Outcomes Associated With Balloon Angioplasty for Recurrent Coarctation in Neonatal Univentricular and Biventricular Norwood-Type Aortic Arch Reconstructions

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Objectives: We evaluated the use of, and outcomes associated with, balloon angioplasty (BA) for recurrent coarctation in single ventricle (SV) and two ventricle (2V) patients following a Norwood-type aortic arch reconstruction (NTAR). Background: Extended patch augmentation of the aorta, a NTAR, is utilized in SV patients undergoing the Norwood procedure (NP) as well as 2V patients with a diffusely hypoplastic aorta. While many studies have evaluated recurrent coarctation following the NP, the incidence of recurrent coarctation and outcomes associated with BA in 2V patients following NTAR are unclear. Methods: A retrospective review was performed of all neonates who underwent a NTAR at our institution between 2000 and 2010. The incidence of recurrent coarctation requiring intervention and factors associated with successful BA were evaluated. Results: A NTAR was performed in 361 SV patients and 88 2V patients. The incidence of recurrent coarctation requiring intervention was 19.3% in 2V vs. 9.7% in SV patients ($P = 0.01$) at a median of 0.5 (interquartile range 0.3–1.2) years from initial surgery. BA was successful in 25 SV patients (81%) and 10 2V patients (71%; $P = 0.70$). Of the characteristics evaluated, lower initial peak-to-peak gradient ($P = 0.02$), larger balloon size for angioplasty ($P = 0.02$) and larger diameter of the descending aorta ($P = 0.01$) were associated with BA success. Conclusions: Recurrent coarctation following NTAR is more common in 2V patients than in SV patients. BA for recurrent coarctation has similar success in both groups and should continue to be utilized in this population.

Key words: recoarctation; coarctation; homograft patch

INTRODUCTION

Recurrent aortic coarctation is a relatively common complication following the Norwood procedure (NP) as part of the surgical palliation of single ventricle (SV) anatomy. The incidence of recurrent coarctation following the NP varies widely in the literature, from 2 to 40% [1–11], and balloon angioplasty (BA) has been shown to be an effective therapy for relief of recurrent

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coarctation in this setting with success rates upward of 85% [3,5,7,11–13]. Few factors have been consistently identified to be associated with an increased risk of recurrent coarctation [1,9,14,15], and there is even more uncertainty as to factors associated with the success or failure of BA in these patients [11,12].

Increased familiarity with the NP in SV patients has allowed translation of a similar technique of aortic reconstruction to the repair of two ventricle (2V) patients with complicated aortic arch anatomy necessitating more extensive aortic arch repair [16,17]. In our center, extended patch augmentation of the aorta in a manner similar to the NP is referred to as a Norwood-type aortic arch reconstruction (NTAR). The incidence of recurrent coarctation following this type of repair has been reported in only one small series [17] and outcomes of BA in this population have not been previously described. The aim of this study was to evaluate the use, timing, and midterm outcomes associated with BA in 2V and SV patients following NTAR and to describe factors associated with BA success.

METHODS

Study Population

SV and 2V neonates, less than 1 month of age, who underwent a NP or NTAR, respectively, at the University of Michigan Congenital Heart Center between January 2000 and December 2010 were identified using the institutional cardiac surgical database. For this study, a NTAR was defined as extended patch augmentation of the underside of the aorta, extending across the transverse arch, utilizing a median sternotomy and cardiopulmonary bypass. Patients were excluded if they died within 1 month of the initial surgery or had less than 1 month of follow-up available after their initial surgery. Patients who developed significant recurrent coarctation requiring intervention (either catheter based or surgical) were identified by utilizing the Electronic Medical Record Search Engine (EMERSE) system. EMERSE is a web-based tool used to search patient specific information in the University of Michigan Clinical Data Repository, which includes medical documentation from inpatient and outpatient records and allows for automated searches of specific keywords. Using EMERSE, the medical record was searched for the terms "recurrent coarctation," "recoarctation," "aortic arch obstruction," "aortic arch gradient," "residual arch obstruction," and "ascending aortic stenosis." There were no defined parameters to determine the need for intervention and therefore the decision to intervene was at the discretion of the clinical team and made on a case-by-case basis as determined by clinical status, arch gradient, and angiographic appearance of the aorta. Patients who had intervention for recurrent coarctation performed at an outside institution were included in determination of recurrent coarctation rate but were excluded from further analysis, as procedural data from the intervention was unavailable.

