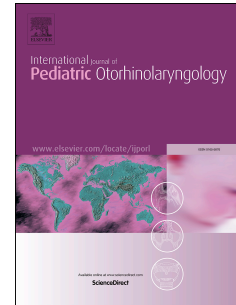


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Injection laryngoplasty in infants with unilateral vocal cord paralysis: a survey of ASPO members

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Abstract:

Introduction: Unilateral vocal cord paralysis (UVCP) in infants may be managed medically or surgically, with the latter including injection laryngoplasty (IL). However, there is limited information regarding injection laryngoplasty in infants. We therefore proposed a survey of American Society of Pediatric Otolaryngology (ASPO) members to elucidate current practices, outcomes, and complications.

Methods: An online survey was distributed to all 548 ASPO members via email. The survey was closed for data analysis 2 months after initial distribution. Statistical analysis was deferred due to the primarily descriptive nature of the data and lack of comparative studies.

Results: We received 113 responses for a response rate of 20.6%. Only 31% of the respondents (n=36) reported performing IL in infants 12 months old or younger. The most commonly cited reasons for not injecting in this age group were preference for non-surgical management and concern for increased risk of airway obstruction. IL was most commonly performed to treat persistent aspiration despite attempts at medical management. The majority (66%) reported no complications, while the remainder noted stridor requiring intensive care unit observation. Re-intubation due to airway obstruction occurred in 6% (n=2 of 33). Carboxymethylcellulose gel (Prolarynx Gel) was the most commonly used injectable material, but a variety of other materials were used as well. Two respondents noted they perform reinnervation procedures in children, but not in infants, as they require at least a 12 month period of observation for possible spontaneous recovery before considering the option.

Discussion: There is limited data regarding management of UVCP in infants with IL, and considerable variation among those who do perform the procedure. While adverse events are rare, multi-institutional studies should be considered to help determine best practices.

Introduction

Unilateral vocal cord paralysis (UVCP) in infants and children is often associated with clinically significant dysphonia and/or aspiration. While there are a variety of causes, the most commonly cited etiology is iatrogenic trauma during surgery. Treatment options for older children and adults are varied and include observation, positioning, feeding modifications with thickeners, voice therapy, injection laryngoplasty, thyroplasty, arytenoid surgery and recurrent laryngeal nerve re-innervation. Despite a number of case series¹⁻⁶, systematic reviews⁷, and expert opinions⁸⁻⁹ documenting the effects of these treatments in older children, there is limited information regarding surgical management of UVCP in infants less than 12 months old.^{3, 23-24} We therefore proposed a survey of members of the American Society of Pediatric Otolaryngology (ASPO) to elucidate current practices, successes and complications. By compiling this data, we aimed to give a broad view of current practices and to encourage pediatric otolaryngologists to work toward developing a standard of practice.

Methods

A survey was developed based on discussion with the senior authors (R.C., T.R., and C.S.), who have previously performed injection laryngoplasty in infants at the Children's Hospital of Wisconsin (Table 1). "Infant" was defined as a child 12 months old or younger. Common areas of variation in practice that were identified included the indications, timing, ventilation methods, and material used in injection laryngoplasty, and survey questions were developed to further understand current practices. In addition, ASPO members were surveyed regarding any potential complications that had been experienced in their practices.

Statistical analysis was anticipated to be primarily descriptive. Comparisons between groups, such as rates of complications by type of injection technique, were to be analyzed using chi-squared or Fisher exact tests depending on sample size, with a 95% confidence level to be utilized in all determinations of significance. Assuming a normal distribution, 95% confidence level, and 7.5% confidence interval (margin of error), the study would be appropriately powered with >125 participants. Based on the 471 target participants mentioned in a recent ASPO survey study by Raol et al¹⁰, a target of 126 would represent a 26.8% response rate. This would be in line with the predicted 20-30% response rates historically achieved in such surveys, and nearly identical to the 127 responses obtained in the study by Raol et al.

