Published in final edited form as:

Congenit Heart Dis. 2009 ; 4(4): 258–264. doi:10.1111/j.1747-0803.2009.00304.x.

Exercise Function of Children with Congenital Aortic Stenosis Following Aortic Valvuloplasty during Early Infancy

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Abstract

Objectives—The objectives of this study were to characterize the exercise function of patients treated with balloon aortic valvuloplasty at 6 months of age, and identify factors associated with exercise dysfunction.

Background—Balloon aortic valvuloplasty is the primary therapy for neonatal aortic stenosis (AS). Residual and/or acquired abnormalities of left heart structure and function may adversely affect exercise capacity.

Methods—We prospectively recruited patients >6 years old with a history of neonatal AS to undergo exercise testing.

Results—We enrolled 30 patients (median age 13.1 years) who underwent balloon aortic valvuloplasty at a median age of 12 days. At time of exercise testing, the median maximum Doppler AS gradient was 34 mm Hg (0–70 mm Hg); 11 patients had moderate or severe aortic regurgitation. All patients were asymptomatic. Overall, peak oxygen consumption (VO_2) was below normal ($87 \pm 18\%$ predicted; $P < .001$), and was severely depressed ($< 70\%$ predicted) in 7 patients (23%). Although peak O_2 pulse was well preserved overall ($97 \pm 22\%$ predicted; $P = .36$), 11 patients had an O_2 pulse $< 85\%$ predicted, including all patients with VO_2 $< 70\%$ predicted. Peak heart rate was below normal overall ($91 \pm 7\%$ predicted, $P < .001$), but severe chronotropic dysfunction ($< 70\%$ predicted) was rare ($n = 1$). Age at testing correlated inversely with peak VO_2 ($R^2 = 0.30$; $P = .002$). No other demographic, historical, or echocardiographic variables were associated with peak VO_2 .

Conclusion—Although exercise function is preserved in most patients with a history of AS treated in early infancy, a subset have markedly reduced peak VO_2 , usually because of inability to increase stroke volume.

Keywords

Aortic Stenosis; Exercise; Balloon Aortic Valvuloplasty

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The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Conflict of interest: None

Introduction

For the past two decades the first-line treatment for neonates and infants with severe aortic stenosis (AS) at most centers has been transcatheter balloon aortic valvuloplasty (BAV).^{1,2} The adequacy and functional integrity of the left heart structures and the effectiveness of the primary intervention affect outcomes of neonatal AS. Most patients are able to support a biventricular circulation, but a subset of patients with hypoplastic left-sided structures rely on post-intervention left ventricular (LV) growth toward normal dimensions. Following BAV, patients often have residual and/or acquired abnormalities of left heart structure and/or function that may affect the capacity of the cardiovascular system to support the hemodynamic demands of exercise.¹ Although exercise testing is a simple and well-validated tool for measuring the functional capacity of the cardiopulmonary system, long-term follow-up studies of patients undergoing BAV in early infancy have not documented exercise capacity.

For patients with neonatal AS and borderline LV size and function, it can be difficult to determine whether a biventricular or single-ventricle management strategy is optimal. Models developed to predict suitability for biventricular management provide some guidance. However, these are based solely on consideration of survival and do not incorporate functional outcome parameters.³⁻⁵ The long-term functional implications of strategies aimed at salvaging the borderline left ventricle to achieve a biventricular circulation using fetal and postnatal interventions are unknown.^{6,7} Theoretically, patients who achieve a biventricular circulation may be comparable with (and probably no better than) patients with neonatal AS who are the focus of this study. Therefore, the characterization of the exercise function of these patients may have important clinical implications, not only for the patients with neonatal AS, but also for the patients with a broader spectrum of left heart disease. Consequently, the primary aim of this study was to characterize the exercise capacity of children who underwent BAV or surgical aortic valvotomy for congenital AS before age 6 months, and to identify the clinical, hemodynamic, and echocardiographic factors associated with poor exercise function in this unique group of patients.

Methods

Patients

Following Institutional Review Board approval, we identified patients over 6 years of age with a biventricular circulation who had undergone an intervention for severe, congenital AS during the first 6 months of life and were followed at our institution. Children with AS and significant additional cardiac anomalies (including ventricular septal defect, valvar atresia, abnormally related great arteries, and systemic or pulmonary venous anomalies) were excluded. Patients with anomalies solely within the spectrum of left heart hypoplasia were included, as were those who had undergone subsequent left heart interventions, including aortic valve repair or replacement. To ensure patient safety during exercise testing, we excluded children with a mean aortic Doppler gradient >50 mm Hg and those without an internal cardiac defibrillator who had documented or suspected exercise-induced life-threatening arrhythmias.