Data Collection

Retrospective review of the medical record was performed, and preoperative, operative, and echocardiographic data were collected. Angiographic images for those who underwent cardiac catheterization were reviewed and measurements made using AP and lateral images, as available. For patients with recurrent coarctation, additional data including pre- and post-intervention echocardiogram results and procedural characteristics were reviewed. For patients who underwent BA, coarctation index, defined as the ratio of the narrowest arch dimension and the diameter of the aorta at the diaphragm [18], and ratios of the smallest to largest arch dimensions, angioplasty balloon size to the narrowest arch dimension, and angioplasty balloon size to the diameter of the aorta at the diaphragm, were calculated, and location (proximal or distal to the left subclavian artery) and type of coarctation (discrete or long segment) were recorded. Intervention was considered acutely successful if the peak-to-peak aortic arch gradient by catheterization was $\leq$10 mm Hg [5,8] in SV patients and $\leq$15 mm Hg in 2V patients and was determined retrospectively based upon institutional preferences. Subsequent recoarctation and time to last available follow-up or death were recorded on all patients. The University of Michigan Institutional Review Board approved this protocol with waiver of informed consent.

Statistical Analysis

Data are presented as frequency with percentage for categorical variables and median with interquartile range (IQR), or mean $\pm$ standard deviation, as appropriate, for continuous variables. Group comparisons between SV and 2V groups were made using chi-square test or Fisher's exact test for categorical variables and Wilcoxon rank-sum test or *t* test for continuous variables. Similarly, clinical and procedural characteristics were also compared between patients with BA success and those with BA failure to determine potential factors associated with success of BA. Due to small sample size, the SV and 2V groups were combined for this comparison. Freedom from recurrent coarctation after initially successful BA was computed using Kaplan–Meier method. All analyses were performed using SAS Version 9.3 (SAS Institute, Cary,

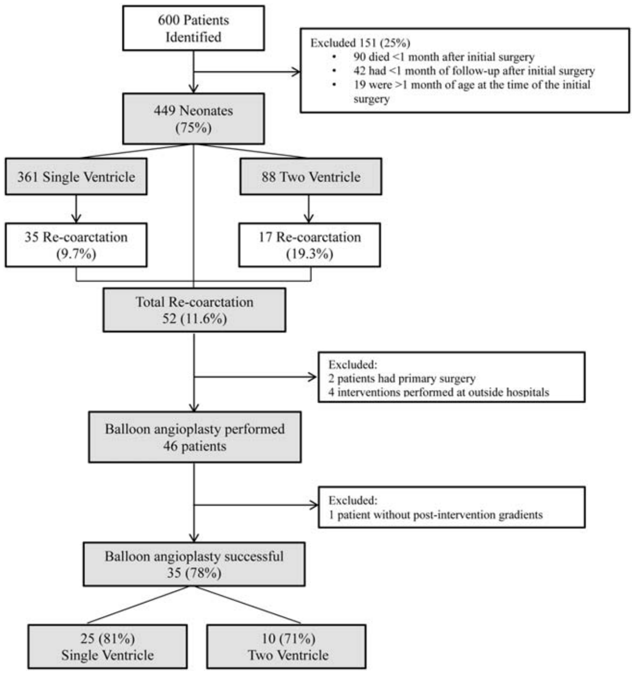

Fig. 1. Flow diagram showing the short-term outcomes of the included study patients.

NC), with statistical significance set at a P value <0.05 using a two-sided test.

RESULTS

Study Population

A total of 600 patients were identified as having a NTAR during the study period. After applying the exclusion criteria, 449 neonates were included in the final study population. A flow diagram outlining the short-term outcomes of these patients are displayed in Fig. 1. The clinical characteristics of patients who underwent intervention for recurrent coarctation are shown in Table I.

