PERCUTANEOUS BALLOON AORTIC VALVULOPLASTY IN CHILDHOOD

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We assessed the effectiveness of aortic balloon valvuloplasty (AoVP) in 34 children who were admitted for aortic valve balloon dilatation over 7 years (Feb 1997-Feb 2004) in two institutions (Stuttgart and Zagreb). There was a prevalence of male children (28/6; p<0.01), mean age at dilatation 35.55±55.59 months (mean ± SD, min 1 day, max 14.2 years) and mean body weight 13.1±15.9 kg (min 2640 g, max 57 kg). Patients were divided into two groups as follows: group 1 including neonates and small infants younger than 2 months at dilatation with criteria for critical aortic stenosis (n=18); and group 2 including infants older than 2 months at dilatation (n=16). Sixteen (47%) of all patients had no clinical symptoms, 12 (35.3%) were dyspneic at rest and sweating at feeding (NYHA III), and 6 (17.6%) had severe heart failure (NYHA IV). All NYHA IV patients were in group 1 (n=6) *versus* 0 in group 2 (p<0.05). According to ECHO estimation, left ventricular (LV) function was normal in 16 (47%), moderately limited in 12 (35.3%) and severely impaired in 6 (17.6%) patients. All patients with severely impaired LV function belonged to group 1 (n=6) *versus* 0 in group 2 (p<0.05). Balloon dilatation was performed retrogradely *via* the percutaneous femoral artery approach in all except one patient in which the balloon catheter was introduced anterogradely *via* the mitral valve (MV). Indexed aortic valve-annulus/body surface area (BSA) (mm/m^2) was 30.97±10.02) (max 47.5, min 12.02) for overall study sample, 37.60±5.99 in group 1 and 23.03±7.86 in group 2 (group 1 *vs.* group 2, p<0.05). Ao/Ba ratio (mm) was 0.85±0.09 for overall study sample, 0.81±0.11 for group 1 and 0.89±0.05 for group (group 2 *vs.* group 1, p<0.01). Immediately after dilatation, the mean systolic pressure gradient across the aortic valve decreased from 70.62±20.78 (max 120, min 45 mm Hg) to 20.03±13.7 (max 65, min 0 mm Hg) in the whole study group (p<0.05), from 73.23±21.57 (max 120, min. 50 mm Hg) to 15.25±11.09 (max 40, min 0 mm Hg) in group 1 (p<0.05), and from 67.78±20.21 (max 111, min 45 mm Hg) to 24.81±14.71 (max 65, min 10 mm Hg) in group 2 (p<0.05) (catheter measurement). Follow-up results were studied in 31 (91%) patients at 3.5-84 months (20.91±22.19) after AoVP and revealed continuously increasing residual aortic valve gradient (31.35±12.01, max 50, min 15 mm Hg), still being significantly lower (p<0.001) than before valvuloplasty. The overall actuarial survival rate after 7 years was 91%. Freedom of three categories (any reintervention, surgical reintervention, and re-dilatation) was 77, 74, 61; 87, 84, 77; and 90, 90, 83 at 2, 4 and 7 years for the total number of patients, respectively. The actuarial freedom for the same categories in group 1 *vs.* group 2 was 72, 67, 56 *vs.* 87, 87, 75 (p<0.05); 89, 83, 78 *vs.* 87, 87, 75 (NS); 83, 83, 78 *vs.* 100, 100, 94 (p<0.05) at 2, 4 and 7 years. The degree of aortic regurgitation immediately after catheterization did not significantly increase; only 1 patient developed moderate aortic regurgitation, which was treated with surgical valve reconstruction on day 1 after intervention. At follow-up, aortic regurgitation increased to grade 3 in 3 (10%) and to grade 2 in 7 (23.3%) patients. All three patients with high grade of aortic insufficiency were from group 1 *vs.* 0 in group 2 (p<0.05). Eight (26%) patients required reintervention, 4 (13%) balloon valvuloplasty plus surgery, and 4 surgery only. Of 8 patients requiring surgery, 4 (13%) were operated on during a period of 27-78 months and 4 within one month after dilatation. One patient died one week after dilatation, re-dilatation and surgery due to fibroelastosis (confirmation by histology). *Conclusion:* Percutaneous balloon valvotomy provides an effective palliative interventional method in the treatment of infants and children with aortic valve stenosis. The majority of problems in the early and late period after dilatation appear in the group of patients with critical aortic stenosis.

Key words: aortic stenosis, interventional catheterization, balloon aortic valvuloplasty, neonates, infants, children, outcome, immediate and mid-term follow-up

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INTRODUCTION

Since the first description in 1983 (1), aortic balloon valvuloplasty has been accepted as a form of first-choice treatment of aortic stenosis in children. The effectiveness of the method in gradient reduction was published for children with congenital aortic stenosis as short-term (2,3), mid-term (3,4) and long-term results (5,6). Dilatation of critical aortic stenosis was performed for the first time in 1986 (7) and since has been established as a palliative method of choice for newborns and young infants (8,9) despite controversial discussion in the literature about surgery and percutaneous dilatation (10). Patients with critical aortic stenosis that require balloon dilatation very early have a high rate of early re-intervention and have a poorer outcome than those requiring the procedure later (8,11,12). Our study aimed to evaluate the mid-term results of percutaneous balloon valvuloplasty in 34 children during a 7-year period, including the subgroup of children with critical aortic stenosis.

PATIENTS AND METHODS

Patients and criteria

This retrospective study reviewed 34 patients who admitted for valve balloon dilatation during a 7-year period (from February to February 2004) at two institutions (Stuttgart and Zagreb). Indication for the procedure was based on clinical symptoms, patient presenting with syncope and left ventricular (LV) strain on electrocardiography (ECG) independent of transvalvular gradient. Early balloon dilatation was indicated in a subgroup of neonates and small infants younger than 2 months (group 1). They had clinical criteria (presence of low cardiac output, cardiogenic shock, heart failure, need of inotropic support or mechanical ventilation, prostaglandin dependency) and echocardiographic criteria (morphological evidence of LV hypertrophy, depression of LV function, see the criteria below*)* for critical aortic stenosis, irrespective of transvalvular gradient. This group included age-matched patients with (and/or) a Doppler gradient >70 mm Hg and those with preserved LV function. Group 2 included all patients older than 2 months at dilatation.

