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Outcomes and Predictors of Surgical Management in Type 1 Laryngeal Cleft Swallowing Dysfunction

Prasad John Thottam, DO; Matthew Georg, BS; David Chi, MD; Deepak K. Mehta, MD

Objectives/Hypothesis: To examine the effect of and predict the success of type 1 laryngeal cleft (LC-1) augmentation through swallowing evaluations.

Study Design: Retrospective chart analysis.

Methods: Sixty-eight patients with LC-1s underwent interarytenoid injection laryngoplasty (IL) and were examined. The median age at IL was 9 months. Swallowing evaluations were performed pre- and postoperatively using fiberoptic endoscopic examination of swallowing or modified barium swallow. The presence of aspiration or penetrations at various consistencies was recorded. McNemar's tests were used to detect changes in swallowing pre- and postoperatively. Logistic regression was used to assess factors affecting the odds of postoperative success.

Results: Preoperatively, 89.7% of patients demonstrated penetration or aspiration. Post-IL, 69.1% were safe for thins, and 75% showed improvement in swallowing. Postoperatively, there was a significant reduction in patients experiencing problems with thin liquids ($P < 0.001$) and in those with frank or silent aspiration ($P < 0.001$). Patients with penetrations on thin liquids had higher likelihood of a successful IL (odds ratio [OR] = 3.68, $P = 0.021$). The probability of success with silent aspiration at any consistency was significantly decreased (OR = 0.26, $P = 0.015$). Fifteen patients underwent formal endoscopic surgical repair, and 90.0% were safe with thin consistencies postoperatively.

Conclusion: A large proportion of patients with LC-1 and associated swallowing dysfunctions respond favorably to IL and formal repair. Children who demonstrated penetration with thin liquids had a higher rate of swallowing dysfunction resolution post-IL; whereas patients demonstrating silent aspiration had poorer responses to IL.

Key Words: Airway, aspiration, fiberoptic endoscopic evaluation of swallowing, injection laryngoplasty, laryngeal cleft, modified barium swallowing, pediatrics, penetration, swallowing.

Level of Evidence: 4.

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INTRODUCTION

Over the past several years, swallowing dysfunction associated with laryngeal penetration and aspiration has become more recognizable in the pediatric population. Estimated to affect 5% to 7.6% of children with chronic aspiration, type 1 posterior laryngeal cleft (LC-1) has been proposed as a more common anatomic abnormality responsible for swallowing disorders.[1–4]

Benjamin and Inglis first characterized a LC-1 as a supraglottic interarytenoid defect that extends no deeper than the level of the true vocal folds and does not involve the cricoid cartilage.[5,6] Children with this disorder generally present with vague, nonspecific aerodigestive associated complaints. They are often misdiagnosed with a litany of digestive and airway ailments.[1] The most substantial swallowing findings consistent with a LC-1 are aspiration or penetration.[7] An increase in the utilization of modified barium swallow (MBS) and fiberoptic endoscopic evaluation of swallowing (FEES) examination has improved the ability to identify this key finding.

After a child is identified as possibly having a LC-1 by associated symptomatology, conservative therapy is generally attempted first. This entails thickening feeds, addressing pacing, positioning, and reflux therapy—among other practices. If conservative management fails, the presence of a LC-1 is then confirmed through intraoperative palpation of the interarytenoid space. If present, surgical augmentation of the LC-1 may be conducted through interarytenoid injection laryngoplasty (IL) or formal surgical closure.

The purpose of this study is to examine the effect of both IL and permanent surgical repair on swallowing in children with LC-1 utilizing MBS and FEES. Preoperative swallowing examinations were also assessed to determine how specific swallowing dysfunctions responded to intervention.