Recurrent Coarctation

A total of 35 SV patients (9.7%) and 17 2V patients (19.3%) required intervention for recurrent coarctation ($P = 0.01$). In 46 patients (88%) the intervention was a planned procedure with recurrent coarctation suspected by echocardiogram. Preprocedural characteristics of the 46 patients who had BA performed at our center are listed in Table II. SV and 2V groups had similar initial aortic arch gradients as measured by catheterization ($P = 0.11$) but 2V patients had a significantly higher peak instantaneous pressure gradients by echocardiogram ($P = 0.001$). All 2V patients had normal systemic ventricular function by echocardiogram compared with eight patients (26%) in the SV group who had at least moderately depressed systemic ventricular function ($P = 0.04$). While there was a trend toward patients with better ventricular function having higher aortic arch gradients, this association was not significant. Likely a reflection of the larger proximal patch created in SV patients to allow for the anastomosis of the two native outflow tracts, SV patients had higher largest aortic arch dimensions ($P = 0.01$).

BA for Recurrent Coarctation

All but 2 patients underwent BA as the primary intervention for recurrent coarctation at a median of 0.5 years (IQR 0.3–1.2) from their initial surgery. The two patients who had surgery as their primary intervention were SV patients and were repaired surgically because of long segment stenosis in one case and because of a concomitant surgery for another indication in the second case. A retrograde approach for BA through the femoral artery was used in 37 (80%) of patients with an antegrade approach performed in nine SV patients.

Acute success with BA was achieved in 25 SV patients (81%) and 10 2V patients (71%; $P = 0.70$). Procedural characteristics of the SV and 2V patients are compared in Table II. Median balloon size chosen was 106% of the descending aortic diameter at the diaphragm with a significantly higher ratio in SV compared with 2V patients (median 109%, IQR 100–129% and median 100%, IQR 80–106%, respectively; $P = 0.03$). Balloon size was 2.2 times the narrowest aortic arch dimension in both groups. There was a reduction in gradient by a median of 83% (IQR −100 to −64) in the SV patients and 74% (IQR −85 to −55) in the 2V patients ($P = 0.12$). There were six patients who had procedural complications (13%); five SV patients (16%) and one 2V patient (6.7%). Complications included transient heart block, bradycardia/hypotension requiring resuscitation, respiratory depression as a result of anesthesia, and death. The one procedural death occurred in a 2V patient with preexisting sepsis who was referred for emergent BA. Catheter perforation, pericardial tamponade, and death occurred during the diagnostic portion of the case and BA was not performed. Two patients had small intimal tears noted by postangioplasty angiogram but no patient required intervention or had aneurysm development during the follow-up period. No patient had femoral vessel complications.

Factors Associated With Outcome of BA

Association of clinical and procedural characteristics with outcome of BA by univariate analysis is shown in Table III. Due to small sample size, the 2V and SV groups were combined for this analysis and multivariable analysis was not performed. Among the 45 patients who underwent BA at our

TABLE I. Patient and Clinical Characteristics of Neonates Who Underwent Any Intervention for Recurrent Coarctation Following NTAR[a]

		Type of anatomy		
Characteristics	All ($N = 52$)	SV ($N = 35$)	2V ($N = 17$)	P value[b]
Male sex	28 (53.8)	18 (51.4)	10 (58.8)	0.62
Premature (less than 37 weeks)	10 (19.2)	6 (17.1)	4 (23.5)	0.71
Diagnosis for SV patients				
HLHS		28 (80.0)		
Other systemic right ventricle		4 (11.4)		
Other systemic left ventricle		3 (8.6)		
Type of initial shunt in SV patients				
Blalock–Taussig shunt		23 (65.7)		
RV-PA shunt		11 (31.4)		
Central		1 (2.9)		
Stage II completed		32 (91.4)		
Fontan completed		26 (74.3)		
Diagnosis for 2V patients				
Interrupted aortic arch (IAA)			7 (41.2)	
Coarctation/arch hypoplasia			8 (47.1)	
Other			2 (11.8)	
Type of 2V repair				
Arch reconstruction alone			11 (64.7)	
Arch reconstruction and Rastelli			3 (17.6)	
Arch reconstruction and arterial switch operation			3 (17.6)	
Smallest aortic arch dimension (by echo; $N = 32$; mm)	2.0 (1.7–2.4)	2.0 (1.6–2.6)	2.0 (2.0–2.0)	0.63
Surgical factors				
Age at (initial) surgical repair (days)	7 (5–9)	6 (5–8)	8 (6–13)	0.03
Weight at (initial) surgical repair (kg)	3.1 ± 0.6	3.1 ± 0.6	2.9 ± 0.8	0.36
Cardiopulmonary bypass time (min)	85 (67.5–111.5)	82 (67–96)	110 (68–165)	0.23
Follow-up				
Deceased	8 (15.4)	6 (17.1)	2 (11.8)	1.00

