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Modified Best-Practice Algorithm to Reduce the Number of Postoperative Videofluoroscopic Swallow Studies in Patients With Type 1 Laryngeal Cleft Repair

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IMPORTANCE There is no consensus as to the timing of videofluoroscopic swallow studies (VFSSs) in determining resolving aspiration after laryngeal cleft repair. There is a growing literature on the effect of radiation exposure in children.

OBJECTIVE To modify a previously published best-practice algorithm based on a literature review and our clinical experience to maintain the quality of care provided after successful type 1 laryngeal cleft repair, while reducing the total number of postoperative VFSSs by 10% or greater.

DESIGN, SETTING, AND PARTICIPANTS The previously published algorithm was modified by a multidisciplinary group at a tertiary care academic medical center (Massachusetts Eye and Ear) and was prospectively applied to 31 children who underwent type 1 laryngeal cleft repair from January 1, 2013, to February 28, 2015.

MAIN OUTCOMES AND MEASURES The number of VFSSs obtained in the first 7 months after surgery was compared with the peer-reviewed literature and with a retrospective cohort of 27 patients who underwent type 1 laryngeal cleft repair from January 1, 2008, to December 31, 2012.

RESULTS The study cohort comprised 31 patients. Their ages ranged from 10 to 48 months, with a mean (SD) age of 23.94 (9.93) months, and 19% (6 of 31) were female. The mean (SD) number of postoperative VFSSs per patient before and after implementation of the algorithm was 1.22 (0.42) and 1.03 (0.55), respectively. The use of the algorithm reduced the number of VFSSs by 0.19 (95% CI, −0.07 to 0.45). This reduction in radiation exposure is equivalent to 1.47 chest radiographs per child per course of care. Surgical success was 87% (27 of 31) compared with our group's previously published success rate of 78% (21 of 27) (absolute difference, 0.09; 95% CI, −0.17 to 0.34).

CONCLUSIONS AND RELEVANCE This modified algorithm to help guide decisions on when and how often to obtain VFSSs after type 1 laryngeal cleft repair can limit patients' radiation exposure, while maintaining high surgical success rates.

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A laryngeal cleft is a rare congenital defect in the tissue that separates the laryngotracheal complex from the esophagus. The etiology is incomplete development of the tracheoesophageal septum.[1] It was first described by Richter[2] in 1872 and was first successfully repaired by Pettersson[3] in 1955. The most widely used classification scheme for laryngeal clefts was developed by Benjamin and Inglis,[4] categorizing laryngeal clefts into 4 types. Type 1 laryngeal clefts have tissue deficiency that does not extend past the true vocal folds. Type 2 laryngeal clefts extend past the true vocal folds into the cricoid cartilage. Type 3 laryngeal clefts extend completely through the cricoid cartilage and into the cervical trachea. Type 4 laryngeal clefts extend to the thoracic trachea.

The true incidence of laryngeal clefts is difficult to report because the condition is likely underdiagnosed. Studies[5-8] have shown the incidence to range from 0.1% to 7.6%. After the establishment of aerodigestive centers, laryngeal clefts were found to be more common than previously reported.[7] The incidence of type 1 laryngeal clefts was reported to be 7.6% in 2006 and 4.4% in 2013 in patients who were seen at our aerodigestive center (Massachusetts Eye and Ear).[9,10] The earlier higher incidence reflects that there were more unrecognized cases before the establishment of our aerodigestive center, and we believe that the 4.4% perhaps is the more representative baseline incidence.[10]

Children with laryngeal clefts are seen with recurrent aspiration pneumonia, asthma-like symptoms, chronic cough, or choking episodes when feeding.[3-7] Nutrition can be impaired due to feeding difficulties.[7] Diagnosis of a laryngeal cleft requires a multidisciplinary approach involving pediatric otolaryngologists, pulmonologists, gastroenterologists, and speech and language pathology (SLP) professionals. Flexible laryngoscopy can be performed in the clinic; however, definitive diagnosis requires direct laryngoscopy with palpation of the interarytenoid area.[6] A vocal fold distractor can be useful to aid in visualization of the interarytenoid space.[10]

The degree of aspiration can be assessed with a functional endoscopic evaluation of swallowing (FEES) or a videofluoroscopic swallow study (VFSS).[6,8] The FEES allows for excellent visualization of the laryngeal anatomy and vocal fold movement, in addition to assessment of lateral vs anterior to posterior spillage. Lateral spilling over the aryepiglottic folds suggests neurological aspiration, thus making diagnosis of laryngeal cleft less likely. However, FEES can be difficult to perform in many children due to patient intolerance and reduced cooperation. The VFSS (also known as modified barium swallow) has the advantage of being noninvasive, so it is commonly used both before and after laryngeal cleft repair.[6,8,10]

