Original Investigation

Type 1 Laryngeal Cleft
A Multidimensional Management Algorithm

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IMPORTANCE Early diagnosis and assessment in children with type 1 laryngeal cleft are essential in preventing aspiration and associated comorbidity. Appropriate use of conservative and surgical interventions in an evidence-based management strategy can improve overall outcome.

OBJECTIVE To evaluate the management of care for children with type 1 laryngeal cleft in our practice and develop an updated management algorithm.

DESIGN, SETTING, AND PARTICIPANTS We performed a review of medical records at a tertiary pediatric aerodigestive center. During a period of 7 years (July 18, 2005, to July 18, 2012), 1014 children younger than 18 years were evaluated for aspiration, choking, cough, or recurrent pneumonia. Of these, 44 children (4.3%) had a type 1 laryngeal cleft. Two were lost to follow-up; thus, 42 children were included in our final sample (28 males, 14 females).

INTERVENTIONS The care of 15 patients (36%) was managed conservatively, and 27 patients (64%) underwent endoscopic surgical repair of their laryngeal cleft.

MAIN OUTCOME AND MEASURE Assessment of our current management strategy.

RESULTS Success was defined as *improving* when a child was able to tolerate a feeding without aspirating or *resolved* when the child had transitioned to tolerating thin liquids. All patients received a trial of conservative therapy. Fifteen of the 42 patients (36%) had an anatomic cleft and were able to maintain the feeding regimen; thus, conservative treatment was successful in this group. The remaining 27 patients (64%) received surgical intervention. Overall operative success rate was 21 of the 27 patients (78%). The age of the child ($P < .01$) and comorbid conditions ($P < .001$) affected the outcomes of conservative measures and surgical repair. Only 6 patients did not demonstrate resolution, 5 of whom had significant comorbidities.

CONCLUSIONS AND RELEVANCE Age, comorbidity status, severity of aspiration, and the ability to tolerate a feeding regimen should be taken into account when deciding on conservative or surgical management for children with a type 1 laryngeal cleft. A clinical pathway for conservative and surgical management is presented.

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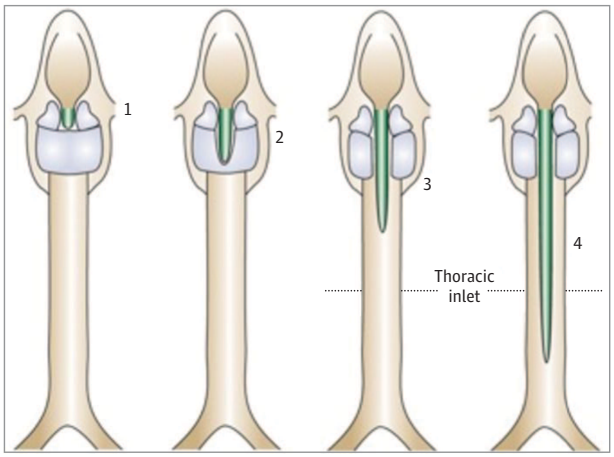
Figure 1. The Benjamin-Inglis Classification System of Laryngeal Clefts



The Benjamin-Inglis classification divides laryngeal clefts into 4 categories. We are interested in type 1 laryngeal clefts, which lie above the level of the true vocal cords (supraglottic interarytenoid clefts). Reprinted from Benjamin and Inglis[13] with permission from Annals Publishing Co.

The first description of a laryngeal cleft was by Richter in 1792.[1] Laryngeal cleft is an anomalous connection between the larynx and hypopharynx. The incidence of laryngeal cleft has varied over the years; initial reports cited a range from 0.1% to 0.47%.[2-6] By 1974, only 33 cases of laryngeal cleft had been reported in the literature[7]; however, current studies report an incidence of 6.2%.[2,8-11] The incidence of type 1 laryngeal cleft in our institution was last reported as 7.6%.[2]

Pettersson devised the initial classification system of laryngeal cleft in 1955.[12] In 1989, Benjamin and Inglis[13] modified this classification system, and this revision is used widely today (**Figure 1**). In the Benjamin and Inglis system, laryngeal clefts are divided into 4 categories. Type 1 laryngeal clefts lie above the level of the true vocal cords (supraglottic interarytenoid clefts).

