DOI: 10.2298/SARH1402017P
UDC: 616.132-007.271-089.819.1

Balloon Valvuloplasty as a Treatment of Congenital Aortic Stenosis in Children and Adolescents

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SUMMARY

Introduction Balloon valvuloplasty (BVP) is one of the primary therapies for congenital aortic stenosis in children and adolescents. The aim of this interventional procedure is to gain time before possible surgical therapy (aortic valve replacement) until adulthood.

Objective The aim of this study was to evaluate the efficacy, safety and mid-term results of transcatheter BVP in children and adolescent in our Center.

Methods From 2004 to 2011, 50 patients, aged 18 days to 18 years (mean 6.3 years) underwent BVP. Retrospective analysis of the echocardiographic and hemodynamic parameters were performed before and after procedure, especially peak pressure gradient (PG) across the aortic valve, semiquantification of the aortic regurgitation (AR) after the BVP as well as the left ventricle dimensions and functions.

Results The mean peak PG in the whole group decreased from 74.80±27.72 mm Hg to 27.86±13.04 mm Hg ($p<0.001$) after BVP. In 39 patients (78%), residual PG was lower than 30 mm Hg just after dilation. At the end of follow-up period, 25 patients (50%) had PG above 50 mm Hg, measured by Doppler technique, and four of them underwent re-dilation. Eight patients (16%) had severe AR. During the follow-up period (12-80 months, mean 51 months), six patients (12%) were referred to cardiac surgeons for aortic valve replacement or Ross procedure.

Conclusions This retrospective study analyzes our first experience of BVP as primary therapy of the congenital aortic stenosis. The results confirmed that BVP effectively postponed the need for surgery in children and adolescents toward the adulthood.

Keywords: congenital aortic stenosis; balloon valvuloplasty; children

INTRODUCTION

Balloon valvuloplasty (BVP) is one of the therapeutic solutions in the initial treatment of the congenital aortic stenosis in children and adults [1-6]. This interventional procedure is alternative to surgical valvotomy (commissurotomy). Both procedures usually serve as the first step in treatment of infants and children with the aortic stenosis (AS), tending to postpone definite surgery (i.e. artificial valve replacement) until the adulthood [2, 5]. Although BVP is well-known and accepted method in treatment of AS, there are still controversies about advantages and disadvantages of BVP compared to the surgical valvotomy, regarding successfulness (residual stenosis), complications (i.e. aortic regurgitation) and long-term results. Distinctions between these two procedures were summarized in Table 1.

OBJECTIVE

The aim of this study was to evaluate the efficacy of BVP in children with a severe congenital aortic stenosis based on our own data, to analyze reliability of the method and frequency of serious complications as well as to estimate long-term success of BVP based on freedom from surgery.

METHODS

Fifty children and adolescents with the congenital aortic stenosis, treated with BVP in the period between October 2004 and June 2011 at the University Children's Hospital in Belgrade, were included into retrospective analysis.

The major criteria for BVP procedure was the maximum pressure gradient (PG) measured across the aortic valve, achieved by echocardiography, and other criteria were the presence of heart failure, impaired systolic function of the left ventricle or increased myocardial hypertrophy and the presence of effort related symptoms.

All patients were examined by echocardiography at three different occasions: immediately prior to heart catheterization, the day after BVP and on the last check-up visit during follow-up. Concerning the amount of echocardiographic parameters, the following were analyzed for the purpose of study: left ventricular wall thickness and mass (end-diastolic and end-systolic), assessment of systolic function by fractional shortening (FS), dimensions of aortic annulus

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Table 1. Advantages and disadvantages of balloon valvuloplasty compared with surgical valvotomy

Procedure	Advantages	Disadvantages
Balloon valvuloplasty	– avoidance of CPB – short hospitalization – avoidance of chest opening	– uncontrolled valvotomy (higher incidence of aortic regurgitation) – local complications (femoral artery thrombosis)
Surgical valvotomy	– valvotomy under visual control (lower incidence of aortic regurgitation)	– weaning from CPB (especially in newborns with the congestive heart failure) – higher residual stenosis

CPB – cardiopulmonary bypass

indexed to body surface, the maximum PG measured across the aortic valve, and the degree of aortic regurgitation assessed by semi-quantitative method.

