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ORIGINAL RESEARCH

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Interarytenoid injection outcomes in pediatric feeding disorders

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Abstract

Objectives: Type 1 laryngeal clefts (LC1) and deep interarytenoid grooves contribute to pediatric feeding disorders. Management of these defects remains heterogeneous among surgeons and interarytenoid injection augmentation (IIA) is not always offered as a treatment option. This study evaluated IIA outcomes among a pediatric patient cohort comprised mostly of those with deep interarytenoid grooves.

Methods: A single-institution retrospective chart review featured children under the age of 5 years presenting for aspiration, dysphagia, or choking. Over the period of 7 years (January 2014–October 2021), 39 met inclusion criteria and had sufficient follow-up data. Descriptive statistics and subgroup analyses were performed.

Results: Of the 39 included patients, 76.92% had clinical improvement post-injection, with the mean time to follow-up being 47 days. Within the deep interarytenoid groove group, improvement rates were 82.76%. Bronchoscopy findings revealed 29 (74.36%) patients with a DIG, 3 (7.69%) with LC1, 3 (7.69%) with no anatomic abnormality, and 4 (10.26%) with vocal cord paralysis. There were no adverse events. There were no associations with the outcomes based on subgroup analysis and logistic regression.

Conclusions: IIA is an effective and safe treatment for pediatric feeding disorders. No covariates were associated with symptom improvement. Within the deep interarytenoid groove diagnosis subgroup, IIA effectively improved symptoms. Further investigations are needed to explore predictors of success with IIA in this population.

Level of Evidence: VI.

KEYWORDS

deep interarytenoid grooves, dysphagia, Interarytenoid injection augmentation, Type 1 laryngeal clefts

1 | INTRODUCTION

Type 1 laryngeal clefts (LC1) and deep interarytenoid grooves (DIG) are anatomic abnormalities contributing to pediatric feeding disorders.[1] The management and diagnosis of these defects remain controversial. In fact, DIG management has yet to be standardized and is commonly treated according to LC1 recommendations. Within these recommendations, interarytenoid injection augmentation (IIA) is

a surgical option for LC1 repair and is often adapted for DIG management.[2] Heterogeneity exists among surgeon practices, as not all otolaryngologists utilize IIA.[2] While literature exists on the LC1 treatment efficacy of IIA,[3–9] few studies have evaluated this surgical technique in DIG patients.

A diagnosis of DIG is made when a laryngeal cleft does not meet the criteria for LC1. More specifically, the International Pediatric Otolaryngology Group defines a DIG as a defect 0–3 mm above the true vocal cords.[2,10] Although LC1s are a more pronounced anatomic abnormality than DIG, functional differences between the two defects have yet to be determined. The presenting symptoms of DIG and LC1 are similar, with the most common including choking, dysphagia, and aspiration.[11] Because these symptoms are nonspecific, delays in diagnosis and treatment are common.

DIG treatment is not standardized; therefore, management often follows LC1 recommendations. LC1 recommendations cite conservative management, which includes diet modification and antireflux medication, as the first-line treatment.[2] Conservative treatment has been shown to have improvement rates ranging from 19% to 91%.[7,12,13] Cases refractory to conservative therapy may be surgically repaired with endoscopic repair or IIA. Although IIA is effective and low risk,[3–9] only 40% of International Pediatric Otolaryngology Group (IPOG) members utilize this surgical option.[2]

IIA has many benefits over endoscopic repair. Symptom improvement rates range from 42%–100% for LC1 IIA treatment.[3–9,14,15] Compared to endoscopic closure, IIA carries less risk.[16] In fact, a systematic review comprised of 27 studies reported only one study with an adverse event.[11] IIA is a short procedure that can be performed on endoscopic evaluation, therefore reducing the number of procedures and cost. Unlike endoscopic repair, IIA does not require postoperative sedation or hospitalization. Considering these benefits, some suggest that the threshold to perform IIA should be lowered.[14]

Management of IIA remains underutilized for LC1 and little is known about its utilization or efficacy in DIG treatment. In past studies, these two anatomic defects have been grouped into one category due to poor differentiating diagnostic standards.[17] Importantly, treatment standards for LC1s, upon which DIG management is adapted, continue to be developed.[2] Although growing in popularity, the role of IIA is poorly defined, leading to inconsistent practices. Few studies evaluate IIA outcomes solely among DIG patients.[10,17] This study aims to evaluate IIA outcomes among pediatric patients with DIG and LC1, hypothesizing that IIA will alleviate dysphagia symptoms in the short-term follow-up period.