Presenting symptoms of type 1 laryngeal cleft are nonspecific and include aspiration, chronic cough, and choking during feeding. In our center, children with suspected laryngeal cleft undergo a videofluoroscopic swallow study (VFSS) to assess the degree of aspiration or penetration. Definitive diagnosis then involves visualization of the laryngeal cleft via suspension laryngoscopy, with vocal fold distraction, bimanual interarytenoid palpation, and bronchoscopy.[14]

The current literature consists primarily of reports on small series of patients. Evans et al[15] were one of the first groups to present a large case series, including 26 pediatric patients with type 1 laryngeal cleft, followed by Parsons et al[8] with 41 pediatric patients and Rahbar et al[10] with 53 pediatric patients. All 3 studies suggested an association with comorbidities predisposing children to aspiration, but none looked at how this association may affect overall outcome.

Parsons et al[8] suggested that care of children could be managed successfully with conservative measures. In 2006, the study by Chien et al[2] proved that conservative measures (including the use of thickened liquids and maneuvers to prevent aspiration) could generate a successful clinical outcome. In their study, all children with a confirmed diagnosis of type 1 laryngeal cleft received a trial intervention with a thickened liquid diet, and only those who had worsening symptoms or infection went on to have surgical repair.

None of the studies, however, mentioned what the long-term success rates were and what long-term management should involve. The debate is ongoing regarding when conservative management should be considered over surgical intervention.

In this article, we report our experience with 42 type 1 laryngeal clefts, diagnosed and treated at our aerodigestive center during a period of 7 years, evaluating the long-term outcomes of children whose care was managed conservatively and surgically. We aim to clarify what postoperative management should involve and establish the effect that comorbidities can have on eventual outcome. We also outlined an update to the multidimensional diagnostic and management algorithm devised by Chien et al in 2006.[2]

Methods

A review of the medical records of all patients who received a diagnosis of type 1 laryngeal cleft by the senior author (C.J.H.) from July 18, 2005, to July 18, 2012, was performed (this study was approved by the Massachusetts Eye and Ear Infirmary Institutional Review Board). The following variables were assessed:

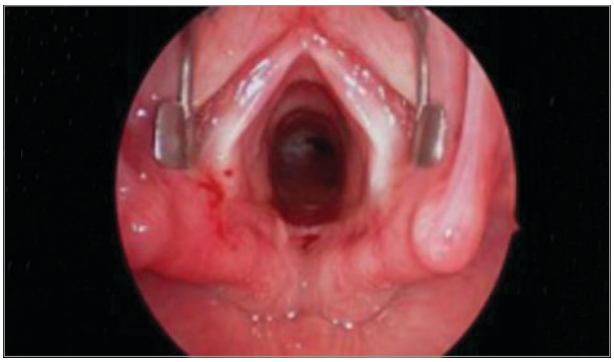
- Demographic information (age and sex),
- Presenting symptoms,
- Diagnostic methods and use of VFSS,
- Success and failure rates at postoperative follow-up,
- Long-term clinical outcomes, and
- Prevalence of comorbidities and their association with the outcome.

To assess the presence, severity, and mechanism of aspiration, all patients received an initial VFSS and were evaluated by our pediatric speech and language pathologists (J.E.A. and C.H.). Each child was defined as having *passed* the VFSS (penetration was absent or minimal, with no aspiration and clinically well) or *failed* the VFSS (aspiration was documented or clinically observed, with a need to continue a thickened diet).

For definitive diagnosis, all 42 patients underwent bronchoscopy and suspension laryngoscopy. In these procedures, the larynx was exposed and vocal cord distractors were used to separate the vocal folds to allow close inspection of the posterior glottis and supraglottis. A suction probe (with suction not used) was then used to palpate the interarytenoid region to confirm the existence of a cleft and assess its depth with relationship to the vocal cord position (**Figure 2**).