From the Department of Otolaryngology, Children's Hospital of Pittsburgh (P.J.T., M.G., D.C., D.K.M.), Pittsburgh, Pennsylvania; the Department of Pediatric Otolaryngology, Children's Hospital of Michigan (P.J.T.), Detroit; the Department of Pediatric Otolaryngology, Michigan Pediatric Ear, Nose & Throat Associates (P.J.T.), West Bloomfield; Department of Pediatric Otolaryngology, Beaumont Children's Hospital (P.J.T.), Royal Oak, Michigan; and the Department of Pediatric Otolaryngology, Texas Children's Hospital (D.K.M.), Houston, Texas, U.S.A.

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Send correspondence to Prasad John Thottam, Department of Pediatric Otolaryngology, Michigan Pediatric Ear, Nose and Throat Associates, 7001 Orchard Lake Rd, Suite 320, West Bloomfield, MI 48322.

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MATERIALS AND METHODS

The institutional review board at the University of Pittsburgh (Pittsburgh, PA) approved the retrospective collection, analysis, and reporting of all data prior to beginning this study. A procedural database search was conducted on all patients from January 2008 to May 2014 using the Current Procedural Terminology code 31599. Upon review, only those who underwent IL for the treatment of LC-1 were included. Patients with laryngeal clefts other than LC-1, interarytenoid patterns of aspiration or penetration in the absence of diagnosed LC-1 at time of surgery, and incomplete information were excluded. All patients in this study diagnosed with LC-1 had supraglottic interarytenoid defects that extended no lower than to the level of the true vocal folds. This was confirmed with intraoperative palpation and documentation. Chart review and data extraction included patient demographics, medical comorbidities, presenting symptomatology, type of procedure conducted, pre- and postoperative swallowing assessment, duration of follow-up, and associated complications.

The preoperative presence of stridor, choking/coughing, apneic events, retractions, and cyanosis were investigated through clinical chart review. The age at which patient's symptoms began and age at LC-1 diagnosis were recorded. All patients had general laryngeal function assessed by flexible fiberoptic laryngoscopy and had a direct laryngoscopy and bronchoscopy at the time of IL.

Pre- and postoperative swallowing status was examined utilizing MBS and/or FEES, as well as feeding assessments. A pediatric speech-language pathologist (SLP) and pediatric otolaryngologist evaluated all of these studies. Comparisons of these observations and a consensus on findings were made. The presence or absence of aspiration or penetration and consistency of recommended safe feeds were recorded from SLP reports. Patient improvement was determined based on the ability to tolerate a thinner consistency, with absence of aspiration or penetration, than prior to intervention. A successful operation was defined as complete resolution of swallowing dysfunction and being judged safe for thin liquid consumption by speech and language pathology. Patients were examined in a designated aerodigestive clinic by a pediatric otolaryngologist and speech pathologist. Postoperative follow-up visits were in general 2 to 4 weeks post-IL, but they varied on frequency and duration based on clinical and physical findings

A select group of patients who underwent IL either did not improve, or initially improved and later had a return of symptomatology and documented swallowing dysfunction. Some of these patients went on to have formal surgical repair of their LC-1. All patients who underwent formal repair demonstrated a reoccurrence of clinical symptoms and had confirmation on FEES and/or MBS prior to repair. Their improvement and the success of this surgery was also cataloged and analyzed.

Injection laryngoplasty of the interarytenoid space was performed as described by Cohen et al. in 2011.[6] For this study, only children injected with aqueous/glycerin/carboxy-methylcellulose gel (Radiesse Voice Gel or Prolaryn Gel; Merz Pharma, Frankfort, Germany) were included. Formal surgical repair was conducted under spontaneous ventilation with the utilization of CO_2 laser technology (Omniguide Surgical; Cambridge, MA) to create interarytenoid mucosal incisions. The interarytenoid mucosa was then elevated on both the laryngeal and esophageal sides and reapproximated using two 4-0 polydioxanone sutures, with one suture placed on each side.