2 | MATERIALS AND METHODS

2.1 | Patient population

This single-site retrospective chart review from 2014 through 2020 included pediatric patients who underwent interarytenoid injection augmentation (IIA) by one surgeon. Those under 5 years old at the time of the procedure with clinical symptoms of aspiration or dysphagia and concurrent findings on VFSS were included. All patients enrolled previously trialed conservative therapy (modified diet/antiacids). Patient demographics, procedure indication, presenting complaint, post-procedure diagnosis, and Prolaryn plus (hydroxyapatite) volume were abstracted. Definitive diagnoses were determined by laryngoscopy. The primary endpoint of this study was the overall subjective improvement in swallowing function, as reported by a patient's caregiver. To evaluate for improvement, caregivers were asked questions about patients' feeding habits, aspiration events, observed swallowing function, and reflux symptoms. For patients with a pre- and post-operative VFSS assessment improvement in liquid consistency safely swallowed was noted. Improvement in liquid consistency safely swallowed was defined as cessation of aspiration events at the same liquid consistencies or lack of necessity of thickened liquid. This study was covered under IRB# 22-0978.

2.2 | Diagnostic workup

To establish a definitive diagnosis, a comprehensive evaluation was conducted on all patients. This included general anesthesia with spontaneous ventilation, accompanied by bronchoscopy and suspension laryngoscopy. Microlaryngoscopy was performed to expose the larynx and separate the vocal folds, facilitating examination of the posterior glottis and supraglottis. The interarytenoid region was carefully palpated to detect the presence of a cleft and assess its depth. Cleft height was measured using a right-angle laryngeal instrument. Diagnosis of DIG was established when the cleft measured less than 0–3 mm but was located above the level of the true vocal cords. An LC1 classification was assigned where the cleft extended to the level of the true vocal cords according to the Benjamin–Inglis Classification. In instances where no alternative cause of aspiration was identified (such as tracheoesophageal fistula), IIA was performed using Prolaryn Plus (hydroxyapatite) injected at the apex of the notch. All diagnoses and injections were completed by one pediatric otolaryngologist. Postoperatively, patients were seen at 6 weeks for follow-up. Postoperative swallow studies were obtained if a patient remained symptomatic after their injection.

2.3 | Statistical analysis

Data normality was assessed using Shapiro–Wilk test. Descriptive statistics were performed for demographic and outcome data. These data were presented as means and standard deviations (continuous variables) and absolute (*n*) and relative (%) frequencies (categorical variables). Subgroup analyses were performed using Fisher's exact test. A multivariate logistical regression model was used to examine relationships between predictors and dysphagia improvement. An alpha level of 0.05 was considered statistically significant. Statistical analyses were performed using R (v4.2.1)[18] in RStudio Version 1.3.1093.[19]

TABLE 1 Overall patient characteristics.

