Variation in Feeding Practices following the Norwood Procedure

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Objectives To assess variation in feeding practice at hospital discharge after the Norwood procedure, factors associated with tube feeding, and associations among site, feeding mode, and growth before stage II.

Study design From May 2005 to July 2008, 555 subjects from 15 centers were enrolled in the Pediatric Heart Network Single Ventricle Reconstruction Trial; 432 survivors with feeding data at hospital discharge after the Norwood procedure were analyzed.

Results Demographic and clinical variables were compared among 4 feeding modes: oral only (n = 140), oral/tube (n = 195), nasogastric tube (N-tube) only (n = 40), and gastrostomy tube (G-tube) only (n = 57). There was significant variation in feeding mode among sites (oral only 0%-81% and G-tube only 0%-56%, $P < .01$). After adjusting for site, multivariable modeling showed G-tube feeding at discharge was associated with longer hospitalization, and N-tube feeding was associated with greater number of discharge medications ($R^2 = 0.65$, $P < .01$). After adjusting for site, mean pre–stage II weight-for-age *z*-score was significantly higher in the oral-only group (−1.4) vs the N-tube–only (−2.2) and G-tube–only (−2.1) groups ($P = .04$ and .02, respectively).

Conclusions Feeding mode at hospital discharge after the Norwood procedure varied among sites. Prolonged hospitalization and greater number of medications at the time of discharge were associated with tube feeding. Infants exclusively fed orally had a higher weight-for-age *z* score pre–stage II than those fed exclusively by tube. Exploring strategies to prevent morbidities and promote oral feeding in this highest risk population is warranted. *(J Pediatr 2014;164:237-42)*.

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Despite improvements in survival of infants with hypoplastic left heart syndrome (HLHS) following the Norwood procedure, this population remains at risk for a number of medical morbidities. One of the most difficult to manage medical problems in these infants following surgical palliation is poor growth. The pattern of poor growth following the Norwood procedure has been well described,[1-4] with the poorest growth occurring during the early postoperative period and the interstage period, the time between hospital discharge following the Norwood procedure, and the performance of the volume-unloading superior cavopulmonary anastomosis (stage II procedure). Both poor growth during early infancy and longer hospitalizations are risk factors for poor neurodevelopmental outcome[5-7] and increased late mortality.[8]

Although many feeding strategies have been proposed in neonates with HLHS, including standardized feeding protocols[9,10] and preemptive gastrostomy tube (G-tube) placement,[11] none have resulted in dramatic improvement in weight gain during the interstage period or become "standard care" to promote growth in this population. Because of this, there is significant center variation in feeding practice and growth outcomes in these high-risk infants.[3,12]

G-tube	Gastrostomy or gastrojejunostomy tube
HLHS	Hypoplastic left heart syndrome
N-tube	Nasojejunal or nasogastric tube
PI	Principal investigator
SVR	Pediatric Heart Network Single Ventricle Reconstruction Trial
WAZ	Weight-for-age *z* score

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The National Heart, Lung, and Blood Institute–sponsored Pediatric Heart Network Single Ventricle Reconstruction (SVR) Trial was a multicenter, randomized trial of shunt type (modified Blalock-Taussig shunt vs right ventricle–to–pulmonary artery shunt) in neonates with HLHS and other single right ventricular anomalies who were undergoing a Norwood procedure.[13] The purposes of this analysis were to assess differences in feeding practices at the time of hospital discharge after the Norwood procedure among participating centers, identify factors associated with tube feeding, and assess associations among site, mode of feeding, and growth before the stage II procedure.

