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ORIGINAL ARTICLE

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Incidence of aspiration in infants with single-ventricle physiology following hybrid procedure

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Abstract

Background: Swallowing dysfunction is a known complication for infants with complex congenital heart disease (CHD), but few studies have examined swallowing outcomes following the hybrid procedure for stage 1 palliation in children with single ventricle physiology.

Objectives: (1) Identify the incidence of aspiration in all infants with single ventricle physiology who underwent the hybrid procedure and (2) Compare results of clinical bedside and instrumental swallowing evaluations to examine the predictive value of a less invasive swallowing assessment for this population of high-risk infants.

Methods: This was a retrospective cohort chart review study. All patients with single-ventricle physiology who underwent the hybrid procedure received a referral for subsequent instrumental swallow assessment during a 4-year period. Results from clinical bedside evaluations were compared to those of the instrumental assessment.

Results: Fifty infants were included in this study. During instrumental swallow assessment, aspiration was observed in 28% of infants following the hybrid procedure. Normal swallowing function was identified in 44% of infants, and 28% demonstrated laryngeal penetration. Neither length of intubation nor prematurity were found to be predictors of aspiration. Thirty-six of these infants were assessed via clinical bedside evaluation prior to the instrumental evaluation. The sensitivity of the clinical bedside evaluation was 0.73 and the specificity was 0.92.

Conclusions: This study reports on a cohort of infants with single ventricle physiology following the hybrid procedure and found the incidence of aspiration to be lower than previously reported. Improved clinical bedside evaluation guidelines are needed so that clinicians can predict more reliably which infants are at risk for aspiration following the hybrid procedure.

KEYWORDS
dysphagia, hybrid procedure, hypoplastic left heart syndrome, single ventricle, swallowing

1 | INTRODUCTION

Oropharyngeal dysphagia is a known complication for infants with congenital heart disease (CHD), though estimates of both incidence and severity of swallowing dysfunction are variable.[1–3] Many infants born with CHD, including those with hypoplastic left heart syndrome (HLHS), require invasive cardiothoracic surgery within the first days of life. Despite recent advances in medical care, the morbidity and mortality continue to be significant for these infants.[4] The Norwood procedure is the most commonly used surgical stage 1 approach for these newly born infants. More recently, the hybrid procedure was introduced as a less invasive alternative to the Norwood surgery.[5,6] The hybrid procedure involves bilateral pulmonary artery banding and maintenance of ductal patency with a ductal stent. The goal of the hybrid procedure is to minimize the impact of having a major surgery early in life in hopes of improving overall clinical outcomes.[6,7]

Swallowing and feeding concerns are common challenges reported for infants with CHD, specifically those following surgical repair procedures.[2,8–10] Studies that examined swallowing following the Norwood procedure have reported high rates of swallowing dysfunction.[3,11] Specifically, the Norwood procedure involves arch reconstruction, which may result in right laryngeal nerve damage and thus dysphagia.[12] Because the hybrid procedure does not involve arch reconstruction, it is possible that feeding and swallowing outcomes might differ from those observed following the Norwood procedure.

Despite the importance that nutrition has on recovery and growth in infants with CHD, especially as infants with single ventricle physiology prepare for their second major surgical procedure, overall research to guide clinical decision making is sparse.[10,13] Much of the data that exists regarding swallowing in infants with CHD is reported following the Norwood procedure. Only two studies specifically examine feeding and swallowing outcomes following the hybrid procedure.[1,14] However, both of these studies were limited because rates of swallowing dysfunction were reported only among patients that were already suspected of having dysphagia, increasing the likelihood of subsequently identifying swallowing impairments during instrumental assessment. Specifically focusing on outcomes for each surgical approach would clarify if impairments in swallowing function differ based on surgical technique. To inform clinical practice and determine which infants might be at greatest risk for feeding and swallowing dysfunction, we must improve our knowledge of current swallowing outcomes following the hybrid procedure for infants with single ventricle physiology. Additionally, we must determine how we can best assess those infants who are at highest risk for swallowing difficulties, and therefore, increased morbidity or mortality.[15,16]

