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Celiac Artery Flow Pattern in Infants with Single Right Ventricle Following the Norwood Procedure with a Modified Blalock-Taussig or Right Ventricle to Pulmonary Artery Shunt

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Abstract

A potential advantage of the right ventricle to pulmonary artery versus modified Blalock–Taussig shunt in patients undergoing the Norwood procedure is limitation of diastolic runoff from the systemic to pulmonary circulation. We evaluated mesenteric flow patterns and gastrointestinal outcomes following the Norwood procedure associated with either shunt type. Patients randomized to a right ventricle to pulmonary artery versus modified Blalock–Taussig shunt in the Pediatric Heart Network Single Ventricle Reconstruction Trial at centers participating in this ancillary study were eligible for inclusion; those with active necrotizing enterocolitis, sepsis, or end-organ dysfunction were excluded. Celiac artery flow characteristics and gastrointestinal outcomes were collected at discharge. Forty-four patients (five centers) were included. Median age at surgery was 5 days [interquartile range (IQR) = 4–8 days]. Median celiac artery resistive index (an indicator of resistance to perfusion) was higher in the modified Blalock–Taussig shunt group ($n = 19$) versus the right ventricle to pulmonary artery shunt group ($n = 25$) [1.00 (IQR = 0.84–1.14) vs. 0.82 (IQR = 0.74–1.00), $p = 0.02$]. There was no difference in interstage weight gain, necrotizing enterocolitis, or feeding intolerance episodes between the groups. The celiac artery resistive index was higher in patients with the modified Blalock–Taussig shunt versus the right ventricle to pulmonary artery shunt but was not associated with measured gastrointestinal outcomes.

Keywords

Single ventricle; Norwood procedure; Mesenteric blood flow

Introduction

The modified Blalock–Taussig shunt and right ventricle to pulmonary artery shunt are the two main options for providing pulmonary blood flow in patients with a single right ventricle undergoing the Norwood operation [16, 23]. A theoretical advantage of the right ventricle to pulmonary artery shunt is the limitation of diastolic blood flow from the systemic into the pulmonary circulation that is present with the modified Blalock–Taussig shunt [2, 5, 11–14, 18, 20, 21]. The diastolic runoff present in the modified Blalock–Taussig shunt can be associated with impaired coronary artery and end-organ perfusion [12, 14, 18, 21]. Evaluation of mesenteric blood flow in patients with the modified Blalock–Taussig shunt to date has revealed reduced or retrograde diastolic blood flow but conflicting results regarding mesenteric vascular resistance, which is thought to be inversely related to gut perfusion [4, 8, 9, 22]. Mesenteric vascular resistance has not been previously evaluated in single ventricle patients with a right ventricle to pulmonary artery versus modified Blalock–Taussig shunt.

Gastrointestinal disturbances ranging from gastroesophageal reflux to necrotizing enterocolitis are common in patients with single ventricle defects [1, 3, 6, 15]. Previous studies have suggested that persistent retrograde diastolic flow in the abdominal aorta is a risk factor for necrotizing enterocolitis in patients with congenital heart disease [3]. Others have also shown alterations in mesenteric flow patterns in patients with necrotizing enterocolitis [7, 10]. It is unclear whether changes in mesenteric flow patterns impact gastrointestinal outcomes in patients with shunt-dependent single ventricle disease.

The purpose of this study was to evaluate celiac artery flow characteristics in patients undergoing the Norwood procedure randomized to either a right ventricle to pulmonary artery shunt or a modified Blalock–Taussig shunt in the Pediatric Heart Network Single Ventricle Reconstruction Trial [19]. Gastrointestinal outcomes were also evaluated.