Cardiovascular condition was assessed by *the New York Heart Association (NYHA)* criteria, i.e., NYHA III (defined as dyspnea at rest and sweat at feeding) and NYHA IV (as presence of low cardiac output, severe cardiac failure) for neonates. Ventricular function before dilatation was estimated by *echocardiogram (echo*); fractional shortening (FS) by more than 30% was estimated as normal (despite LV hypertrophy), FS 20%-29% as moderately limited, and FS <20% as severely restricted. Annulus diameter was measured on echocardiography and angiocardiography with a smaller size chosen as reference. Balloon diameter/aortic valve size were indexed to body surface area (Figure 1, Table 1).

Valvoplasty

All procedures were performed in analgosedation or general anesthesia *via* the percutaneous femoral artery approach except for one patient in whom the balloon

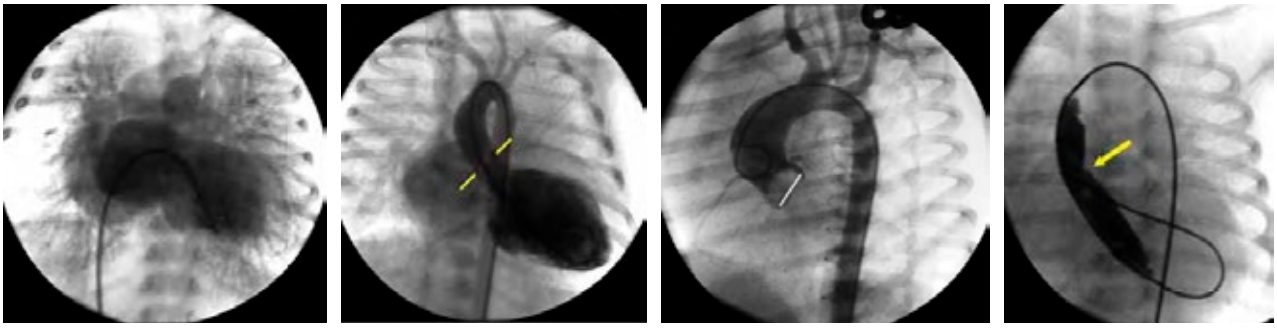

Figure 1. *Critical aortic stenosis*

A*. Angiographic presentation (pre-dilatation); congestive heart failure, pulmonary congestion, enlargement of LA and LV, massive mitral insufficiency, need for inotropic support, pulmonary arterial hypertension, PGE1 dependency* ***B****. Immediately after dilatation; mild mitral insufficiency, LA enlargement, LV hypertrophy (and enlargement), enlargement of ascending aorta (bicuspid aortic valve).* ***C.*** *Difficulties with introduce of balloon catheter into the LV; special guidewires, special catheters, using „washout" phenomen, retrograde femoral artery approach, carotid artery approach or anterograde (via PFO-LA-MV-LV-AO). Importance of aortic ring measurement and balloon selection and calculation of balloon/aortic rig ratio (0,81-0.89).* ***D.*** *Balloon inflation technique; pressure 4-6 bar, quickly (< 5 sec), cum Adenosine use, general anesthesia and analgosedation, ductus dependency (PGE_1 use) – incisura on the level of aortic valve during inflation of balloon (yellow arrow).*

Table 1. *Clinical and echocardiographic features in the two patient groups*

Variable (±SD)	Overall	Group 1 <2 months	Group 2 ³2 months	p value
Median age at dilatation (months)	35.55 (55.59)	0.64 months (19 days)	74.78 (60.39)	
Median weight (kg)	13.1 (15.9)	3 666 g (4.280)	24.44 (18.09)	
Median BSA (m2)	0.51 (0.44)	0.25 (0.02)	0.85 (0.46)	
No clinical symptoms	16	7	9	NS
NYHA III	12	6	6	NS
NYHY IV	6	6	0	P<0.01
Normal LV function	16	7	9	NS
Moderately limited LV function	12	6	7	NS
Severely limited LV function	6	6	0	P<0.01
Serious procedure complications	7	5	2	NS
Early death	1	1	0	NS
Severe AO insufficiency on follow-up (Gr ³3)	3	3	0	P<0.01
Severe limitation of LV on follow-up	10	6	4	?

Table 2. *Immediate and follow-up mid-term results of dilatation*

Variable: mean ± SD	Overall (N=34)	Group 1 (N=18)	Group 2 (N=16)	p value
Gradient before dil. (mm Hg)	70.62 (20.78)	73.23 (21.57)	67.8 (20.21)	NS (t=0.74)
Gradient after dil. (mm Hg)	20.03 (13.7)	15.25 (11.09)	24.81 (14.71)	p<0.05 (t=2.7)
Ao/Ba Ratio	0.85 (0.09)	0.81 (0.11)	0.89 (0.05)	p<0.01 (t=2.96)
Follow-up (months)	20.91 (22.19)	19.98 (21.89)	16.50 (16.79)	NS
Gradient follow-up	31.35 (12.01)	29.4 (10.75)	33.92 (13.49)	NS (t=1.02)
Fluoroscopy time (min)	23.54 (16.31)	29.19 (19.42)	18.94 (12.02)	NS (t=1.74)
Indexed ao. annulus (mm/m^2)	30.97 (10.02)	37.60 (5.99)	23.03 (7.86)	p<0.01 (t=6.04)

catheter was introduced antegradely *via* mitral valve. The chosen balloon diameter was preferably slightly smaller. We did not use any balloon larger than aortic valve annulus (ratio balloon/annulus less than 1.0). The inflation pressure was 4-6 bar. The resulting balloon to annulus diameter ratio ranged from 0.60 to 1.00 (mean 0.85±0.09) in all study patients. The aortic annulus/body surface are (BSA) index ranged from 12.02 to 47.5 (mean 30.97±10.02). Fluoroscopy time was 23.54±16.31, range 6.7-86.6 minutes. All important differences between the two patient groups were statistically tested (Tables 1 and 2).

