# Single Ventricle Reconstruction Trial Norwood shunt size variation and association with post-operative outcomes

### INTRODUCTION

Morbidity and mortality is high following the Norwood procedure.

Shunt size may significantly impact outcomes

Impact of shunt size and optimal size has not been well described

The Single Ventricle Reconstruction (SVR) trial randomized subjects with a single morphologic right ventricle undergoing a Norwood procedure to a modified Blalock–Taussig-Thomas shunt (MBTTS) or a right ventricle-to-pulmonary artery shunt (RVPAS)

Using data from the SVR trial, we sought to assess variation in shunt to patient size and the association of shunt size with postoperative outcomes.

# METHODS

- The SVR public use dataset was queried.
- Normalized shunt diameter (NSD) was calculated as:

Shunt diameter (mm) Normalized Shunt Diameter 1 (NSD1) = -3weight (Kg)

Shunt diameter (mm) Normalized Shunt Diameter 2 (NSD2) = BSA

- Primary outcome was 30-day mortality after Norwood procedure.
- Secondary outcomes were survival to Glenn procedure, Intensive Care Unit (ICU) length of stay (LOS), and total Norwood length of
- stay. • Pre-operative, operative and post-operative data were collected.

#### Statistical Approach

- Descriptive statistics used to describe patient demographics and preoperative, operative, and postoperative characteristics.
- Logistic regression models with NSD1 and NSD2, receptively, as primary predictor used to evaluate the association of NSD with 30-day mortality and the survival of Glenn.
- Semiparametric ordinal regression models used to model the impact of NSD on ICU length of stay and Norwood length of stay.
- The NSD modeled with restricted cubic splines (3 knots) to allow for the potential non-linear association. Shunt type (MBTS vs. RV to PA) and interaction of NSD by shunt type were included to test NSD-by-shunt type interaction.
- Models adjusted for birth weight, race, gestational age, ECMO use, and CPR use.
- Partial effects plots for NSD by shunt type were generated.
- Effects of model covariates on outcomes were reported as odd ratios (OR).

Table 1

Norwood A Sex (M) Race<sup>a</sup> Non-wh White Hispanic<sup>b</sup> Norwood V Norwood E

Gestationa

Anatomic HLHS **Aortic Atre** Yes

**ECMO**<sup>d</sup> **CPR**<sup>e</sup>

Shunt type MBTTS RVPAS

Shunt dian MBTTS

**RVPAS** 

NSD 1 (mm) MBTTS

**RVPAS** 

NSD 2 (mm)

MBTTS

RVPAS

**Table 1.** Demographic, anthropometric, and perioperative data. <sup>1</sup> Statistics presented: n (%); median (IQR).<sup>2</sup> Statistical tests performed: chi-square test of independence; Wilcoxon rank-sum test. <sup>a</sup>Race data missing for 5 patients. <sup>b</sup> Ethnicity data missing for 10 patients. <sup>c</sup>Aortic atresia status data missing for 70 patients. <sup>d</sup>ECMO status data missing for 5 patients. <sup>e</sup>CPR status data missing for 5 patients. <sup>f</sup>Shunt diameter data missing for 7 patients.

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# Luisa Raga MD, Haleh Heydarian MD, David Winlaw MD, Huaiyu Zang PhD, Nicholas Ollberding PhD, Garick Hill MD