All statistical analyses were conducted using STATA 13.1 (STATA Corporation, College Station, TX). Wilcoxon rank-sum and Fisher's exact tests were used to determine differences in demographics and presenting symptomology between those with and without a successful IL. McNemar's tests were used to detect changes in swallowing evaluations pre- and post-IL. Logistic regression was used to identify factors that affected the odds of having a successful IL. A P value < 0.05 was considered significant.

TABLE I.
Patients Sex, Birth, Symptom, Diagnosis and Treatment Information.

Demographics	
Patient Information	Total (n = 68)
Sex	
Male (%)	63.2
Female (%)	36.8
Birth Information	
Gestation age (weeks)	
Median (range)	40 (30–40)
% premature (≤ 36 weeks)	36.8
NICU stay (days)	
Median (range)	10.5 (3–120)
% NICU after birth	20.6
Symptom, Diagnosis, Treatment	
Age symptoms began (months)	
Median (range)	1 (0–28)
Age at diagnosis (months)	
Median (range)	7 (0–29)
Age at injection (months)	
Median (range)	9 (2–36)

NICU = neonatal intensive care unit.

RESULTS

A total of 68 patients underwent IL for LC-1 from 2008 to 2014 at our tertiary care pediatric institution. The median patient age at time of IL was 9 months (range 2–36 months). A total of 63.2% of patients were male; 36.8 % of patients were premature (< 36 weeks); and 20.6% of patients spent at least 1 day in the neonatal intensive care unit after birth (Table I). A total of 11.8% of patients had been diagnosed with a congenital disorder; 27.9% had an underlying neurological condition; 16.2% were noted to have an underlying cardiac abnormality; and 4.4% had diagnosed eosinophilic esophagitis. Preoperatively, 86.8% of patients' caregivers reported choking and coughing with feeds (Table II). The median duration of follow-up was 4 months (range 2–16 months). A total of 52.9% of patients had a synchronous airway abnormality noted (Table II), and 16.2% of patients had grade 1 (SGS). Of the patients with subglottic stenosis, 36.4% (4 of 11) had successful IL, whereas among those without SGS, 75.4% (43 of 57) demonstrated successful IL. The presence of subglottic stenosis decreased the odds of a successful IL (odds ratio [OR] = 0.19, confidence interval [CI]: 0.05, 0.73, P = 0.016). There were no additional significant differences in demographics, comorbidities, or presenting symptoms between patients who had a successful IL and those who did not.

TABLE II.
Presenting Symptoms and Comorbid Conditions of Patients Examined.

Presenting Symptoms	% (n = 68)
Stridor	35.29%
Choking/coughing	86.76%
Failure to thrive	5.88%
Apnea	10.29%
Retractions	4.41%
Cyanosis	17.65%
OSA	4.41%
Comorbid Conditions	
Neurological	27.94%
Congenital	11.76%
Eosinophilic esophagitis	4.41%
Heart abnormality	16.18%
Healthy	58.82%
Laryngomalacia	35.29%
Tracheomalacia	10.29%
Subglottic stenosis	16.18%

OSA = obstructive sleep apnea.

Pre- and postoperative FEES and MBS observations and recommendations were analyzed at thin, nectar, and honey-thick consistencies (Table III). All patients had a MBS or FEES preoperatively. The median time from swallowing evaluation to IL was 1 month (range 0.25–4 months). When analyzing patients with multiple studies, the most recent examination was utilized. A MBS was done preoperatively for 91.2% of the patients. Postoperatively, 61 patients had a MBS or FEES, and seven underwent a detailed swallowing evaluation involving clinical feeding observation, advancement, and pulse oximetry monitoring. The median time from IL to swallowing evaluation was 0.5 months (range 0–5 months). A total of 50.8% of the postoperative swallowing evaluations came from a MBS. Of the patients examined preoperatively, 60.3% demonstrated penetration; 33.8% exhibited frank aspiration; and 39.7% had silent aspiration with any consistency. A total of 89.7% had penetration or a form of aspiration. The remaining 10.3% had previously documented aspiration or penetration with ongoing clinical symptoms, despite the absence of abnormality on the most recent preoperative MBS or FEES. In the 61 patients with post-IL swallowing evaluations, 45.9% had penetration; 14.8% exhibited frank aspiration; and 21.3% had silent aspiration. Only 50.8% demonstrated penetration or a form of aspiration post-IL.