The primary objective of this retrospective chart review study was to identify the incidence of aspiration in all patients with single ventricle physiology who underwent the hybrid procedure at one large pediatric institution. As a secondary objective, we compared results of Bedside Swallowing Evaluations (BSE) and videofluoroscopic swallow study (VFSS) to examine the predictive value of a less invasive swallowing assessment for this population of high-risk infants.

2 | METHODS

2.1 | Participants

This was a retrospective cohort chart review study that took place at a large, tertiary care pediatric hospital in the Midwest of the United States. The study was approved through the institutional review board prior to its initiation. In 2011, our facility implemented a protocol so that all patients with single ventricle physiology who underwent the hybrid procedure would be sent for a VFSS prior to implementing oral feeds. This protocol change was driven by a desire, at the national level, to address interstage mortality in these infants.[17]

Patient charts were identified via a database maintained by the Department of Cardiology that contains data on all patients identified with single-ventricle physiology. Patients were included in the present study if the patient was admitted to our hospital with single ventricle physiology between June 1, 2012 and August 30, 2016, underwent the hybrid procedure, and had a VFSS. Infants were excluded if they had noncardiac abnormalities typically associated with swallowing dysfunction (eg, craniofacial anomalies, stroke). Fifty patients met these inclusion criteria, and their charts were included in this review.

2.2 | Data collection and reliability

Variables collected from patient charts included the following: (a) demographics (gender, race, gestational age), (b) medical diagnoses (both cardiac and noncardiac), (c) number of and length of intubations, (d) consults placed for (and results of) assessments from Otolaryngology (regarding vocal cord function) and BSE with Occupational Therapy (OT; including feeding recommendations made at the conclusion of the BSE), (e) age at time of hybrid surgery, (f) age and results of VFSS (including specifics of all liquids and bottle nipples attempted during the VFSS), and (g) liquid consistency for feeding at discharge.

Penetration-Aspiration Scale Score[18] was recorded as the primary outcome variable during VFSS. The Penetration-Aspiration Scale is an 8-point scale that characterizes swallowing during a VFSS, with 1 indicating a normal swallow with no laryngeal penetration or aspiration. Scores 2–5 indicate laryngeal penetration (bolus entering the laryngeal vestibule but not passing the vocal cords, with depth of penetration increasing with higher values). Scores 6–8 indicate aspiration (bolus passing below the level of the vocal cords, with 8 indicating "silent aspiration," where there is no cough response or attempt to clear). For the purposes of this study, each infant was given a Penetration-Aspiration score for each liquid consistency + nipple combination attempted during the VFSS. Because higher scores on this scale are indicative of greater functional impairment, we considered the highest score (eg, highest value) as the outcome for a given VFSS.

Charts were reviewed by two experienced clinicians within the Department of Cardiology who were blind to the aims of the present study. A code book was created as a reference for both reviewers. Reviewer 1 reviewed all charts contained in this study while reviewer