Methods

Patient Population

Patients enrolled in the National Heart, Lung, and Blood Institute-sponsored Pediatric Heart Network Single Ventricle Reconstruction Trial (ClinicalTrials.gov number, NCT00115934) were eligible for inclusion in this prospective observational study. Details of the Pediatric Heart Network Single Ventricle Reconstruction Trial have been previously published [17, 19]. In brief, infants with a diagnosis of a single, morphologically right ventricle undergoing the Norwood procedure were eligible for inclusion in the trial. Exclusion criteria included a single, morphologically left ventricle, preoperative anatomic features rendering either a modified Blalock–Taussig shunt or a right ventricle to pulmonary artery shunt technically impossible, and any major congenital or acquired extracardiac abnormality that could independently affect the likelihood of the subject meeting primary outcome of transplant-free survival at 1 year. Patients were then randomized to receive either a Norwood procedure with a modified Blalock–Taussig shunt or a right ventricle to pulmonary artery shunt.

Patients from five centers participating in the main trial were eligible for recruitment for the present study. Patients were recruited after the Norwood operation was completed, and they were eligible if they did not have active necrotizing enterocolitis, active sepsis, active hemodynamic instability, end-organ dysfunction, or an umbilical catheter in place during the 48 h prior to the Norwood hospitalization discharge echocardiogram. Informed consent was obtained from parents/guardians of all patients, and the institutional review board at each participating center approved the study.

Data Collection

Patient demographics and baseline characteristics were collected and included diagnosis, age at Norwood procedure, birth weight, gender, and gestational age at birth. Operative data included shunt type performed during the Norwood procedure. If an intraoperative shunt crossover occurred after initial randomization, we analyzed patients according to the final shunt type received.

Echocardiograms were performed postoperatively at Norwood hospitalization discharge as part of the Single Ventricle Reconstruction trial [17]. The use of sedation at the time of the echocardiogram was collected. The presence and degree of right-sided atrioventricular valve regurgitation, neo-aortic valve regurgitation, and the right ventricular ejection fraction were recorded.

At the time of the Norwood hospitalization discharge echocardiogram, data on celiac artery flow characteristics were collected for patients enrolled in the present study. The patients had their feedings held for at least 1 h prior to image acquisition. Data collected included sagittal images and Doppler interrogation of the celiac artery through the epigastrium with a 5–6.5-MHz phased array transducer and a low-wall filter. The probe was positioned to minimize the angle of interrogation of the celiac artery. The origin of the celiac artery was avoided to exclude turbulent flow from the takeoff from the aorta. Measurements were made in the proximal position of the celiac artery where flow is in a posterior to anterior direction. Three images of the celiac artery and five Doppler waveforms per patient were obtained. For our study, we chose to evaluate the celiac artery instead of the superior mesenteric artery based on work done by Deeg et al. [7]. Their study found that velocity measurements between the two arteries were highly correlated, but it was easier to capture blood flow velocities in the celiac artery compared to the superior mesenteric artery due to less interference from intestinal gas around the celiac artery and the smoother course of the celiac artery toward the ultrasound transducer reducing the need for angle correction during measurements. All echo-cardiographic data, including celiac artery flow data, were

evaluated at the Single Ventricle Reconstruction trial echocardiography core laboratory. Peak systolic velocity, end-diastolic velocity, and celiac artery diastolic flow direction were measured and averaged over the five measurements obtained. The celiac artery resistive index was calculated using the following equation: resistive index = (peak systolic velocity – end-diastolic velocity)/(peak systolic velocity). End-diastole was the lowest point on the waveform trough.