In our center, conservative measures are used to manage the care of every child with anatomic type 1 laryngeal cleft confirmed on suspension laryngoscopy who is able to maintain a feeding regimen using thickened liquids. This trial of conservative management involves antireflux therapy, a thickened liquid feeding regimen, and maneuvers during feeding to pre-

Figure 2. Type 1 Laryngeal Cleft

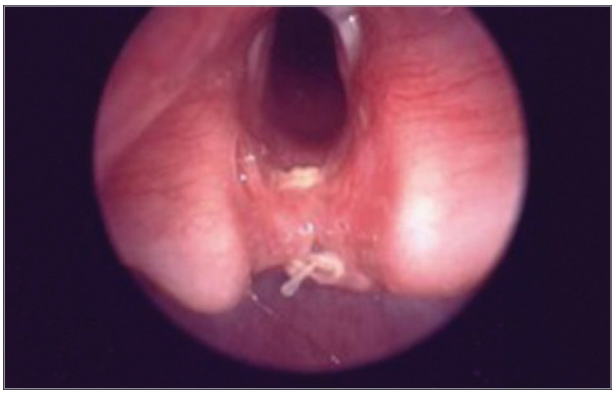


This type 1 laryngeal cleft is viewed with suspension laryngoscopy.

vent aspiration. For children who continue to cough, choke, or aspirate and/or develop recurrent respiratory illnesses despite clinical measures, surgical repair is then recommended unless the severity of the symptoms warrants immediate surgical intervention (**Figure 3**).

Children with surgically managed care underwent a VFSS 6 weeks postoperatively. The results were reviewed by our speech and language pathologists (J.E.A. and C.H.) and defined as *pass* or *fail*. A clinical assessment was then conducted by the senior author (C.J.H.). The patient's status was defined as having *improved* or *resolved* according to the multidisciplinary team assessment. Depending on the severity of the patient's aspiration, the feeding consistency was titrated from thick to thin liquid as the child improved. Patients were then monitored at 3-, 6-, and 12-month intervals based on the multidisciplinary team's recommendations.

Figure 3. Repaired Type 1 Laryngeal Cleft



The cleft was repaired with the use of 5-0 polyglactin 910 sutures.

Table 1. Predominant Presenting Symptoms of Patients with Type 1 Laryngeal Cleft

Predominant Presenting Symptom	No. (%) of Patients[a]
Choking on feedings	19 (45)
Aspiration of thin liquids	9 (21)
Chronic cough	8 (19)
Hoarse voice	2 (5)
Previous diagnosis of laryngeal cleft	2 (5)
Coincidental diagnosis on examination	1 (2)
Recurrent pneumonia	1 (2)
Total	**42** (100)

[a] Because of rounding, percentages do not sum to 100.

Results

During the study period, 1014 pediatric patients were evaluated at our airway center. Forty-four of those 1014 children (4.3%) received a diagnosis of type 1 laryngeal cleft, and 2 of these patients (5%) were lost to long-term follow-up. Forty-two children therefore composed our final sample; the care of 15 of these (36%) was conservative, and 27 children (64%) underwent surgical intervention.

The age at diagnosis ranged from 1 to 72 months, with a mean (SD) age of 16.9 (15.0) months. Of the 42 pediatric patients, 28 were male (67%) and 14 were female (33%), giving a male to female ratio of 2:1. The common presenting symptoms were choking during feeding (19 [45%]), aspiration with thin liquids (9 [21%]), and chronic cough (8 [19%]) (**Table 1**).

We classified success as a child improving (able to transition to a less-thickened liquid) and as resolved (able to tolerate a full diet, including thin liquids) (**Table 2**). Success was established on the basis of discussions with the parents and from medical record documentation. At the 6-week postoperative evaluation, 19 of the 27 surgically managed cases (70%) had improved and none had resolved. At 3 months, 13 of the 27 cases (48%) had improved and 7 cases (26%) had resolved. At 6 months, 10 cases (37%) had improved and 10 cases (37%) had resolved.