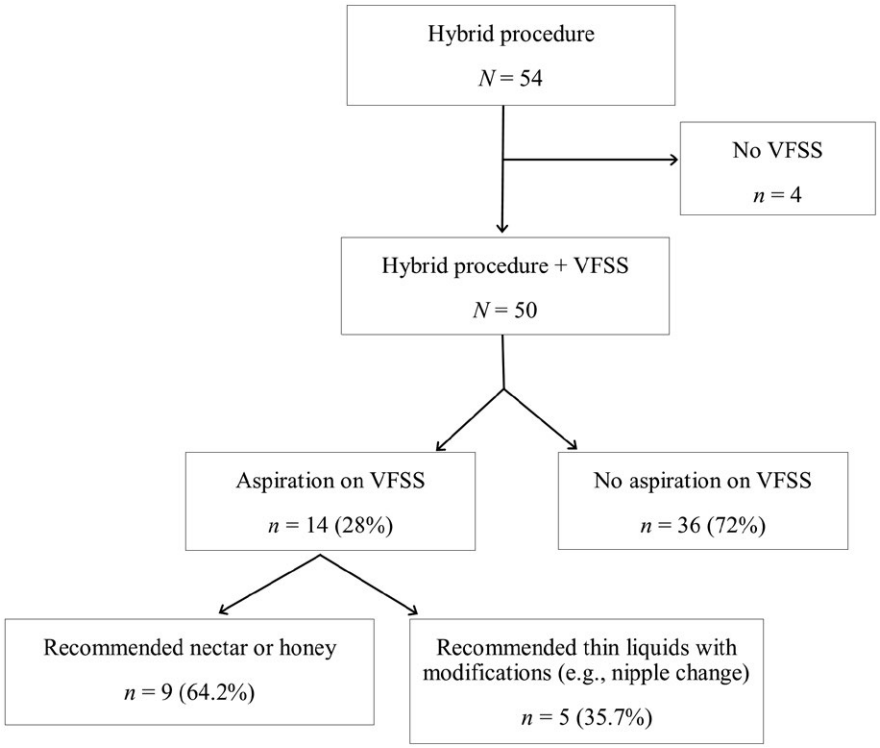

FIGURE 1 Flow diagram for chart selection and swallowing outcomes

2 completed reliability checks on 20% of the charts. Interrater and intrarater point-by-point agreement was calculated for 20% of the charts chosen at random. Intrarater reliability was 98% and interrater reliability was 94%.

2.3 | Data analysis

A descriptive analysis of abstracted charts was completed to explore patient characteristics, results of BSE and VFSS, and to compare findings from these two evaluations. Figure 1 shows the flow diagram for chart selection and breakdown of swallowing outcomes.

Fisher's exact test was used to examine associations between two predictor variables and the primary outcome variable (ie, swallowing function). The predictor variables analyzed were prematurity (yes or no) and tracheal intubation lasting >1 day at any point prior to VFSS (yes or no). These predictors were chosen because in a past study by Davies and colleagues,[14] mechanical ventilation and younger age were both found to be significant predictors of abnormal feeding abilities. The outcome variable was set as dichotomous (aspiration or no aspiration), with a Penetration-Aspiration Scale Score of >6 indicating aspiration and <6 indicating a "normal" swallow.

Sensitivity and specificity analyses were conducted comparing BSE to VFSS. Because a BSE is not expected to detect penetration, patients were grouped by Penetration-Aspiration Scale score into aspiration (scores 6 and above) and nonaspiration (scores 5 and below). As a proxy for detection of potential aspiration, BSEs were coded based on whether feeding modifications were recommended due to clinical observations that indicated possible aspiration.

3 | RESULTS

3.1 | Participants

A total of 50 infants (Figure 1) were included in this retrospective review; 36% (n = 18) of these infants were female. Twenty-nine of these infants were diagnosed with HLHS. The other 21 infants had functional single ventricle physiology. On average, patients underwent the hybrid procedure 6 days after birth. Table 1 provides additional infant demographics and variables of interest.

3.2 | VFSS results

Table 2 shows VFSS results. Of the 50 infants included in this review, 44% (n = 22) showed neither penetration nor aspiration during their VFSS. Penetration (but not aspiration) was identified in 28% (n = 14) of infants during VFSS, indicated by a Penetration-Aspiration Scale[18] score between 2 and 5. Aspiration was identified in 28% of infants (n = 14), indicated by a Penetration-Aspiration Scale score between 6 and 8. Thirteen of these 14 infants who aspirated exhibited silent aspiration (Penetration-Aspiration Scale score = 8).