Historical data included the age at first aortic valve intervention (surgical or interventional catheterization), neonatal measurements from echocardiograms and cardiac catheterizations, including aortic valve size and Z-score, indexed LV dimensions and function, LV pressures, and aortic valve gradient before and after intervention. The degree of aortic regurgitation (AR) prior to, and following, intervention(s), the number and types of additional procedures (surgical or catheterization), and history of internal cardiac defibrillator placement was also recorded. Current data included age at exercise test and data from recent (within 6 months) echocardiogram, including aortic dimensions, AR severity, peak and mean residual AS gradients, LV volumes, mass, ejection fraction, and fractional shortening. Based on the coinciding clinic visit note, the presence and type of cardiac symptoms (such as shortness of breath, chest pain, and exercise intolerance) and prescription for cardiac medications were recorded.

Exercise Testing

Patients who agreed to participate in the study had a symptom-limited, progressive cycle ergometer with a continuous graded ramp protocol.^{8,9} For patients whose legs were too short to reach the pedals, a treadmill was used instead of a cycle ergometer.⁹ Electrocardiographic monitoring and breath-by-breath expiratory gas analysis were performed using a Cardio2 exercise testing system (Medical Graphics Corp., Minneapolis, MN, USA). Cuff blood pressure determinations and complete 12-lead electrocardiograms were obtained at 2–3 minute intervals during exercise, at peak exercise, and at 1, 3, and 5 minutes after exercise. Peak oxygen consumption (VO_2), peak heart rate, peak O_2 pulse, and minute ventilation vs. carbon dioxide production slope were recorded. Because of the variation in patient age, size, and gender in this cohort, our primary outcome variable, peak VO_2 , is reported as the percent of the level predicted for age, size, and gender based on previously published normative data.^{10,11} Secondary outcome parameters of exercise performance included percent predicted peak heart rate, percent predicted O_2 pulse at peak exercise, and minute ventilation vs. carbon dioxide production slope (an index of the efficiency of gas exchange during exercise). The incidence of exercise-induced symptoms, ectopy, and ST depression was recorded. Qualifying AS patients who had routine echocardiograms and exercise tests within the past year were retrospectively included.

Data Analysis

Values for aortic and LV dimensions, volume, mass, fractional shortening, and ejection fraction were expressed as Z-scores relative to body size and age in normal subjects.¹² Summaries for continuous variables are presented as median values with ranges, or means with standard deviations. A one-sample *t*-test was used to compare outcome measures between AS patients and normative data. Comparison of demographic, historical, and echocardiographic variables between dichotomous groups within the population of AS patients was performed with independent samples *t*-test or Fisher's exact test. Univariate analysis was used to assess the correlation between peak VO_2 and demographic, historical, and echocardiographic variables. Statistical significance was considered as a two-sided *P* value <.05.

Results

Patients

Thirty-six eligible patients were considered for enrollment. In six cases, the patients or their referring cardiologist declined participation. The remaining 30 patients were enrolled at the time of a routine cardiology clinic visit ($n = 26$) or during a preoperative visit prior to surgical aortic valvuloplasty ($n = 2$) or aortic valve replacement ($n = 2$). The cohort had undergone intervention for AS at a median age of 12 days (0–5.9 months) and was enrolled at a median age of 13.1 years (6.8–23.6 years; Table 1). The 6 screened patients who did not enroll did not differ from participating patients with regard to age at BAV, current age, or current degree of aortic valve disease; 3 of these patients did not keep scheduled clinic visits, 2 had undergone a Ross procedure and had current right ventricle to pulmonary artery conduit stenosis, and 1 had developed restrictive cardiomyopathy with pulmonary hypertension. These last 3 patients were thought by their primary cardiologists to be at excessively high risk for complications during exercise testing.

Of the patients with first intervention before 30 days of age ($n = 19$), 17 had adequate neonatal anatomic information to calculate a Congenital Heart Surgeons' Society (CHSS) score⁴ and modified Rhodes stratification score.⁵ Nine of these patients were predicted to have a survival advantage with single-ventricle palliation by CHSS score, 3 of whom were characterized by the modified Rhodes score to have an inadequate left heart for biventricular repair. Nine patients had grade 0 (absence of endocardial fibroelastosis [EFE]), 5 had grade 1, and 5 had grade 2 or 3 (moderate to extensive LV involvement with EFE) according to the CHSS scale.