The online survey was then distributed to all ASPO members via email. After the initial distribution to 548 members, a second reminder email was sent out 4 weeks later to any non-responders. The survey was closed for data analysis 2 months after initial distribution.

Results

We received 113 responses for a response rate of 20.6%. Six of the responses were incomplete. A similar number of incomplete responses were noted for practitioners who performed injection laryngoplasty in infants versus those who did not (Figure 1).

Of the 113 respondents, 31% (n=36) reported performing injection laryngoplasty in infants (Figure 1). The most commonly cited reason for not injecting in this age group was preference

for non-surgical management. Other reasons cited included concern for increased risk of airway obstruction and low incidence of aspiration that could not be addressed with positioning and thickened feeds in this age group.

Of those who performed injection laryngoplasty in infants, experience levels varied, with the majority having performed fewer than 5 injections (64%, 22 of 34 respondents, Figure 2). The majority of this group also did not have a minimum age criteria (Figure 3). Injection laryngoplasty in infants was most commonly performed to treat aspiration and/or improve pulmonary toilet by improving glottic closure and cough, rather than dysphonia (Figure 4). The most commonly associated etiology was post-cardiac surgery.

The majority of practitioners were willing to try feeding modifications with speech language pathology for an average of 3.5 months prior to considering injection laryngoplasty (range less than 1 to 6 months, median 3 months, n=32). However, several practitioners noted that earlier injection could be considered if speech and swallow pathologists determined the patient was a poor candidate for further therapy, or the patient's pulmonary or medical status was fragile enough to warrant aggressive prevention of aspiration. Indeed, one respondent noted that if aspiration was present, they would proceed directly to IL. Only one respondent noted that they would not try feeding modifications.

Regarding airway management during injection laryngoplasty in infants, most surgeons preferred maintaining spontaneous breathing. Intermittent apnea with mask ventilation or intubation as needed was also a common choice (Figure 5). The most common adverse event noted was stridor or airway obstruction (6 out of 33), with four respondents noting need for ICU monitoring and only two respondents reporting need for re-intubation, followed by dysphagia/poor feeding (5 out of 33). One respondent noted difficulties with bleeding after injection, especially in the setting of anticoagulation for congenital cardiac disease, while another cited failure to improve as a complication (Figure 6). Each respondent was allowed to select one or more complications listed on the survey as applicable. However, the majority of respondents, 66% (22 out of 33) noted no complications.

Carboxymethylcellulose gel (Prolaryn™ Gel) was the most commonly used injectable material. One respondent noted that the choice of material might vary depending on if it was the first or subsequent injection and the etiology of UVCP (Figure 7). Injections lasted an average of 4.8 months when taking into account all responses (n=30). The average length of duration by injection material was 4.7 months for carboxymethylcellulose gel (n=17); 6 months for hyaluronic acid (n=2), micronized Alloderm (n=1), and calcium hydroxyapatite (n=4), and 1 month for Gelfoam (n=1). Responses where participants listed use of multiple injection materials were excluded. One respondent noted variability between different materials and cited carboxymethylcellulose gel (Prolaryn™ Gel) as lasting only 1 month.

The majority of respondents identified improvement in aspiration as an indicator of a successful procedure, with willingness to perform repeat injections as often as necessary if helpful. However, other respondents noted that frequency of injection was dependent on patient factors such as etiology of the vocal fold mobility and other medical co-morbidities (Figure 9). One

respondent noted that although they would perform injection as often as necessary, after 18-24 months they would consider recurrent laryngeal nerve re-innervation.

Discussion

The diagnosis of unilateral vocal cord paralysis (UVCP) in infants is not an uncommon one, especially following cardiac surgery. Although many infants with UVCP may be asymptomatic, still others may present with symptoms such as aspiration and/or dysphonia, which may be indications for injection laryngoplasty (IL).