Data collected regarding feeding characteristics and gastrointestinal outcomes included evidence of necrotizing enterocolitis, day of life feeds was started, feeding intolerance episodes, any gastrointestinal surgery, whether patients were on antireflux medications at time of discharge from Norwood hospitalization, and weight at Norwood hospitalization and Pre-Stage II echocardiogram. Necrotizing enterocolitis or suspected necrotizing enterocolitis was classified based on the modified Bell Staging Criteria [15]. The modified Bell Staging Criteria classifies necrotizing enterocolitis as suspected necrotizing enterocolitis (Stages 1a and 1b), proven necrotizing enterocolitis (Stages 2a and 2b), and advanced necrotizing enterocolitis (Stage 3a and 3b). Feeding intolerance episodes were defined as the number of times feeds were held due to significant emesis (>one-third of given feed), abdominal distention, or bloody stools from time of the Norwood operation until Norwood discharge echocardiogram and grouped into either 0, 1–3, 4–6, and >6 episodes. Gastrointestinal surgeries were defined as gastrostomy tube, Nissen fundoplication, or any bowel surgery performed from birth to Stage II palliation. The use of antireflux medications was collected, as well as the use of angiotensin-converting enzyme inhibitors or any other vasoactive medication. Finally, data were collected on death or heart transplant prior to planned Stage II operation, including cause of death.

Analysis

Data were summarized using frequencies and percentages for categorical variables and median and interquartile ranges for continuous variables. Only patients with complete celiac flow and gastrointestinal outcomes data were included in the analysis. Baseline characteristics, celiac artery flow characteristics, and gastrointestinal outcomes were compared between the shunt types using the χ^2 test (or Fisher's exact test when expected counts in at least one category were <5) for categorical data and the Wilcoxon rank sum test for continuous variables. Weight gain was evaluated and calculated as grams per day weight gain from birth to the Norwood discharge and Pre-Stage II echocardiograms and from Norwood discharge echocardiogram to Pre-Stage II echocardiogram. Finally, linear regression was performed to evaluate the impact of shunt type on the celiac artery resistive index adjusting for the use of sedation at the time of echocardiogram, presence of $\geq$ moderate right-sided atrioventricular valve or neo-aortic regurgitation, and the use of any afterload reducing medication (including angiotensin-converting enzyme inhibitors or milrinone). All analyses were conducted using SAS version 9.2 (SAS Institute Inc., Cary, NC). A p -value <0.05 was considered statistically significant.

Results

Patient Characteristics

A total of 44 patients from 5 centers were included. The median birth weight was 3.13 kg (2.90–3.31 kg) and 61% were male. During the Norwood operation, 19 patients (43%) received a modified Blalock–Taussig shunt and 25 patients (57%) received a right ventricle to pulmonary artery shunt. Patient characteristics are displayed for the overall cohort as well as the different shunt types in Table 1. Birth weight, gender, diagnosis, and age at surgery were similar across shunt types. There was no significant difference in the proportion of patients on angiotensin-converting enzyme inhibitors at the time of Norwood discharge

between the two shunt types [7 patients (39%) in the modified Blalock–Taussig shunt group vs. 11 patients (46%) in the right ventricle to pulmonary artery shunt group, $p = 0.89$]. One patient in the modified Blalock–Taussig shunt group was on another vasoactive medication (milrinone) at the time of Norwood discharge.

Echocardiographic Data

Table 2 displays echocardiographic and celiac artery flow data from the Norwood discharge echocardiogram. The median celiac artery resistive index was significantly higher in the modified Blalock–Taussig shunt group. After adjusting for sedation use, presence of $\geq$ moderate right sided atrioventricular or neo-aortic valve regurgitation, and the use of any afterload reducing medication, the celiac artery resistive index remained significantly higher in the modified Blalock–Taussig shunt group (least squares mean difference in modified Blalock–Taussig shunt group—right ventricle to pulmonary artery shunt group = 0.12; 95% confidence interval = 0.02 – 0.22; $p = 0.02$).

Five patients in the modified Blalock–Taussig shunt group versus one patient in the right ventricle to pulmonary artery shunt group had flow reversal noted in the celiac artery. Figure 1 displays the pulse wave spectral Doppler signal from the celiac artery in a patient with a right ventricle to pulmonary artery shunt and no diastolic flow reversal (Fig. 1a) compared with a patient with a modified Blalock versus Taussig shunt (Fig. 1b) with flow reversal in diastole.

Gastrointestinal Outcomes

Table 3 displays gastrointestinal outcomes data. There were no differences in necrotizing enterocolitis, number of feeding intolerance episodes, or interstage weight gain between shunt types.