When examining the 61 patients with pre- and postoperative testing, there was a significant reduction in those experiencing frank aspiration ($P = 0.029$), silent aspiration ($P = 0.019$), both forms of aspiration ($P < 0.001$), and penetration or aspiration ($P < 0.001$). Of the 60 patients who had pre- and postoperative testing on thin liquids, there was a significant reduction after IL in those experiencing aspiration and/or penetration ($P < 0.001$). A total of 75% of children examined had either

TABLE III.
Swallowing Study Results in Patients at Various Consistencies Pre- and Postoperatively.

	Preinjection (n = 68)		Postinjection (n = 64)		
Consistency Tested	Abnormality	Not Tested	Abnormality	Not Tested	*P* Value†
Thin Liquids, n (%)	60/68, (88.24%)	0	30/60, (50.00%)	4	< 0.001*
Penetrations	34/68, (50.00%)		19/60, (31.67%)		0.058
Frank aspiration	19/68, (27.94%)		8/60, (13.33%)		0.078
Silent aspiration	21/68, (30.88%)		10/60, (16.67%)		0.115
Any aspiration	40/68, (58.82%)		16/60, (26.67%)		< 0.001*
Nectar, n (%)	39/57, (68.42%)	11	17/28, (26.56%)	36	0.065
Penetrations	20/57, (35.09%)		12/28, (42.86%)		0.508
Frank aspiration	7/57, (12.28%)		3/28, (10.71%)		1
Silent aspiration	17/57, (29.82%)		6/28, (21.43%)		0.109
Any aspiration	24/57, (42.11%)		8/28, (28.57%)		0.039*
Honey, n (%)	9/35, (25.71%)	33	5/19, (26.32%)	45	1
Penetrations	7/35, (20.00%)		3/19, (15.79%)		1
Frank aspiration	0/35, (0.00%)		0/19, (0.00%)		1
Silent aspiration	3/35, (8.57%)		2/19, (10.53%)		1
Any aspiration	3/35, (8.57%)		2/19, (10.53%)		1
Any consistency, n (%)	61/68, (89.71%)	0	31/61, (50.82%)	0	< 0.001*
Penetrations	41/68, (60.29%)		28/61, (45.90%)		0.176
Frank aspiration	23/68, (33.82%)		9/61, (14.75%)		0.029*
Silent aspiration	27/68, (39.71%)		13/61, (21.31%)		0.019*
Any aspiration	44/68, (64.71%)		17/61, (27.87%)		< .001*

†*P* values are testing the change for subjects who had both pre- and postswallowing assessments.
FEES = fiberoptic endoscopic evaluation of swallowing; MBS = modified barium swallow.

TABLE IV.
Probability of Successful Injection Laryngoplasty Based on Preoperative Swallowing Findings.

Consistencies, n (%)	Success With	Success Without	Odds Ratio	Confidence Interval		*P* Value
				Lower Limit	Upper Limit	
Thin Liquids (n = 68)						
Penetrations	34 (82.35%)	34, (55.88%)	3.68	1.21	11.20	0.021*
Frank aspiration	19 (68.42%)	49, (69.39%)	0.96	0.31	3.00	0.938
Silent aspiration	21 (52.38%)	47, (76.60%)	0.34	0.11	1.00	0.050*
Penetrations and no silent aspiration	21 (95.24%)	47, (57.45%)	14.84	1.83	1119.77	0.011*
Nectar (n = 57)						
Penetrations	20 (75.00%)	37, (59.46%)	2.05	0.61	6.83	0.245
Frank aspiration	7 (57.14%)	50, (66.00%)	0.69	0.14	3.43	0.647
Silent aspiration	17 (47.06%)	40, (72.50%)	0.34	0.10	1.10	0.071
Honey (n = 36)						
Penetrations	7 (71.43%)	28, (50.00%)	2.50	0.41	15.11	0.318
Frank aspiration	0 (–%)	35, (54.29%)	–	–	–	–
Silent aspiration	3 (0.00%)	32, (59.38%)	–	–	–	–
At Any Consistency (n = 68)						
Penetrations	41, (75.61%)	27, (59.26%)	2.13	0.75	6.08	0.157
Frank aspiration	23, (69.57%)	45, (68.89%)	1.03	0.35	3.07	0.954
Silent aspiration	27, (51.85%)	41, (80.49%)	0.26	0.09	0.77	0.015*