In adults, early IL for UVCP has been reported to avert aspiration and allow resumption of an oral diet, especially after iatrogenic injury such as cardiothoracic surgery,¹¹ with some reporting fewer pulmonary complications such as pneumonia.¹² It has also been suggested that early IL might decrease the likelihood of requiring more permanent open neck procedures to address their paralysis, perhaps due to increased ability to maintain an adducted vocal cord position over time as synkinetic reinnervation occurs¹³, but this has not been borne out in subsequent studies¹⁴.

In the pediatric population, there are several retrospective case reports that also document the safety and efficacy of injection laryngoplasty¹⁻⁶. However, most injections were performed in older children rather than infants, for whom the primary indication was more often dysphonia rather than aspiration^{7,8}. In infants, aspiration and poor pulmonary toilet are indications for IL, but the short-term benefit of injections must be weighed with the usual complex cardiorespiratory, neurologic, and syndromic comorbidities found commonly in this patient population. Indeed, prior studies have shown that despite IL, many of these children with their comorbidities may still need a tracheotomy (25.7%) or gastrostomy tube (40.8%)²². In addition, it is important to recognize that many children may have spontaneous resolution of symptoms over time, with 28-43% of pediatric cases reporting spontaneous resolution of the UVCP within 1-2 years^{3,22}.

More recent series have provided additional insight regarding IL in infants, but have still been limited to descriptive information given small subject numbers. Shapiro et al. reviewed a series of 8 patients, 6 of whom were 12 months old or younger and reported no complications. Of these 6 patients, 3 were reported to be able to advance their diet.²³ A study by Meister et al. has described the largest cohort of very young children undergoing IL to date, with 19 subjects under 18 months old in their retrospective review of 41 children. In the patients that developed perioperative complications such as need for increased oxygen, laryngospasm, prolonged operative time, and readmission, 4 of 6 were noted to be under 18 months old, but they noted confounding factors such as patient history of severe bronchopulmonary dysplasia or congenital heart disease. Both studies were limited by small sample size with respect to young infants and this precluded statistical analysis regarding outcomes of IL in this specific population.²⁴ Although it appears that IL is being increasingly considered in infants with UVCP and dysphagia, the practice still appears to be less common than in older patients, and therefore may benefit from further multi-institutional studies to pool data and allow for a more rigorous analysis.

Our survey confirms that injection laryngoplasty may safely be performed in infants younger than 12 months old who have UVCP, and is the first study to provide a description of experiences across multiple institutions. Although our survey was designed to specifically query injection laryngoplasty practices, most respondents noted performing IL with concurrent medical therapy, and we do not consider the two to be mutually exclusive. While complications are rare, practitioners should counsel families about the possibility of temporary airway obstruction post-operatively with subsequent need for intensive care unit monitoring, and perhaps even re-intubation. Caution should also be considered in children with coagulopathy, as bleeding could become problematic despite the minimally invasive nature of the procedure, as reported by one survey respondent. Although there was heightened concern regarding airway obstruction in infants due to the smaller airway diameter in comparison with older children amongst our respondents, we were not able to compare whether there was a statistically significant difference in complications between infants and older children due to the small number of cases reported in the literature.

Carboxymethylcellulose gel (Prolaryn Gel) was the most commonly used material in our survey. In infants, given the rapid growth and changes of the larynx with age and the possibility of spontaneous resolution of the vocal cord paresis, this may explain the preference towards using more temporary injectables in this age group. Although we did not explicitly inquire into complication type by injection material, the two respondents who reported needing re-intubation used calcium hydroxyapatite (Prolaryn Plus), although many others reported using calcium hydroxyapatite without complication. Notably, there have been case reports in the adult population of intense granulomatous and inflammatory reactions, migration of injected material, and even severe systemic reaction with calcium hydroxyapatite, perhaps exacerbated by its slow resorption and long-lasting effects²¹. We did not query members as to why they may have preferred a certain injectable, or injection quantity or complications by injectable type, but at least one respondent noted using different materials depending on etiology of UVCP and number of prior IL, and these questions could be included in future studies or surveys.