	Overall	30-day mortality		<b>D-</b>				30-day mortality	Survival of Glenn	ICU days	Norwood LOS
	(N=544)	No (N = 482) <sup>1</sup>	<b>Yes (N=62)</b> <sup>1</sup>	value <sup>2</sup>	Variable	Reference	Contrast	OR (95% CI)	OR (95% CI)	OR (95% CI)	OR (95% CI)
an (days)			6 [5 7]	07	Race	Non-White	White	1.29 (0.60-2.77)	1.27 (0.76-2.13)	0.90 (0.62-1.32)	0.93 (0.64-1.35)
ye (uays)	338 (62%)	307 (64%)	0 [5,7] 31 (50%)	0.7	Birth weight	2.75	3.48	<b>0.34 (0.14-0.85</b> )	1.65 (0.88-3.07)	1.02 (0.67-1.54)	1.10 (0.73-1.64)
	000 (0270)	JUT (U+70)	01 (00 /0)	>0.9	Gestational age	37.00	39.00	1.50 (0.94-2.40)	1.14 (0.82-1.58)	0.87 (0.69-1.10)	0.85 (0.67-1.07)
ite	107 (20%)	95 (20%)	12 (20%)	2010	ЕСМО	No	Yes	0.50 (0.21-1.21)	0.64 (0.31-1.31)	4.52 (2.47-8.29)	4.05 (2.23-7.38)
	432 (80%)	383 (80%)	49 (80%)		CPR	No	Yes	<b>10.40 (5.10-21.23</b> )	0.20 (0.11-0.35)	1.65 (1.01-2.70)	1.05 (0.64-1.72)
	100 (19%)	93 (20%)	7 (12%)	0.2	Table 2. ORs a	and 95% CI	s for each	n outcome accord	ing to predictors w	here primary pr	edictor is NSD1
Veight (kg)	3.19 (2.79-3.50)	3.2 (2.8, 3.5)	3.00 (2.40-3.27)	0.002							
<b>BSA</b> (kg/m2)	0.21 (0.19,0.22)	0.21 (0.20, 0.22)	0.20(0.18,0.22)	0.002	Variable	Reference	Contrast	OR (95% CI)	OR (95% CI)	OR (95% CI)	Norwood LOS OR (95% CI)
al age (weeks)	38.0 (37.0.39.0)	38.0 (38.0. 39.0)	38.5(37.0.39.0)	0.5	Race	Non-White	White	1.26 (0.59-2.70)	1.29 (0.77-2.17)	0.91 (0.62-1.32)	) 0.93 (0.64-1.35)
					Birth weight	2.75	3.48	0.43 (0.22-0.84)	1.31 (0.83-2.07)	0.96 (0.70-1.32)	) 1.06 (0.79-1.44)
Diagnosis	400/000/)		40 (770/)	0.2	Gestational age	37.00	39.00	1.47 (0.92-2.35)	1.15 (0.83-1.60)	0.87 (0.69-1.10)	) 0.85 (0.67-1.07)
	469(86%)	443 (92%)	48 (77%)	0.2	ЕСМО	No	Yes	0.48 (0.20-1.17)	0.64 (0.31-1.30)	4.60 (2.50-8.43)	4.04 (2.22-7.36)
siac	311 (73%)	301 (72%)	10 (82%)	0.2	CPR	No	Yes	10.52 (5.15-21.5)	0.20 (0.12-0.36)	1.63(0.997-2.67	) 1.05 (0.64-1.73)
	55 (10%)	<u> </u>	40 (02 %)	0.03	Table 3. ORs a	and 95% CI	s for each	n outcome accord	ing to predictors w	here primary pr	edictor is NSD2
	96 (18%)	65 (13%)	31 (54%)	< 0.001							
•				0.4							
	267 (49%)	233 (48%)	34 (55%)		60 -			Shupt type			Shunt tuno
	277 (51%)	249 (52%)	28 (45%)					MBTS			
neter (mm) <sup>f</sup>								RV to PA			RV to PA
	3.5 (3.5,3.5)	3.50 (3.50, 4.00)	3.5 (3.5,3.5)	0.2					40 -		
	5.00 (5.00,6.00)	5.00 (5.00, 6.00)	5.00 (5.00, 5.12)	0.3							
n/Kg)f					40 -						
	1.12 (1.03,1.27)	1.12 (1.03, 1.27)	1.3 (1.03,1.28)	0.7	ount						
	1.75 (1.55,1.94)	1.74 (1.54, 1.92)	1.89 (1.66,2.16)	0.005	ŏ			C			
n/BSA)f									20-		
	16.92 (15.82,18.24)	16.93 (15.80, 18.24)	16.90 (16.07,18.29)	0.8	20 -						
	25.98(23.72,29.08)	25.90 (23.61, 27.85)	27.22 (25.16, 29.81)	0.03							

#### RESULTS

544 patients were included with 5 patients excluded for ambiguous shunt crossover data. 529 patients were included in the multivariable analyses due to the missing covariates.	•	T n () 0
The 30-day post-operative mortality was $11.4\%$ (n = 62), survival to Glenn was $72.6\%$ (n= 395), the median of ICU length of stay was $14.00$ (IQR: 9.00 to 27.75) and the median of Norwood's length of stay was [24.00 (16.00, 41.00)].	•	T ir S
No significant association between NSD1 or NDS2 and 30-day mortality in either the MBTTS (NSD1 p = $0.238$ , NSD2 p = $0.786$ ) or RVPAS (NSD1 p = $0.968$ , NSD2 p = $0.527$ ) group.		к (Г



The odds of survival to Glenn procedure decreased with increasing NSD1 >1.5 mm/kg and NSD 2 > 20 mm/m<sup>2</sup> in the MBTTS group, but not statistically significant (NSD1: OR = 0.28, 95% CI = 0.04 to 1.90, p = 0.191, NSD2: OR = 0.06, 95% CI = 0.002 to 1.45, p = 0.083) (Figure 2 and Figure 3).

The odds of a longer ICU length of stay increased with increasing NSD1 >1.5 mm/kg n the MBTTS group (OR = 4.11, 95% CI = 1.25 to 13.49, p = 0.020) (Figure 2).

Similarly, the odds of a longer Norwood length of stay increased with increasing NSD1 >1.5 mm/kg in the MBTS group (OR = 4.89, 95% CI = 1.41 to 16.90, p =0.012) (Figure 2).



Figure 2. The non-linear conditional association for NSD 1 (to weight) by shunt type



Figure 3. The non-linear conditional association for NSD 2 (to BSA) by shunt type



### **CONCLUSIONS**

- This is the first multicenter comparative analysis of Norwood shunt size.
- There is significant variation in the shunt sizing relative to patient size for both MBTTS and RVPAS groups.
- In the RVPAS group, there is a wider range of NSD1 and NSD2 associated with good outcomes when compared to MBTTS group.
- A MBTTS NSD1 of  $\geq$  1.5 mm/kg is associated with higher odds of worse post-operative outcomes.
- 30-day mortality is an inadequate outcome in isolation to evaluate optimal shunt sizing due to low event rate. This may represent the ability to prolong life in situations of poor post-operative outcomes in which survival to Glenn is improbable.