Interventional catheterization was performed in all patients after detailed explanation of the procedure and obtaining the parental informed consent form. All patients were treated under general anesthesia, and previously were administered antibiotics according to recommended infective endocarditis prevention. Arterial access was obtained through the femoral artery (catheter was placed retrogradely through the stenotic valve into the left ventricle). The heparin was intravenously injected immediately after the puncture of femoral artery (in a single dose of 75-100 IU/kg), and continuous heparin infusion was extended in the next 18-24 hours (15-20 IU/kg/h).

Aortography and left ventriculography, conducted before the intervention, enabled adequate choice of the initial balloon catheter size. Thus, the appropriate initial balloon catheter size was 1-2 mm smaller than the diameter of the aortic valve annulus. In the majority of patients older than one year, during the balloon inflating, the fast right ventricle stimulation was performed with the frequency of 220-250 beats/min (through the temporary pacemaker wire which was inserted through the femoral vein), with the purpose to stabilize the balloon catheter. In case of an inadequate fall in PG recorded after the initial dilation, procedure was repeated by using balloon catheter 1-2 mm larger than the first one. In this study, the following parameters achieved by catheterization were analyzed: diameter of the aortic valve annulus, annulus size to balloon catheter size ratio, PG between aorta and left ventricle measured by the direct manometry before and after BVP, as well as degree of the aortic regurgitation before and after the intervention.

For the purpose of determination of the safety of method, development of some of the following complications in patients before and immediately after the intervention was particularly analyzed: serious arrhythmia during the procedure, severe aortic regurgitation after BVP, need for blood transfusion or transfer to intensive care unit after the intervention or thrombosis of femoral artery.

At the end of the follow-up period, degree of the residual aortic stenosis and aortic insufficiency were analyzed, as well as freedom from surgery (artificial valve implantation or Ross procedure), as parameters of efficacy of procedure. In patients who were referred to surgical intervention, period between BVP and operation, as well as factors that contributed to surgical intervention were analyzed.

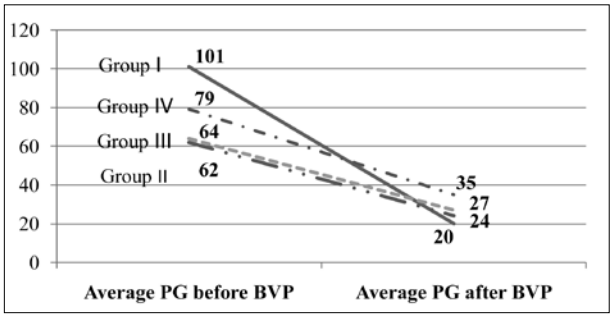
Statistical analyses of data were performed by using the student's t-test and χ square-test. Furthermore, freedom from surgery result was achieved by Kaplan-Meier curve analysis. All data were analyzed using SPSS program (version 17.0).

Table 2. Demographic and diagnostic data of analyzed population

Parameter		Number of patients (%)		
Sex	Male	37 (74.0)		
	Female	13 (26.0)		
Age	0-3 months (Group I)	9 (18.0)		
	3-12 months (Group II)	8 (16.0)		
	1-10 years (Group III)	18 (36.0)		
	10-18 years (Group IV)	15 (30.0)		
Severity of the aortic stenosis before BVP (according to PG measured invasively during catheterization)	38-50 mmHg (Group A)	6 (12.0)		
	51-80 mmHg (Group B)	26 (52.0)		
	>80 mmHg (Group C)	18 (36.0)		
Severity of the residual aortic stenosis just after BVP (according to PG measured invasively during catheterization)	<30 mmHg	39 (78.0)		
	31-50 mmHg	8 (16.0)		
	>50 mmHg	3 (6.0)		
			Balloon/aortic annulus ratio (measured by ECHO)	
Severity of the aortic regurgitation at the end of follow-up compared to the ballon size	None (trivial)	19 (38.0)	0.90	NS
	Mild (grade I)	10 (20.0)	0.91	NS
	Moderate (grade I to II)	13 (26.0)	0.89	NS
	Significant (more than grade II)	8 (16.0)	0.87	NS