Another option for UVCP rehabilitation in children is recurrent laryngeal nerve innervation. While this has been successfully performed in children as young as 2 years old, it may not be the ideal procedure in infants younger than 12 months old. Resolution of symptomatic UVCP has been shown to occur in up to 43% of children, with recovery noted on average between six and eleven months, but as long as 38 months after initial diagnosis²²; therefore, in the setting of possible functional recovery, this procedure is not indicated in infants. Indeed, although 1-2 respondents noted their preference for reinnervation rather than injection laryngoplasty, none indicated that they would perform in infants younger than 12 months old.

In summary, this study is the first to examine injection laryngoplasty specifically in infants younger than 12 months old. By performing a survey of ASPO members, we were able to capture a multi-institutional view of current practices. However, limitations of this study included small sample size, and the wide variability in and subjective nature of responses, which subsequently precluded statistical analysis. Future efforts could be directed towards developing multi-institutional studies with objective outcomes measures to produce the data needed to

elucidate best practices regarding surgical management of UVCP in infants. Development of standardized metrics to evaluate severity of symptoms from UVCP such as dysphagia, dysphonia, and respiratory symptoms would be critical to the success of such studies. Prospective data collection could be considered as well, with analysis of outcomes such as improvements in oral feeding and rate of pneumonia. Based on the available data, we conclude that injection laryngoplasty may be safely pursued in infants with aspiration due to unilateral vocal cord paralysis, but that careful consideration should be given to the natural history of UVCP and associated co-morbidities in this population before proceeding.

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Table 1. Survey Questions

- 1) Do you perform injection laryngoplasty in infants (≤ 12 months of age) with unilateral vocal fold paralysis?
 - Yes (proceed to question 3)
 - No (proceed to question 2)
- 2) What are your reasons for NOT performing injection laryngoplasty in infants (≤ 12 months of age)?
 - Too young
 - Not enough experience with this age group
 - I prefer re-innervation as first line procedure if intervention is required
 - I prefer nonsurgical management
 - I refer them to a colleague who performs injection laryngoplasty at my own institution
 - I refer them to another institution/medical center where they can get the procedure
 - Other (please specify)
- 3) How many injection laryngoplasties have you performed in infants (≤ 12 months of age)? (select one)
 - 0
 - <5
 - 5-10
 - >10
- 4) Is there a minimum age at which you will consider injection laryngoplasty in infants (≤ 12 months of age)?
 - If so, please write in that age in months
 - No age criteria
- 5) For which indications do you commonly perform injection laryngoplasty in infants (≤ 12 months of age)? (select all that apply)
 - Persistent aspiration and to improve oral intake
 - Poor vocal quality or hoarse voice
 - Improve glottic closure and cough for pulmonary toilet
 - Other (please specify)
- 6) For which populations do you commonly perform injection laryngoplasty in infants (≤ 12 months of age)? (select all that apply)
 - Post-congenital cardiac surgery
 - Post -tracheal or esophageal surgery
 - Infants with neurologic tumors, malformations, or s/p stroke
 - Other (please specify)
- 7) How long will you try non-surgical management (feeding modifications) for before considering injection laryngoplasty in infants (≤ 12 months of age)?
 - Please enter duration in months
 - I do not try feeding modifications
 - Other (please specify)
- 8) How do you prefer to manage ventilation while performing injection laryngoplasty under general anesthesia in infants (≤ 12 months of age)? (select all that apply)
 - Intubation throughout the procedure
 - Jet ventilation
 - Spontaneous ventilation
 - Intermittent apnea, with mask ventilation or intubation as needed
 - Other (please specify)
- 9) What complications have you experienced with injection laryngoplasty in infants (≤ 12 months of age)? (select all that apply)
 - Airway obstruction requiring ICU monitoring
 - Airway obstruction requiring intubation
 - Bleeding
 - Dysphagia/poor feeding
 - None
 - Other (please specify)
- 10) What material do you prefer to use for injection in infants (≤ 12 months of age)? (select all that apply)
 - Cymetra (micronized Alloderm)
 - Prolaryn Gel (carboxymethylcellulose gel)
 - Prolaryn Plus (calcium hydroxyapatite)
 - Renu Gel (Hydrogel)
 - Renu Voice (calcium hydroxyapatite)
 - Restylane/Juvederm (hyaluronic acid)
 - Autologous fat
 - Other (please specify)

11) How long do you feel the effects of injection last?