Echocardiography

Aortic valve gradient and development of aortic insufficiency on follow-up was estimated by continuous and pulsed Doppler from the subcostal, jugular and supraclavicular approach. The highest gradient measured was accepted. Aortic insufficiency was assessed by color flow mapping and pulsed Doppler and scored on a four-grade scale according to Moore *et al.* (4).

Follow-up

The follow-up period ranged from 3 to 84 (median 21±22) months in survivors. One patient who died was not included and two patients were lost for follow-up. All other patients had complete clinical and echocardiographic evaluation in our outpatient clinic at different intervals after intervention or operation. Follow-up data were available for 91% of patients.

Statistical analysis

Data were tested for normal distribution and displayed in ranges and as mean ± standard deviation (SD). Groups were compared by unpaired t-test. Difference in the proportion were tested by χ^2-test. Difference between the two groups was considered significant at $p<0.05$. The Kaplan-Maier estimate was used to calculate actuarial probabilities, followed by a log rank test.

RESULTS

From February 1997 to February 2004 (7 years), 34 patients underwent balloon valvuloplasty. The prevalence of male patients was significant (25/9, 73.5%; p<0.05). The patients were divided into two groups according to the criteria for dilatation. Group 1 consisted of 18 (53%) patients with the criteria for critical aortic stenosis, whereas group 2 of 16 (47%) patients had indications for balloon dilatation following the criteria described above. Clinical and echocardiographic data before dilatation are summarized in Table 1. The age at dilatation was 35.55±55.59 months (mean ± SD, min 1 day, max 14.2 years), body weight (BW) 13.1±15.9 kg (min 2 640 g, max 57 kg), BSA 0.51±0.44 (min 0.18, max 1.58 all).

Sixteen (47%) patients did not have obvious clinical symptoms before dilatation (group 1:group 2=7:9), 12 (35%) were in NYHA III (group 1:group 2=6:7), and 6 (18%) patients in NYHA IV, all in group 1 (p<0.01). Following echocardiographic and Doppler assessment, 11 (32%) patients had aortic regurgitation grade I before dilatation without difference between the two groups (5/6, p>0.05). LV function as estimated by echocardiography was normal in 16 patients (group 1:group 2=7:9), 12 had moderately limited function (group 1:group 2=6:7), while all 6 patients with severe limitation of LV belonged to group 1 (p<0.01). We think that severe limitation of LV function causes a very high level of clinical symptoms. We conclude from this analysis that our selection criteria for critical aortic stenosis were correct.

One group 1 patient died one week after dilatation, redilatation and surgery due to fibroelastosis (confirmed histologically). There were no late deaths on follow-up. Survival rate for all patients was 97%. The degree of aortic regurgitation immediately after catheterization did not significantly increase; only 1 patient developed moderate aortic regurgitation which was treated with surgical valve reconstruction on the day of intervention. Two patients developed severe aortic regurgitation on follow-up and both underwent Ross operation at 27/78 months after initial dilatation. These three patients belonged to group 1 (p<0.01). A lower degree of aortic regurgitation was observed in all (group 1/group 2) patients, as follows: competent valve in 5 (4/1), aortic regurgitation grade I in 15 (7/8) and grade II in 7 (3/4) patients. Using the criteria described above, we estimated LV function by ECHO for all and (group 1/group 2) patients, as follows: normal in 17 (10/7), moderately limited in 7 (3/4), and severely limited in 6 (6/4) patients. We did not find any statistically significant difference between the two groups with respect to LV function on follow-up. Complications during and immediately after dilatation procedure were seen in 5 patients, all in group 1. These complications were serious and included 1) left ventricular perforation by exchange guidewire without development of tamponade; 2) severe cardiac impairment during the procedure, which required inotropic support, re-dilatation, urgent Kaye-Damus-Stansel (K-D-S) operation and central AO-PA shunt; this patient died a week later (fibroelastosis, histologically confirmed), 3) supraventricular tachycardia that required medical treatment; 4) insufficiency of aortic valve grade IV caused by dilatation, surgical reconstruction of aortic valve on the same day; and 5) insufficiency of aortic valve grade II, early Ross procedure because of increasing insufficiency over the next months. In group 2, complications were recorded in two patients, including 1) arrhythmias, early surgical commissurotomy and later aortic stenosis; and 2) serious arrhythmias that required urgent drug treatment.

Balloon dilatation was performed retrogradely *via* the percutaneous femoral artery approach in all except for one patient with critical aortic stenosis (gradient 70 mm Hg, BW 3,400 g, BSA 0.22 m^2). In this patient, balloon catheter was introduced anterogradely *via* mitral valve. There were no complications except for arrhythmias during intervention. In three newborns, we had transitional pulse loss, no surgical interventions and no permanent pulse loss. Immediate results of balloon dilatation, follow-up results and some other parameters are summarized in Table 2. Immediately after dilatation, invasive mean systolic pressure gradient across the aortic valve decreased from 70.62±20.78 (max 120, min 45 mm Hg) to 20.03±13.7 (max 65, min 0 mm Hg) in the overall group (p<0.05); from 73.23±21.57 (max 120, min 50 mm Hg) to 15.25±11.09 (max 40, min 0 mm Hg in group 1 (p<0.05); and from 67.78±20.21 (max 111, min 45 mm Hg) to 24.81±14.71 (max 65, min 10 mm Hg) in group 2 (p<0.05). Follow-up term results were studied in 31 (91%) survivor patients at 3.5-84 months before valvuloplasty. Although there was no difference in aortic valve gradient after dilatation between group 1 and group 2, success in gradient reduction was favorable in group 1 as compared with group 2 (p<0.05). There were no significant differences between the two groups in follow-up time, increasing gradient on follow-up, and fluoroscopy time (Figures 1 and 2).