Type 1 laryngeal clefts can be managed conservatively with gastroesophageal reflux disease (GERD) management, thickened feeds, and maneuvers during feeding to limit aspiration. Unfortunately, 75% to 80% of patients do not respond to conservative therapy.[8,9] Endoscopic surgical repair is recommended for patients who fail conservative management or have overt clinical signs of aspiration, causing them to be systemically unwell.[8-12]

Successful type 1 laryngeal cleft repair is often evaluated by VFSS.[5,10,13,14] There is no consensus as to the appropriate timing for the use of VFSS after laryngeal cleft repair.[10] Traditional practice at Massachusetts Eye and Ear was to obtain VFSSs on every patient at 6 weeks after repair. If the examination revealed resolution of dysphagia, permitting transition to a thin liquid diet, a trial of this dietary consistency was initiated. Children who continued to require thickened liquids at the 6-week postoperative study were then reevaluated at 3 months and 6 months with further imaging, as clinically indicated. If further studies still demonstrated aspiration after 6 months, a second suspension laryngoscopy would be performed to assess intact cleft repair, or a neurological consultation would be requested (if not done before surgery).[10]

Due to increased awareness of childhood radiation exposure, we thought that it was necessary to reevaluate our practice patterns. The as low as reasonably achievable (ALARA) principle is a radiation safety guideline, focusing on using the smallest amount of radiation necessary to acquire adequate diagnostic information.[15] In an effort to reduce radiation exposure, diet advancement alone after type 1 laryngeal cleft repair may be appropriate for certain children under the careful guidance of a multidisciplinary team. Also, children with comorbidities may need a longer healing time to achieve optimal results. Therefore, we sought to modify a previously published best-practice algorithm based on a peer-reviewed literature review and our clinical experience to maintain the quality of care provided after successful type 1 laryngeal cleft repair, while reducing the total number of postoperative VFSSs by 10% or greater.

Key Points

Question Can the number of videofluoroscopic swallow studies (VFSSs) after type 1 laryngeal cleft repair be reduced by eliminating the postoperative VFSS in a population of healthy children with overt aspiration and by prolonging the interval between surgery and VFSS for children with comorbidities?

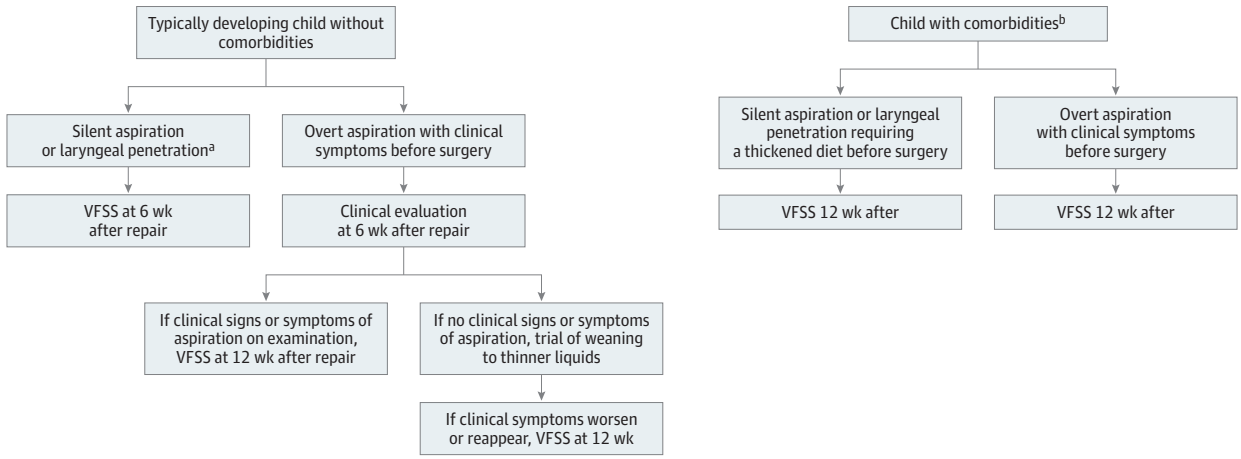
Findings With the use of a modification of a previously published algorithm in 31 patients, the number of VFSSs was reduced at our institution and compared with the published literature.