Anatomic and hemodynamic data at the time of exercise testing are summarized in Table 1. The maximum instantaneous Doppler AS gradient ranged from 0 to 70 mm Hg (median 34 mm Hg), mean AS gradient ranged from 0 to 43 mm Hg (median 20 mm Hg), and 11 patients had moderate or severe AR. The group overall had increased ascending aortic dimension, higher LV end-diastolic volume, and increased LV mass compared with normal children. At the time of the exercise test, LV systolic function was normal. No patient had mitral stenosis or coarctation, and 2 patients had moderate to severe mitral regurgitation. No patient had pulmonary arterial hypertension. The cohort was heterogeneous with respect to the number of aortic valve procedures, history of coarctation repair, and current aortic valve function (Table 2). Few patients were prescribed cardiac medications: 4 were maintained on beta-blocker and 3 with AR were on after load reduction therapy.

Exercise Function

All enrolled patients completed testing by either progressive cycle ergometer ($n = 27$) or treadmill ($n = 3$) protocols (Table 3). Overall effort was excellent, with 90% of patients achieving a respiratory exchange ratio >1.05 . Among the whole cohort, peak VO_2 was significantly lower than normal ($87 \pm 18\%$ predicted; 35.0 ± 8.1 mL/kg/min; $P < .001$). When the 4 patients recruited during preoperative evaluations were excluded from the analyses, peak VO_2 remained depressed ($87 \pm 18\%$ predicted; 35.0 ± 7.7 mL/kg/min; $P < .001$). Exercise capacity was normal (peak $\text{VO}_2 >85\%$ predicted) in 19 patients (63%),

mildly depressed (peak VO_2 71–85% predicted) in 4 (13%), and severely depressed (peak VO_2 70% predicted) in 7 (23%). Although peak O_2 pulse (a surrogate for forward stroke volume at peak exercise) for the group was well preserved ($97 \pm 22\%$ predicted; $P = .36$), 11 patients had an O_2 pulse $<85\%$ predicted and 4 patients had an O_2 pulse 70% predicted. All 7 patients with a severely depressed peak VO_2 also had subnormal O_2 pulse. Peak heart rate, 174 ± 15 beats per minute, was lower than normal ($90 \pm 8\%$ predicted; $P < .001$), but severe chronotropic dysfunction ($<70\%$ predicted) was rare ($n = 1$). There were too few patients treated with beta-blocker medications ($n = 4$) to draw valid comparisons with other patients with regard to peak VO_2 or peak heart rate. Asymptomatic ST depression occurred in 43% of patients during exercise testing, with 8 (27%) having changes >2 mm. These 8 patients had slightly higher peak (45 ± 13 vs. 31 ± 21 mm Hg; $P = .12$) and mean (24 ± 9 vs. 19 ± 14 mm Hg $P = .26$) current AS gradients than the other patients, but these differences did not reach statistical significance. There was a trend toward ST-segment changes in patients with peak VO_2 70% ($n = 5$; $P = .14$). Low-grade ectopy was uncommon (5 patients, 2 with internal defibrillators for a history of ventricular tachycardia), and serious arrhythmia did not occur.

Of the seven patients with severely depressed peak VO_2 , five were <30 days old at first intervention. Each of these five patients had moderate or severe LV dysfunction prior to aortic valvuloplasty. Four of these patients also had data permitting grading of EFE, and calculation of the CHSS and modified Rhodes scores. Three of these four patients were predicted to have a survival advantage with single-ventricle management by CHSS score; one was similarly categorized by the modified Rhodes score. All four had at least moderate LV involvement by EFE. However, six enrolled patients with a CHSS score predicting a survival benefit with single-ventricle palliation and three patients with an unfavorable revised Rhodes score had normal peak VO_2 .

Thirteen of the 19 patients who underwent intervention prior to 30 days of age also had moderate or severe LV dysfunction prior to valvuloplasty. At the time of their exercise tests, however, the peak VO_2 of these patients ($85 \pm 19\%$ predicted; 35.4 ± 9.2 mL/kg/min) did not differ significantly from that of patients who had normal or only mildly depressed LV function prior to valvuloplasty ($88 \pm 17\%$ predicted; 34.6 ± 7.6 mL/kg/min; $P =$ not significant).

