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ORIGINAL ARTICLE

The Use of Cervical Auscultation to Predict Oropharyngeal Aspiration in Children: A Randomized Controlled Trial

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Abstract In this study, we aimed to determine if the use of cervical auscultation (CA) as an adjunct to the clinical feeding evaluation (CFE + CA) improves the reliability of predicting oropharyngeal aspiration (abbreviated to aspiration) in children. The design of the study is based on open label, randomized controlled trial with concealed allocation. Results from children (<18 years) randomized to either CFE or CFE + CA were compared to videofluoroscopic swallow study (VFSS), the reference standard data. Aspiration was defined using the Penetration-Aspiration Scale. All assessments were undertaken at a single tertiary pediatric hospital. 155 children referred for a feeding/swallowing assessment were randomized into the CFE $n = 83$ [38 males; mean age = 34.9 months (SD 34.4)] or CFE + CA $n = 72$ [43 males; mean age = 39.6 months (SD 39.3)] group. *kappa* statistic, sensitivity, and specificity values, area under receiver operating curve (aROC). No significant differences between groups were found, although CFE + CA (kappa = 0.41, 95 % CI 0.2–0.62) had higher agreement for aspiration detection by VFSS, compared to the clinical feeding exam alone (kappa = 0.31, 95 % CI 0.10–0.52). Sensitivity was 85 % (95 % CI 62.1–96.8) for CFE + CA and 63.6 % (95 % CI 45.1–79.6) for CFE. aROC was not significantly greater for CFE + CA (0.75, 95 % CI 0.65–0.86) than CFE (0.66, 95 % CI 0.55–0.76) across all age groups. Although using CA as an adjunct to the clinical feeding evaluation improves the sensitivity of predicting aspiration in children, it is not sensitive enough as a diagnostic tool in isolation. Given the serious implications of missing the diagnosis of aspiration, instrumental assessments (e.g., VFSS), remain the preferred standard.

Keywords Cervical auscultation · Child · Deglutition disorders · Randomized control trial · Oropharyngeal aspiration · Deglutition

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Introduction

The entry of foreign material into the airway, beneath the level of the vocal cords during swallowing, is known as oropharyngeal aspiration (abbreviated to aspiration) [1]. Aspiration is common; the incidence is as high as 34 % in a hospital cohort [2], and 40–90 % in children with

developmental and neurological disorders [3–8]. Delayed diagnosis of aspiration can lead to acute and chronic lung disease and reduced nutritional intake in children resulting in reduced health and quality of life.[9, 10] Aspiration is also a high risk factor (48 %) associated with hospitalizations for recurrent pneumonia in children [11]. The high incidence of aspiration, coupled with complications when diagnosed late, and the economic cost to the health sector (e.g., repeated hospitalizations for pneumonia) necessitate accurate and early diagnosis of aspiration in children.

Aspiration is typically suspected with a clinical feeding evaluation (CFE) undertaken by a speech pathologist and confirmed by an objective instrumental test (e.g., videofluoroscopic swallow study, VFSS; or fiberoptic endoscopic evaluation of swallowing, FEES). VFSS and FEES are the preferred assessments for aspiration, as they can reliably detect aspiration with the lowest risk of false-negative results [12–18]. However, accessing these assessments is problematic as they may not be readily available in rural areas and developing communities. VFSS involves exposure to radiation, although at acceptable levels [19], while FEES and FEESST may require use of nasal anesthesia due to the invasive nature of the techniques [20]. Both procedures evaluate the child's swallow in a single instance in time and may encounter reduced compliance from the child resulting in limited ingestion of food/fluid volumes affecting diagnosis. Hence, a technique that is well tolerated by children, enhances the accuracy of the readily available CFE to diagnose aspiration risk and reduces reliance on such instrumental assessments will improve the diagnosis of aspiration in children in the wider community.

Many non-instrumental assessments designed for the evaluation of feeding/swallowing disorders in children are limited by robust data on psychometric measures, such as reliability and validity [21]. Using CFE alone to detect aspiration is insufficient due to reduced ability to detect aspiration on solids (30 % sensitivity) and a false-negative rate of up to 40 % on thin/unmodified regular fluids, particularly for patients where there are no overt clinical signs of aspiration present (also known as silent aspiration) [17, 22–26]. A technique that can improve the accuracy of CFE when screening for aspiration would thus be clinically beneficial.

One such technique is cervical auscultation (CA). CA involves the placement of a microphone, stethoscope, or accelerometer onto the surface of the neck to audibly detect breathing and swallowing sounds. Reported differences in acoustic swallowing waveform patterns between pre-term infants with and without chronic neonatal lung disease [27] have demonstrated proof of concept for the use of this technique in pediatrics. Differences in the acoustic parameter of amplitude (loudness) for normal versus abnormal swallowing sounds in a small group of 26 children have also been documented [28]. CA is still, however, limited by a lack of robust data on standardized terminology and descriptors of specific sound features associated with aspiration.