We found statistically significant differences in the ratio of aortic annulus/balloon

(group 1 *vs*. group 2=0.81±0.11 *vs*. 0.89±0.05; p<0.01) and indexed ao-annulus to BSA (group 1 *vs*. group 2=37.60±5.99 *vs*. 23.03±7.86; p<0.01), but this relationship was extra studied

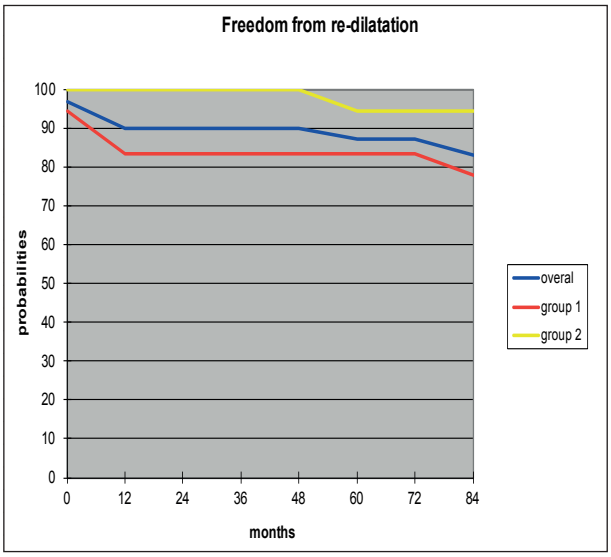

Figure 2. *Graphically presentation of immediate results of aortic valvule dilatation in two different groups. (G1 and G2).*

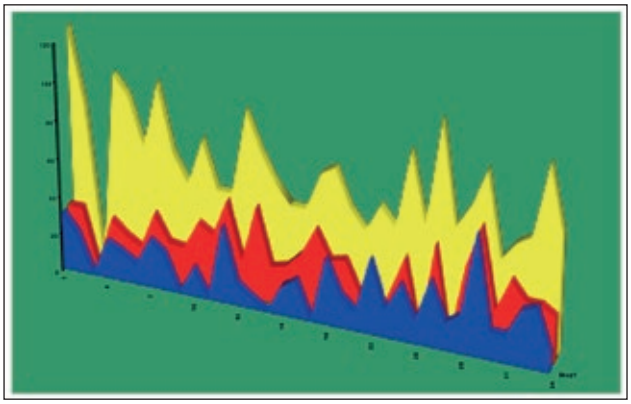

Figure 3. *Graphic presentation of valvular gradient before dilatation (yellow), immediately after dilatation(blue) and intermediate follow-up (red) for all of patients.*

Actuarial freedom analysis

The overall actuarial survival rate after 7 years was 96.6%. Three freedom categories (any re-intervention, surgical re-intervention and re-dilatation) are summarized in Table 3.

Thirty-one of 34 patients could be followed-up, 23 (75%) needed any reintervention, and 8 (26%) needed different re-interventions (4 re-dilatation and surgery, 4 surgery only). Five of them belonged to group 1 and three to group 2 (Table 2). Three of the five patients from group 1 had re-dilatation at 1, 5 and 6 months after first dilatation. All of them were finally treated surgically, i.e., one by Ross procedure 27 months after first dilatation (because of progressive development of aortic insufficiency), one by K-D-S operation with central shunt and atrial septectomy (this patient died from fibroelastosis in the second week of life), and one by commissurotomy 5 months after dilatation and by Ross procedure 78 months after dilatation (because of the progressive development of aortic stenosis and insufficiency). Two of the five patients from group 1 were treated surgically only, i.e., one by reconstruction of the aortic valve because of insufficiency grade IV after dilatation (on the same day), and one by Ross procedure 60 months after dilatation because of the development of aortic stenosis and insufficiency. One of the three patients from group 2 with re-intervention had unsuccessful re-dilatation 52 months after first dilatation and Ross procedure five months later (because of progressive aortic stenosis), one had commissurotomy 36 days after dilatation, and one had commissurotomy 1 month after dilatation and aortic homograft implantation three weeks later (Table 4).

Actuarial freedom from reintervention at two, four and seven years was 77%, 74% and 71% for overall pa-

Table 3. *Actuarial freedom from any re-intervention, re-dilatation and surgery intervention for overall, Gr1 and Gr2 at 2, 4, and 7 years.*

Reintervention	Group	2y	4y	7y	p-value
No	Overall	77	74	61	
	1	72	67	56	
	2	87	87	75	P<0.01
Re-dilatation	Overall	90	90	83	
	1	83	83	78	
	2	100	100	94	P<0.01
Surgery	overall	87	84	77	
	1	89	83	78	NS
	2	87	87	75	

Table 4. *Reintervention in 8 patients (26%)*

4 surgery (surg.) only
1. G1. AoI – gr. IV (caused by dilatation)-reconstruction on the same day
2. G1. AoS (50 mm Hg) + gr. AoI-III - Ross 60 mo. later
3. G2. surgery commissurotomy 4 months later
4. G2. surgery commissurotomy I mo. later, and Ao homograft 2 mo. later
4 redilatation (re-d.) and surgery (surg.)
1. G1. Re-d. 6 months later, Ross 27 mo. later (AOI gr III, Schone)
2. G1. Re-d. 5 days later, K-D-S 8 days later - died (fibroelastosis)
3. G1. Re-d. 3 days later, surg. commissurotomy 5 mo. later, Ross 6 ys. later (AoI, AoS)
4. G2. Re-d. after 52 months, Ross after 58 months (AoS, AoI)