Characteristic	Diagnosis				
	DIG, $N = 29$[a] (74.36%)	LC1, $N = 3$[a] (7.69%)	No abnormality, $N = 3$[a] (7.69%)	Vocal cord paralysis, $N = 4$[a] (10.26%)	Total, $N = 39$[a]
Improvement	24 (82.76%)	2 (66.67%)	1 (33.33%)	3 (75.00%)	30 (76.92%)
Sex					
Female	11 (37.93%)	2 (66.67%)	2 (66.67%)	3 (75.00%)	18 (46.15%)
Male	18 (62.07%)	1 (33.33%)	1 (33.33%)	1 (25.00%)	21 (53.85%)
Indication					
Aspiration on thin liquids	10 (34.48%)	1 (33.33%)	0 (0.00%)	1 (25.00%)	12 (30.77%)
Dysphagia	17 (58.62%)	2 (66.67%)	2 (66.67%)	1 (25.00%)	22 (56.41%)
Dysphonia	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (50.00%)	2 (5.13%)
Respiratory Symptoms	2 (6.90%)	0 (0.00%)	1 (33.33%)	0 (0.00%)	3 (7.69%)
Volume					
0.1	6 (20.69%)	0 (0.00%)	2 (66.67%)	3 (75.00%)	11 (28.21%)
0.2	13 (44.83%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	14 (35.90%)
0.3	6 (20.69%)	0 (0.00%)	1 (33.33%)	0 (0.00%)	7 (17.95%)
0.4	1 (3.45%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	2 (5.13%)
0.5	3 (10.34%)	2 (66.67%)	0 (0.00%)	0 (0.00%)	5 (12.82%)
Age					
0–12 Months	11 (37.93%)	2 (66.67%)	1 (33.33%)	1 (25.00%)	15 (38.46%)
13–24 Months	9 (31.03%)	0 (0.00%)	1 (33.33%)	1 (25.00%)	11 (28.21%)
25–36 Months	7 (24.14%)	1 (33.33%)	1 (33.33%)	1 (25.00%)	10 (25.64%)
26–48 Months	2 (6.90%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	3 (7.69%)
Comorbidities					
Asthma	9 (31.03%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	10 (25.64%)
GERD	14 (48.28%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	15 (38.46%)
Eczema	3 (10.34%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	4 (10.26%)
Ankyloglossia	4 (13.79%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	5 (12.82%)
Premature	6 (20.69%)	0 (0.00%)	1 (33.33%)	0 (0.00%)	7 (17.95%)
G-tube	4 (14.81%)	1 (33.33%)	0 (0.00%)	2 (50.00%)	7 (18.92%)
Trisomy 21	0 (0.00%)	1 (33.33%)	1 (33.33%)	0 (0.00%)	2 (5.13%)
OSA	3 (10.34%)	1 (33.33%)	0 (0.00%)	1 (25.00%)	5 (12.82%)

Abbreviations: DIG, deep interarytenoid groove; GERD, gastroesophageal reflux disease; LC1, type 1 laryngeal cleft.
[a]*n* (%).

3 | RESULTS

During the study period, 51 patients met inclusion criteria. Of these, 12 were lost to follow-up and were removed from the analysis. Of the 39 remaining patients, 30 (76.92%) showed clinical improvement in swallowing function. There were 29 (74.36%) patients with a DIG, 3 (7.69%) with LC1, 3 (7.69%) with no anatomic abnormality, and 4 (10.26%) with vocal cord paralysis. Of those with a DIG diagnosis, 24/29 (82.76%) had symptom improvement. Of the three patients with no anatomic abnormalities, one had subjective improvement. Patient characteristics are detailed in Table 1.

The median age at the time of IIA was 17.70 months (range 3–31 months). The mean time to follow up was 46.7 days. Of all included patients, 15/39 (38.46%) had GERD, 10/39 (25.64%) had asthma, and 7/39 (17.95%) had premature births (<36 weeks). Subgroups by outcome are described in Table 2.

Most patients had mild to moderate oropharyngeal dysfunction, as determined by a pre-injection Videofluoroscopic Swallow Study (VFSS) (Table 3). Pre-injection VFSS records were available for 36/39 patients and post-injection records were available for 19/39 patients. Thirteen patients had both pre- and post-injection VFSS (Table 4). Of these, 10/13 (76.92%) had improvement in liquid consistency safely swallowed ($p = <.0001$).

There were no statistically significant differences in age ($p = .7$), injection volume ($p = .5$), or sex ($p = .7$) between the group with improvement vs. the group without improvement. Subgroup analysis

TABLE 2 Patient characteristics by outcome.

Characteristic	Improvement, $N = 30$[a]	No improvement, $N = 9$[a]	p value[b]
Sex			.7
Female	13 (43.33%)	5 (55.56%)	
Male	17 (56.67%)	4 (44.44%)	
Indication			.3
Aspiration on thin liquids	11 (36.67%)	1 (11.11%)	
Dysphagia	16 (53.33%)	6 (66.67%)	
Dysphonia	1 (3.33%)	1 (11.11%)	
Respiratory symptoms	2 (6.67%)	1 (11.11%)	
Bronchoscopy			.2
DIG	24 (80.00%)	5 (55.56%)	
LC1	2 (6.67%)	1 (11.11%)	
No abnormality	1 (3.33%)	2 (22.22%)	
Vocal cord paralysis	3 (10.00%)	1 (11.11%)	
Volume			.5
0.1	7 (23.33%)	4 (44.44%)	
0.2	11 (36.67%)	3 (33.33%)	
0.3	6 (20.00%)	1 (11.11%)	
0.4	1 (3.33%)	1 (11.11%)	
0.5	5 (16.67%)	0 (0.00%)	
Age			.14
0–12 Months	12 (40.00%)	3 (33.33%)	
13–24 Months	10 (33.33%)	1 (11.11%)	
25–36 Months	5 (16.67%)	5 (55.56%)	
26–48 Months	3 (10.00%)	0 (0.00%)	
Comorbidities			.7
Asthma	7 (23.33%)	3 (33.33%)	
GERD	13 (43.33%)	2 (22.22%)	
Eczema	2 (6.67%)	2 (22.22%)	
Ankyloglossia	3 (10.00%)	2 (22.22%)	
Premature	4 (13.33%)	3 (33.33%)	
G-tube	5 (17.86%)	2 (22.22%)	
Trisomy 21	0 (0.00%)	2 (22.22%)	
OSA	3 (10.00%)	2 (22.22%)	