Nevertheless, using CA alone to detect aspiration, sensitivities in the range of 45–94 % and specificities in the range of 56–88 % have been reported in adults [29–33]. A pilot study of 49 children reported CA with CFE (CFE + CA) had a sensitivity of 89 % and specificity of 83 % for aspiration/penetration detection, compared to VFSS [34]. However, the study was limited by a small sample size. To date, there are no other published data evaluating the clinical accuracy of CA to detect aspiration in children [35]. An improved understanding of the diagnostic value of this technique is required before it can be advocated for clinical use. In this randomized controlled trial (RCT), we aimed to determine whether the inclusion of CA during the CFE was more accurate than the traditional CFE in predicting patients who later aspirated during a VFSS.

Methods

We conducted an open label, randomized controlled clinical trial (RCT) at a tertiary children's hospital between October 2012 and August 2014. An RCT protocol for the study has previously been published [36], and the trial was approved by the hospital (HREC/11/QRCH/52) and university (2011001295) Research Ethics Committees. Informed consent was obtained from one legal guardian for each participant.

Participants

Children (aged < 18 years) referred to the speech pathology department for CFE or VFSS were eligible for inclusion. Children were excluded if they were deemed medically unfit by the treating medical team to complete a CFE and VFSS. All data were collected prospectively on-site. All CFEs were completed by speech pathologists.

Randomization, Allocation, and Blinding

A randomization list, stratified by age (<1 or ≥ 1 year), was created by an independent statistician. Assessment allocation (CFE or CFE + CA) was concealed in sequentially numbered opaque envelopes and assigned to enrolled children immediately prior to the commencement of the CFE. The envelope was opened in front of the treating speech pathologist and guardian after consent was obtained.

Speech pathologists who performed the CFE completed a training package prior to partaking in the RCT, which included swallowing and respiratory sound definitions and audio examples. Good-to-very good intrarater and interrater reliabilities were found when they rated 20 swallowing sounds, extracted from a group of healthy children in the community ($n = 10$) and children with defined aspiration from VFSS in a hospital cohort ($n = 10$). The speech pathologists had a categorical choice of "Aspiration/Normal swallow" (eTable 1a, b). Speech pathologists were not masked to the allocated assessment modality due to the requirements of headphone use in the CFE + CA group. The radiologist involved in the VFSS was blinded to all index test allocations and results.

Index Tests

Clinical Feeding Evaluation (CFE)

Participant demographics, and medical and feeding history were collected from the caregiver(s) and medical chart. All children were positioned and fed on the caregiver's lap or in an age-appropriate chair. All children were offered a minimum of two boluses of each food texture and/or fluid consistency. A standard presentation of food and fluids was offered for each child (eTable 2); however, this was modified depending on the child's development, age, and medical status during the CFE and VFSS (i.e., some children were not appropriate for assessment on solid textures due to significantly disordered oral sensorimotor skills). Nevertheless, the order of presentation of textures and/or fluids was the same for all participants during the CFE and VFSS. Solid textures were offered before fluid consistencies for children who were deemed appropriate for assessment on both solids and fluid consistencies (see eTable 2).

The CFE involved the clinician screening the child's medical and feeding history in the context of observed oral sensorimotor, and feeding and swallowing skills during a mealtime [37]. All speech pathologists had completed pediatric dysphagia competency training and were trained to administer a dysphagia assessment consistent with the Speech Pathology Australia's Dysphagia Clinical Guidelines [38]. Speech pathologists were asked to complete a standardized data collection form documenting clinician decision (yes/no) for suspected aspiration on each texture/consistency based on a combination of the presence of clinical signs suggestive of aspiration and pharyngeal phase dysfunction (eTable 3), medical and feeding history and observed feeding/swallowing skills. Suspected aspiration presence was determined using a combination of the above observations during the CFE [39].

Clinical feeding evaluation with cervical auscultation (CFE + CA)

The same CFE was completed, with the addition of CA that was performed as follows: swallowing sounds were digitally recorded live during the assessment (Digital H4n, Zoom Corporation, Tokyo, Japan) via an omnidirectional condenser microphone (C417, AKG Acoustics, Vienna, Austria) (sensitivity at 1 kHz of 10 mV/Pa, impedance 200, frequency range 20-20,000 Hz) [40] which was inserted into a fitted circular O-ring and taped onto the skin lateral to the cricoid cartilage. The microphone was chosen as it has previously been described as the ideal instrument to record swallowing sounds due to its relatively low costs, ability to reject ambient noise, good signal-to-noise ratio, and frequency range compared to a stethoscope and accelerometer. The speech pathologist wore headphones (Model ATH-M50, Audio-Technica, Taiwan) and listened to the live recording of swallowing sounds during the assessment.