3.3 | Association between prematurity and days of intubation with swallowing function

There were no statistically significant associations found between aspiration and two predictor variables: prematurity or intubation >1 day (Table 3).

TABLE 1 Infant demographics and variables of interest (n = 50). Summary reporting is n (%) unless otherwise indicated

	Variable	Summary
Demographics	Sex	
	Male	32 (64)
	Female	18 (36)
	Race	
	African American	8 (16)
	Caucasian	31 (62)
	Hispanic	2 (4)
	More than one race	2 (4)
	Unknown	7 (14)
Gestational age	< 35 weeks	1 (2)
	35 weeks	1 (2)
	36 weeks	2 (4)
	37 weeks	6 (12)
	38 weeks	16 (32)
	39 weeks +	24 (48)
Other cardiac diagnoses	Double outlet left ventricle	8 (16)
	Unbalanced artrioventricular canal	5 (10)
	Double inlet left ventricle	3 (6)
	Critical aortic stenosis	4 (8)
	Pulmonary atresia with intact ventricular septum	1 (2)
	Tricuspid atresia	1 (2)
Laryngeal endoscopy by ENT	None	47 (94)
	Yes	3 (6)
	Unilateral vocal cord paresis	2 (4)
VFSS	Average age at procedure (days)	23.4
	Post hybrid (average # of days)	17
	Nasogastric tube in place	16 (32)
	BSE prior to VFSS	36 (72)

TABLE 2 VFSS results for infants tested (n = 50)

Penetration-aspiration scale score	n (%)
Penetration-aspiration scores = 1	22 (44%)
Penetration-aspiration scores = 2–5 (penetration)	14 (28%)
Penetration-aspiration scores = 6–8 (aspiration)	14 (28%)

3.4 | Sensitivity and specificity of BSE

Thirty-six of the 50 infants (72%) included in this study had a BSE with an OT prior to VFSS. Fourteen infants did not receive BSE because during the time of implementation of automatic VFSS, the hospital's clinical protocol transitioned from not requiring a BSE to requiring one for all patients before VFSS. The number of patients identified by VFSS to have aspiration or to exhibit clinical signs indicative of aspiration in BSE can be found in Table 4. Eight infants who aspirated during VFSS were identified appropriately during BSE, as the results of the BSE recommended feeding modifications or VFSS follow-up. BSE resulted in two false-positives (infants who did not aspirate on VFSS were put on modified diets or not recommended to eat by mouth based on findings from the BSE). Thus, sensitivity of BSE (how often BSE detects aspiration) was 0.73.

BSE resulted in three false negatives (infants who were found to aspirate on VFSS but were recommended for ad lib oral feeding after BSE). Twenty-three infants who did not aspirate during VFSS were accurately recommended for ad lib oral feeding following BSE. Thus, specificity of BSE (how often BSE correctly does not recommend feeding modifications because no aspiration is present) was 0.92.

4 | DISCUSSION

Poor growth during the interstage period for infants with single-ventricle physiology has been linked to poorer health outcomes.[19,20] Thus, it is critical that we identify the safest and most efficient way to provide good nutrition to infants following hybrid surgery. One study by Lambert and colleagues[10] found that for infants who underwent the Norwood procedure, only those who were exclusively orally fed had higher weight-for-age during the interstage period when compared to those babies who were exclusively tube fed. These findings reinforce the importance of identifying safe methods of oral feeding to improve the infant's overall outcomes prior to initiating stage 2 surgery.