The remaining 7 patients (26%) who did not achieve success at 6 months again underwent direct laryngoscopy and bronchoscopy to verify intact laryngeal cleft repair. By 12 months, 12 cases (44%) had resolved, 9 (33%) had improved, and 6 (22%) continued to fail. The overall success rate showed 78% resolution (21 of 27 surgically managed cases) and 22% failure (6 of 27 cases).

Table 2. Improved vs Resolved Outcomes for 27 Surgically Managed Cases

	Primary Outcome, No. (%)[a]		
Postoperative Duration	Resolved	Improving	Failed
6 wk	0	19 (70)	8 (30)
3 mo	7 (26)	13 (48)	7 (26)
6 mo	10 (37)	10 (37)	7 (26)
12 mo	12 (44)	9 (33)	6 (22)

[a] Primary outcomes are defined in the Results section.

Table 3. Comorbid Diagnoses in Patients With Type 1 Laryngeal Cleft

Diagnosis	No. (%) of Patients			
	Total	Conservative Care	Successful Surgery	Failed Surgery
Increased aspiration risk comorbidities	22 (52)	7 (47)	9 (43)	6 (100)
Neurologic (ie, hypotonia, seizures)	5	2	2	1
Gastrointestinal (ie, esophageal atresia, GERD)	9	2	6	1
Respiratory (ie, tracheoesophageal cleft)	3	1	0	2
Congenital syndrome (ie, Down syndrome, Smith-Lemli-Opitz syndrome)	5	2	1	2
Other	0	0	0	0
No increased aspiration risk comorbidities	15 (36)	3 (20)	12 (57)	0
Neurologic	0	0	0	0
Gastrointestinal	0	0	0	0
Respiratory (ie, tracheomalacia, asthma)	6	2	4	0
Congenital syndrome (ie, hematologic disorder)	2	1	1	0
Other (ie, renal disease, recurrent otitis media)	7	0	7	0
No comorbidities	5 (12)	5 (33)	0	0
Total	42	15	21	6

Abbreviation: GERD, gastroesophageal reflux disease.

A 2-tailed paired *t* test was performed to test for a difference in age between the 12 surgically managed cases that resolved vs the 9 that improved. The mean age for the children with resolution was 27.3 (21.6) months and for those with improvement, 19.7 (18.7) months. The age difference at the time of surgery was not statistically significant ($P = .40$).

The association between outcomes and comorbidities was analyzed. Of the 42 pediatric cases, 37 patients (88%) had comorbidities, which we classified as *increased aspiration risk* and *no increased aspiration risk*. These comorbidities were then further subdivided into the system affected (ie, neurologic, gastrointestinal, respiratory, congenital syndrome, or other).

Twenty-two of the 42 patients (52%) had increased aspiration risk comorbidities, and 15 patients (36%) had no increased aspiration risk comorbidities (**Table 3**). A Fisher exact test performed to determine the relationship between comorbidities and observed outcomes demonstrated a significant relationship ($P < .001$). The comorbidities further dichotomized into *any comorbidity* vs *no comorbidity* categories also generated a significant difference ($P = .007$).

Six children (22%) whose care was managed surgically did not demonstrate resolution. Each child had increased aspiration risk comorbidities. All 6 children underwent a second suspension laryngoscopy, which demonstrated a healed cleft, indicating that the source of aspiration was not associated with the presence of a cleft.

Other variables analyzed included the duration of postoperative intubation, the presence of gastroesophageal reflux disease (GERD), and whether these factors had any effect on outcome. Twelve of the children whose care was managed surgically (44%) had been intubated. Of the 6 children (22%) who did not achieve resolution, only 2 patients (33%) had been intubated. There was no correlation between intubation and overall failure to resolve ($P > .05$), perhaps because no child was intubated for longer than 48 hours (mean duration, <24 hours).

All 42 cases were discussed with our pediatric gastroenterologist (J.R.) to confirm the diagnoses. Gastroesophageal reflux disease was identified by symptom complex, pH probe, and prior endoscopy. Three of the 6 children who did not achieve resolution with surgical management had a diagnosis of GERD (positive pH probe result) and were receiving maximal medical therapy for acidic reflux.[16] Thus, GERD cannot be considered as the cause of their ongoing symptoms.