Speech pathologists were asked to complete a standardized data collection form documenting perceptual swallowing sounds' parameters (eTable 4) and clinician decision (yes/no) for suspected aspiration on each texture/consistency based on the presence of these parameters, clinical signs suggestive of aspiration and pharyngeal phase dysfunction, medical and feeding history, and observed feeding/swallowing skills.

Videofluoroscopic Swallow Study (VFSS)

After the feeding evaluation, all children had a VFSS within an average of 6.6 days (95 % CI 3.8–9.44) to objectively define the presence/absence of aspiration. The VFSS was chosen as the reference standard due to its reliability and popularity in aspiration assessment with children [23, 41, 42], availability at our facility, and ability to observe all phases of the swallow. A standard VFSS protocol was used based on previous research in pediatric VFSS [19, 39, 42, 43]. The order of presentation of textures and/or fluids was the same for all participants during the CFE and VFSS. Solid textures were offered before fluid consistencies for children who were deemed appropriate for assessment on both solids and fluid consistencies (see eTable 2). A pediatric radiologist and speech pathologist performed the procedure, watched, and interpreted the VFSS findings and determined the aspiration rating at the conclusion of each procedure. Aspiration was considered present when the Penetration-Aspiration Scale was ≥ 6 for any swallow during the assessment [44]. The Penetration-Aspiration Scale describes the level of entry of contrast media into the airway and its response to the penetration/aspiration on a 1–8 point ordinal scale. The Penetration-

Aspiration Scale has high inter- and intrarater reliability for aspiration detection [17, 23].

Statistical Analyses

We planned a sample size of 216 children (80 % power to detect a 15 % difference between the groups, 0.05 significance level) [36]. A blinded preliminary analysis was planned after the first 150 children were recruited due to the imminent relocation of our tertiary hospital to a new location. As a between-group difference of >15 % in kappa coefficients and sensitivities was found when the preliminary analysis was undertaken, recruitment was ceased in August 2014.

Our principal estimates of diagnostic accuracy in aspiration detection were percent agreement and kappa coefficient between CFE or CFE + CA and VFSS assessment. Other estimates of diagnostic accuracy included area under the receiver operating curve (aROC), sensitivity, and specificity; positive and negative likelihood ratios; and positive and negative predictive values. 95 %CI for estimate differences were calculated using nonparametric bootstrapping where parametric methods were unavailable, which included 10000 iterations. Comparisons between the diagnostic accuracy of CFE and CFE + CA were also stratified across both age groups (<1 or ≥1 year). A two-tailed $p < 0.05$ was considered statistically significant. Stata v13 (Stata Corporation, Texas, USA) was used.

Results

We screened 217 referrals for eligibility (Fig. 1) and randomized 157 children between September 2012 and August 2014. Two children from the CFE + CA group were excluded from analyses because of refusal to microphone placement ($n = 1$) and consent withdrawal prior to VFSS completion ($n = 1$), thus leaving 155 children for analysis.

Of the 155 children, 46 (56 %) were referred for suspicion of aspiration or investigation of coughing/choking/gagging during feeding. Demographics were similar between the two groups (Table 1), except that more males were enrolled in the CFE + CA group.

Of the 155 children, 53 (34.2 %) had aspiration diagnosed on VFSS on at least one texture or fluid consistency. For the whole cohort, there was no statistically significant difference between CFE + CA and CFE for aspiration prediction, compared with VFSS (Table 2). aROC was greater for CFE + CA compared to CFE for all age groups (Fig. 2a–c). Specifically, in children <1 year, a larger difference was present between groups (CFE + CA: 0.67 vs CFE: 0.47), whereas in children ≥1 year, the group difference was small (CFE + CA: 0.77 vs CFE: 0.72), in relation to the reference line.

When looking at specific food or fluid textures (eTable 5), the positive predictor value for thin fluids for CFE was significantly higher than that for CFE + CA (difference of 34.5, 95 % CI 30.0–38.9). CFE + CA was better at predicting aspiration on thickened fluids than CFE, with higher sensitivities found for infant thick fluids and level 150 mildly thick/nectar-like fluids. As ≤4 children had aspiration on VFSS (both groups combined) for level 400 moderately thick/honey-like fluids ($n = 1$), semisolids ($n = 0$), and unmodified regular food/level 4 regular diet ($n = 3$), we did not calculate the various accuracy indices for CFE and CFE + CA.

