-systolic and end-diastolic diameters, left ventricle wall thickness, left ventricular systolic function, aortic valve morphology, and continuous wave Doppler across the aortic valve. The outcome measure was defined as freedom from any reintervention (surgical repair or repeated balloon dilation) during the follow-up. Surgical aortic valve repair referred both to aortic annuloplasty and valve replacement. Accordingly, we divided patients into two groups: those who underwent reintervention and those who did not.

Statistical analysis

Descriptive data were expressed as means with standard deviation for continuous variables, and as count with percentage for categorical variables. The normality of data was assessed by Shapiro–Wilk test. Differences between continuous variables were compared using the Mann–Whitney *U* test and Student's t-test, according to the data distribution, and $\chi 2$ test was used for categorical variables. Incidence rates of study outcome were calculated and expressed per 100 patient-years. Kaplan–Meier survival curve with log-rank testing estimated probability of freedom from reintervention for the levels of various prognostic factors from the time of index intervention to the event. The Cox proportional hazards models were used to estimate the relationship between predictor variables and hazard ratios for reintervention. The adjusted Cox regression models were formed in a "two-step" process. First, we used univariable regression analysis in which study outcome (i.e. reintervention) was regressed on explanatory variables, including age, sex, anatomy of the aortic valve, baseline end-to-end systolic gradient measured by continuous wave Doppler, left ventricular systolic function, presence of left ventricle hypertrophy, rapid pacing during balloon aortic valvuloplasty, balloon/annulus ratio, immediate post-procedural aortic valve insufficiency >+1/4, procedural success and residual peak systolic end-gradient (not presented). Then we used five covariates strongly associated with study outcomes (bicuspid aortic valve, neonatal age, residual peak gradient over 35 mmHg, immediate aortic valve insufficiency >+1/4, and rapid pacing during intervention) to adjust Cox regression models for the association between prognostic factors and freedom from surgical aortic valve

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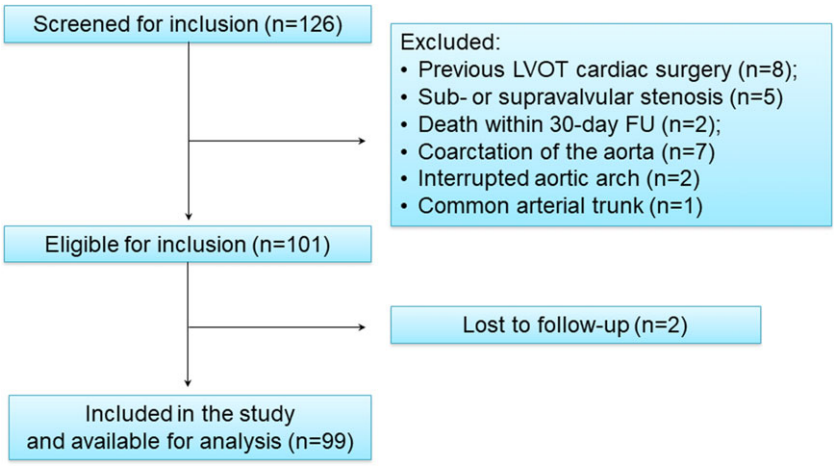

Figure 1. The Study flow chart.

repair and repeated balloon aortic valvuloplasty. Taking into account relatively small number of outcome events due to a small sample size, this approach prevented overfitting the Cox adjusted models.[24,25] Data were analysed using STATA MP 13. Two-sided p value < 0.05 was considered statistically significant.

Results

Baseline characteristics

From 2004 to 2018, a total of 126 patients underwent balloon aortic valvuloplasty for congenital aortic valve stenosis and were potentially eligible for inclusion in the study. After exclusion, a total of 99 patients were included in the study (Fig 1). There were no deaths in mid-term follow-up.

Baseline characteristics of the study population are presented in Table 1. Patients were predominantly male (76%), and the median age at the time of balloon aortic valvuloplasty was 4 years (age range 1 day to 26 years). Bicuspid aortic valve was found in 63 (64%), and there was more than a mild aortic regurgitation in four patients (4%) as detected by colour Doppler before the procedure. Pre-procedural invasively measured peak gradient was 68.0 ± 24.2 mmHg; after balloon aortic valvuloplasty it decreased to 24.5 ± 11.2 mmHg (mean decrease of 44.4 ± 22.3 mmHg, paired samples t-test, $p < 0.001$). Median balloon/annulus ratio was 0.92 (range 0.56–1.0). Majority of interventions (69%) required one balloon dilation to achieve the result. Procedure was successful in 84% of cases. Reasons for considering the procedure unsuccessful were high residual gradient (≥35 mmHg) in 15 patients, aortic valve insufficiency >+2/4 in 4 patients, and both high residual gradient and significant aortic valve insufficiency in 3 patients. Post-procedural aortic valve dysfunction (aortic valve insufficiency >+1/4 or residual peak gradient ≥35 mmHg) had been present in 27 (27%) and 15 (15%) cases, respectively.