Abbreviations: SV, single ventricle; 2V, two ventricle; HLHS, hypoplastic left heart syndrome; RV-PA, right ventricle to the main pulmonary artery.
[a]Data are presented as N (%) for categorical variables and median (interquartile range) or mean ± standard deviation, for continuous variables.
[b]P value from chi-square test or Fisher's exact test, for categorical variables, and Wilcoxon rank-sum test or t test, for continuous variables, for comparison between SV and 2V patients.

center and had postintervention aortic arch gradients available, male sex, lower initial peak-to-peak gradient measured during catheterization, and larger diameter of the descending aorta at the diaphragm were significantly associated with BA success. While balloon type was not associated with angioplasty success (89% used a Tyshak II balloon [NuMED, Hopkinton, NY]), balloon size was associated with success (Table III).

Additional Outcomes

Over a median follow-up period of 2.3 years (IQR 1.6–5.3) since initial surgery, subsequent recoarctation following an initially successful BA occurred in four SV patients (11%). Time to subsequent recoarctation encompassed a wide range from 5.4 months to 9.7 years with all but one case occurring within the first 15 months after initial intervention. Freedom from recurrent coarctation after initially successful BA is shown in Fig. 2. The four patients who had an initially successful BA with subsequent development of recoarctation, had a repeat BA performed. Of the 10 unsuccessful BA procedures, 2 patients did not undergo repeat intervention, 1 patient underwent repeat BA procedure at 42 days after their initial procedure, and 7 patients proceeded with surgical arch intervention at a median of 6 days (range from 1 day to 50 days) after their initial BA procedure.

DISCUSSION

This study, evaluating recurrent coarctation in both univentricular and biventricular NTAR, found rates of recurrent coarctation of 19.3% in the 2V population and 9.7% in the SV population. Despite this difference, however, BA was shown to be equally effective in relief of recurrent coarctation with combined success rates in the SV and 2V groups of 78%. In this combined population, lower initial peak-to-peak gradient, larger diameter of the aorta at the diaphragm, and larger angioplasty balloon size were identified as being associated with BA success.

TABLE II. Preprocedural and Procedural Characteristics of Neonates Who Underwent Balloon Angioplasty as Intervention for Recurrent Coarctation Following NTAR[a]

		Type of ventricle		
Characteristics	All ($N = 46$)	Single V ($N = 31$)	Two V ($N = 15$)	P value[b]
Weight at intervention ($N = 41$; kg)	6.4 (5.1–9.6)	6.4 (4.7–9.6)	6.3 (5.4–13.4)	0.65
Location of coarctation				
Proximal	5 (10.9)	3 (9.7)	2 (13.3)	0.64
Distal	40 (87.0)	28 (90.3)	12 (80.0)	
Coarctation segment type				
Discrete	40 (87.0)	27 (87.1)	13 (86.7)	1.00
Long	5 (10.9)	4 (12.9)	1 (6.7)	
Preprocedure PIPG by echocardiogram	40 (18–64)	36 (21–44)	64 (50–75)	0.001
Initial cath peak-to-peak gradient (mm Hg)	27 (20–40)	26 (15–34)	35 (25–48)	0.11
Largest balloon size (mm)	8 (7–12)	8 (7–12)	8 (6–9)	0.10
Aortic arch dimensions by angiography (mm)				
Narrowest	3.7 (2.5–5)	3.6 (2.7–5.5)	3.9 (1.7–4.5)	0.41
Largest	14 (12.5–17.5)	17 (13–20)	12 (10.8–14)	0.01
Diameter of DAO at diaphragm	7.8 (6.3–10)	7.8 (6.7–10)	8 (6–10)	0.80
Coarctation index	0.46 (0.38–0.57)	0.49 (0.42–0.58)	0.39 (0.34–0.44)	0.04
Postprocedure peak-to-peak gradient (mm Hg)	5 (0–12)	2 (0–10)	10.5 (5–20)	0.02