*P, 0.05.

improvement or resolution of their swallowing dysfunction after IL, and 25% demonstrated no change.

Preoperative swallow examinations were evaluated to predict success from IL (Table IV). Patients with penetrations on thin liquids had higher odds of a successful IL (unadjusted OR = 3.68, CI: 1.21, 11.20, $P = 0.021$). Those with silent aspiration on thin liquids had decreased odds of success (unadjusted OR = 0.34, CI: 0.11, 1.00, $P = 0.05$). When examining swallowing dysfunction across all consistencies, the odds of success for patients with silent aspiration were significantly decreased (unadjusted OR = 0.26, CI: 0.09, 0.77, $P = 0.015$). There was no difference between the odds of success for those with frank aspiration. Overall, 47 of the 68 patients examined (69.1%) were considered safe for thin consistencies by SLP evaluation post-IL and designated a success.

Of the 68 children reviewed, three patients required reinjection and 15 patients underwent formal endoscopic surgical repair. All patients who underwent reinjection later required formal surgical repair. Of the patients who later underwent formal repair, eight demonstrated complete resolution post-IL but later had reoccurrence of swallowing dysfunction; four had swallowing improvement temporarily; and three did not respond. The median time lapse between IL and surgical repair was 5 months (range 2–12 months). Postsurgical repair follow-up data was available for 10 of the patients who underwent formal surgical repair. The median time from repair to end of study was 14 months, with a range of 6 to 20 months. The swallowing function of all patients postrepair improved: 90.0% had a successful surgical repair and were safe with thin consistencies. One patient improved but still demonstrated penetration with thin liquids. No recorded factors significantly impacted the odds of requiring formal surgical repair after IL.

DISCUSSION

Over the past decade, the diagnosis and surgical intervention of LC-1 has increased. Originally estimated to effect only 0.2%, more recent estimations are as high as 7.6% in children with respiratory symptoms.[1,8–11] This is likely secondary to the increased detection and awareness of childhood swallowing disorders in the medical community. In this current study, we sought to examine associated swallowing dysfunction and patient response to both IL and surgical closure in a large population of children with LC-1 while identifying possible outcome predictive swallowing patterns.

Comorbid conditions have been noted as common among patients with LC-1.[7] The prevalence of these conditions has ranged from 33% to 100% depending on the conditions examined, the institution, and the study.[4,5,7,12] A total of 41.2% of the patients in our study demonstrated a comorbid condition, the most common being neurological in origin in 27.9% of patients with LC-1. In a recent study, Ketcham et al. reported neurological disorders to affect 44% of the patients they reviewed with LC-1.[7] Contrary to a recent article by Horn et al. reporting increased swallowing success rates post-IL in patients with neurodevelopmental risk factors, this was not demonstrated in our current study.[2]

Aspiration has been reported in as high as 90% of children with laryngeal clefts. [3] In our current study, 86.7% of patient caregivers described signs of swallowing dysfunction and possibly observed aspiration and/or penetration. Similarly, 88.2% of patients had abnormal

findings preoperatively when drinking thin liquids, and 64.7% demonstrated aspiration on various consistencies with MBS or FEES.