Meaning It is possible to limit the number of VFSSs (and thus radiation exposure) in children after type 1 laryngeal cleft repair by applying a best-practice algorithm.

Methods

The study was performed at a tertiary care academic center (Massachusetts Eye and Ear). The Massachusetts Eye and Ear Human Studies Committee was approached, and approval was waived because this investigation is a quality report and was not designed as a research study. Informed consent was not applicable because this is a quality review study. In 2012, a multidisciplinary team—consisting of pediatric otolaryngology (C.J.H.), SLP (C.H. and S.S.), pulmonology (M.S.F.), and gastroenterology (S.H.) (whose key members had worked together for >8 years and cared for and managed >100 children

Figure 1. Modified Best-Practice Algorithm



VFSS indicates videofluoroscopic swallow study.

[a] Symptomatic laryngeal penetration such that the patient required a thickened diet before surgery.

[b] Comorbidities that included cardiorespiratory disease, congenital syndromes, or known neuromuscular disorder (eg, hypotonia or seizure disorder).

with aspiration and laryngeal cleft)—modified the previously published algorithm by Ojha et al[10] to decrease the use of postoperative VFSSs (**Figure 1**). Children who had no comorbidities and who had overt clinical signs of aspiration were selected to have diet advancement with close observation by the multidisciplinary team. If the child clinically did not tolerate advancement of diet, a VFSS was then performed at 12 weeks after surgery. Children who had no comorbidities but who had silent aspiration or deep penetration (requiring a thickened diet) on VFSS had a postoperative VFSS performed at 6 weeks. Children with comorbidities, including cardiorespiratory disease, congenital syndromes, or known neuromuscular disorder (eg, hypotonia or seizure disorder), received a swallow evaluation at 12 weeks after surgery. A history of prematurity, asthma (without a history of pediatric intensive care unit admission), or GERD was not considered to represent significant comorbidity.

The modified algorithm was then prospectively applied to any child (age range, 1 month to 17 years) who had type 1 laryngeal cleft repair from January 1, 2013, to February 28, 2015. Repair was performed with an endoscopic microlaryngeal technique using electrocautery to demucosalize the cleft and 1 to 2 7.0 polyglactin sutures to repair the cleft. The number of VFSSs obtained up to 7 months after surgery was recorded. The 7-month interval was chosen because often children who fail the 12-week VFSS receive a second VFSS at 6 months after surgery, and we wanted to have a 1-month window to allow for scheduling conflicts. We then compared the number of VFSSs obtained after surgery with a retrospective cohort of 27 patients who underwent type 1 laryngeal cleft repair at our institution from January 1, 2008, to December 31, 2012. Medical records were retrospectively reviewed, and the number of swallow studies performed in the first 7 months after surgery was recorded.

Results

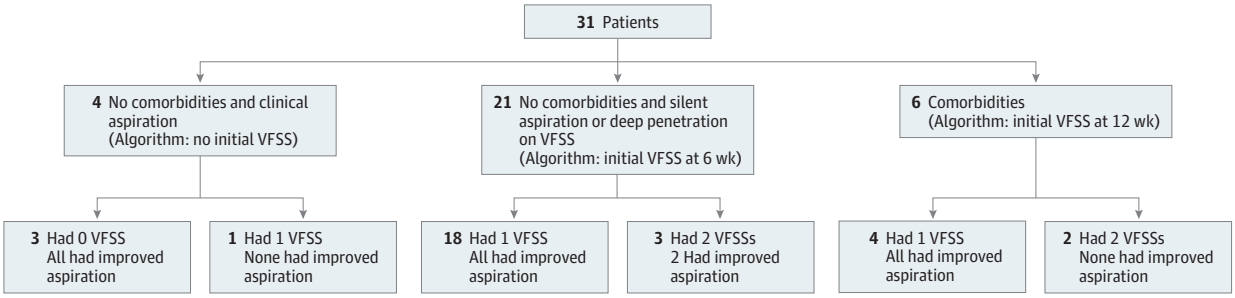
From January 1, 2013, to February 28, 2015, a total of 34 children at Massachusetts Eye and Ear had type 1 laryngeal cleft repair performed by the senior author (C.J.H.). Three (9%) were lost to follow-up, leaving 31 participants. Their age ranged from 10 to 48 months, with a mean (SD) age of 23.94 (9.93) months. In the cohort, 25 (81%) were male, and 6 (19%) were female.