AoI – aortic insufficiency, AoS – aortic stenosis

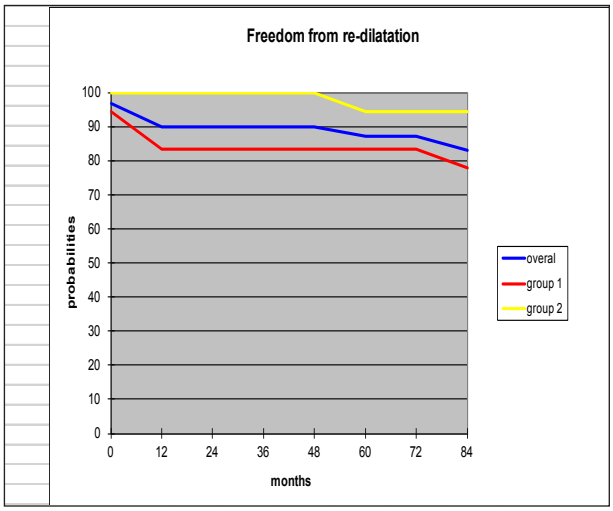

Figure 4. *Kaplan-Meier freedom curves for any reintervention for overall (77.4%, 74.2%, 61.3%), Gr.1 (72,3%, 67.7%, 55,6%) and Gr.2 (87.5%, 87.5%, 75%) for 2, 4 and 7 years*

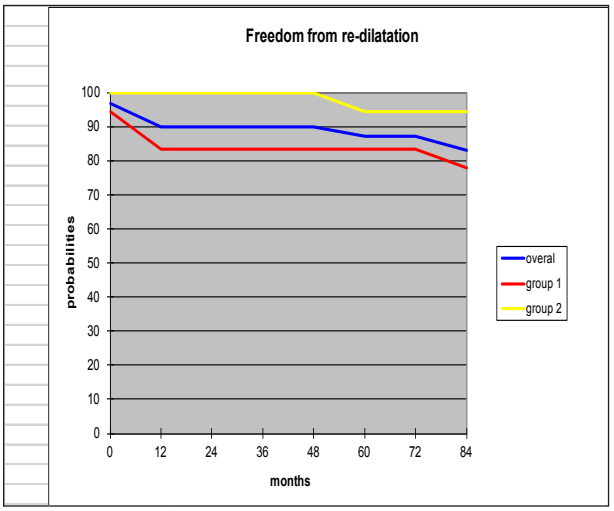

Figure 5. *Kaplan-Meier freedom curves from re-dilatation for overall (90%, 90%, 83%), Gr. 1 (83.3%, 83,3%, 77,8%) and Gr.2 (100%, 100%, 94,5%) for 2, 4 ad 7 years*

tient population, 72%, 67% and 56% for group 1, and 87%, 87% and 75% for group 2. Following Kaplan-Meier equation, there were obvious differences for re-intervention between group 1 and group 2. Group 1 patients needed re-intervention more often than group 2 patients ($p<0.01$) (Figure 4).

Actuarial freedom from re-dilatation at two, four and seven years was 90%, 90% and 83% for overall patient population, 83%, 83% and 78% for group 1, and 100%, 100% and 94% for group 2. Group 1 patients needed re-dilatation more often than group 2 patients ($p<0.01$) (Figure 5).

According to Kaplan-Meier equation, there was no difference in surgical reintervention between the two groups in time and number of surgical reoperations. Actuarial freedom from surgery at two, four and seven years was 87%, 87% and 77% for overall patient population, 89%, 83% and 78% for group 1, and 87%, 87% and 75% for group 2 ($p>0.05$ (Figure 6).

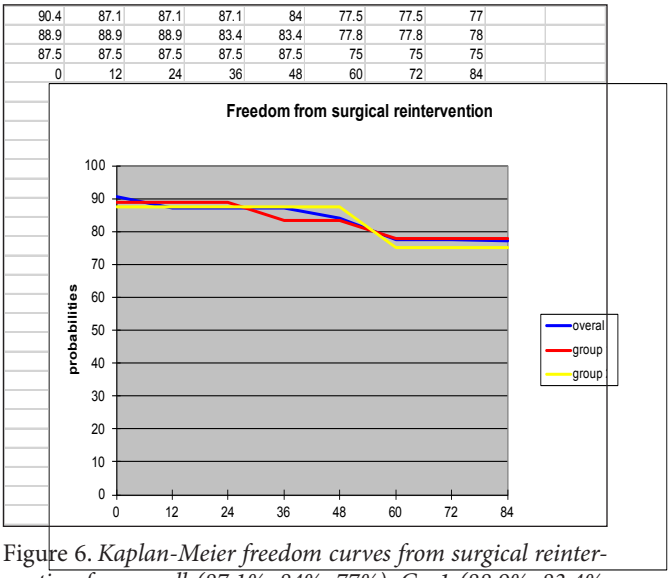

Figure 6. *Kaplan-Meier freedom curves from surgical reintervention for overall (87.1%, 84%, 77%), Gr. 1 (88.9%, 83.4%, 78%) and Gr.2 (87%, 87%, 75%) for 2, 4 ad 7 years*

DISCUSSION

Congenital aortic stenosis occurs at an incidence of 5%-6%, more common in male than in female children (13). The pathophysiological background is most commonly found in the bicuspid aortic valve (BAV), although there is a monocuspid but also an amorphous aortic valve. It is a progressive disease, especially in bicuspid aortic valve, which in adulthood is also called BAV syndrome due to usually progressive accompanying changes in the entire left ventricular outflow tract (mitral and aortic valve, ascending aorta, aortic arch, aortic isthmus). AoVP has become the method of choice in the treatment of aortic stenosis from neonatal period to adulthood, and has recently entered fetal age. Since the first dilatation of aortic stenosis in 1983 (1) and first dilatation of critical aortic stenosis in 1986 (7), both in neonatal and later age, pediatric cardiology has been of increasing interest (2-5). It has been established, in fact, as a palliative method for the treatment of aortic stenosis with the aim of postponing cardiac surgery until later childhood or already adult age. The success reports of the method refer to early (immediate) results (2-4), intermediate-term follow-up results (3,4), and then to the results of long-term follow-up

monitoring of AoVP (5, 6). Although there is still debate about justification, especially in some conditions (9), the method has nevertheless proved to be very successful, both in critical and non-critical aortic stenosis (8, 9), not only according to the degree of success but also for a relatively small number of complications (8, 11,12). The balloon dilatation technique in pediatric cardiology emerged as early as 1950 with Rubio and Limon who dilated tricuspid and pulmonary valves with a modified catheter (14). A balloon catheter with a double lumen was constructed by Gruntzig *et al.* (15). It took almost 30 years from the first heart balloon intervention to AoVP in children (1,11, 14-18). We are using the current criteria for the diagnosis of aortic stenosis, critical aortic stenosis, heart failure, ventricular function, and cardiovascular status according to the NYHA criteria listed in the Materials and Methods section (4,12,19-21).