Mortality Data

Overall, 12 patients (27%) died or were transplanted during the time period between the Norwood discharge echocardiogram and planned Stage II procedure. In the modified Blalock–Taussig shunt group this included seven patients (37%), versus five patients (20%) in the right ventricle to pulmonary artery shunt group ($p = 0.37$). No deaths in either group were thought to be related to gastrointestinal causes. Causes of death in the modified Blalock–Taussig shunt group included: sudden death ($n = 2$), pneumonia ($n = 1$), bronchiolitis ($n = 1$), respiratory failure ($n = 1$), and right ventricular dysfunction ($n = 1$). In the right ventricle to pulmonary artery shunt group, causes of death included: sudden death ($n = 2$), progressive pulmonary failure ($n = 1$), sepsis ($n = 1$), and right ventricular dysfunction ($n = 1$).

Discussion

In this multicenter analysis of single ventricle patients undergoing the Norwood procedure, we found higher celiac artery resistive index in patients randomized to a modified Blalock–Taussig shunt versus a right ventricle to pulmonary artery shunt. This was not associated with any difference in measured gastrointestinal outcomes.

The classic Norwood procedure with a modified Blalock–Taussig shunt has been associated with diastolic runoff into the pulmonary circulation “stealing” blood away from the coronary and systemic circulation [12, 14, 18, 21]. A modification to the classic Norwood procedure, involving a right ventricle to pulmonary artery shunt, has been shown to be associated with higher diastolic blood pressures compared to the modified Blalock–Taussig shunt [2, 5, 12–14, 18, 20, 21]. Several previous studies have evaluated mesenteric blood flow in patients

with a modified Blalock–Taussig shunt and showed absent or reversed diastolic flow [4, 8, 9].

Similar to these studies, we found a greater proportion of patients with a modified Blalock–Taussig shunt compared to those with a right ventricle to pulmonary artery shunt had diastolic flow reversal in the celiac artery, and the modified Blalock–Taussig shunt group had lower end-diastolic velocities. The modified Blalock–Taussig shunt group also had higher celiac artery systolic velocities and, therefore, a higher celiac artery resistive index. The celiac artery resistive index remained greater in the modified Blalock–Taussig shunt group after adjusting for factors known to promote lower end-diastolic velocities, such as sedation, atrioventricular and neo-aortic valve regurgitation, and the use of afterload reducing medications. Our results are similar to Harrison and colleagues, who showed that 10 patients who had undergone the Norwood procedure with a modified Blalock–Taussig shunt had higher mesenteric blood flow resistive indexes compared to healthy neonates with no heart disease [9].

A study by del Castillo and colleagues evaluated mesenteric flow in 27 single ventricle patients with a modified Blalock–Taussig shunt versus right ventricle to pulmonary artery shunt [8]. They found an increase in mesenteric blood flow velocities in postprandial patients with a modified Blalock–Taussig shunt that was not seen in patients with a right ventricle to pulmonary artery shunt [8]. The authors speculated that the increased flow velocities seen in modified Blalock–Taussig shunt patients might be correlated with better gut perfusion and decreased risk of mesenteric ischemia compared with patients with a right ventricle to pulmonary artery shunt. The resistive index—an indicator of resistance to perfusion—was not measured in that study. In our analysis, we found that whereas patients with a modified Blalock–Taussig shunt had higher celiac artery systolic flow velocity, they also had lower end-diastolic velocities and therefore a higher celiac artery resistive index. Mesenteric vascular resistance, rather than flow velocity, has been more closely related to gut perfusion and gastrointestinal outcomes in previous studies [22]. Rychik and colleagues found similar superior mesenteric artery systolic velocities in patients following the Fontan operation with and without protein-losing enteropathy but elevated mesenteric vascular resistance in the group of patients with protein-losing enteropathy [22]. In addition, other studies have shown both increased superior mesenteric artery velocities and an elevated resistive index in infants with necrotizing enterocolitis, particularly in preterm infants with a patent ductus arteriosus [7, 10].