Methods

Subjects who were consented and enrolled in the SVR Trial between May 2005 and July 2008 at the 15 participating North American centers and who had feeding data recorded at the time of hospital discharge after the Norwood procedure were included in this post-hoc analysis. Institutional review board approval was obtained at each individual site. Briefly, inclusion criteria for the SVR Trial included a diagnosis of HLHS or a related single right ventricular anomaly and a planned Norwood procedure. Exclusion criteria included preoperative identification of an anatomic abnormality that would render either a modified Blalock-Taussig shunt or a right ventricle–to–pulmonary artery shunt technically impossible, and any major congenital abnormality (eg, congenital diaphragmatic hernia, tracheoesophageal fistula, trisomy 13, and trisomy 18) or acquired extracardiac disorder (eg, meconium aspiration with need for high-frequency ventilation, persistent renal failure requiring dialysis) that, in the opinion of the investigator, could independently affect the likelihood of the subject meeting the primary end point.[13] Subjects who were not discharged from the hospital before their stage II procedure were not included in this analysis.

Subject data collected during the SVR Trial included sex, gestational age, birth weight, specific anatomic diagnosis, and the presence or absence of a genetic syndrome. Norwood hospitalization data collected included pre–Norwood procedure intubation, number of discharge medications, number of additional surgical or catheter-based procedures, and Norwood procedure hospitalization length of stay. Mode of feeding at hospital discharge after the Norwood procedure was classified into 4 groups as follows: (1) oral only: all nutrition provided via oral route (breastfeeding or bottle feeding); (2) oral/tube: nutrition provided via oral feeding and supplemented by enteral tube feeding; (3) nasogastric/nasojejunal tube (N-tube) feeding only: all nutrition received via an N-tube; and (4) G-tube only: all nutrition received via a G-tube.

Information regarding the specific type of nutritional support (type of formula, caloric density, total calories per day, bolus vs continuous feedings) was not collected during the SVR Trial.

As part of the SVR Trial, subject weights were obtained at the time of study enrollment (before the Norwood procedure), at the time of hospital discharge after the Norwood procedure, and weight at admission for the stage II procedure. Weight-for-age *z* scores (WAZs) were calculated using the World Health Organization standard.

Statistical Analyses

Associations between WAZ and feeding mode at hospital discharge after the Norwood procedure and clinical site were assessed using ANOVA modeling. Univariate and multivariable logistic regressions were used to examine patient and clinical factors associated with tube feeding.

Continuous variables included gestational age, total cardiopulmonary bypass time, total deep hypothermic circulatory arrest time, oxygen saturation at hospital discharge after the Norwood procedure, number of medications at discharge, number of adverse events, and log-transformed length of hospitalization stay, length of intensive care unit stay, and days of ventilator support. Categorical variables included sex, ethnicity, prematurity (gestational age <37 weeks), confirmed genetic syndrome, diagnosis of HLHS, shunt type (modified Blalock-Taussig shunt vs right ventricle–to–pulmonary artery shunt), associated diagnosis, pre–Norwood procedure intubation, extracorporeal membrane oxygenation support, and whether the patient was discharged on oxygen following the Norwood procedure.

Because the outcome (mode of feeding) is a nominal variable with 4 unordered categories and it is not clinically clear how to convert feeding mode into ordered categories (especially for G-tube vs N-tube), a multinomial logit model was used to analyze associations between the outcome and each of the potential predictors. Therefore, the results are presented as ORs (and estimates) for each of 3 feeding categories vs a reference one (pure N-tube or pure G-tube). To inform selection of the final multivariable model, multinomial logit stepwise regression (with P value for entry = .15 and P value for staying = .05) was used. Multivariable modeling was limited to the predictors that demonstrated reasonably strong univariate associations ($P < .2$). Tukey test was used for post-hoc multiple comparisons. Missing values presented only a minor issue in these analyses, and imputation was not performed.

Results

Of the 555 subjects enrolled in the SVR Trial, 467 survived to discharge and 435 had feeding data recorded at the time of hospital discharge after the Norwood procedure. Three subjects receiving only total parenteral nutrition were excluded, leaving a cohort of 432 for the analysis. There were 140 subjects in the oral-only group, 195 in the oral/tube group, 40 in the N-tube group, and 57 in the G-tube group. WAZs were available before the stage II procedure in 377 of 432 subjects (87%). Data were missing due to death or heart transplant in 48 of 55 cases (87%). Those subjects with missing WAZs before the stage II procedure had lower WAZs at hospital discharge after the Norwood procedure (-2.3 ± 1.2 vs -1.8 ± 1.2, $P = .008$).