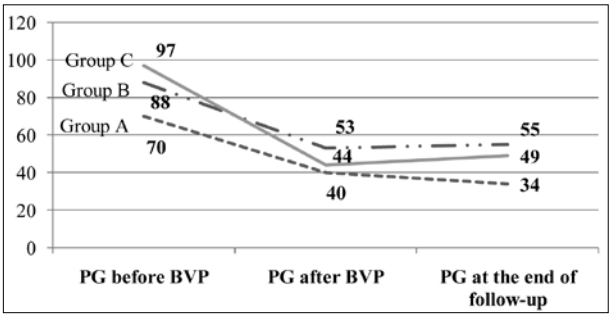
BVP – balloon valvuloplasty; PG – pressure gradient

doi: 10.2298/SARH1402017P



Graph 1. Average peak pressure gradient (PG) among different age groups before and after balloon valvuloplasty (BVP), measured by catheterization

Group I: age 0-3 months; Group II: age 3-12 months; Group III: 1-10 years; Group IV: 10-18 years



Graph 2. Average peak pressure gradient (PG) among different groups according to severity of stenosis, measured before balloon valvuloplasty (BVP), just after procedure and at the end of follow-up period (by ECHO)

PG before procedure: Group A – 38-50 mmHg; Group B – 51-80 mmHg; Group C – >80 mmHg (according to catheterization measurements)

RESULTS

From October 2004 to June 2011, a total of 52 children and adolescents underwent BVP of the aortic valve at the University Children's Hospital (later on, two patients were lost during the follow-up). Among 50 patients, there were 37 boys (74.0%) and 13 girls (26.0). At the time of intervention, the youngest patient was 18 days old, and the oldest 18 years old (mean age 6.3 years). Age distribution of patients was presented in Table 2.

Peak pressure gradient at the aortic valve, measured by echocardiography, was 44-143 mm Hg (mean 88.90±20.65). Two neonates with the critical aortic stenosis had dilated left ventricle with diminished systolic function (FS<0.28) and clinical signs of heart failure, while in all other patients, size and systolic function of the left ventricle were normal before BVP. Myocardial hypertrophy indexed to body surface was present in 36 patients (72.0%).

Peak pressure gradient at the aortic valve measured by direct manometry during catheterization ranged from 38 mm Hg to 145 mm Hg (mean 74.80±27.72 mm Hg). Considering severity of obstruction, patients were categorized into three groups (Table 2). Most patients (44 of them or 88.0%) had relatively severe stenosis with peak PG across the aortic valve higher than 50 mm Hg, under sedation and general anesthesia.

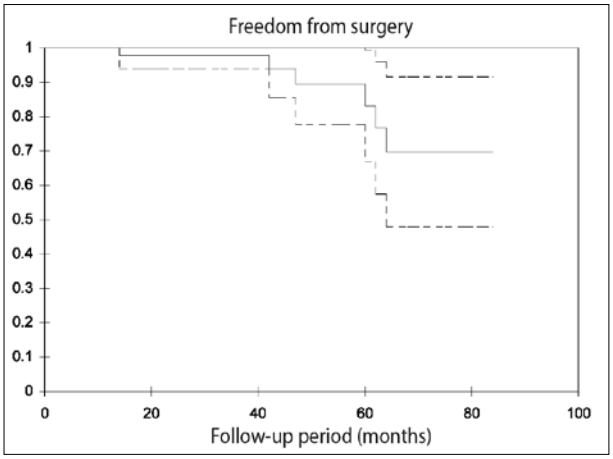
Residual peak PG at the aortic valve measured by direct manometry at the end of procedure was from 7 to 68 mm Hg (mean 27.86±13.04). Most patients (39 of them or 78.0%) had residual gradient less than 30 mm Hg (Table 2). The best results were achieved in the youngest group (infants bellow 3 months), while no significant differences were found among other age groups (Graph 1).

At the end of the follow up period, half of patients (25 of them or 50%) had peak residual PG more than 50 mm Hg. There was no significant difference among groups according to severity of stenosis before dilation (Graph 2). BVP was repeated in four patients with the highest residual PG (9 to 48 months after the first BVP, mean 24.75 months), and only one of them had high residual PG after the second intervention, which required surgical correction.

Degree of aortic regurgitation (AR) was estimated by echocardiography. The distribution of patients according to severity of AR at the end of the follow up period (the last echocardiography examination) was shown in Table 2. More than a half of patients (29 of them or 58.0%) had trivial or mild AR, moderate AR was present in 13 patients (26.0%) and 8 patients (16.0%) had significant AR.