Study outcomes

Over the mean follow-up of 4.0 years (range 0.1–12.0 years), 30% of patients had reintervention; 19% of patients (n = 19) underwent surgical aortic valve repair, while 13% (n = 13) required repeated balloon aortic valvuloplasty. Mean time from primary balloon aortic valvuloplasty to reintervention (surgical aortic valve repair or balloon aortic valvuloplasty) was 4.0 ± 3.3 years Overall freedom from reintervention at 1, 5, and 10 years was 94, 82 and 75%, respectively.

Patients who underwent reintervention had higher invasively measured peak gradient prior to balloon dilation ($p = 0.011$), more frequent post-procedural acute aortic valve insufficiency >+1/4 after balloon aortic valvuloplasty ($p = 0.002$), and lower rates of procedural success ($p = 0.05$). There were no significant differences in mean age, sex, pre-procedural peak end-systolic gradient as assessed by continuous wave Doppler, rapid pacing during intervention, and balloon/annulus ratio between reintervention and non-reintervention group.

In 19 patients requiring surgical aortic valve repair, the indications for the surgery were as follows: isolated severe aortic valve insufficiency (n = 12), significant residual gradient (n = 3), severe aortic valve insufficiency, and significant residual gradient (n = 4).

Group of patients with aortic valve insufficiency >+1/4 and/or residual peak gradient ≥35 mmHg had higher incidence-rate ratio for reintervention (Table 2).

The cumulative Kaplan–Meier curve illustrating freedom from reintervention according to aortic valve insufficiency grade and/or residual gradient is presented in Figure 2.

In unadjusted Cox proportional hazards analysis, the risk for reintervention was significantly higher in patients with post-procedural aortic valve insufficiency grade >+1/4 and/or residual peak gradient ≥35 mmHg as compared with group of patients without significant aortic regurgitation or residual gradient. Following adjustment, this association showed a 2.55-fold higher risk for reintervention (Table 3). There was no statistical interaction between reintervention group and pre-interventional aortic valve stenosis gradient, annulus size, use of rapid pacing, or balloon/annulus ratio.

Discussion

Key findings of this retrospective, observational cohort study of 99 patients with congenital aortic valve stenosis, are the following: (I) in children and young adults, primary balloon aortic valvuloplasty provides sufficient freedom from subsequent aortic valve interventions (repeated balloon aortic valvuloplasty or surgical aortic valve repair) in mid-term follow-up; (II) immediate post-procedural aortic valve insufficiency grade >+1/4 and/or residual peak gradient ≥35 mmHg are independently associated with increased risk for reintervention in mid-term follow-up, following adjustment for covariates.

Although data from several registries demonstrate effectiveness and safety of balloon aortic valvuloplasty, we sought to determine

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Table 1. Demographic, clinical, and balloon aortic valvuloplasty data, as well as echocardiographic findings at baseline and after the primary balloon valvuloplasty for all patients with congenital aortic valve stenosis, and those who eventually had or had not reintervention (surgical repair or catheter reintervention) during the follow-up.