Clinical characteristics of the study subjects by feeding mode are shown in Table I. Sex, specific diagnosis, and

Table I. Associations of clinical characteristics with feeding mode at hospitalization discharge after the Norwood procedure

Characteristic	Oral only	Oral/tube	N-tube only	G-tube only	Site-adjusted *P* value*
No. of patients	140	195	40	57	
Sex, n					.40
Male	82 (59%)	137 (70%)	24 (60%)	32 (56%)	
Female	58 (41%)	58 (30%)	16 (40%)	25 (44%)	
HLHS, n					.35
Yes	123 88%)	176 (90%)	34 (85%)	53(93%)	
No	17 (12%)	19 (10%)	6 (15%)	4 (7%)	
Birth weight <2.5 kg, n					.10
Yes	12 (9%)	20 (10%)	7 (18%)	8 (14%)	
No	128 (91%)	175 (90%)	33 (83%)	49 (86%)	
Pre–Norwood procedure intubation, n					**.001**
Yes	44 (31%)	99 (51%)	24 (62%)	33 (58%)	
No	96 (69%)	95 (49%)	15 (38%)	24 (42%)	
Genetic syndrome, n					**.01**
Yes	3 (3%)	8 (6%)	3 (12%)	4 (10%)	
No	115 (98%)	137 (94%)	21 (88%)	36 (90%)	
Gestational age, wk	38.3 ± 1.4	38.4 ± 1.5	38.3 ± 1.8	37.7 ± 1.7	**.02**
No. of discharge medications	4.2 ± 1.6	5.1 ± 1.5	6.4 ± 3.0	6.3 ± 2.7	**<.01**
Median	4	5	6	6	
Log length of Norwood hospitalization, d	3.0 ± 0.4	3.2 ± 0.5	3.3 ± 0.7	3.9 ± 0.6	**<.01**

Data are mean ± SD. Bolded values are statistically significant.
*Wald $\chi 2$ or ANOVA test.

birth weight were similar among the 4 feeding groups. Subjects in the oral-only group were less likely to have required intubation before the Norwood procedure. They also appear less likely to have a genetic syndrome (although overall only 4% of subjects had a genetic syndrome). Subjects in the oral-only group had a shorter length of stay following the Norwood procedure and were receiving fewer medications at the time of discharge. Subjects who were exclusively tube fed (N-tube or G-tube group) at the time of discharge were receiving a greater number of total medications including antireflux medications. Necrotizing enterocolitis, tricuspid regurgitation, and right ventricular function were not associated with feeding mode. A minority of patients were followed using some form of a home monitoring program during the SVR Trial, and therefore this variable was not included in the analysis.

There was significant variability among participating centers in the percentage of subjects receiving each mode of feeding at the time of hospital discharge after the Norwood procedure ($P < .001$). The range across centers for the oral-only group was 0%-81% with a median of 28%, 13%-86% with a median of 48% for the oral/tube group, 0%-43% with a median of 5% for the N-tube group, and 0%-56% with a median of 12% for the G-tube group.

There was no significant difference in WAZ at baseline, discharge, or before the stage II procedure among enrolling sites. However, there were significant differences by site in the change in WAZ from baseline to hospital discharge after the Norwood procedure and from hospital discharge after the Norwood procedure to the stage II procedure ($P \leq .001$).