The number of patients with complications during or immediately after BVP was minor. Two patients (4.0%) had severe arrhythmias during procedure (only one required treatment, while another was spontaneously converted to the sinus rhythm), and two more patients (4.0%) required blood transfusion after the procedure. One patient (2.0%) had procedural complication (rupture of the guide wire), resolved during the same catheterization, and did not require surgical intervention. Due to hemodynamic instability, one newborn was transferred to the intensive care unit during the first 24 hours after the procedure, while all other patients were transferred back to the cardiology department after the procedure. None of the patients had complications at the site of the artery puncture (i.e. femoral artery thrombosis), and none of the patients had severe aortic regurgitation which required early surgical intervention.

At the end of follow-up period, which was 51 months on average (12-86 months), 44 patients (88.0%) had moderate residual stenosis and/or moderate aortic regurgitation,



Graph 3. Kaplan-Meier curve depicting freedom from surgery in study group of 50 patients with the congenital aortic stenosis after balloon valvuloplasty

Table 3. Data of patients requiring surgery during follow-up: age at BVP, PG measured by ECHO and catheterization before BVP, residual PG and AR at the last ECHO control, time between BVP and surgery and type of surgery

Patient	Age at BVP	PG ECHO	PG CATH	Residual PG ECHO	AR	Time to surgery (months)	Type of surgery
1	1 month	87	84	45	+3	64	Ross
2	6.5 years	90	65	38	+3	42	Ross
3	8.5 years	72	50	71	+2	60	AVR
4	16.5 years	77	58	69	+3	14	AVR
5	3 month	98	130	56	+3	62	Ross
6	10 years	104	74	66	+2	47	AVR

BVP – balloon valvuloplasty; PG – pressure gradient; AR – aortic regurgitation; ECHO – data obtained by echocardiography; CATH – measurement obtained by catheterization; Ross – Ross procedure; AVR – artificial valve replacement

without significant left ventricular hypertrophy or dilation, and without clinical symptomatology, so they have not been candidates for surgical intervention yet. Freedom from surgery was shown in Graph 3.

Six study patients (12.0%) were operated, three had Ross procedure and three had artificial aortic valve implantation (Table 3). Period from BVP to surgery in these patients varied from 14 to 64 months (mean 48.17±18.92). Table 3 shows age of patients during initial BVP, period from BVP to surgery and main indication for surgery.

DISCUSSION

The initial treatment of congenital aortic stenosis in children can be either surgery (commissurotomy) or interventional catheterization procedure (BVP). Many studies in the last few decades compared safety and efficacy of these two methods and concluded that BVP had absolute advantage in newborns and young infants with heart failure because of avoidance of cardiopulmonary bypass, while in other children and adolescents the method of choice is up to experience of certain cardiology and cardiac surgery center [1, 2, 3, 5, 7, 8].

This study analyzed first seven years of experience of our institution with BVP of the aortic stenosis in children. Out of 50 patients one third was younger than one year, and 9 of them (18.0%) were younger than 3 months. Whenever clinical condition of a patient allowed, BVP was performed after the neonatal period, because of significantly higher incidence of complications reported (like femoral artery thrombosis or need for reintervention) in children younger than one month [6, 9]. Only in two patients BVP was done during the first month of life as emergency procedure because of severe systolic dysfunction of the left ventricle and heart failure.

The final criterion in decision-making for BVP was peak pressure gradient (PG) at the aortic valve above 60 mm Hg, while other criteria in decision-making for optimal time of the procedure were the clinical signs of heart failure, left ventricular dysfunction, myocardial hypertrophy and/or fatigue during exertion. Only one patient underwent BVP though PG was less than 50 mm Hg, but this patient was one of the most difficult patients in this study (a newborn with the critical aortic stenosis, severe left ventricular dysfunction, and falsely low PG).

It is well known that values of PG obtained by echocardiography are different from those obtained by direct manometry during cardiac catheterization for at least two reasons [2-5]. The first, PG obtained by cardiac catheterization is maximal pressure difference (so called "peak to peak" gradient) which does not occur simultaneously in real time cardiac cycle, while Doppler echocardiography measures the highest pressure difference in certain moment of time. The second reason is the fact that echocardiography measurements are obtained while the child is awake and more or less excited, while PG during the catheterization is obtained under the conditions of sedation and general anesthesia. In our study, peak echocardiography PG was slightly higher than that measured during cardiac catheterization (average 88.9±20.65 vs. 74.80±27.72 mm Hg, $p<0.001$).