Abbreviation: GERD, gastroesophageal reflux disease.
[a]*n* (%).
[b]Fisher's exact test.

revealed outcome similarities regardless of demographic factors and injection volume. Furthermore, logistic regression did not reveal associations between demographic variables and outcomes (Table S1). There were no adverse events associated with IIA.

4 | DISCUSSION

Management of LC1 and DIG is transforming as IIA gains popularity. Although low-risk, there is a lack of consensus surrounding the utilization of this technique.[2] This analysis offers insight into the efficacy of IIA treatment of pediatric feeding disorders, which remains understudied. As a consensus on DIG management has yet to be formed, we provide a much-needed analysis of DIG improvement rates after IIA.

Akin to other reports,[3–9] our results revealed a post-injection symptom improvement rate of 76.92% in the short-term follow-up. On VFSS assessment, 10/13 (76.92%) had improvement in liquid consistency safely swallowed. Improvement rates were even higher in the DIG group at 82.76%, further substantiating prior reports of improvement post-IIA, even when no anatomic abnormalities were present.[1,5] There was one case of improvement in the "no abnormality group," which also supports the hypothesis that IIA may be beneficial even

when large anatomic defects are not present. As protocols specific to DIG are not yet decided upon, these findings will be important in guiding future research and the use of IIA.

Presenting symptoms were similar to previous reports,[3,20] with aspiration and dysphagia being the most common. A 2021 systematic review found GERD (59%) and asthma (23%) to be common comorbidities among those with LC1.[11] Comparatively, the most common comorbidities in our cohort, comprised mostly of those with a DIG diagnosis, were GERD (38.46%) and asthma (25.64%).

TABLE 3 Pre-injection Videofluoroscopic Swallow Study (VFSS) results.

Characteristic	Pre-injection VFSS N = 36
Oral	
No abnormality	7 (18%)
Mild oral dysfunction	16 (41%)
Moderate oral dysfunction	11 (28%)
Severe oral dysfunction	2 (5.1%)
Pharyngeal	
No abnormality	1 (2.6%)
Mild pharyngeal dysfunction	14 (36%)
Moderate pharyngeal dysfunction	15 (38%)
Severe pharyngeal dysfunction	6 (15%)
Aspiration consistency	
No aspiration events	1 (2.6%)
Thin	9 (23%)
Nectar	9 (23%)
Thick	5 (13%)
Multiple	2 (5.1%)

No IIA-related adverse events occurred in our cohort. This finding, in addition to many other studies that reported no adverse events,[11] further supports lowering the threshold for IIA utilization. Although conservative therapy is generally the first line for LC1 treatment, it is not without risks. For those eventually requiring surgical intervention, trialing conservative management may ultimately delay definitive treatment and increase the risk of aspiration events. Endoscopic repair, which is a widely utilized surgical option, has higher success rates than IIA; however, the risk and cost are greater. IIA is a low-risk technique that can be utilized at the time of diagnosis, thus reducing risks associated with multiple procedures (i.e., anesthesia) and financial toxicity. Considering these advantages, IIA is an excellent option from a risk–benefit standpoint.

Little is known about predictors of IIA success. Our study design utilized subgroup analysis and logistic regression to determine differences in treatment results based on covariates, including age, comorbidities, and injection volume. Consistent with a prior study,[9] injection volume did not affect improvement rates. Likewise, there were no statistically significant differences in improvement rates among comorbidities, bronchoscopy findings, and age subgroups. These findings are important as they potentially simplify treatment protocols and make such procedures more widely accessible to patients. As our subgroup sample sizes are small, more research is required to explore potential associations and predictors of IIA success.