Discussion

Our RCT involving 155 children found that overall there was no statistically significant difference between CFE + CA and CFE at predicting aspiration. Sensitivity values were 85 % for CFE + CA and 63.4 % for CFE overall. The largest difference in favor of CFE + CA was seen in children aged <1 year and when screening for aspiration using thickened fluids.

There are little data on diagnostic test accuracy using CA in the detection of aspiration in children [35]. The sole published study on CA in children involved only 49 children and did not report sample size calculations, randomization, and timing of index tests with VFSS [34]. Nevertheless, the sensitivity of CFE + CA in our study (85 %) was comparable to Eicher et al's [34] study (89 %). However, comparisons of sensitivity values between studies should be interpreted with caution, as the studies likely differed in the aspiration prevalence (not reported in Eicher et al's study) [34] and threshold cutoff used for aspiration. Eicher et al's [34] definition for aspiration combined aspiration and swallows with laryngeal penetration. This may have resulted in an over-diagnosis of true aspiration (entry of foreign material below the level of the true vocal cords) and likely also accounts for higher specificity (83 %) compared to that of our study (65.4 %).

Adult studies [29, 30, 32, 33] have documented sensitivity (66–94 %) and specificity (50–88 %) values for aspiration identification using stethoscope-recorded swallowing sounds. However, these studies utilized CA in isolation, and results cannot be generalized to children as a clinical adjunct to the CFE. Only one adult study [31] has used auscultation in conjunction with the CFE, but the stethoscope was placed on the chest rather than the cervical region. Compared with our study, Shaw et al. [31] reported a much lower sensitivity (45 %) for aspiration detection. Possible reasons for the different results between studies