Though PG obtained by echocardiography is used in long term follow up because of simplicity and safety, for the estimation of immediate result and efficacy of BVP, we used residual PG obtained by direct manometry (catheterization), just after the intervention. Most of authors agree that good result after BVP is if residual PG is less than 30 mm Hg [2-6]. If the residual PG is higher (especially more than 40 mm Hg), the suggestion is to try dilation again with 1-2 mm larger balloon, if there is no significant aortic regurgitation after the first attempt. Using this criterion, we can say that in our study BVP was successful in 78.0% patients. At the remaining 11 patients, residual gradient was not optimal, though there was a significant fall in PG values comparing to the initial PG. We decided not to perform another BVP with larger balloon in these 11 patients, because of major aortic regurgitation or their young age. During the follow up period, BVP was performed again in 4 of these 11 patients, 9 to 48 months after the first interventional procedure (mean 24.75 months). Good results were achieved in 3 patients, while only one patient had to undergo surgery after the second BVP.

The results of our study are comparable with other studies regarding average PG, which was reduced from 74.80±27.72 mm Hg to 27.86±13.04 ($p<0.001$). Efficacy of BVP, measured by degree of residual PG did not depend on patient's age, but on severity of stenosis before the intervention. In a large multicenter study from many German centers [6], an average value of peak PG in the studied group dropped from 65±24 mm Hg to 26±16 mm Hg (though in this study, out of 1004 patients 58.2% were

younger than one year). In another large study from Boston authors, which evaluated 563 patients with similar age distribution like in our study, 51% of patients had residual PG less than 30 mm Hg after BVP while 21% (108 patients) had residual PG greater than 40 mm Hg [4]. Author's opinion is that in newborns with the critical aortic stenosis and clinical signs of heart failure one should not strive for obtaining perfect result, but for reducing PG enough to achieve relief to the left ventricle without producing major aortic regurgitation.

Significant aortic regurgitation is the most common and most serious complication during BVP [1-9]. For this reason, procedure should be started with the balloon diameter 1-2 mm smaller than aortic annulus. Mild to moderate aortic regurgitation (AR) is usual after the uncontrolled splitting of the valve after dilation but generally is not significant hemodynamic problem in these patients. On the other hand, major aortic regurgitation is one of the most important reasons for surgery (artificial aortic valve implantation or Ross procedure) [10]. In our study, 8 patients (16) had significant AR and four of them had to be operated, while other four are still at regular follow up because they are without symptoms or significant hemodynamic consequences (i.e. left ventricular dilation or divergent blood pressure).

For many years it was believed that the degree of the aortic regurgitation after BVP was directly related to the size of the balloon, but many large studies rejected this correlation [4-6]. On the other hand, long term follow ups have shown that significant residual stenosis is a more frequent cause for early surgery than AR, and is also much poorly tolerated by patients than moderate AR (limited physical activity, inability for sport competition). So, the conclusion of these studies was that in case of borderline residual PG (between 30 and 40 mm Hg), it might be better to choose dilation with larger balloon diameter than leave such significant residual gradient unsolved [4, 5, 6]. One of the important factors that may contribute to the reduction of AR due to BVP is the stabilization of the balloon during the inflation, so some centers use temporary pacing in the majority of patients (except in young infants) [6]. The degree of AR also depends on patient's age, because it has been proven that adolescents have more severe AR before dilation than infants and small children, most probably because of valve degeneration [6]. Our study also failed to find correlation between the size of the balloon compared to aortic annulus and the degree of the aortic regurgitation (Table 2).

Other complications during BVP in this study were rare, two patients required blood transfusion, and one patient needed conversion of ventricular tachycardia. In our study, the safety of the procedure was confirmed by the fact that all patients but one were returned to the cardiology ward immediately after the procedure (intensive care was not necessary) and most of them was discharged the following day after the intervention. There were no patients with the occlusion of the cannulated femoral artery, due to the protocol by which all patients, apart from the bolus of heparin during the intervention, received continuous infusion of heparin 18-24 hours after the procedure.