In addition to the small subgroup sample sizes, this study is also inherently limited by its retrospective nature. Data were abstracted from physician notes and were therefore subject to medical history omissions or inaccuracies. Furthermore, the lack of VFSS data also limits this study. Patient-reported improvement was recorded in the follow-up note and depended on patients attending their appointment. Within our cohort, 12/51 (23.53%) of patients were lost to follow-up. While losing patients to follow-up can introduce selection bias, we do

TABLE 4 Pre-injection and post-injection Videofluoroscopic Swallow Study (VFSS) results.

	Pre-Injection VFSS			Post-Injection VFSS		
Diagnosis	Oral	Pharyngeal	Aspiration consistency	Oral	Pharyngeal	Aspiration consistency
DIG	Mild	Severe	Nectar	Moderate	No abnormality	Thins
DIG	Mild	Moderate	Nectar	No abnormality	Severe	Thick
DIG	Mild	Mild	Thins	Moderate	Moderate	Thins
DIG	Mild	Moderate	Thick	No abnormality	No abnormality	None
DIG	No abnormality	Severe	Nectar	No abnormality	Severe	None
DIG	Moderate	Severe	Thick	Mild	Mild	None
DIG	Moderate	Moderate	Nectar	Moderate	Moderate	Nectar
DIG	Moderate	Moderate	Thin	Mild	Mild	None
DIG	Moderate	Moderate	Nectar	Mild	Mild	Thin
LC1	No abnormality	Severe	Thin	No abnormality	Severe	Thin
LC1	Mild	Mild	Nectar	Mild	Mild	Thin
Vocal cord paralysis	Moderate	Moderate	Thick	No abnormality	Moderate	Thin
Vocal cord paralysis	Moderate	Moderate	Thin	Mild	Mild	None

Abbreviations: DIG, deep interarytenoid groove; LC1, type 1 laryngeal cleft.

not anticipate this data loss to skew our results toward a type-1 error. We hypothesize that those lost to follow-up were due to a "missing not at random" (MNAR) mechanism due to the resolution of symptoms. Lastly, as DIG and LC1 continue to be defined, some literature suggest that the subtle differences between the anatomical defects may not be clinically meaningful regarding symptom presentation.[1]

Deglutition is a complex behavior involving coordination among many organ systems. While anatomic defects contribute to swallowing dysfunction, etiologies are often multifactorial and should not be treated with surgery alone. However, surgical treatment algorithms for laryngeal clefts still need to be better defined and the role of IIA has yet to be standardized.[2] In clinical practice, clinicians can strategically incorporate IIA into their management approach, especially for patients presenting with dysphagia and minimal anatomical abnormalities (DIG). This approach becomes particularly valuable for patients who are deemed unsuitable for surgical interventions. Furthermore, IIA serves as a viable option to consider when patients are not yet prepared to undergo more invasive surgical procedures. Lastly, this approach may benefit those without anatomic defects with dysphagia refractory to conservative therapy; however, further studies are needed to investigate this. By exploring IIA as an alternative therapeutic strategy, clinicians can provide patients with additional options tailored to their specific needs and circumstances.

These results provide evidence supporting the use of IIA as a safe and effective intervention, even in the absence of obvious structural abnormalities. Healthcare providers can use this information to guide their decision-making process and consider IIA as a potential therapeutic option in the comprehensive management of pediatric dysphagia. As IIA use becomes increasingly prevalent in LC1 and DIG treatment, future investigations are needed to determine predictors of IIA success. Direct comparisons of IIA versus endoscopic repair via randomized control trials are also needed. This is one of the few studies to evaluate the efficacy of IIA in a cohort comprised mostly of those with a DIG diagnosis. While we found IIA treatment effective in most of this cohort, more research is needed to substantiate these findings.

5 | CONCLUSION

Our data suggest that Prolaryn IIA is a safe and effective treatment option for oropharyngeal dysphagia in children. Furthermore, IIA was effective in those diagnosed with a DIG, an anatomic abnormality that has not been thoroughly studied and therefore lacks management guidelines. We found no differences in improvement based on age, injection volume, or comorbidities. Considering these findings, future research should investigate the influence of covariates on the effectiveness of Prolaryn IIA. Moreover, DIG defects are understudied and more data evaluating IIA effectiveness in these patients is needed.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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