We did not find any difference in gastrointestinal outcomes, including necrotizing enterocolitis, number of feeding-intolerance episodes, gastrointestinal surgeries, or weight gain between the two shunt types. However, our study was likely underpowered to detect a significant difference in many of these outcomes. Contrary to the results seen in our study, one previous study has suggested that the interstage rate of weight gain was increased in patients with a right ventricle to pulmonary artery shunt compared to those with a modified Blalock–Taussig shunt [11]. Gastrointestinal outcomes, including necrotizing enterocolitis and interstage weight gain, are important in the single ventricle population, as these factors have been shown by others to impact the success of future palliative surgical procedures [1, 6].

Limitations

This study is subject to the limitations associated with all observational investigations, including the potential impact of confounders. As an ancillary study of a randomized control trial, selection bias might not be as prominent as is present in many observational studies. In addition, we were able to adjust for several other factors that might influence mesenteric

flow characteristics in our analysis. However, there might be other variables impacting outcome for which we were not able to account. In addition, in regard to postoperative gastrointestinal outcomes, there is likely significant center variation in postoperative management that may influence outcomes assessment. This includes feeding protocols, practice regarding tube feeding and use of the Nissen/G-tube, and use of antireflux medications. Due to the rarity of events such as necrotizing enterocolitis, this study was likely underpowered to detect significant differences between the different shunt types. Finally, this study was limited to assessment of mesenteric flow characteristics at one time point in the postoperative course, and postprandial measurements were not obtained. Therefore, we are not able to assess the impact of feeding on mesenteric blood flow characteristics, including resistive index, in these patients.

Conclusions

We found that the celiac artery resistive index is higher in patients with a single right ventricle following the Norwood procedure with the modified Blalock–Taussig shunt compared to those with the right ventricle to pulmonary artery shunt. Although this would suggest that patients with a modified Blalock–Taussig shunt are at risk for increased mesenteric ischemia, it did not translate into increased gastrointestinal complications in this small group of patients. Further study in a larger population will be necessary to evaluate whether alterations in mesenteric flow patterns and resistance are associated with gastrointestinal complications or feeding difficulties.

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Fig. 1. Spectral Doppler images of the celiac artery: **a** spectral Doppler image of the celiac artery with no retrograde flow; **b** spectral Doppler image of the celiac artery with evidence of retrograde flow in diastole

Table 1

Patient characteristics

	MBTS (n = 19)	RVPAS (n = 25)	Overall (n = 44)	p-Value
Diagnosis				0.40
HLHS	18 (95%)	22 (88%)	40 (91%)	
Critical AS	1 (5%)	0 (0%)	1 (2%)	
Right dominant AVCD	0 (0%)	2 (8%)	2 (5%)	
Other	0 (0%)	1 (4%)	1 (2%)	
Median age at surgery, days (IQR)	4 (4–8)	6 (4–8)	5 (4–8)	0.26
Gender, male	10 (53%)	17 (68%)	27 (61%)	0.36
Median birth weight, kg (IQR)	3.15 (2.88–3.35)	3.10 (2.93–3.31)	3.13 (2.90–3.31)	0.89
Median gestational age, weeks (IQR)	38 (37–38)	38 (37–39)	38 (37–39)	0.20

HLHS hypoplastic left heart syndrome, *AS* aortic stenosis, *AVCD* atrioventricular canal defect, *Other* other single ventricle with critical left ventricular hypoplasia, systemic outflow obstruction, and planned Norwood procedure, *MBTS* modified Blalock–Taussig shunt, *RVPAS* right ventricle to pulmonary artery shunt, *IQR* interquartile range

Table 2

Echocardiographic and celiac artery flow characteristics from Norwood discharge echocardiogram