	All patients (n = 99)	Reintervention (n = 30)	No reintervention group (n = 69)	p value
Age (years, mean, SD)	6 ± 6	7 ± 7	5 ± 5	0.33
≤28 days (%)	16.2	13.3	17.4	0.77
29 days to ≤2 years (%)	32.3	20.0	37.7	0.10
>2 years to ≤5 years (%)	6.1	6.7	5.8	0.99
>5 years to ≤11 years (%)	20.2	36.7	13.0	0.013
>11 years to ≤18 years (%)	22.2	20.0	23.2	0.79
>18 years (%)	2.0	3.3	1.4	0.51
Sex (% of male)	76.0	77.0	78.0	0.99
Weight (kg, SD)	27.6 ± 26.3	29.6 ± 24.3	26.7 ± 29.0	0.63
Genetic syndrome (%)	4.0	3.0	4.0	0.99
Pre-procedural echocardiography assessment				
Bicuspid valve (%)	64.0	76.7	58.0	0.11
Aortic valve diameter (mm, SD)	14.6 ± 7.2	16.5 ± 7.8	13.8 ± 6.8	0.09
Aortic valve diameter Z score (SD)	1.3 ± 1.3	1.6 ± 1.7	1.2 ± 1.1	0.13
Any pre-procedural AVI (%)	34.0	48.3	29.0	0.10
Pre-procedural AVI more than mild (%)	4.0	10.0	1.0	0.084
Pre-procedural PG (mmHg, SD)	91.4 ± 20.3	93.9 ± 19.7	90.2 ± 20.6	0.41
LVEDD (mm, SD)	32.0 ± 11.1	33.9 ± 10.4	30.9 ± 11.4	0.26
LVEDD Z score (mean, SD)	−0.52 ± 1.28	−0.46 ± 0.93	−0.55 ± 1.45	0.79
LVESD (mm, SD)	18.4 ± 6.9	19.3 ± 6.8	17.8 ± 7.0	0.41
LVESD Z score (mm, SD)	−1.09 ± 1.84	−1.18 ± 1.38	−1.04 ± 2.08	0.76
Fractional shortening (%, SD)	41.2 ± 8.8	42.3 ± 8.8	40.8 ± 8.8	0.53
Procedural characteristics				
PG pre-BAV (mmHg, SD)	68.0 ± 24.2	77.1 ± 27.0	63.7 ± 21.7	0.011
Balloon/annulus ratio (SD)	0.92 ± 0.18	0.92 ± 0.22	0.92 ± 0.17	0.88
Balloon/annulus ratio >1 (%)	22.0	20.7	22.4	0.54
Rapid pacing (%)	44.0	40.0	46.0	0.66
Balloon dilation >1 (%)	31.0	33.0	30.0	0.48
Residual PG (mmHg, SD)	24.5 ± 11.2	27.7 ± 11.9	23.1 ± 10.6	0.067
Residual PG ≥35 mmHg (%)	15.0	27.6	7.6	0.019
Post-procedural AVI >+1/4 (%)	27.0	48.3	16.4	0.002
Procedural success (%)	84.0	75.0	91.0	0.05
Post-procedural echocardiography assessment				
Post-procedural PG (mmHg, SD)	48.0 ± 15.0	54.3 ± 16.6	45.0 ± 13.9	0.006
Any increase in AVI (%)	46.5	50.0	45.7	0.82
LVEDD (mm, SD)	32.7 ± 10.2	35.0 ± 9.8	31.4 ± 10.3	0.15
LVEDD Z score (mean, SD)	−0.02 ± 1.43	−0.05 ± 1.12	−0.03 ± 1.59	0.94
LVESD (mm, SD)	18.4 ± 6.3	19.5 ± 6.1	17.9 ± 6.4	0.31
LVESD Z score (mean, SD)	−0.85 ± 1.62	−1.0 ± 0.96	−0.79 ± 1.89	0.65
Fractional shortening (%, SD)	42.5 ± 9.2	41.3 ± 12.8	43.1 ± 6.3	0.42
Follow-up				
Time from BAV to reintervention (years, SD)	–	4.0 ± 3.3	–	–

AVI=aortic valve insufficiency; BAV=balloon aortic valvuloplasty; CAVS=congenital aortic valve stenosis; LVEDD=left ventricle end-diastolic dimension; LVESD=left ventricle end-systolic dimension; PG=peak gradient; SAVR=surgical aortic valve repair; SD=standard deviation.

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Table 2. The incidence rate and incidence rate ratio of reintervention in patients with aortic valve insufficiency (AVI) ≤1/4 and/or residual gradient <35 mmHg compared to those with aortic valve insufficiency (AVI) >1/4 and/or residual gradient ≥35 mmHg.

	No of events (%)	Incidence rate per 100-patient years (95% CI)	Incidence rate ratio (95% CI)	p value
Reintervention (SAVR or repeated BAV)				
AVI ≤+1/4 and/or RG <35 mmHg	11 (16.0)	4.78 (2.64–8.63)	–	–
AVI >+1/4 and/or RG ≥35 mmHg	19 (63.3)	11.65 (7.43–18.27)	2.43 (1.10–5.66)	0.008