The number of postoperative VFSSs for the prospective group ranged from 0 to 2, with a mean (SD) of 1.03 (0.55). **Figure 2** shows the number of swallow studies obtained in each separate arm of the management algorithm. Among the 31 patients, 4 without comorbidities had overt clinical signs of aspiration; therefore, a VFSS was not initially ordered. Of those, 3 patients did not have any further evidence of aspiration and were advanced to a regular diet at the 6-week visit based on clinical symptoms. The fourth patient had clinical signs of aspiration at the 6-week visit, and a VFSS was ordered at 12 weeks. That patient was later diagnosed as having a neuromuscular disorder.

Twenty-one patients had silent aspiration or laryngeal penetration without additional comorbidities and had a VFSS ordered at 6 weeks after surgery. Improvement in symptoms was noted in 18 of 21 (86%) after the initial swallow study. Three patients required a second swallow study at 6 months after the procedure. Two of those 3 had improvement in symptoms at that time.

Gastroesophageal reflux disease was an associated diagnosis (based on either pH probe or clinical suspicion) in 77% (24 of 31). There were 6 patients with comorbidities, including congenital heart disease (n = 1), seizure disorder (n = 2), neuromuscular hypotonia (n = 1), autism with developmental delay (n = 1), and Loeys-Dietz syndrome (n = 1). A VFSS was

Figure 2. Number of Videofluoroscopic Swallow Studies (VFSSs) and Swallow Results After Implementation of the Modified Algorithm in 31 Patients



The figure shows the number of patients in each arm of the algorithm, the number of VFSSs each group received, and the resolution of aspiration in each group.

Table. Characteristics and Postoperative Course of 4 Patients Undergoing Type 1 Laryngeal Cleft Repair Without Resolution of Symptoms

Preoperative Comorbidity	Age at Surgery	Initial Swallow Study	Clinical Course	Total No. of VFSSs	6-mo Postoperative Bronchoscopy Findings
None	13 mo	At 12 wk (the patient was in the observation arm initially)	The patient was diagnosed as having a neuromuscular disorder, and a neurology workup was obtained	1	No cleft
Seizure disorder, developmental delay	22 mo	At 12 wk	The patient had a second VFSS at 6 mo and then was recommended to have gastrostomy tube placement due to continued aspiration pneumonia	2	No cleft
Autism, developmental delay	3 y	At 12 wk	Additional workup found marked food allergies. We are waiting until these allergies are better controlled before repeating the VFSS	1	Not done
None	2 y	At 7 wk	A second VFSS performed 6 mo after surgery showed no improvement. The patient is hypotonic, with growth and speech delay, and was referred for a neuromuscular workup	2	No cleft

Abbreviation: VFSS, videofluoroscopic swallow study.

ordered in these 6 patients with comorbidities at 12 weeks after surgery, and only 2 patients required more than 1 study. Resolution of aspiration was present in 67% (4 of 6) of this population.

The number of postoperative VFSSs ordered before implementation of the modified algorithm was reviewed. From January 1, 2008, to December 31, 2012, a total of 27 patients had type 1 laryngeal cleft repair performed by the senior author (C.J.H.). There were 7 (26%) females and 20 males. The mean (SD) age was 28 (18) months. The number of postoperative VFSSs ranged from 1 to 2, with a mean (SD) of 1.22 (0.42). After implementation of the modified algorithm, the mean number of postoperative VFSSs was reduced by 0.19 (95% CI, −0.07 to 0.45), from 1.22 (0.42) to a mean (SD) of 1.03 (0.55).

In terms of overall surgical success, there was complete resolution of swallowing symptoms in 55% (17 of 31), meaning that the patient was weaned to a diet of thin liquids. Improvement (transition to a less thickened diet) was noted in 32% (10 of 31). Overall, 87% (27 of 31) of patients had improvement in VFSS results and clinical symptoms. Only 4 patients did not have any improvement in their VFSS results. Of these 4 patients, 3 had a neuromuscular disorder, and 1 had severe food allergy with chronic emesis. A second bronchoscopy was performed at 6 months after the initial repair in 3 of the patients, and there was no evidence of residual cleft. The details of the characteristics and postoperative course for the patients who did not improve are listed in the **Table**.