There was no difference in WAZ at baseline by mode of feeding (range −0.8 to −0.4, $R^2 = 0.01$, $P = .18$). However, significant differences in the WAZ by mode of feeding at discharge (range −2.5 to −1.6, $R^2 = 0.06$, $P < .001$) and before the stage II procedure (range −2.1 to −1.5, $R^2 = 0.03$, $P = .01$) were seen (**Figure**). The changes in WAZ also differed by feeding mode, with the change from baseline to discharge ranging from −1.9 to −1.2 ($R^2 = 0.08$, $P < .001$) and the change from discharge to the stage II procedure ranging from −0.2 to 0.3 ($R^2 = 0.02$, $P = .03$). Subjects in the oral-only feeding group had the least decline in mean WAZ from baseline to discharge (mean change −1.2 ± 0.5), and those in the G-tube group had the greatest decline (mean change −1.9 ± 0.9). Those subjects in the G-tube group demonstrated the greatest increase in mean WAZ between hospital discharge after the Norwood procedure and the stage II procedure (mean change 0.3 vs 0.1 for the oral-only group).

There was significant variability in WAZ by feeding mode at discharge and before the stage II procedure. After adjustment for clinical site, variability in WAZs by feeding mode remained significant at discharge ($R^2 = 0.09$, $P < .001$) and before the stage II procedure ($R^2 = 0.08$, $P = .01$). Clinical site and feeding mode combined explained 21% of the variation in the change in WAZ from baseline to discharge ($R^2 = 0.21$, $P < .001$). Comparisons of WAZs for each feeding mode after adjusting for clinical site and for post-hoc multiple comparisons (Tukey) are shown in **Table II**, which reports adjusted means and pairwise *P* values. Subjects in the oral-only feeding group generally had the highest adjusted mean WAZ and had the lowest decline in WAZ from baseline to hospital discharge after the Norwood procedure.

Univariate analysis revealed a number of significant associations with feeding mode at discharge. Higher odds of being in the oral-only or oral/tube vs N-tube feeding groups were associated with some positive clinic factors, including not receiving supplemental oxygen at discharge (OR and 95% CI 8.6 [2.5-30.5] for oral only, 3.6 [1.4-9.6] for

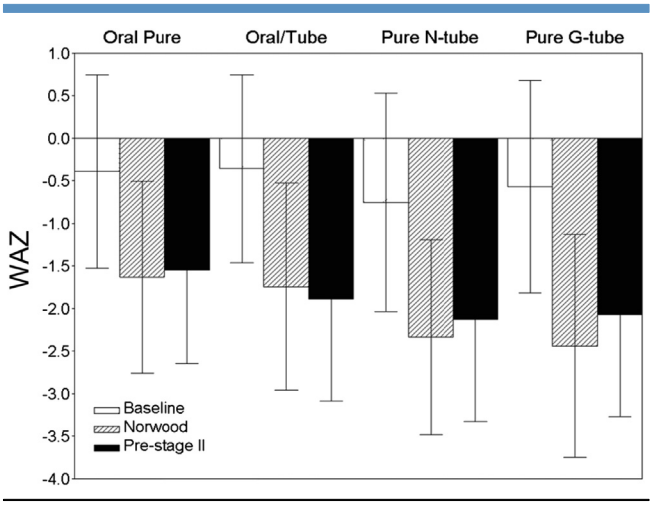

Figure. WAZs at baseline, at hospital discharge after the Norwood procedure, and before stage II.

oral/tube) and absence of significant pre–Norwood procedure complications (OR 2.6 [1.2-5.7] for oral only). Similarly, lower odds were associated with some negative clinical factors including increased log-transformed length of ventilation (OR 0.3 [0.2-0.5] for both), intensive care unit stay (OR 0.3 [0.2-0.5] for oral only, 0.4 [0.3-0.7] for oral/tube) and hospital stay (OR 0.3 [0.2-0.7] for oral only), number of discharge medications (OR 0.5 [0.4-0.6] for oral only, 0.7 [0.6-0.9] for oral/tube), and number of post–Norwood procedure complications (OR 0.8 [0.6-0.9] for oral only, OR 0.8 [0.7-0.96] for oral/tube). Similarly, higher odds of being in the oral-only or oral/tube groups vs G-tube feeding groups were associated with positive clinical factors including decreased post–Norwood procedure complications (OR 0.7 [0.6-0.8] for oral only and 0.8 [0.7-0.8] for oral/tube), and lower odds were associated with negative clinical factors including increased number of discharge medications (OR 0.5 [0.4-0.6] for oral only and 0.7 [0.6-0.9] for oral/tube), and log-transformed length of intensive care unit stay (OR 0.1 [0.06-0.2] for oral only and 0.2 [0.1-0.3] for oral/tube).