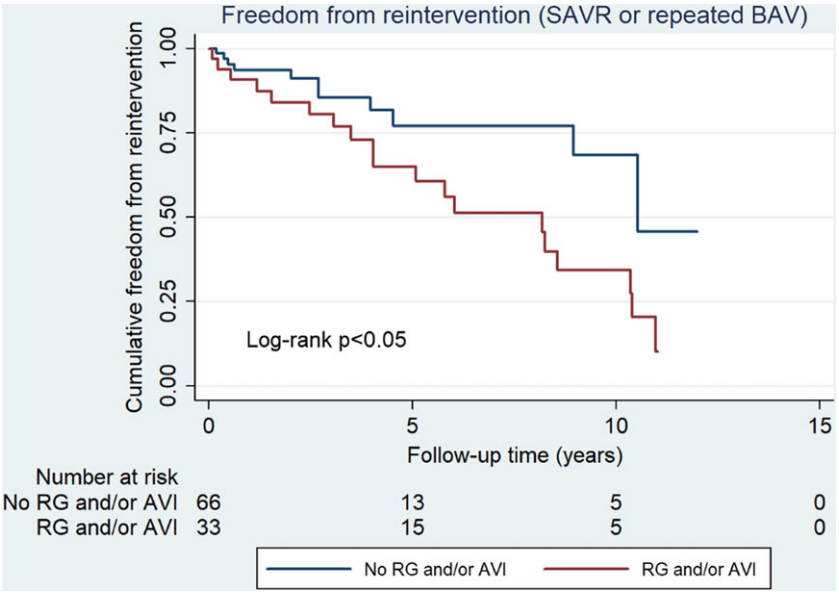

Figure 2. Freedom from reintervention (SAVR or repeated BAV) according to aortic valve insufficiency >+1/4 and/or residual gradient ≥35 mmHg.

independent predictors for surgical aortic valve repair and repeated balloon aortic valvuloplasty in the follow-up in uniform subset of patients with isolated, previously untreated congenital aortic valve stenosis.[2,6,7,9,11] Therefore, the present study encompassed a well characterised, contemporary cohort of paediatric and young adult patients with congenital aortic valve stenosis undergoing primary balloon aortic valvuloplasty. The primary balloon aortic valvuloplasty resulted in significant decrease in peak gradient with an interventional success rate of 84%, comparable with the results of previous, similar studies.[2,3,6,7,9,11,20,21]

We found that overall freedom from reintervention at 1 and 5 years was 94 and 82%, respectively. However, there was a notable decrease in freedom from reintervention, at 10 years (75%). Of note, similar trend was demonstrated in a large cohort of children with congenital aortic valve stenosis from Boston, with an 18% decrease in freedom from intervention when comparing 5- and 10-year follow-up (72% versus 54%, respectively).[24] This could be attributed to morphological and haemodynamic changes owing to natural course of growth, especially in adolescents, which possibly could affect the aortic valve mechanics after balloon aortic valvuloplasty.[22,23] Consistent with our findings, in a study by Fratz et al., approximately two thirds of patients were surgical aortic valve repair-free in 10-year follow-up, while the meantime from balloon aortic valvuloplasty to surgery was 4.2 years.[23] Conversely, Siddiqui et al. favoured primary surgical aortic valve repair over balloon aortic valvuloplasty in their cohort of infants and neonates with congenital aortic valve stenosis, however, with lower freedom of reintervention after primary balloon aortic valvuloplasty in 5-year follow-up (25%), and higher rates of surgical aortic valve repair (35%) compared with our study.[26] These discrepancies could be attributed to older age of our cohort and to differences in therapeutic algorithms and the treatment of choice for congenital aortic valve stenosis between centres.

Interestingly, in a meta-analysis comparing outcomes of primary balloon aortic valvuloplasty and surgical aortic valve repair by Hill et al., comprising 2368 patients with congenital aortic valve stenosis, in balloon aortic valvuloplasty group, 10-year freedom from valve replacement was 76% versus freedom from reintervention of 46%.[12] This partially corroborates our findings.

Expectedly, the relevance of immediate post-procedural valvar dysfunction, both higher aortic valve insufficiency grade and higher residual peak gradient, is reflected in a substantially increased need for reintervention in the mid-term follow-up.