Abbreviations: DAO, descending aorta; PIPG, peak instantaneous pressure gradient.
[a]Data are presented as N (%) for categorical variables and median (interquartile range) for continuous variables.
[b]P value from Fisher's exact test for categorical variables and Wilcoxon rank-sum test for continuous variables on comparison between SV and 2V patients.

TABLE III. Association of Clinical and Procedural Characteristics With Outcome of Balloon Angioplasty by Univariate Analysis[a]

	Success of balloon angioplasty		
Characteristics	Yes ($N = 35$)	No ($N = 10$)	P value[b]
Male sex	23 (65.7)	1 (10.0)	0.003
Age at (initial) surgical repair (days)	7 (5–11)	6.5 (5–8)	0.96
Weight at (initial) surgical repair (kg)	3.2 ± 0.6	2.8 ± 0.8	0.14
Cardiopulmonary bypass time (min)	86 (67–112)	80 (71–98)	0.59
Intervention with balloon angioplasty			
Age at intervention (years)	0.5 (0.4–1.3)	0.4 (0.3–1.1)	0.27
Weight at intervention ($N = 41$; kg)	6.6 (5.1–10.9)	5.7 (4.6–7.1)	0.51
Location of coarctation			
Proximal	2 (5.7)	3 (30.0)	0.06
Distal	33 (94.3)	7 (70.0)	
Coarctation segment type			
Discrete	32 (91.4)	8 (80.0)	0.31
Long	3 (8.6)	2 (20.0)	
Initial peak-to-peak gradient (mm Hg)	26 (15–34)	44 (26–60)	0.02
Largest balloon size	8 (7–12)	7 (6–8)	0.02
Aortic arch dimensions (mm)			
Narrowest	3.9 (2.7–5.7)	3.0 (2.0–3.9)	0.06
Diameter of DAO at diaphragm	8.5 (6.7–10)	6.5 (5.0–7.0)	0.01
Coarctation index	0.46 (0.39–0.58)	0.46 (0.34–0.54)	0.69
Ratio of balloon size/narrowest aortic diameter	2.16 (1.79–3.03)	2.60 (2.05–3.04)	0.34
Ratio of balloon size/DAO diameter	1.06 (0.91–1.20)	1.05 (1.00–1.14)	0.60

Abbreviation: DAO, descending aorta.
[a]Data are presented as N (%) for categorical variables and median (interquartile range) or mean ± standard deviation, as appropriate, for continuous variables.
[b]P value from Fisher's exact test for categorical variables and Wilcoxon rank-sum test or t test for continuous variables on comparison between patients with/without success of balloon angioplasty.

The incidence of recurrent coarctation found in our study is comparable to the reported rates of 4–20% across various types of arch repairs in 2V patients [17,19–26] and 2–40% reported from numerous studies in SV patients following the NP [1–6,9–11,27]. Our study is unique, however, in evaluating these groups