The final multivariable model for predicting feeding mode at the time of hospital discharge after the Norwood procedure included the number of post–Norwood procedure medications, log-transformed length of Norwood hospitalization, and clinical site ($R^2 = 0.65$, $P < .001$). When clinical site was not included in the model the number of post–Norwood procedure medications and log-transformed length of Norwood hospitalization explained 30% of the variation in feeding mode ($R^2 = 0.30$, $P < .001$). When antireflux medications were excluded from the analysis, total number of medications remained an independent predictor of feeding mode. The OR of being in a particular feeding category vs N-tube or G-tube ($P < .05$) at the time of discharge is shown in Table III.

Discussion

Despite improvements in surgical techniques and medical management of infants with HLHS who undergo the Norwood procedure,[14] these infants remain at high risk for major morbidities, including growth failure.[1-3,12] In other studies of growth in infants following cardiac surgery, increasing caloric intake has resulted in improved weight gain[15]; however, similar studies are not available in infants with HLHS. Inadequate caloric intake in this population may be due to a number of factors, including oromotor dysfunction, vocal cord paralysis, and gastroesophageal reflux.[16-19] These infants are also at increased risk for the development of necrotizing enterocolitis,[19-21] which may result in multiple interruptions in feeding.

For these reasons, one would hypothesize that enteral feeding tubes would be helpful in infants who have poor feeding and growth, yet the data are mixed in regard to feeding tubes resulting in improved growth,[2,12] and failure to feed orally before hospital discharge after the Norwood procedure is associated with interstage mortality.[22] Our results suggest that this may be due to the fact that those subjects with feeding tubes are a sicker cohort and suffer other medical morbidities, such as longer length of hospital stay and increased medication use, which may contribute to poor growth. These findings are similar to those of DiMaria

Table II. Post-hoc multiple comparison tests (Tukey) for mean WAZs by feeding mode at hospitalization discharge after the Norwood procedure (adjusted for clinical site)

Outcome	Feeding mode	Adjusted mean	Oral only, *P*	Oral/tube, *P*	N-tube, *P*	G-tube, *P*
WAZ at discharge	Oral only	−1.53		.5	.002	<.001
	Oral/tube	−1.75	.5		.02	.003
	N-tube	−2.43	**.002**	.2		.99
	G-tube	−2.5	**<.001**	**.003**	.99	
Change in WAZ from baseline to discharge	Oral only	−1.24		.06	.03	<.001
	Oral/tube	−1.47	.06		.64	**<.001**
	N-tube	−1.62	**.03**	.64		**.04**
	G-tube	−2.01	**<.001**	**<.001**	**.04**	
WAZ before stage II procedure	Oral only	−1.44		.17	.04	.02
	Oral/tube	−1.77	.17		.36	.49
	N-tube	−2.23	**.04**	.36		.95
	G-tube	−2.06	**.02**	.49	.95	

Bolded values are statistically significant.

Table III. Final multivariable model for feeding mode at hospitalization discharge after the Norwood procedure (N = 432, $R^2 = 0.65$)

Reference category	Effect	N	Response	OR	95% CI Lower	95% CI Upper	*P* value*	*P* value†
N-tube	Number of discharge medications (post–Norwood procedure)							<.001
		140	Oral only	0.56	0.42	0.75	<.01	
		195	Oral/tube	0.64	0.50	0.82	<.01	
		57	G-tube only	0.66	0.50	0.88	<.01	
	Log-transformed length of hospital stay‡							<.001
		140	Oral only	0.26	0.09	0.73	.01	
		195	Oral/tube	1.14	0.48	2.70	.76	
		57	G-tube only	12.76	4.36	37.36	<.01	
	Clinical site							<.001
G-tube	Number of discharge medications (post–Norwood procedure)							<.001
		140	Oral only	0.85	0.64	1.12	.25	
		195	Oral/rube	0.97	0.77	1.24	.83	
		40	N-tube only	1.51	1.14	2.01	<.01	
	Log-transformed length of hospital stay‡							<.001
		140	Oral only	0.02	0.01	0.06	<.01	
		195	Oral/tube	0.09	0.04	0.21	<.01	
		40	N-tube only	0.08	0.03	0.23	<.01	
	Clinical site							<.001