In our study, a statistically significant difference between the two groups was clearly evident in the clinical symptoms of severe heart failure (NYHA IV), echocardiographic assessment of severe LV insufficiency, and the development of severe aortic valve insufficiency after AoVP, all to the detriment of group 1 *versus* group 2 ($p<0.01$). All procedures in our study were performed *via* the percutaneous femoral artery approach except for one patient where balloon catheter was introduced antegradely *via* mitral valve. Retrograde femoral arterial approach is most common (12, 22-25), and other approaches are rarely described and are used when the usual approach is not available for some reason, primarily in neonatal period, *via* carotid artery (26), transumbilical (27) and anterograde *via* mitral valve (28, 29). We measured immediate effects of dilatation and further development of the disease over a 7 years (mediate-term follow up at 2, 4 and 7 years). Direct pressure drop in the whole group and subgroups is shown in Table 2 and Figures 2 and 3. Gradients were measured by direct passage of the catheter through the valve. We found more severe aortic valve insufficiency in three (16.7%) patients from group 1 or 8.8% of all patients, without severe aortic insufficiency in group 2 ($p<0.01$). Data on a steeper gradient drop and higher number of aortic insufficiency in group 1 as compared to group 2 may be important in discussing improving indications for AoVP. Immediate result and mid-term follow-up are possible, as reported in different publications (2, 3, 25). The first series reported by Lababidi in 1984 shows the peak-to-peak systolic gradient across the aortic valve to have decreased form 113±48 mm Hg to 32±15 mm Hg ($p<0.001$) after AoVP. Very mild aortic insufficiency was noted in 10 (43%) patients after balloon dilatation and two patients required surgery because of high-grade aortic insufficiency. Acute results following balloon AoVP reported during a decade (1983-1992) following their description have been tabulated elsewhere (25). Similar results were reported in our study for the whole group (70.62±20.78, max 120, min 45 at 20; 0.03±13.7, max 65, min 0 mm Hg; $p<0.05$) and similar for group 1 and group 2. Rao showed early AoPV results in 10 centers in which newborns were mostly excluded, in others almost entirely similar to our group 2 with a residual gradient immediately after dilatation of 22.46 mm Hg, and in our group 2 the mean gradient was 24.81 mm Hg. In our study, Table 2 shows a statistical difference in the post-dilatation gradient between group 1 and group 2, which was due to a steeper pressure drop in LV in group 1 (group 1 *vs.* group 2, $p<0.05$). However, there was no statistically significant difference between the two groups in the gradient rising at mid-term follow up (2, 4, and 7 years). A steep gradient drop in group 1 was a possible reason for the development of post-dilatation aortic insufficiency. According to the presented results, a gradual increase of the gradient (up to a maximum of 50 mm Hg) is visible, and severe aortic insufficiency developed in three patients (see graphic presentation of events in Figure 3). In the literature, we found exact descriptions of intermediate-term follow-up by Galal (12) and in the aforementioned article by Rao, with a review of a large number of papers (25). With careful examination of the results, restenosis defined as a peak-to-peak gradient of ≥50 mm Hg was found in 23% of children, some requiring surgical valvotomy or repeat balloon valvuloplasty. The degree of aortic insufficiency remained stable during intermediate-term follow-up. There are the similar results in other publications (12, 25, 29-32).

The Kaplan-Maier estimate was used to calculate actuarial probabilities, followed by a log-rank test. All results of the actuarial freedom from any re-intervention, re-dilatation and surgery for overall patient population, group 1 and group 2 at 2, 4, and 7 years in our study are shown in Table 3 and Figures 5 and 6. Figure 1 shows that more than 60% of children after 7 years were exempted from additional interventions on the aortic valve. Group 1 children were least spared from re-interventions (about 56%), and group 2 children were spared significantly better (about 75%) ($p<0.05$). Figure 5 shows that after 7 years, about 83% of all children were spared from re-dilatation. Group 1 children were spared from re-dilatation in about 78%, and group 2 children in as much as 95% of cases ($p<0.05$). According to the presentation in Figure 6, there was no difference in the need of surgical intervention between the two patient groups in all periods of mid-term follow-up (2, 4 and 7 years). After 7 years, between 75% and 78% of children did not need surgical reintervention (NS). In Croatia, the method was introduced in 1999, and the first publication was published in 2005 (33).

The question of predictors of two important problems arises, namely, progressive post-dilatation aortic valve stenosis in long-term follow-up and immediate or rapidly progressive post-dilatation aortic insufficiency, especially in group 1. Predictors of post-dilatation progressive stenosis were studied by Galal *et al.* and Rao *et al.* (12, 31). Based on multivariate logistic regression analysis of the two groups of patients (pre-dilatation gradient >50 mm Hg and <50 mm Hg), they concluded that the main predictor of progressive post-dilatation stenosis was the residual peak-to peak gradient >30 mm Hg after first dilatation. Sholler *et al.* studied the possible influence of the dilatation technique itself on the occurrence of post-dilatation stenosis, but found no additional predictor significance in the derivation technique (34). Subsequent studies, including their own, particularly bicuspid aortic valve studies, have shown that an important factor in restenosis is conditioned by the morphology of the aortic valve itself (35).