4.1 | VFSS results

In past studies that have examined swallowing function in infants following the Norwood procedure[3,11] and one study comparing outcomes of the hybrid to the Norwood procedure,[14] rates of swallowing dysfunction have been reported as high as 87.5%,[14] as assessed using VFSS. One study that compared feeding and swallowing outcomes for infants who underwent the Norwood or hybrid procedure[14] found similar rates of swallowing dysfunction regardless of the surgical approach (80% vs 87.5%, respectively). The challenge with these past studies is that the population of interest is characterized by selection bias. That is, the incidence of swallowing dysfunction is often reported amongst the group of patients who is suspected of dysphagia. For example, Yi and colleagues[11] retrospectively examined swallowing dysfunction in infants who underwent open heart surgery. Among these children, they reported that 97% had at least one abnormal finding on VFSS, and 63.6% aspirated. However, these findings should not be surprising, because the infants who were referred for and received a VFSS were exhibiting clinical signs of swallowing problems during feeding at bedside. Looking at their entire sample of patients with open-heart surgery, only 14.4% (21 of 146)

TABLE 3 Associations between swallowing function (as indicated by scores on the Penetration-Aspiration Scale) and both prematurity and days of intubation

	Prematurity			Days of intubation		
	No n = 46	Yes n = 4	P^a	Intubated ≤ 1 day n = 28	Intubated > 1 day n = 22	P^a
Swallowing function			1.0			.78
Normal (Score = 1)	20 (43.5)	2 (50)		13 (46.4)	9 (40.9)	
Penetration or aspiration (Score = 2–8)	26 (56.5)	2 (50)		15 (53.6)	13 (59.1)	

Measures shown are frequency (%).
[a]Fisher's exact test.

TABLE 4 BSE sensitivity analysis: comparison of findings of BSE to VFSS (n = 36)

	VFSS aspiration	VFSS nonaspiration	Total
BSE recommended modifications or VFSS	8 (true positive)	2 (false positive)	10 (# test positive)
BSE recommended ad lib oral feeding	3 (false negative)	23 (true negative)	26 (# test negative)
Total	11 # aspiration	25 # nonaspiration	36 Total

had aspiration that was later identified via VFSS. Yet, it is also important to consider that only 33 of 146 (22.6%) patients reviewed in the study by Yi and colleagues had a VFSS. Therefore, we are not certain that those who did not have a VFSS exhibited normal swallowing, only that there were no significant concerns about safe swallowing raised for these infants during bedside feeding.

The study presented here is the first to report on the incidence of laryngeal penetration and aspiration in a cohort of infants with single ventricle physiology who all had a VFSS following the hybrid procedure, thus removing the self-selection bias that exists in some past studies. In our cohort of infants with single ventricle physiology, 44% had Penetration-Aspiration Scale scores of 1 during their VFSS, indicating no laryngeal penetration or aspiration was observed. Twenty-eight percent demonstrated laryngeal penetration but not aspiration, but all were able to tolerate thin liquids orally using a modified means of feeding identified to be safe and functional during VFSS (eg, change of nipple type).

On the other hand, aspiration was observed in 28% of infants post hybrid, with 93% of those aspirating demonstrating silent aspiration. A closer examination of those infants who aspirated during VFSS showed that three of these infants (21.4%) were able to tolerate thin liquids given a modification of nipple-type or position identified to be safe and functional during VFSS (eg, sidelying vs semi-reclined). Fifty per cent of infants (n = 7) who aspirated thin liquids during VFSS were recommended to take nectar thick liquids, and 28.6% (n = 4) were recommended to take honey thick liquids. The cohort of infants examined retrospectively in this study demonstrated a lower incidence of aspiration (28%) than reported in past studies. McGratten et al[1] prospectively identified aspiration in 50% of infants (n = 36) with single ventricle physiology who underwent both the Norwood and hybrid procedures. Results were not reported in such a way that surgical procedure could be studied as a unique variable.