*Wald χ^2 test for the null hypothesis that this coefficient is equal to 0 (ie, has no effect on the outcome variable). We reject the null hypothesis if $P < .05$. This *P* value should be ignored if overall $P > .05$.
†Wald χ^2 test test for the null hypothesis that all coefficients are equal to 0. We reject the null hypothesis if $P < .05$.
‡Over the course of the Norwood surgery hospitalization.

et al,[4] who demonstrated associations between tube feeding and disease complexity in a single-center report in a heterogeneous population of infants with shunt-dependent congenital heart disease. Alternatively, growth failure in the tube feeding groups may be due to lack of advancement of daily caloric intake as the child grows. In our study, only a minority of subjects were involved in a home monitoring program. Home monitoring may allow for increased nutritional surveillance, promoting growth as has been shown in other studies.[23-25]

Although subjects at all sites had a decline in mean WAZ from baseline to discharge, subjects at some centers had less of a decline than did subjects at others. Our results, which demonstrate that 21% of the variability in the change in WAZ from baseline to discharge is explained by clinical center and feeding mode, suggest that there are center-specific practices that may result in better growth during this time period.

The National Pediatric Cardiology Quality Improvement Collaborative HLHS registry database revealed significant variability in feeding mode at hospital discharge after the Norwood procedure, as well as interstage growth. Centers using a growth bundle that included standardized feeding evaluation before discharge, use of red flags for weight gain/loss, and an interstage home monitoring program had the best interstage growth.[12] However, feeding mode and its impact on center variability in growth were not analyzed.

Those subjects who were feeding orally at the time of discharge demonstrated the lowest decline in WAZ from baseline to discharge and had stable WAZs during the interstage period. Subjects who were feeding orally but receiving some supplemental tube feedings had a higher WAZ at the time of discharge. Subjects who were receiving exclusively enteral tube feedings at the time of discharge were receiving a greater number of medications and had a longer hospital stay, suggesting this group was generally more ill than the subset of subjects receiving at least some oral feedings. Those subjects who were fed via a G-tube at the time of discharge demonstrated the poorest growth during the hospitalization but did demonstrate some catch-up growth during the interstage period. This finding suggests that these patients may benefit most from the G-tube feedings and would have had poor outcomes with only oral alimentation. Although it is not clear which center-specific practices might lead to a greater proportion of orally fed infants following the Norwood procedure or if those subjects receiving nutrition via enteral tubes are simply too ill to tolerate oral feedings, further exploration of these factors may lead to improved nutritional and feeding recommendations in these patients.

Our study has important limitations. Detailed nutritional data, including preoperative nutrition practices, specific formula, caloric density of the formula, and daily caloric intake, were not collected as part of the SVR Trial. Details regarding the specifics of gastrointestinal disorders including gastroesophageal reflux or necrotizing enterocolitis were not collected. Other anthropometric data including length and head circumference were not collected at every time point; therefore, evaluation of growth was limited to weight only. There may be center-specific practices other than feeding mode that affect growth that were not analyzed. The mode of feeding at hospital discharge after the Norwood procedure was not necessarily the mode of feeding throughout the entire interstage period.

Our findings suggest that understanding center-specific practices that improve growth may result in better outcomes in this high-risk population and potentially other complex congenital heart disease populations at risk for growth failure.

These practices are likely multifactorial and may be impacted by the development of feeding protocols and best practice guidelines to promote oral feeding, as well as standardization of postoperative care through a collaborative approach. ■

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Appendix

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