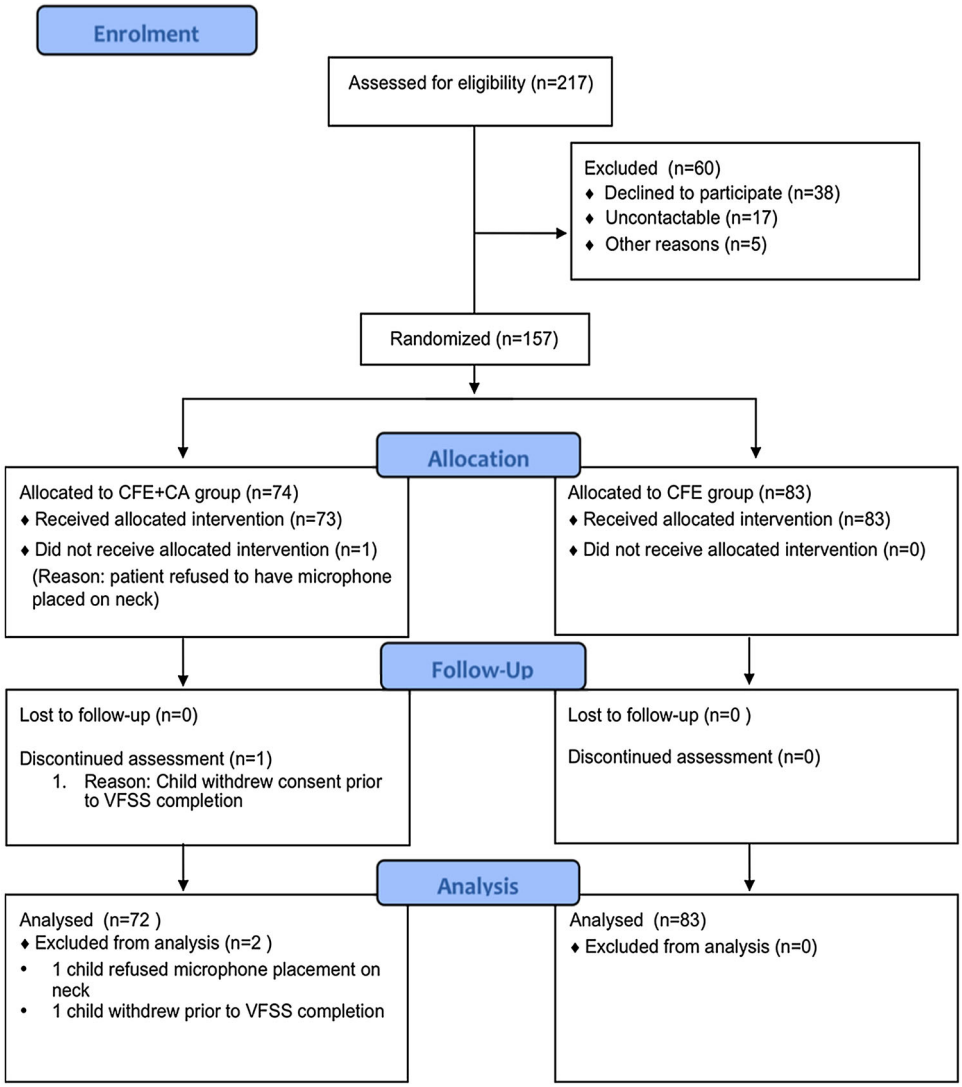


Fig. 1 CONSORT trial overview

include differences in (1) auscultation site and clinical population; (2) use of auscultation methods (a stethoscope likely limits the assessor's ability to detect higher frequencies that are typically associated with swallowing sounds) [45]; and (3) assessors (Shaw et al's study used speech pathologists and physiotherapists). Compared to trained speech pathologists, physiotherapists may be less likely to appreciate the perceptual sounds (eTable 4) known to be important in predicting aspiration [2].

Although intergroup differences were not statistically different across all measures of accuracy (Table 2), there were important clinical differences in sensitivity (i.e., difference of >20 %) [46] as well as aROC values. In the overall cohort, the aROC for CFE + CA of 0.75 (95 % CI 0.65–0.86) is at the level of being clinically relevant [47], whereas that for CFE alone (0.66 95 % CI 0.55–0.76) was below par. This is an important difference as a delayed or missed aspiration diagnosis can lead to acute and chronic lung disease in children.

Our study found that CFE + CA was significantly more accurate in predicting aspiration on thickened fluids, compared to the CFE only. It is well known that fluids with increased viscosity facilitate longer swallow durations [48, 49]. Accessing longer audible individual swallow sound segments via CA may have allowed clinician's extra time to internally process and differentiate components related to their idea of abnormal swallowing sounds. This is important given the lack of standardized sound features and terminologies currently available for the prediction of aspiration using CA in children.

Similarly, better accuracy in the prediction of aspiration for infants under 12 months old was found for CFE + CA, compared to the CFE only. It is possible that the increased adipose tissue around the neck for infants may have aided

Table 1 Baseline characteristics of children randomized to assessment modality of CFE ($n = 83$) or CFE + CA ($n = 72$)

	CFE ($n = 83$)	CFE + CA ($n = 72$)
Age		
Mean (months)	34.9 (34.4)	39.6 (39.3)
Range (months)	2–143	2–185
Age group		
<1 year	22 (26.5 %)	16 (22.2 %)
≥1 years	61 (73.5 %)	56 (77.8 %)
Sex		
Male	38 (46 %)	43 (60 %)
Female	45 (54 %)	29 (40 %)
Weight at clinical evaluation (kg)	14.7 (8.8)	13.5 (6.7)
Height at clinical evaluation (cm)	89.0 (19.8)	89.2 (19.0)
Breastfeeding		
Exclusively breastfed at birth	29 (34.9 %)	16 (22.2 %)
Not breastfed	36 (43.4 %)	43 (59.7 %)
Combination breast, bottle or tube feeding	10 (12.1 %)	6 (8.3 %)
Duration of breast feeding (months)	6·1 (1–18)	4·8 (1–14)
Unknown	8 (9.7 %)	7 (9.7 %)
Solids		
Age commenced solids (months)	5.7 (2.2) $n = 58$	5.6 (3.2) $n = 53$
Medical diagnoses		
Developmental delay	4 (4.8 %)	0 (%)
Neurological	5 (6.0 %)	8 (11.1 %)
Genetic syndrome	8 (9.6 %)	6 (8.3 %)
Multiple co-morbidities	34 (40.1 %)	35 (48.6 %)
Visual or hearing impairment	1 (1.2 %)	0 (%)
Respiratory	15 (18.1 %)	12 (16.7 %)
Gastroenterology	6 (7.2 %)	4 (5.6 %)
No known	10 (12.1 %)	7 (9.7 %)
Reason for referral		
Behavioral feeding issues	0 (%)	3 (4.2 %)
Coughing/choking/gagging on feeds	29 (34.9 %)	17 (23.6 %)
Delayed feeding skills	1 (1.2 %)	0 (%)
Restrictive diet	2 (2.4 %)	1 (1.4 %)
Other	24 (28.9 %)	15 (20.8 %)
Query oropharyngeal aspiration	17 (20.5 %)	24 (33.3 %)
Reduced oral intake	2 (2.4 %)	0 (%)
Query ability to upgrade texture/fluid	8 (9.6 %)	12 (16.7 %)
Speech Pathologist who undertook the feeding evaluation		
Level of dysphagia experience <2 years	0 (%)	0 (%)
Level of dysphagia experience ≥2 to ≤5 years	20 (24.1 %)	11 (15.3 %)
Level of dysphagia experience 5 to ≤10 years	10 (12.1 %)	9 (12.5 %)
Level of dysphagia experience >10 years	53 (63.9 %)	52 (72.2 %)
Feeding status		
Full oral	54 (65.1 %)	46 (63.9 %)
Total oral with modifications	4 (4.8 %)	3 (4.2 %)
Predominantly oral with supplemental tube feeding	5 (6.0 %)	4 (5.6 %)
Predominantly tube feeding with small oral tastes (<20ml liquids or solids)	11 (13.3 %)	11 (15.3 %)
Full tube feeding (e.g., gastrostomy)	9 (10.9 %)	8 (11.1 %)