Discussion

There is limited literature on the long-term outcome and functional status of patients treated for AS in the neonatal period. Prior to this study, there were no published reports that focused specifically upon the exercise function of children and adolescents treated for AS in early life. Our data indicate that the exercise capacity of these patients, although heterogeneous, is in general remarkably well preserved. Despite variable degrees of residual aortic valve disease at the time of testing, exercise capacity was normal in 65% of our patients and only mildly depressed in another 12%. However, we also noted that a substantial subset (23%) of patients, while denying symptoms, had profoundly depressed peak VO_2 when subjected to formal exercise testing. Depressed exercise function in these patients was related primarily to an inability to augment forward stroke volume to

appropriate levels at peak exercise, and not to chronotropic incompetence. Aside from age at the time of exercise testing, none of the clinical factors assessed were associated with the level of exercise function. Indeed, nothing from the patient history, physical examination, or echocardiogram reliably identified individuals with poor exercise capacity.

Among this group of survivors of critical AS with sufficient data to compute a CHSS score, several with a score predicting a survival advantage for single-ventricle palliation had normal exercise capacity. Because this study focused only on survivors of aortic valvuloplasty with biventricular circulation (and not all patients born with critical AS), this observation does not clarify exactly how the assessment of infants with critical AS and borderline left heart structures should be refined. It does, however, underscore the imperfect nature of our current understanding of the factors that determine whether these patients can achieve a successful biventricular circulation and emphasizes the need for additional quantitative studies of the long-term functional status of patients born with borderline left heart structures. Data from these studies will undoubtedly constitute an important consideration for clinicians contemplating the treatment options for infants (or fetuses) with critical AS.

We also noted that demographic, historical, and resting echocardiographic parameters could not reliably identify patients with poor exercise function. These observations highlight how formal exercise testing, when incorporated into the routine evaluation of patients with a history of severe neonatal AS, can significantly enhance the clinician's ability to accurately assess the functional status of these patients. Our study concurs with the recently published Bethesda conference guidelines for athletic competition by children and athletes with cardiovascular abnormalities.¹³ These guidelines urge at least annual evaluations of AS severity for patients with mild AS, and specifically recommend exercise tests for patients with moderate AS. In practice, however, while echocardiography is often carried out annually, fewer physicians routinely order exercise tests for their patients. In a study by Khalid et al., exercise tests were performed in only 8–28% of children with AS, while 84–92% of pediatric cardiology centers used echocardiograms at each follow-up visit.¹⁴

Comparisons with Previous Studies

Several previous studies have examined the exercise function of pediatric patients with aortic valve disease, although none have focused on patients with severe neonatal AS.^{15–17} These studies have found that the exercise function of children and adolescents with aortic valve disease is usually no more than mildly impaired. Mitchell et al. noted normal exercise duration but blunted heart rate response in AS patients compared with normative data.¹⁵ In preoperative exercise testing of children (ages 7.5–24.1 years) undergoing the Ross procedure, Marino et al. described normal metabolic and hemodynamic exercise parameters, including peak VO_2 , that did not change significantly 7–30 months following surgery.¹⁶ Notably, in a study of 26 pediatric patients with moderate or severe AR, Rhodes et al. found an average peak VO_2 of $94 \pm 23\%$ predicted, and only three patients (12%) with a peak $\text{VO}_2 < 70\%$ predicted.¹⁷ Hence, although the exercise function of patients treated for severe AS early in life is often well preserved, significant compromise of exercise function appears to be more common in these children than in other pediatric patients with aortic valve disease.

Rhodes et al. also reported that pediatric patients with AR and poor exercise capacity had difficulty increasing forward stroke volume appropriately during exercise. In that series, baseline echocardiographic measurements could not distinguish between patients with preserved and depressed exercise function.¹⁷ These findings are consistent with the observations made in the current study.

Past studies have reported that the peak VO₂ of Fontan patients is typically depressed to approximately 60–70% of predicted normal values.^{18,19} Hence, the exercise function of the patients with severe neonatal AS in this series tended to be significantly superior to that of the average Fontan patient. We have also demonstrated that in some patients with borderline left ventricle and unfavorable CHSS scores who undergo biventricular repair, exercise capacity in follow-up through early adulthood can be normal. These observations may be relevant to those pursuing fetal interventions for critical AS.⁶

Limitations

In this study of a relatively rare congenital heart defect, an extended enrollment period (first intervention 1984–2001) was necessary to provide sufficient statistical power. Evolution in periprocedural and interventional management across this period may partially account for the relationship between age at exercise testing and percent predicted peak VO₂. In addition, we included patients <6 months at the time of intervention instead of using a stricter neonatal cutoff of <1 month. Although neonates and young infants with severe AS may differ, this was a practical decision motivated by the need to generate a sufficiently large study population. Furthermore, age at first intervention was not correlated to predicted peak VO₂. Quantitative information on the routine exercise habits, including participation in competitive sports in these patients, was unavailable. Patients in this study were recruited at scheduled clinic visits and during preoperative assessments, and there was a relatively high prevalence of significant AR. Accordingly, our findings may not be generalizable to the broader population of children and adolescents who have undergone intervention for severe neonatal AS.