- Please enter duration in months

12) How do you define success of injection laryngoplasty? (select all that apply)

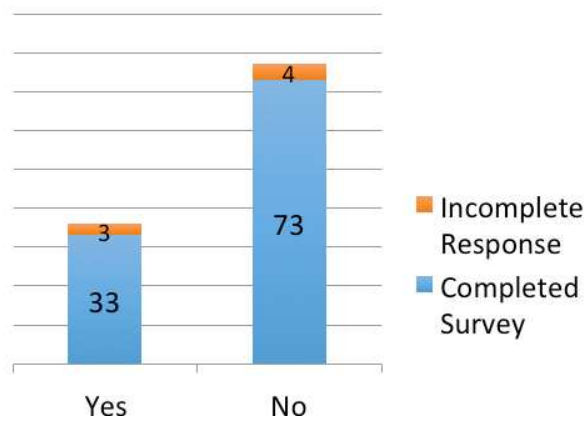
- Avoidance of a feeding tube
- Avoidance of future thyroplasty or arytenoid adduction
- Improvement in aspiration
- Improvement in voice/cry

13) How many times will you repeat injection if patient has benefit with the initial injection?

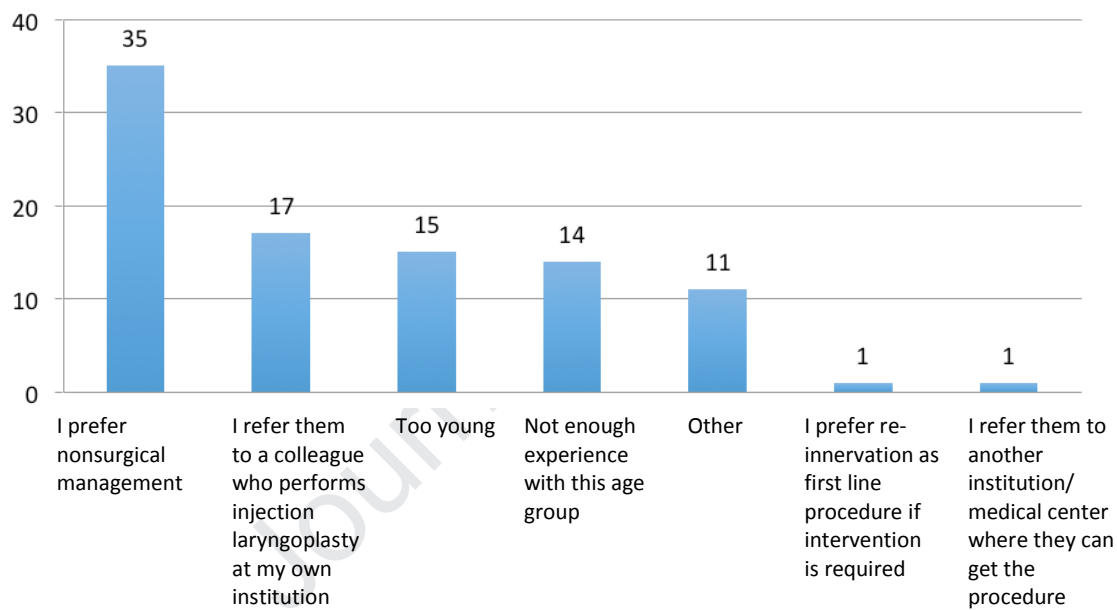
- 0
- 1
- 2
- 3
- As often as necessary
- Other

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A)



"Other" responses

- Low concern for aspiration that cannot be treated by medical therapy (4)
- Prefer to await potential resolution (4)
- Concern about compromising airway (3)

B)