Table 1 continued

	CFE ($n = 83$)	CFE + CA ($n = 72$)
Tracheostomy present		
Yes	3 (3.6 %)	1 (1.4 %)
No	80 (96.4 %)	71 (98.6 %)
Oxygen requirement at time of assessment		
Yes	3 (3.6 %)	1 (1.4 %)
No	80 (96.4 %)	71 (98.6 %)
Type of tube feeding	$n = 27$	$n = 23$
Nasogastric tube feeding	12 (44.4 %)	6 (26.1 %)
Nasal jejunal tube feeding	0 (%)	2 (8.7 %)
Transplyloric tube feeding	0 (%)	0 (%)
Percutaneous endoscopic gastrostomy	15 (55.6 %)	15 (65.2 %)
Service delivery		
Inpatient	20 (24.1 %)	13 (18.1 %)
Outpatient	63 (75.9 %)	59 (81.9 %)
Time between clinical evaluation and VFSS		
$\leq$1 day	36 (43.4 %)	41 (56.9 %)
>1 to $\leq$7 days	26 (31.3 %)	14 (19.4 %)
>7 to $\leq$14 days	10 (12.1 %)	8 (11.1 %)
>14 days	11 (13.3 %)	9 (12.5 %)

Data are mean (SD), *n* (%), or median (IQR)

CFE Clinical feeding evaluation. *CFE + CA* clinical feeding evaluation with cervical auscultation. *VFSS* videofluoroscopic swallow study

better attachment and concealment of the microphone. This may have reduced the clinician's exposure to any audible background noise and/or artifact and improved their access to the quality of breath/swallow sounds auscultated. Compared with previous research on CA, our study was the first to document the use of an O-ring (similar to a washer) and tape to attach a microphone. Further research investigating how CA via a microphone is attached to the cervical region would be beneficial for improved standardization of this technique.

CFE + CA had consistently higher negative predictor values across all textures, demonstrating excellent ability to rule out aspiration in children. The clinical relevance of our finding is the potential to facilitate more appropriate referrals for VFSS and other instrumental assessment of aspiration following feeding evaluation. This would reduce the potential radiation to the child and financial burden on the health care sector than if VFSS was used as the primary procedure.

Based on current data reported in this study, the routine use of CA for the prediction of aspiration in children is not recommended. However, as use of CA can increase the sensitivity in detection of aspiration at the bedside by 20 %, our data suggest that when there are limited options for instrumental evaluation available, CA should be considered. Such situations include dysphagia clinicians who are located in developing countries or rural areas where access to 'gold standard' instrumental assessments are unavailable. Under these circumstances, one could consider CA as an additional clinical tool (in conjunction with the 3-ounce water challenge, and/or other relevant feeding checklists) [50, 51]. A second scenario pertains to those circumstances that may require frequent feeding/swallowing assessments e.g., children with acute traumatic brain injury [52]. Daily exposure to VFSS and/or FEES would not be feasible from a cost and patient comfort perspective. Thus, a clinical tool such as CA may be used as an additional clinical tool, which is sufficient to implement conservative management strategies (such as recommending thickened fluids in the short term) while awaiting formal instrumental assessment.

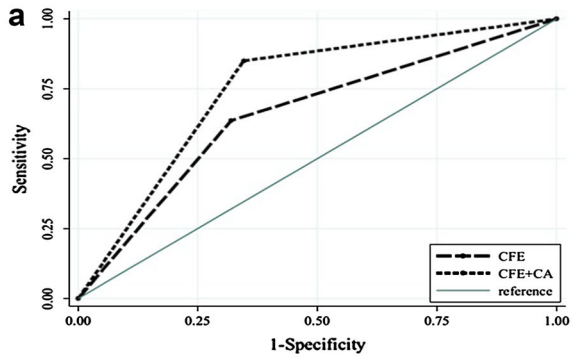
Our study is novel and has several limitations. First, feeding evaluations and VFSS were not completed on the same day, and this may have resulted in false negatives or positives, compared to VFSS results. Our VFSS clinic scheduling was fixed in nature relating to a particular day and the number of available appointments. It was not feasible from an ethical perspective to fast-track VFSS appointments for children involved in the research project and exclude children who did not consent to be a part of the RCT. Hence, outpatient children were booked into the next available VFSS slot, although inpatient children had access to extra slots resulting in a shorter time delay between