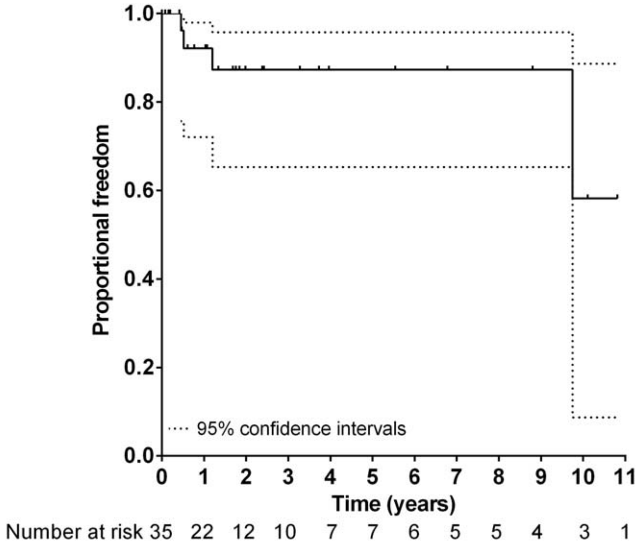

Fig. 2. Kaplan–Meier curve showing freedom from recurrent coarctation after initially successful balloon angioplasty in SV and 2V patients combined (with 95% confidence interval). Freedom from recurrent coarctation was 100% at 1 month, 96% at 6 months, 92% at 1 year, and 87% at 5 years.

across the same time period using the same group of surgeons and thereby minimizing the effect of variations in surgical technique. While the aortic arch repair may be similar between the SV and 2V groups, differences in intracardiac anatomy remain which may affect flow patterns and aortic growth in ways that cannot be measured by the clinical factors evaluated in this study and which may account for the different recurrent coarctation rates found here between the two groups.

Despite these anatomic differences, BA on a similar type of arch repair was expected to have similar technical success between the SV and 2V groups and, in fact, BA is shown in this study to have similarly high success rates in both groups. Variability in the definition of BA success makes it difficult to compare our results directly with prior studies, however our results are comparable to the 74–90% reported in 2V patients following an assortment of traditional aortic arch repairs [13,28–30] and 85–100% success for SV patients following the NP [5,7,8,11,12]. We chose two separate residual pressure gradients to define success in the SV and 2V groups as it is our practice to intervene at a lower residual gradient in SV patients who presumably have a limited ability to tolerate residual obstruction.

While success rates of BA are high, 31% of the patients who underwent BA as a primary intervention for recurrent coarctation either had an unsuccessful BA or had subsequent recoarctation requiring an additional intervention. Similar to previous studies, however, our study also has shown that it is difficult to predict which patients may be at higher risk for BA failure. A recent study by Bendaly et al. [11] of 39 patients with recurrent coarctation following the NP found that increased preprocedure gradient and increased ratio of balloon size to size of the descending aorta were associated with BA success. An earlier multicenter study by Soongswang [12] found that earlier time of intervention, increased preprocedure gradient, and increased balloon to coarctation ratio were associated with an increased absolute reduction in peak-to-peak gradient. We found no association with patient age, size, or time from initial surgical procedure with BA success. Increased balloon size, whether this suggests a relatively less severe recoarctation or oversizing of the balloon, is the only factor that seems to be consistent among studies and therefore it remains difficult to guide the choice of intervention and to further prevent development of recurrent coarctation.

Limitations

Identification of recurrent coarctation was limited to those receiving intervention and therefore patients with unrecognized coarctation or patients who died prior to intervention would be missed. In addition, patients were excluded if they underwent intervention for recurrent coarctation at an outside institution or if they did not have at least 1 month of follow-up available which may have introduced some selection bias in the study population. Finally, due to the small number of angioplasty patients, analysis of factors associated with BA outcomes could only be analyzed with the 2V and SV groups combined. While outcomes of BA in the two groups were similar, clinical factors including preoperative and postoperative anatomy were markedly different between groups and may have diluted the results of our risk factor analysis.

Conclusions

In summary, while the aortic reconstruction of the NP and NTAR are similar, there are differences in the residual intracardiac anatomy and postoperative physiology between these groups which may affect outcomes. Despite these differences, BA is a valuable intervention for relief of recurrent obstruction in both groups with high success rates and few complications. There are no identifiable preprocedural factors and limited intraprocedural factors that predict successful BA but it is still reasonable to attempt BA as first-line intervention in both groups of patients, prior to consideration of surgical repair.

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