Despite balloon/annulus ratio <1 (median 0.92; range 0.56–1.0) in the majority of balloon aortic valvuloplasties and high rate of single balloon dilation (69%), there was a high percent (27%) of post-procedural aortic valve insufficiency grade >+1/4 in our cohort. Conversely, in IMPACT registry, as well as other contemporary studies, significant post-procedural aortic valve insufficiency (more than mild) was present in 12–19% of cases.[9,12,27] In our cohort, there was immediate post-procedural residual peak gradient ≥35 mmHg in 15% of cases. Comparatively, multi-centre analysis by Torres et al. revealed similar rates of the residual pressure gradient greater than 35 mmHg (18% of cases), as opposed to data from IMPACT registry by Boe et al., with only 11.4% of cases having higher residual gradient.[6,9] However, in contrast to 16% of

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Table 3. Unadjusted and adjusted Cox proportional hazards for reintervention (SAVR or repeated BAV) for patients with AVI >+1/4 and/or residual gradient ≥35 mmHg.

	Intervention (SAVR or repeated BAV) risk			
	Unadjusted analysis		Adjusted analysis	
	HR (95% CI)	p value	HR (95% CI)	p value
AVI ≤+1/4 and/or RG <35 mmHg	I (reference)	–	I (reference)	–
AVI >+1/4 and/or RG ≥35 mmHg	2.62 (1.17–5.82)	0.018	2.55 (1.13–5.75)	0.024

AVI=aortic valve insufficiency; BAV=balloon aortic valvuloplasty; CI=confidence interval; HR=hazard ratio; RG=residual gradient; SAVR=surgical aortic valve repair.

neonates in our cohort, both Torres and Boe included significant population of neonates (~33 and 27%, respectively) in their analyses.

We found high incidence rates (~12 patients per 100 patients-years) of aortic valve insufficiency grade >+1/4 and/or residual gradient ≥35 mmHg in patients undergoing reintervention. Even after adjusting for relevant confounders, prognostic significance of immediate post-procedural aortic valve insufficiency and residual gradient translates into higher rates of reinterventions in the mid-term follow-up. Notably, we found almost 2.6-fold higher risk for reintervention in patients with more than mild aortic regurgitation after valvuloplasty and/or residual gradient ≥35 mmHg. However, the observed hazard ratios were high, probably due to a small sample size.

Concordantly, in a large single-centre study by Brown et al., longer freedom from surgical aortic valve repair was associated with lower grade of post-dilation aortic regurgitation, whereas higher residual aortic stenosis was an independent predictor both for surgical aortic valve repair and repeated balloon aortic valvuloplasty.[20] By contrast, in a study by Maskatia et al., neonatal age, low baseline left ventricular systolic function, and residual gradient ≥25 mmHg yielded increased risk for composite adverse outcomes in the long-term follow-up.[13]

In our cohort, of all the patients undergoing surgical aortic valve repair, more than 50% had severe aortic valve insufficiency with or without consequential significant left ventricular strain and/or dilation, which demonstrated significant progression of acute post-procedural aortic valve insufficiency. It is expected that in patients with greater grade of acute post-procedural aortic valve insufficiency a larger tissue injury occurred during balloon aortic valvuloplasty. Notwithstanding, aortic valve insufficiency was acceptably tolerated in our cohort in the follow-up, while the progression of valve dysfunction due to greater tissue injury might have been the reason for earlier reintervention.

Wide array of risk factors across different studies witnesses the need to conduct a large-number multi-centre analysis in order to revise old and formulate a new, contemporary guideline for management of these patients, especially with the emergence of the new techniques in transcatheter treatment in selected paediatric congenital aortic valve stenosis patients.[28] This only emphasises the need for large-scale, randomised, multi-center prospective trials in this group of patients.

There are several limitations of our study. Most importantly, this was a single-centre study of a retrospective nature, with a small cohort of patients, which have reduced the statistical power and resulted in high hazard ratios with wide confidence intervals. Further on, we have focused on immediate post-interventional factors, and have not taken into account subacute or chronic changes in aortic valve which might contribute to the outcome. Also, the criteria for the reintervention were made on case-by-case basis, in consultations with cardiac surgeons. Still, our results are consistent with previous findings in the literature and provide clinically relevant information that needs to be confirmed in a larger, prospective study.

In conclusion, balloon aortic valvuloplasty proves to be a safe and effective treatment modality for congenital aortic valve stenosis. Acute post-procedural aortic valve insufficiency and/or residual gradient independently confer higher risk for reintervention. These findings should inform the operator in decision making and balancing benefit/risk ratio when planning primary balloon aortic valvuloplasty in paediatric patients with congenital aortic valve stenosis, but also inform counselling and careful evaluation of patients before and after the balloon aortic valvuloplasty.

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Conflicts of interest. None.

Ethical standards. 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, and has been approved by the Ethics Committee of the University Children's Hospital in Belgrade, Serbia.

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