Table 2 Comparison of the presence of aspiration on any consistency per group (CFE or CFE + CA), with VFSS results

	CFE ($N = 83$)		CFE + CA ($N = 72$)		Difference (CFE vs. CFE + CA)	
	Aspiration on VFSS	Aspiration on CFE	Aspiration on VFSS	Aspiration on CFE + CA	% (95 % CI)	*p* value
Overall						
Aspiration present, *n*	33	37	20	35		
Sensitivity (95 % CI)	63.6 (45.1–79.6)		85.0 (62.1–96.8)		21.4 (−1.3 to 44.0)	0.09
Specificity (95 % CI)	68.0 (53.3–80.5)		65.4 (50.9–78.0)		−2.6 (−20.9 to 15.7)	0.78
PPV (95 % CI)	56.7 (39.5–72.9)		48.6 (31.4–66.0)		−8.1 (−31.1 to 72.7)	0.49
NPV (95 % CI)	79.9 (58.9–85.7)		91.9 (78.1–98.3)		12.0 (−2.5 to 26.5)	0.13
LR+ (95 % CI)	1.99 (1.23–3.21)		2.46 (1.62–3.72)			
LR− (95 % CI)	0.54 (0.33–0.87)		0.23 (0.08–0.66)			
Kappa coefficient (95 % CI), *n**	0.31 (0.10–0.52)		0.41 (0.20–0.62)		0.10 (−0.18 to 0.38)[a]	0.60
Percent agreement (95 % CI), *n**	66.3 (55.1–76.3), 55		70.8 (58.9–81.0), 51		4.5 (−10.1 to 19.1)	0.55
Age group <1 year	($N = 22$)		($N = 16$)			
Aspiration present, *n*	10	14	5	9		
Sensitivity (95 % CI)	60.0(26.2–87.8)		80.0 (28.4–99.5)		20.0 (−26.4 to 66.4)	0.44
Specificity (95 % CI)	33.3 (9.9–65.1)		54.6 (23.4–83.3)		21.3 (−24.2 to 66.8)	0.36
PPV (95 % CI)	42.9 (17.7–71.1)		44.4 (13.7–78.8)		1.5 (−40.0 to 43.0)	0.94
NPV (95 % CI)	50.0(15.7–84.3)		85.7 (42.1–99.6)		35.7 (−7.6 to 79.0)	0.14
LR+ (95 % CI)	0.90 (0.47–1.72)		1.76 (0.81–3.85)			
LR− (95 % CI)	1.2 (0.4–3.62)		0.37 (0.06–2.3)			
Kappa coefficient (95 % CI), *n**	−0.06 (−0.46 to −0.33), 10		0.28 (−0.15 to 0.71), 10		0.33 (−0.22 to 0.90)[a]	0.25
Percent agreement (95 % CI), *n**	45.5 (24.4–67.8), 10		62.5 (35.4–84.8), 10		17.0 (−14.6 to 48.6)	0.30
Age group ≥1 year	($N = 61$)		($N = 56$)			
Aspiration present, *n*	23	23	15	26		
Sensitivity (95 % CI)	65.2 (42.7–83.6)		86·7 (59.5–98.3)		21.5 (−4.5 to 47.5)	0.14
Specificity (95 % CI)	79.0 (62.7–90.5)		68·3 (51.9–81.9)		−10.3 (−30.0 to 8.6)	0.28
PPV (95 % CI)	65.2 (42.7–83.6)		50·0 (29.9–70.1)		−15.2 (−42.6 to 84.7)	0.28
NPV (95 % CI)	79.0 (62.7–90.5)		93·3 (77.9–99.2)		14.3 (−1.4 to 30.0)	0.10
LR+ (95 % CI)	3.1 (1.56–6.14)		2.73 (1.67–4.47)			
LR− (95 % CI)	0.44 (0.25–0.79)		0.2 (0.05–0.72)			
Kappa coefficient (95 % CI), *n**	0.44 (0.19–0.69), 45		0.45 (0.21–0.69), 41		0.01 (−0.3 to 0.33)[a]	0.87
Percent agreement (95 % CI), *n**	73.8 (60.9–84.2), 45		73.2 (59.7–84.2), 41		−0.6 (−16.6 to 15.4)	0.94