Fifteen of the 42 patients (36%) responded to initial conservative management. Review by the multidisciplinary team and clinical assessment by the senior author (C.J.H.) determined that they were fit to continue with conservative measures.

Eleven of the 15 children (73%) whose care was managed conservatively underwent an initial VFSS; of these, 10 patients (67%) failed the VFSS and 1 child (7%) passed. The remaining 4 patients (27%) underwent no initial VFSS because of either parental or patient refusal.

All 15 patients (36%) with conservative management showed improvement within 2 months and then were able to tolerate thin liquids (ie, resolved). Of these, 7 children had increased aspiration risk comorbidities, 3 had no increased aspiration risk comorbidities, and the remaining 5 cases had no comorbidities. The mean time of use for thickened liquid diet was 6.14 (4.85) months, with a range of 2 weeks to 18 months (**Table 4**).

A *t* test showed a statistically significant difference in age between successful cases managed conservatively compared with those managed surgically ($P < .01$). The mean age for the 15 patients who received conservative intervention was 10.3 (6.3) months and for the 21 successful surgical cases was 22.2 (18.4) months. Follow-up ranged from a minimum of 6 weeks to a maximum of 7 years.

Table 4. Duration of Thickened Feeding Regimen for 15 Conservatively Managed Cases

Time of Thickened Feeding Regimen, mo	No. (%)[a]
0-3	6 (40)
4-6	3 (20)
7-9	2 (13)
10-12	2 (13)
>12	2 (13)
Total	15 (100)

[a] Because of rounding, percentages do not sum to 100.

Discussion

The incidence of type 1 laryngeal cleft in the present study was 4.4%, which is lower than that in a study (7.6%) conducted by Chien et al,[2] in which our senior author (C.J.H.) was an investigator. The high incidence recorded by Chien et al was when our aerodigestive center was first implemented. Initially, we accounted for the undiagnosed cases seen in our department before establishment of our center. We believe that our lower incidence of 4.4% is a more accurate reflection of the true incidence of type 1 laryngeal cleft.

Our goal was to assess whether our current management of care for children with type 1 laryngeal cleft may be affecting our successful outcome rates. With the data obtained in the present study, we have shown that we can obtain high rates of successful outcomes by using this management algorithm, which is supported by the fact that 100% (n = 15) of our conservatively managed cases and 70% of our surgically managed cases (n = 19) were successful at 6 weeks postoperatively. In addition, we have proved there is an effect of comorbidities on a successful outcome. We have thus produced an updated management algorithm[2] for children with type 1 laryngeal cleft (**Figure 4**).

Patients with suspected laryngeal cleft should undergo a careful history and physical examination. Our patients' presenting symptoms were comparable to those in the other studies,[1,8,16,17] with aspiration and respiratory difficulties the most common. Such cases should be investigated via VFSS and suspension laryngoscopy with bronchoscopy to evaluate a suspected laryngeal defect.

We recommend VFSS over functional endoscopic evaluation of swallowing (FEES); in our experience, children younger than 4 years are often distressed during the FEES procedure with episodes of crying, rendering the conclusions about baseline feeding difficult to interpret. However, FEES may have a role in identifying neurologic aspiration where there is lateral spillage and aspiration over the aryepiglottic fold as opposed to posterior to anterior aspiration.

Gastroesophageal reflux disease can be present with laryngeal clefts; an associated incidence of 21% to 44% has been reported.[4,9] Gastroesophageal reflux disease can lead to surgical failure if not managed effectively prior to repair.[10,12] All patients with type 1 laryngeal cleft should be assessed for GERD by a pediatric gastroenterologist, with definitive diagnosis determined via endoscopy and pH probe; if indicated, trial therapy using a proton pump inhibitor should be initiated.[17]

If the VFSS shows a confirmed laryngeal cleft with significant aspiration, the child receives a trial of thickened liquid feedings followed by subsequent swallow evaluations and another VFSS. There remains some debate as to when and how frequently a VFSS should be obtained and when a clinical swallow evaluation alone is sufficient.