Acknowledgments

This study was supported by the National Institutes of Health under award number: T32HL007572.

The authors gratefully acknowledge the expert technical assistance of Tracy J. Curran, Julieann O'Neill, Jennifer L. Smith, and Kathleen M. Solly.

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Figure 1.

Scatterplot depicting the relationship between age at the time of exercise testing and peak VO₂ as a percent of the predicted value for age and gender. The regression equation is defined by the equation: $Y = (-2.043X) + 115.597$ ($R^2 = 0.30$, $P = .002$).

Table 1**Patient Characteristics**

At Neonatal Intervention for AS	
Gender (number of male patients)	25 (83%)
Age at first intervention (days)	12 (0–178)
Aortic annulus diameter (mm)	6.6 (5.2–10.3)
Aortic annulus Z-score	−0.92 (−2.37 to +2.38)
AS gradient * by echocardiogram, pre-intervention (mm Hg)	64 (15–102)
AS gradient by catheterization, pre-intervention (mm Hg)	64 (34–85)
AS gradient by cath post-balloon dilation (mm Hg)	28 (10–35)
AR post-dilation (number of patients)	
None	15 (54%)
Mild	6 (21%)
Moderate-to-severe	7 (25%)
At Time of Exercise Test	
Age at exercise test (years)	13.1 (6.8–23.6)
Aortic valve Z-score	+1.23 (−1.2 to +2.6)
Aortic root Z-score	+1.4 (−0.8 to +3.3)
Ascending aorta Z-score	+3.3 (0.04 to 8.0)
LVEDV Z-score	+2.1 (−2.7 to 9.5)
LV mass Z-score	+2.1 (−1.6 to +8.7)
AS maximum gradient by echo (mm Hg)	34 (0–65)
AS mean gradient by echo (mm Hg)	20 (0–42)
AR (number of patients)	
Trivial to mild	19 (63%)
Moderate	9 (30%)
Severe	2 (7%)
Ejection fraction (%)	66 (48–73)
Fractional shortening (%)	37 (23–47)
Medications (number of patients)	
Betaxolol	4 (13%)
Enalapril	2 (7%)
Nifedipine	1 (3%)

Values are expressed as median (range) or counts (percentage).

* Maximum instantaneous gradient.

AS, aortic stenosis; AR, aortic regurgitation; LVEDV, left ventricular end-diastolic volume.

Table 2

Interventions Following Primary Valvuloplasty for Entire Cohort Prior to Exercise Test

Type of Intervention	Number of Patients	Median Age in Years (Range)
Coarctation repair	4	0.3 (0–0.5)
Second balloon valvuloplasty	9	1.6 (0.2–15.7)
Third balloon valvuloplasty	3	8.2 (2.0–10.0)
Surgical aortic valvuloplasty	6	6 (1.2–20.2)
Ross procedure	2	1.1 (0.4–1.8)
Mechanical aortic valve replacement	2	17.9 (13.3–16.3)

Table 3**Exercise Test Results**

	Mean (SD)
Peak VO ₂ (mL/kg/min)	35 (8.2)
Peak VO ₂ (percent predicted)	87 (18)
Peak O ₂ pulse (mL/beat)	10.6 (4.2)
Peak O ₂ pulse (percent predicted)	97 (22)
Peak HR (bpm)	174 (15)
Peak HR (percent predicted)	90 (8)
	Number of Patients (%)
RER < 1.05	3 (10)
Presence of ectopy	5 (17)
ST-segment changes	14 (47)
Chest pain	0

HR, heart rate; RER, respiratory exchange ratio

Table 4Univariate Correlates of Peak Predicted VO₂

Variable	r	Intercept	B	95% CI	P Value
Age at ETT (years)	−0.55	115.3	−2.06	−3.3, −0.85	.002
Age at intervention (months)	0.05	86.1	0.47	−3.4, 4.3	.80
BMI at ETT (kg/m ²)	0.34	113.7	−1.24	−2.55, 0.08	.07
LVEF at ETT (%)	−0.06	98.7	−0.17	−1.32, 0.98	.77
% FEV ₁ at ETT	0.12	79.0	0.09	−0.19, 0.37	.53
% peak HR at ETT	−0.08	103.3	−0.18	−1.07, 0.70	.67

ETT, exercise test; BMI, body mass index; LVEF, left ventricular ejection fraction; % FEV₁, percent predicted of forced expiratory volume in 1 s; HR, heart rate; CI, confidence interval