Discussion

This modification of a previously published algorithm by Ojha et al[10] allows for a reduction in the number of VFSSs obtained after type 1 laryngeal cleft repair. Before implementation of the algorithm at Massachusetts Eye and Ear, all children were receiving a VFSS at 6 weeks after repair. We have shown that children without comorbidities who have overt clinical signs of aspiration before surgery can be evaluated clinically at 6 weeks after surgery. At that point, if there is continued clinical aspiration, time is allowed for further healing, and a VFSS is obtained at 12 weeks after repair. Three out of the 4 patients managed with observation had no residual symptoms and were

transitioned to a regular diet uneventfully. One patient had continued clinical aspiration and received a VFSS at 12 weeks after surgery. That patient was later found to have a neuromuscular disorder and is undergoing a neurological evaluation.

Children with silent aspiration before surgery require more extensive evaluation after surgery. Diet advancement alone may lead to recurrent silent aspiration, resulting in aspiration pneumonia. A VFSS is used to determine if the diet can be safely advanced. Children with deep penetration requiring a thickened diet before surgery were also evaluated with a VFSS at 6 weeks after surgery. Deep penetration has been shown to be a predictor of aspiration on VFSS. During a VFSS, if deep penetration is observed with a certain dietary consistency, one can predict that a trial of a thinner consistency would lead to aspiration. Therefore, a more viscous consistency is introduced, sparing the patient additional radiation exposure and aspiration of barium.[16] Of our patients evaluated after 6 weeks, 18 of the 21 (86%) in that category had improvement in symptoms. Three patients required a second VFSS, and 2 of them had improving symptoms at 6 months. The third patient did not have any improvement and is undergoing a neurological evaluation.

Children with comorbidities have been shown to have worse surgical outcomes after laryngeal cleft repair.[6,10,13,17] Therefore, 12 weeks was allotted before performing a VFSS to allow for optimal healing time. Out of the 6 patients with comorbidities in our population, only 2 did not have improvement in symptoms after 7 months. One patient continued to have severe aspiration pneumonia, despite a bronchoscopy showing a well-healed cleft repair. That patient later received a gastrostomy tube. The second patient with comorbidities was found to have severe food allergy with uncontrollable emesis. Management of the food allergies is the priority in that patient's care. It was deemed that the source of aspiration pneumonia in these patients was not secondary to the laryngeal cleft.

There is a paucity of literature available on how to evaluate resolving aspiration after laryngeal cleft repair.[13,14] Methods described to evaluate swallow function after laryngeal cleft repair include FEES, VFSS, or dye testing.[17] At Massachusetts Eye and Ear, SLP professionals perform a bedside evaluation on postoperative day 1 before discharge to clear the patient to return to his or her preoperative diet. Follow-up is then determined based on the modified algorithm.

There has been no set protocol for the timing of a swallow evaluation after laryngeal cleft repair. Alexander et al[13] concluded that VFSS should be performed at 8 weeks after surgery because they believed that supraglottic postoperative edema should be resolved by that time. A study performed by Osborn et al[17] recommended a swallow evaluation at 3 months after surgery because half of the children in that study were cleared for a normal diet in that time frame. Children who continued to have difficulty swallowing after then were recommended to have a second evaluation at 6 months and then 12 months after repair. Ketcham et al[14] perform VFSS at 3 to 5 months after surgery because the studies tended to demonstrate a higher surgical success rate in that delayed period. The mechanism of the higher success was unclear, but they did not believe that it was due to conservative management because it was thought that the same length of observation before surgery did not lead to resolution of symptoms. Chiang et al[18] assessed the mean number of VFSSs performed after laryngeal cleft repair, and 12 of 25 patients underwent more than 1 postoperative VFSS (mean, 1.8; range, 1-6). Studies were performed at 6 to 8 weeks after the procedure. More than 1 VFSS was obtained in 12 of 25 patients.

Comorbidities among children with laryngeal cleft have been reported to be present in 33% to 100%.[14] There is no standard definition of a "significant" comorbidity (ie, potentially affecting the success rate of laryngeal cleft repair). In our study, we defined cardiorespiratory disease, congenital syndromes, or known neuromuscular disorder (eg, hypotonia or seizure disorder) as significant comorbidities. A diagnosis of GERD was excluded because it is common in children with laryngeal clefts.[10-13] In our patient population, 77% (24 of 31) had an associated diagnosis of GERD based on pH probe or clinical suspicion. A history of prematurity was not considered a comorbidity if the child had appropriate growth and development. Overall, the significance of a patient's comorbidities should be determined based on the discretion of the multidisciplinary team.

Implementation of the modified algorithm allowed us to reduce the number of postoperative VFSSs at Massachusetts Eye and Ear by 0.19 (95% CI, −0.07 to 0.45). This result implies a strong trend demonstrating that the use of this algorithm can reduce the number of VFSSs a child will receive after type 1 laryngeal cleft repair.