First introduced in 1999, IL has gained increased notoriety in the management of diagnosed LC-1, and more recently in the management of pediatric chronic aspiration.[2,13] In a study of 16 patients with LC-1, the authors reported swallowing dysfunction resolution in 56% of patients and improvement in 25% after IL.[6] In another study, Horn et al. examined children with chronic aspiration of unknown origin without a LC-1 who underwent IL.[2] In that study, 50% demonstrated at least temporary improvement in swallowing post-IL.[2] In our current study, we examined 68 children with preoperative swallowing dysfunction on either MBS or FEES. All patients underwent conservative management of their swallowing disorder through the utilization of thickened feeds and/or reflux medication prior to the intraoperative confirmation of LC-1 and surgical management. All patients underwent a postoperative swallowing evaluation; 75% of patients displayed a new tolerance to thinner liquids; and 39.7% resolved completely. After further review by SLP, 69.1% of patients demonstrated successful swallowing responses to IL and were considered safe for transition to thin liquids. When examining preoperative swallowing evaluations, we identified thin consistency penetration as a positive predictor for resolution post-IL. Patients with silent aspiration demonstrated less likelihood of demonstrating complete success post-IL. This observed decrease of improvement in silent aspirators may be an indication of underlying pharyngeal coordination or laryngeal sensation and should be considered prior to IL.[14]

Of the 51 patients who originally improved from IL, 39 did not require further permanent surgical repair. It has been theorized that temporizing bulking to the interarytenoid space may allow the time needed to develop improved swallow strategies and coordination without being inhibited by aspiration or penetration.[2,6] It has also been proposed that the inflammatory response of the injected material and needle stimulation may contribute to permanent bulking through the development of scar tissue.[2,6] Either of these factors may have assisted in improving swallowing and associated examinations.

The utilization of IL can serve as both a confirmatory test and direct treatment. A temporizing repair is created by injecting and ultimately filling the interarytenoid defect in LC-1. This gives both the physician and caregiver the possibility to evaluate how the child will swallow if the defect is closed permanently and is a less invasive option. In this study of the 15 children who at a later date underwent surgical repair, 80.0% initially had improvement or resolution of their swallowing issues post-IL. Over time, their dysfunctions reoccurred and they underwent formal repair. Postsurgical repair, nine of the 10 patients demonstrated resolution and one patient had improvement. Similar to our findings, the success rate for endoscopic surgical repair has been reported to range 72% to 100%.[6,15–19]

This study does have some limitations. It is a retrospective study; all information was collected through chart review and there was no control group. Although patients were evaluated through FEES or MBS pre- and postoperatively, there was no set interval of time in which they were evaluated; thus, the possibility of selection bias or IL resorption exists. With this in mind, it is important to point out that the material used in this study is designed to resorb within 3 to 6 months, and all patients in this study were evaluated prior to 6 months post-IL. Currently, pediatric comparative outcome data examining FEES and MBS is limited. While, adult data on this studies have shown promise with comparison to clinical correlation they still remain inconclusive in some cases of dysphagia.[20–22] It also should be noted that IL was often not curative, and 50.8% of patients' still demonstrated penetration or a form of aspiration on a consistency examined post-IL. With the above in mind, this is one of the largest studies describing the effect of both IL and formal surgical repair of LC-1, while utilizing swallowing specific data to analyze pre- and postoperative findings as well as predict response to intervention.

CONCLUSION

Interarytenoid IL has been described in the treatment of aspiration or penetration for children with and without LC-1.[2,6] A large proportion of patients with LC-1 and associated swallowing dysfunctions respond favorably to IL and formal surgical repair. Children who demonstrated preoperative penetration with thin liquids had a higher rate of swallowing dysfunction resolution after IL, whereas patients demonstrating silent aspiration had poorer responses to IL. In LC-1 patients, IL can have a long-lasting effect on some children with swallowing dysfunction, and it can be used as a more conservative option prior to the more invasive but highly effective option of surgical repair.

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