Aortic insufficiency appears to be the most severe complication of AoVP, which is not the case in primary cardiac surgical commissurotomy (12). Among our patients, severe aortic insufficiency was developed by three patients from group 1 (16.6%). The first had AO insufficiency after re-dilation, 5 days after initial dilatation. Due to LV dysfunction, K-D-S procedure was also performed 8 days later, but the patient died and histologically fibroelastosis of the left ventricle was later demonstrated. It is not impossible that the patient was prejudiced for dilatation of the aortic valve because he had the criteria for 'borderline' hypoplastic left heart syndrome (HLHS). Two children in group 1 had re-dilatation, but one developed progressive grade III aortic insufficiency and was operated on according to Ross at 27 weeks of age. He also had the criteria for partial Shone syndrome. The third patient also underwent re-dilatation after initial dilatation, but was operated on according to Ross due to persistent insufficiency with stenosis. Galal refers to as many as seven out of 26 (28%) patients, of whom three (8%) received Ross surgery due to grade III aortic valve insufficiency. Other studies have also shown patients with progressive grade I aortic insufficiency, but the true cause has not yet been determined. The possible reasons include too high difference in post-dilatation gradient (35), mono-commissure valve with post-dilatation prolapse (36), poor or amorphous morphology of bicuspid aortic valve (12), too high ratio of balloon/aortic annulus (36, 35) excessive gradient reduction, and possible unrealistic selection of some patients for balloon dilatation (37, 38). The investigators believe that the relatively high degree of aortic insufficiency immediately after initial dilatation becomes a predictor for later development of severe aortic insufficiency. It appears, however, that children with monocuspid or markedly poor aortic valve morphology should be suggested primarily for cardiac surgery correction and not primarily for balloon dilatation. In some patients, dilatation of the aortic valve is forced in order to get rid of the left ventricle, and according to the strictest criteria, the child belongs to the HLHS, so the situation should be considered prudently.

Numerous complications have been described in the literature, such as transient bradycardia with premature extrasystole during balloon inflation, and therefore inflation in more than 5 seconds is not recommended. Blood loss with the need of transfusion, femoral thrombosis due to which anticoagulation therapy (heparin, streptokinase, thrombectomy), perforation of the myocardium and mitral valve damage, coronary artery occlusion, cerebrovascular incidents, 2 transient ischemia and 35 transient myocardial infarction are also mentioned (2, 24, 25, 35, 40). Complications in our group 1 appeared individually in 6 patients and included ventricular perforation without tamponade, severe cardiac impairment during catheterization (the patient died later), severe arrhythmias during the procedure and successful drug treatment, aortic insufficiency grade IV requiring immediate surgery, and progressive insufficiency, early Ross. In group 2, we had only two complications, in one patient arrhythmias with early post-dilatation surgery (commissurotomy and drug treatment of arrhythmia), and in the other serious arrhythmia that required drug treatment.

Although we did not show long-term follow-up for more than 7 years, we included in discussion some important research results that speak of dilatation of the aortic valve from the experience of studies that lasted a long time. Fratz *et al.* in single center long-term follow-up study (Deutsches Herzzentrum München) of AoVP reviewed 17.5 years of follow-up data on all 188 patients, dividing them into those aged <1 month and >1 months. The main attention was to find out whether AoVP efficacy at long term could be a good guideline to prevent and postpone aortic valve surgery in different groups of patients. The study showed that long-term results of AoVP of congenital aortic stenosis in pediatric patients and their efficacy in preventing or postponing aortic valve surgery was a therapeutic procedure of choice for the treatment of congenital aortic valve stenosis in pediatric patients (40). Similar results have been published from mid-term and long-term follow-up studies (2, 4, 8, 12, 22, 36). Fratz *et al.* conclude that the results of a long-term follow-up study of AoPV congenital aortic valve stenosis in pediatric patients are very good and effective in postponing aortic valve surgery. About one-third of these patients are exempted from the need of surgical approach for ten years. The results of our studies are similar. In a multicenter retrospective survey of more than 1000 patients, which included patients from Olgahos-

pital (Stuttgart), as did out study, Ewert *et al.* (41) show a high survival rate. The results of mid-term follow-up and long-term follow-up are similar to the results of other long-term follow-up studies (40, 42, 43, 44). According to these studies, special attention should be paid to the criteria set in early neonatal age, which relate to neonates with critical aortic stenosis selected for biventricular repair (44). In their long-term follow-up study conducted over a ten-year period, McCrindle *et al.* found patient survival to be 72.9% (44). In neonates, the prognosis appears more severe, clearly related to 'borderline' LV and the challenge of recognizing which is suitable or not for a biventricular management strategy (45). Recently, in some patients with severe aortic stenosis in fetal age, which may be borderline to the HLHS, intrauterine dilatation of the aortic valve begins. Some of these patients have a further successful course in postpartum palliative non-surgical methods (additional dilatation), similar to the findings from the period of immediate-term results. It seems that one should be very careful not only in the criteria for intrauterine dilatation but also in the expectations for further treatment on two ventricles. Early complications also appear to occur with dilatation as a consequence of an excessive desire to conceive to avoid early cardiac surgery. Regardless of the topic, the method of balloon dilatation of the aortic valve has a firm place in the treatment of children with aortic stenosis and postponing of cardiac surgery (46, 47).

CONCLUSION

Percutaneous balloon valvotomy provides an effective palliative interventional method in the treatment of infants and children with aortic valve stenosis. The majority of problems in the early and late period after dilatation appear in the group of patients with critical aortic stenosis. Ealy and late onset and development of high-grade aortic insufficiency after aortic valve dilatation should probably be reduced by avoiding to attain the greatest difference possible, but moderately reducing the gradient. The development of aortic insufficiency is not caused by the corresponding choice of the balloon size, but probably by immaturity of the aortic valve tissue in critical aortic stenosis. We hypothesize, based on our own study and literature review, that the number of early complications would be reduced if a proportion of patients with monocuspid aortic valve and amorphous aortic valve anatomy were primarily referred for cardiac surgery. We are also of the opinion that in most patients with 'borderline' HLHS, the decision to correct two ventricles should not be overestimated, but rather that some children should be referred for the first palliative HLHS operation.