It is important to recognize in children with preoperative overt clinical aspiration that radiation exposure can be avoided after type 1 laryngeal cleft repair, and it is safe to follow up these patients clinically. Before implementation of the modified algorithm, a VFSS was ordered in all patients at 6 weeks after surgery. The new algorithm allows for more healing time in children with comorbidities, with the anticipation of avoiding a second VFSS. Our group had previously calculated the amount of radiation exposure per VFSS at our institution, which was presented at the Third Annual Contemporary Management of Aerodigestive Disease in Children in Aurora, Colorado.[19,20] A pediatric VFSS has a mean (SD) effective irradiation dose of 0.16 (0.13) millisievert (mSv) (range, 0.03-0.59 mSv). We compared this value with a single-view pediatric chest radiograph, which has an effective irradiation dose of 0.02 mSv. Therefore, a pediatric VFSS is equivalent to 9.41 chest radiographs. The amount of radiation exposure reduced by this algorithm is equivalent to sparing 1.47 chest radiographs per child undergoing a type 1 cleft repair.

Our operative success rates in this 1.2-year time frame were similar to the prealgorithm results. In 2014, Ojha et al[10] published our group's results demonstrating that 78% (21 of 27) of patients improved after type 1 laryngeal cleft repair in a 6-month period. In the present study, 87% (27 of 31) of patients had improvement in symptoms, for an absolute difference of 0.09 (95% CI, −0.17 to 0.34). The difference in success rates can be explained by the fact that the later population had fewer patients with increased aspiration risk comorbidities (55% [15 of 27] in the study by Ojha et al[10] and 19% [6 of 31] in the present study). Success rates reported by Chiang et al[18] and by Alexander et al[13] were 79% (15 of 19) and 76% (41 of 54), respectively.

Our results showed that before implementation of the algorithm, the maximum number of swallow studies a child received

after the cleft repair was 2. One would expect that some children would have had 3 studies because our prior practice was to obtain VFSSs at 6 weeks, 12 weeks, and 6 months after repair if results had not normalized. The algorithm allows for possible complete elimination of the 6-week study for healthy children with overt aspiration. Children with comorbidities also do not receive the 6-week study because it is unlikely that they will have resolution of aspiration at that point. We exceeded our goal of a 10% reduction in VFSS use, while maintaining a high surgical success rate. In comparing our results with the published literature,[18] we had a 43% reduction in the number of postoperative VFSSs after laryngeal cleft repair. We acknowledge that these studies were tracked over different time frames; however, pursuing a prospective randomized trial of the optimal timing for VFSS would be unethical, subjecting children to unnecessary radiation exposure. It is also difficult to directly compare radiation exposure from VFSSs between institutions because practice patterns vary. In accord with the ALARA principle,[15] our SLP department is conservative and takes great effort to minimize the amount of radiation exposure per VFSS. Therefore, simply reporting a reduction in the number of VFSSs may be misleading, and attention should also be directed to decreasing the radiation exposure per VFSS.

We did not evaluate any VFSSs performed after 7 months because these data were not affected by the modified algorithm. It is unclear at which point the physician should stop ordering VFSSs. We believe that after 6 months further workup needs to be performed. It is important to obtain a neurological consultation (if not done before surgery) and to consider other comorbidities. If other comorbidities are ruled out, a second suspension laryngoscopy with inspection of the repair site should be performed.

Conclusions

We were able to decrease the number of postoperative VFSSs after type 1 laryngeal cleft repair by following the modified best-practice algorithm. The diet can be safely advanced in children without comorbidities with a history of overt preoperative aspiration. Children with comorbidities need extra time to allow for healing before ordering a VFSS. Surgical success after type 1 laryngeal cleft repair was comparable to our group's previously published rate, and the children were exposed to less radiation.

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Study concept and design: Wentland, Hersh, Sally, Fracchia, Hartnick.
Acquisition, analysis, or interpretation of data: Wentland, Sally, Hardy, Liu, Garcia.
Drafting of the manuscript: Wentland, Hersh, Fracchia, Garcia, Hartnick.
Critical revision of the manuscript for important intellectual content: Sally, Hardy, Liu, Garcia, Hartnick.
Statistical analysis: Wentland, Liu.
Administrative, technical, or material support: Wentland, Fracchia.
Study supervision: Hersh, Hartnick.

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