4.2 | Sensitivity and specificity of BSE

Though it is now standard practice at our facility that hospitalized infants who are referred for VFSS first have a BSE, only 36 of the 50 infants (72%) included in our larger study cohort were examined at bedside before the VFSS was completed. A clinical BSE prior to instrumental assessment allows for a trained clinician to explore feeding in a natural context (including direct breast-feeding) and with liquids that the infant is actually taking (eg, expressed breast milk, fortified formula) and using nipples preferred by the family. Of the 11 infants who had a BSE and then aspirated during VFSS, one infant had a Penetration-Aspiration Scale score of 6 (indicating liquid passed the glottis and was expelled) and 10 infants demonstrated silent aspiration (score = 8). A BSE appropriately raised concerns for swallowing in eight of these 11 cases. Room for improvement clearly remains, as three infants who aspirated during VFSS were not identified at bedside. However, the concerns raised for several infants who exhibited clinical signs of swallowing difficulty at bedside, but silent aspiration during VFSS, reinforces the idea that silent aspiration may be volume dependent.[21] That is, if infants are taking a greater volume of liquid at bedside, compared to the small amount of liquid observed during a VFSS, they may be more likely to show overt signs of aspiration that can be identified by a trained observer. This idea must be examined in future prospective studies.

Furthermore, in this retrospective review, BSE correctly recommended oral feeding with thin liquids for 23 of 26 infants who were also cleared for thin liquids during instrumental assessment

with VFSS. That said, three infants were recommended for ad lib oral feeding who later showed aspiration on VFSS. Additionally, two infants who did not aspirate during VFSS were placed unnecessarily on modified diets following the BSE. Currently, Lefton-Greif and colleagues[22] are working on standardization of VFSS for bottle-fed infants. If BSE were standardized so that sensitivity and specificity were improved, we could reduce the need for instrumental assessment with VFSS. Additional work to increase reliable assessment by BSE could reduce infant exposure to radiation associated with VFSS and allow for more functional feeding assessment of swallowing in infants who are bottle or breast-fed.

4.3 | Limitations and future directions

There are several limitations that impact the generalizability of our study. While we minimized selection bias because all patients in our sample were evaluated via VFSS, we lacked a true control sample. This is a common problem in the pediatric literature due to the ethical challenges associated with radiation exposure for VFSS in nonclinical populations. In our sample, we did not find a significant relationship between prematurity or days of intubation with swallow dysfunction. This may be due to low sample size, since larger retrospective studies have found associations between swallowing outcomes and these predictors.[14] Future studies would benefit from examining additional predictors that could be used with BSE to help predict swallow dysfunction so that clinicians could identify the need for instrumental assessment only in those infants who are at highest risk for swallowing dysfunction. Finally, although BSE was helpful in identifying children with potential swallow dysfunction, our providers did not have a standardized BSE protocol. Creating an evidence-based, valid, and reliable BSE provides promise for identifying infants with swallowing dysfunction in institutions that may not have access to regular VFSS or to help create an evaluation system to identify those infants at highest risk who are most in need of instrumental assessment.

This study identified the rates of aspiration among children with single ventricle physiology who underwent the hybrid procedure. These rates may be different for other forms of CHD or methods of repair, and future study is needed on other specific populations. In our sample, BSE was able to correctly identify most children who had swallowing dysfunction, but further examination is needed to identify other variables or standardized ways of predicting which infants with single ventricle physiology will have swallowing dysfunction. Improved assessment at bedside could reduce the need to assess all patients with VFSS in the future. Using these multiple methods of assessing swallowing function will help to decrease morbidity and mortality by identifying dysfunction in these at-risk infants sooner, in hopes of improving interstage rates of morbidity and mortality.

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CONFLICT OF INTEREST

The Authors disclose that they have no conflicts of interest related to the content of this manuscript.

AUTHOR CONTRIBUTIONS

J. Lundine conceptualized this study, assisted with design, led data analysis/interpretation, and drafted and edited the manuscript.

R. Dempster assisted with design of this study, data analysis, and drafting the manuscript.

H. Miller-Tate assisted with data collection and critical revision of the article.

K. Carpenito assisted with data collection and critical revision of the article.

W. Burdo-Hartman assisted with study design, data interpretation, and critical revision of the article.

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