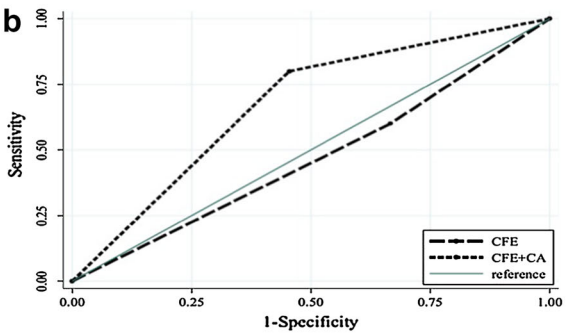
CFE clinical feeding evaluation, *CFE+CA* clinical feeding evaluation with cervical auscultation, *VFSS* videofluoroscopic swallow study, *PPV* positive predictor value, *NPV* negative predictor value. *LR+* positive likelihood ratio. *LR−* negative likelihood ratio, *CI* confidence interval. *n** number of occasions test agreed with VFSS, *N* total number of children in group

[a] Difference obtained from nonparametric bootstrapping of 10000 iterations



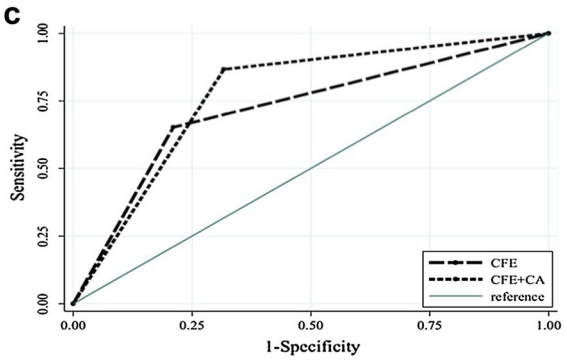
aROC for CFE+CA = 0.75 (95%CI 0.65-0.86); aROC for CFE = 0.66 (95%CI 0.55-0.76).

aROC = area under receiver operant curve; CFE = Clinical feeding evaluation; CFE+CA = Clinical feeding evaluation with cervical auscultation.



aROC for CFE+CA = 0.67 (95%CI 0.42-0.92); aROC for CFE aROC = 0.47 (95%CI 0.25-0.68).

aROC = area under receiver operant curve; CFE = Clinical feeding evaluation; CFE+CA = Clinical feeding evaluation with cervical auscultation.



aROC CFE+CA = 0.77 (95%CI 0.66-0.89); aROC for CFE = 0.72 (95%CI 0.60-0.84).

aROC = area under receiver operant curve; CFE = Clinical feeding evaluation; CFE+CA = Clinical feeding evaluation with cervical auscultation.

Fig. 2 **a** Overall ROC curves comparing CFE + CA and CFE in the detection of aspiration for the whole cohort. **b** Overall ROC curves comparing CFE + CA and CFE in the detection of aspiration for children aged <1 year. **c** Overall ROC curves comparing CFE + CA and CFE in the detection of aspiration for children aged ≥1 year

assessments. This time delay may have led to some difference in the presentation between the two assessments related to recovery over time. However, as the majority of children had a congenital/developmental neurogenic basis to their dysphagia or feeding/swallowing difficulty, which was long standing with symptoms fairly stable over a number of months (i.e., not as a result of an acute event such as cerebrovascular accident or acquired brain injury). Thus, we believe the time difference between clinical and VFSS evaluations would have had a minimal effect on the child's presentation between the two evaluations. This is very different to studies on adult populations in tertiary hospital settings where the majority of patients have acute stroke and clinical presentations may change dramatically over the period of a week related to recovery from the cerebrovascular insult and immediate effects. Nevertheless, future research into the clinical utility of CA should consider completing clinical and instrumental evaluations simultaneously using blinded judges to independently analyze VFSS and CA data separately to minimize swallowing variability.

Second, a majority of CFEs were also completed by speech pathologists with >10 years experience in pediatric dysphagia, which may limit generalization of results for speech pathologists with less experience. However, this could be addressed by appropriate training of less experienced speech pathologists. Third, the high prevalence rate of aspiration in our cohort (from a tertiary center) may not be applicable to data from the community centers (with likely lower aspiration prevalence). Fourth, we ceased recruitment early for reasons expressed above. However, we believe that a difference of >20 % in sensitivity between groups is large enough to influence clinical practice, given the impact of missed or delayed aspiration diagnosis has on the respiratory system in children. Finally, this was an open RCT, which may have influenced the speech pathologist's clinical decision-making on the absence/presence of aspiration.

Conclusion

This study provides diagnostic accuracy data for CA use in children. There was no statistically significant difference between CFE + CA and CFE at predicting aspiration. Advantages for using CA were seen in children aged <1 year and/or when screening for aspiration using thickened fluids. Further research in other clinical settings is required before CA can be advocated for use in conjunction with clinical feeding evaluations. Given the serious clinical implications of missing the diagnosis of aspiration, instrumental assessments (e.g., VFSS) remain the preferred standard to confirm aspiration in children.

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Compliance with Ethical Standards

Conflict of Interest None.

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