The main goal of this study was to estimate the efficacy of the procedure during the midterm follow up based on the freedom from surgery. The basic purpose of BVP in childhood is to postpone surgery as much as possible, either artificial valve implantation or complex Ross procedure. During the follow up period lasting from 12 to 86 months (average 51±22.73 months), only 6 patients (12.0%) had to be operated on. Main reason for surgery in three patients was a significant aortic regurgitation, two had severe residual stenosis, and one had both severe stenosis and regurgitation. Surgery was performed within the period of 14-64 months after BVP (mean 48.17±18.92), meaning that even in these children such interventional procedure delayed artificial valve implantation or Ross procedure for average 4 years. In other patients (44 of them or 88.0%), degree of residual aortic stenosis and/or regurgitation is mild to moderate, they have no symptoms, and therefore, at this point there are no definite indications for surgery.

Our results are in accordance with much larger worldwide studies. One of the largest studies conducted in 20 German, Austrian and Swiss centers analyzed 1004 children and adolescents who were submitted to BVP in 21-year period [6]. Freedom from surgery in this big cohort study was about 70% in 5 years after BVP, and about 50% in 10 years after the intervention. Similar results were published by Boston group of authors (563 patients for the period of 23 years) – freedom from artificial valve implantation was 90% in the first 5 years, and 79% in 10 years after BVP [4].

CONCLUSION

Initial experience of our center confirm that BVP of aortic valve is efficient and safe method in children and adolescents with the congenital aortic stenosis. Though in most cases this is not a final treatment, BVP enables normal physical activity of these patients and good effort tolerance, as well as a significant time delay towards the adulthood of the final surgical intervention.

Despite the fact that BVP is world widely accepted as reliable method of the congenital aortic stenosis treatment, there are still no exact criteria in decision making for optimal first step in treating these children. The choice between BVP and surgical commissurotomy remains the decision of each individual center, based on exchange of experiences and agreement among interventional cardiologists and cardiac surgeons.

The primary limitation of this study was a period of follow up, which is rather short, and secondary limitation is the fact that this was a retrospective study. In addition, in seven year follow up period, surgical commissurotomy was performed in only 7 patients in our center, so the results of these two methods cannot be compared.

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Балон-валвулопластика у лечењу конгениталне аортне стенозе код деце и адолесцената

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КРАТАК САДРЖАЈ

Увод Балон-валвулопластика (БВП) је једна од примарних терапијских опција код деце и адолесцената с конгениталном аортном стенозом. Њена улога је у растерећењу леве коморе срца и одлагању уградње вештачке валвуле до одраслог доба.

Циљ рада Циљ рада је био да се ретроспективно анализирају делотворност и сигурност БВП код деце и адолесцената с конгениталном аортном стенозом који су лечени у нашем центру.

Методе рада У раду је анализирано 50 болесника узраста од 18 дана до 18 година (просечно 6,3 године) код којих је у периоду 2004–2011. године урађена БВП на Универзитетској дечјој клиници у Београду. Код свих болесника анализирани су параметри добијени ехокардиографијом и катетеризацијом пре и после БВП, првенствено максимални градијент притиска (ГП) на аортној валвули, степен аортне регургитације (АР) после интервенције и величина и функција леве коморе.

Резултати Просечна вредност ГП после БВП смањена је са 74,80±27,72 *mm Hg* на 27,86±13,04 *mm Hg* ($p<0,001$). Код 39 болесника (78%) резидуални ГП је непосредно после дилатације био испод 30 *mm Hg*. На крају испитивања 25 болесника (50%) имало је ехокардиографски ПГ већи од 50 *mm Hg*, а код четворо њих била је потребна поновна интервенција. Осам болесника (16%) имало је релативно значајну АР. На крају периода испитивања, који је просечно трајао 51 месец (12–86 месеци), шест болесника (12%) је подвргнуто хируршком лечењу (уградња вештачке валвуле или операција према методи Роса).

Закључак Почетна искуства нашег центра потврђују да је БВП аорте ефикасна и сигурна метода у лечењу деце и адолесцената с конгениталном аортном стенозом, која им омогућава значајан период одлагања коначне хируршке корекције до одраслог доба.

Кључне речи: конгенитална аортна стеноза; балон-валвулопластика; деца

Примљен • Received: 17/01/2013 **Прихваћен • Accepted:** 17/04/2013