All remaining patients who have an anatomic cleft, are able to tolerate thickened feedings, and can maintain a feeding regimen should receive at least 3 months of conservative therapy. We suggest 3 months because our data showed symptomatic improvement in all conservatively managed cases at this point, with 6 of these cases (40%) having resolved within that time.

All of our patients who received conservative management (15 of 42 [36%]) showed overall resolution, and this rate is comparable with that Parson et al[8] and Rahbar et al,[10] in which all conservatively managed cases resolved.

Our data have shown that patients who are younger (mean, 10.3 [6.3] months; $P < .01$) tend to have successful outcomes with conservative therapy. Age is an important factor in deciding whether a child's care should be managed conservatively or surgically. To be successful with conservative management, the parent has to adhere to the feeding regimen; however, by the time these children are 2 to 3 years old, the parents are less adherent. Even though the children are still technically "safe" while receiving conservative measures, most parents opt for surgical repair. This explains our findings as to why fewer older children will improve with conservative measures alone and will require surgery.

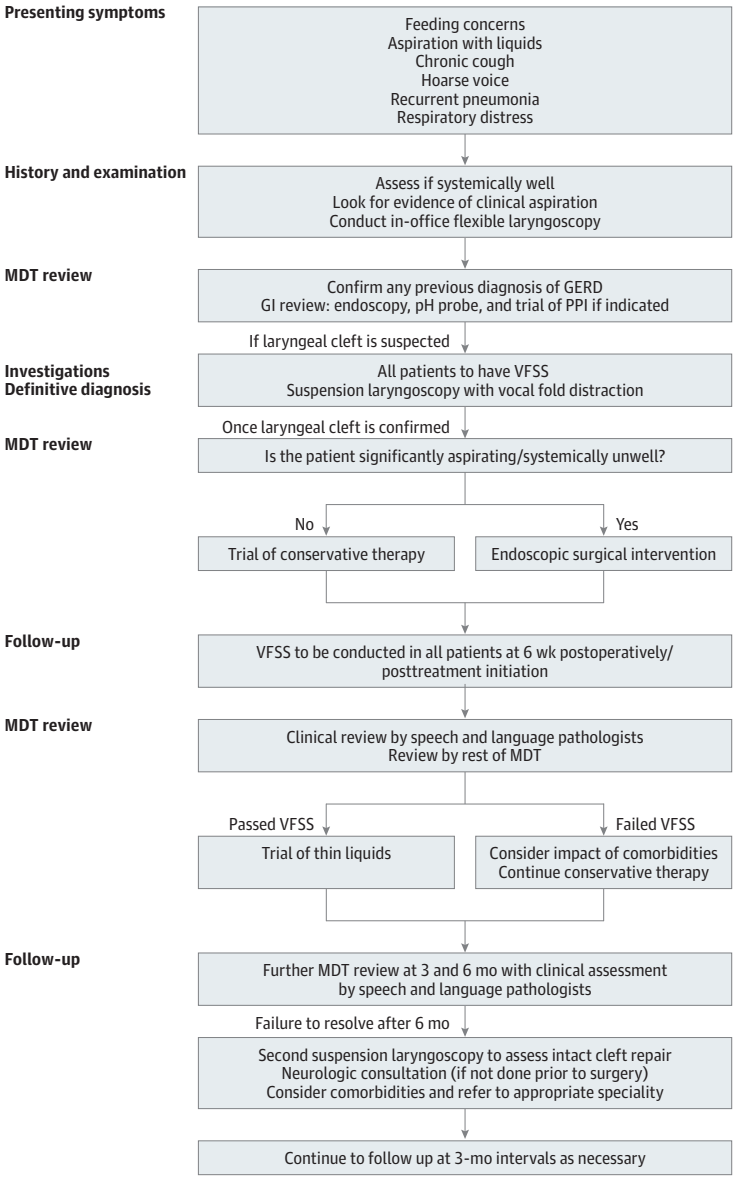
One could argue that it is possible that some children's symptoms may have improved with maturation, with no need for surgical intervention. In the present study, children who underwent surgical intervention had pneumonia when conservative therapy was used initially, thus warranting the procedure. Surgical repair allows for quicker and thereby safer swallowing, allowing these children to transition to oral feedings faster than simply allowing for time and maturation to improve their symptoms.