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S A Ž E T A K

PERKUTANA AORTNA VALVULOPLASTIKA BALONOM U DJECE

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Procijenili smo učinkovitost aortne valvuloplastike (AoVP) kod 34 djece koja su podvrgnuta dilataciji aortne valvule balonom tijekom 7 godina (od veljače 2097. do veljače 2014.) u dvije ustanove (Stuttgart i Zagreb). Prevladavala su muška djeca (28/6; p<0,01), srednja dob (±SD) kod dilatacije bila je 35,55±55,59 mjeseci (minimum 1 dan, maksimum 14,2 godine), a tjelesna težina 13,1±15,9 kg (minimum 2640 g, maksimum 57 kg). Pacijenti su podijeljeni u dvije skupine. Skupinu 1 činila su novorođenčad i dojenčad mlađa od 2 mjeseca kod prve dilatacije s kriterijima za kritičnu aortnu stenozu (N=18), a skupinu 2 djeca starija od 2 mjeseca kod dilatacije (N=16). Šesnaest od 34 (47 %) pacijenata nije imalo kliničkih simptoma, 12 (35,3 %) je imalo dispneju pri mirovanju i pojačano se znojilo tijekom hranjenja (NYHA III), a 6 (17,6 %) pacijenata je imalo simptome teškog srčanog zatajenja (NYHA IV). Svi pacijenti s NYHA IV bili u skupini 1 (n=6) prema 0 u skupini 2 (p<0,05). Prema ehokardiografskom nalazu funkcija lijevog ventrikla (LV) bila je normalna u 16 (47 %), umjereno oslabljena u 12 (35,3 %) i teško oslabljena u 6 (17,6 %) pacijenata. Svi pacijenti s teško oštećenom funkcijom LV pripadali su skupini 1. (n=6) prema 0 u skupini 2. (p<0,05]. AoVP balonom izvedena je retrogradno nakon perkutane punkcije femoralne arterije kod svih osim jednog pacijenta kod kojega je balonski kateter uveden anterogradno putem mitralne valvule (MV). Kvocijent anulusa aortnog zalistka/u odnosu na površinu tijela (BSA) (mm/m^2) bio je 30,97±10,02 (maksimum 47,5, minimum 12,02) i 37,60±5,99 u odnosu na 23,03±7,86 u skupini 1 prema skupini 2 (p<0,05). Omjer Ao/Ba (mm/mm) za cijelu skupinu bio je 0,85±0,09 te 0,81±0,11) u skupini 1 i 0,89±0,05) u skupini 2 (skupina 1 prema skupini 2, p<0,01). Odmah nakon dilatacije srednja sistolička vrijednost gradijenta tlaka na aortnoj valvuli smanjuje se sa 70,62±20,78 (maksimum 120, minimum 45 mm Hg) na 20,03±13,7 (maksimum 65, minimum 0 mm Hg.) u cijeloj skupini (p<0,05) te sa 73,23±21,57 (maksimum 120, minimum 50 mm Hg) na 15,25±11,09 (maksimum 40, minimum 0 mm Hg) u skupini 1 (p<0,05) i sa 67,78±20,21 (maksimum 111, minimum 45 mm Hg) na 24,81±14,71 (maksimum 65, minimum 10 mm Hg) u skupini 2 (skupina 1 prema skupini 2, p<0,05) (mjerenje kateterom). Rezultati termina praćenja proučavani su kod 31 (91 %) pacijenta 3,5-84 (20,91±22,19) mjeseca. Nakon AoVP nađen je kontinuirano rastući rezidualni gradijent aortne valvule (31,35±12,01; maksimum 50, minimum 15 mm Hg), ali je i dalje bio značajno niži (p<0,001) nego prije valvuloplastike. Ukupna stopa preživljavanja nakon 7 godina iznosila je 91 %. Oslobađanje od tri moguće skupine re-intervencija (bilo koja re-intervencija, kirurška re-intervencija; ponovna dilatacija) bila je 77, 74, 61; 87, 84, 77; 90, 90, 83 u 2, 4 i 7 godina za cijelu skupinu te u skupini 1 prema skupini 72, 67, 56 prema 87, 87, 75 (p<0,05); 89, 83, 78 prema 87, 87, 75 (NS); 83, 83, 78 prema 100, 100, 94 (p<0,05) u 2, 4 i 7 godina. Stupanj aortne insuficijencije neposredno nakon kateterizacije nije se značajno povećao; samo je 1 pacijent razvio aortnu insuficijenciju koja je liječena kirurškom rekonstrukcijom zalistaka na dan intervencije. Nakon praćenja aortna insuficijencija povećala se na stupanj III. u 3 (10 %) i na stupanj II. u 7 (23,3 %) pacijenata. Sve troje bolesnika s visokim stupnjem aortne insuficijencije pripadali su skupini 1 (prema 0 u skupini 2; p<0,05). Osam (26 %) pacijenata zahtijevalo je ponovnu intervenciju, a samo 4 (13 %) ponovnu AoVP plus operaciju. Od 8 pacijenata kojima je bila potrebna operacija 4 (13 %) su operirana tijekom razdoblja od 27 do 78 mjeseci, a 4 u roku od mjesec dana nakon dilatacije. Jedan pacijent umro je tjedan dana nakon dilatacije, ponovne dilatacije i kirurškog zahvata zbog fibroelastoze (potvrda histološka). *Zaključak:* Perkutana balonska valvuloplastika je učinkovita palijativna intervencijska metoda u liječenju novorođenčadi i djece sa stenozom aortne valvule. Većina problema u ranom i kasnom razdoblju nakon dilatacije pojavljuje se u skupini bolesnika s kritičnom aortnom stenozom u novorođenačkoj i ranoj dojenačkoj dobi.

Ključne riječi: aortna stenoza, interventna kateterizacija, balonska aortna valvuloplastika, novorođenčad, djeca, neposredan i srednjoročan ishod liječenja