	MBTS (n = 19)	RVPAS (n = 25)	Overall (n = 44)	p-Value
Celiac artery flow characteristics				
Median peak systolic velocity, cm/s (IQR)	96.3 (71.0–117.9)	80.0 (67.9–100.1)	84.1 (69.2–110.3)	0.22
Median end diastolic velocity, cm/s (IQR)	0 (–9.2–16.2)	15.0 (0–21.2)	12.5 (0–19.8)	0.05
Median resistive index (IQR)	1.00 (0.84–1.14)	0.82 (0.74–1.00)	0.86 (0.78–1.00)	0.02
Diastolic flow reversal present	5 (26%)	1 (4%)	6 (14%)	0.07
Echocardiogram data				
AV valve regurgitation				
Any	13 (68%)	22 (88%)	35 (80%)	0.14
≥moderate	4 (21%)	10 (40%)	14 (32%)	0.21
Neo-aortic valve regurgitation				
Any	5 (26%)	12 (48%)	17 (39%)	0.25
≥moderate	0 (0%)	1 (4%)	1 (2%)	1.00
Median right ventricular EF (IQR) ^a	43.7 (38.6–47.1)	45.3 (38.3–47.4)	45.0 (38.5–47.3)	0.44
Study performed with sedation	7 (37%)	15 (60%)	22 (50%)	0.22
Median age at echo, days (IQR)	17.0 (14.0–27.0)	20.0 (15.0–29.0)	18.5 (14.0–28.0)	0.40

MBTS modified Blalock–Taussig shunt, *RVPAS* right ventricle to pulmonary artery shunt, *AV* atrioventricular, *EF* ejection fraction

^a A total of 16 patients did not have right ventricle ejection fraction data: 6 in the RVPAS group and 10 in the MBTS group

Table 3

Feeding characteristics

	MBTS (n = 19)	RVPAS (n = 25)	Overall (n = 44)	p-Value
Necrotizing enterocolitis (modified Bell staging)				0.50
Stage 1a	0 (0%)	2 (8%)	2 (5%)	
Stage 1b	0 (0%)	0 (0%)	0 (0%)	
Stage 2–Stage 3	0 (0%)	0 (0%)	0 (0%)	
Median DOL feeds started, days (IQR) ^a	13.0 (11.0–14.0)	12.0 (9.5–15.0)	12.0 (10.0–15.0)	0.90
Feeding intolerance episodes ^a				0.58
0	9 (53%)	15 (63%)	24 (59%)	
1–3	5 (29%)	4 (17%)	9 (22%)	
4–6	0 (0%)	2 (8%)	2 (5%)	
>6	3 (18%)	3 (13%)	6 (15%)	
Gastrointestinal Surgery	3 (16%)	3 (12%)	6 (14%)	1.00
Antireflux medications at Norwood discharge ^b	12 (63%)	20 (80%)	32 (73%)	0.37
Median weight, kg (IQR)				
Pre-Stage II echo	5.75 (5.40–6.29)	5.77 (5.00–6.17)	5.76 (5.20–6.20)	0.61
Median weight change, g/day (IQR) ^c				
Birth to Norwood discharge	12.1 (–4.1–20.5)	6.7 (0.4–17.7)	7.8 (–1.3–20.0)	0.67
Birth to Pre-Stage II echo	16.9 (13.5–20.2)	17.8 (15.5–24.3)	17.7 (13.5–22.0)	0.48
Norwood discharge to Pre-Stage II echo	18.1 (14.0–23.1)	21.3 (16.3–27.5)	20.7 (15.1–26.4)	0.40

DOL day of life, MBTS modified Blalock–Taussig shunt, RVPAS right ventricle to pulmonary artery shunt, IQR interquartile range

^aThree patients overall—two in the MBTS group and one in the RVPAS group—did not start oral feeds during the study period

^bTwo patients—one in the MBTS group and one in the RVPAS group—did not survive from Norwood discharge echocardiogram to Norwood hospitalization discharge

^cThirty-four patients overall—13 in the MBTS group and 21 in the RVPAS group—survived to Pre-Stage II echocardiogram