In current reports, comorbidities exist in at least 50% of laryngeal cleft cases.[9] In the present study, 88% of our patients (n = 37) had comorbidities. There was a statistically significant relationship ($P < .001$) between increased aspiration risk comorbidities and an overall successful outcome.

When we further dichotomized comorbidities into any (37 [88%]) vs no (5 [12%]) comorbidity, a significant difference ($P = .007$) was identified. We can confidently say that comorbid status affects having a successful outcome. Children with increased comorbidities had worse outcomes in terms of both conservative and surgical success. Although our choice of dichotomizing comorbidities is arbitrary, the point is clear, and further work needs to be done regarding prognostic indicators for specific comorbidities.

Two of the 6 surgical cases that did not resolve had increased aspiration risk congenital syndromes. This is comparable with the findings of Rahbar et al,[10] in which the 7 patients (13%) who continued to be symptomatic after surgical intervention had significant congenital comorbidities. Rah-

Figure 4. Multidimensional Management Algorithm for Type 1 Laryngeal Cleft



An update to the algorithm proposed by Chien et al[2] on evaluating and managing care for patients with type 1 laryngeal cleft. GERD indicates gastroesophageal reflux disease; GI, gastrointestinal; MDT, multidisciplinary team; PPI, proton pump inhibitor; and VFSS, videofluoroscopic swallow study.

bar et al[10] recommend that surgical repair should not be advocated in such cases. However, we believe that surgical repair should be conducted in children with increased aspiration risk comorbidities, particularly if they exhibit significant aspiration. Even though these cases are unlikely to fully resolve or may take more time to achieve resolution, surgery will allow some symptomatic improvement, the benefits of which outweigh the risks.

In our center, the protocol is to perform a postoperative VFSS at the 6-week time point. The success rate of 70% at 6 weeks postoperatively is high enough to outweigh the risks of radiation exposure. That said, we are conducting a study on whether postoperative VFSS is necessary and whether careful diet advancement alone under the guidance of the multidisciplinary team is more appropriate for patients with clinical aspiration.

The duration of postoperative intubation can contribute to loosening and dehiscence of sutures at the site of the cleft repair from pressure applied by an endotracheal tube.[8] The decision to intubate depended on the degree of airway compromise and the recommendations of the multidisciplinary team. Our data showed no correlation between intubation duration and outcome. The duration of postoperative intubation has been controversial, and further studies are required to address this issue.

Conclusions

We suggest that patients with suspected type 1 laryngeal cleft should receive treatment according to our updated diagnostic and management algorithm. Surgical repair should be ad-

vocated in pediatric patients who are older, unable to maintain conservative measures, or exhibit significant aspiration. Treatment decisions should be based on laryngoscopic findings, VFSS, comorbid status, and multidisciplinary team assessment. Families of children with significantly increased aspiration risk comorbidities should be informed before surgical intervention that the children are likely to remain symptomatic despite surgery because of their predisposing comorbidities. All cases should undergo a VFSS at 6 weeks after surgery. If there are no signs of improvement, patients should remain on a thickened feeding regimen.

Follow-up for children who continue to aspirate should be done at 3-month intervals. If by 6 months they are still showing no signs of improvement, comorbid factors should be considered as well as recurrence of a cleft suspected and sought for, and referral should be made to the appropriate specialist.

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Acquisition of data: Ojha, Ashland, Hartnick.
Analysis and interpretation of data: Ashland, Hersh, Ramakrishna, Maurer, Hartnick.
Drafting of the manuscript: Ojha, Ashland, Hersh.
Critical revision of the manuscript for important intellectual content: Ashland, Hersh, Ramakrishna, Maurer, Hartnick.
Statistical analysis: Ojha, Hartnick.
Administrative, technical, and material support: Ojha.
Study supervision: Ramakrishna, Maurer, Hartnick.

Conflict of Interest Disclosures: None reported.

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