Figure 1. A) Do you perform injection laryngoplasty in infants less than 12 months of age with unilateral vocal fold paralysis? B) If you answered no, what are your reason(s)? (select all that apply)

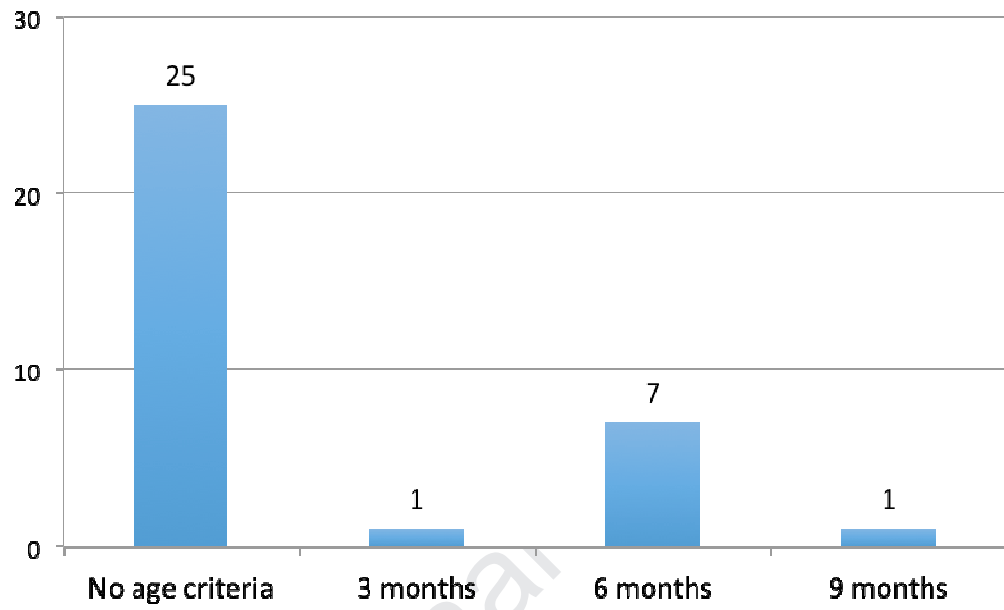


Figure 2. Is there a minimum age at which you will consider injection laryngoplasty in infants?

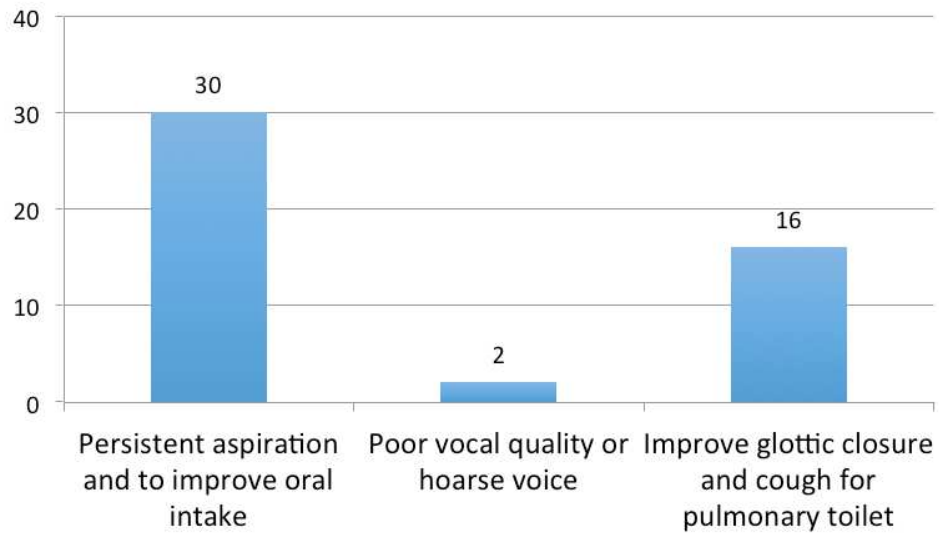


Figure 3. How many injection laryngoplasties have you performed in infants?

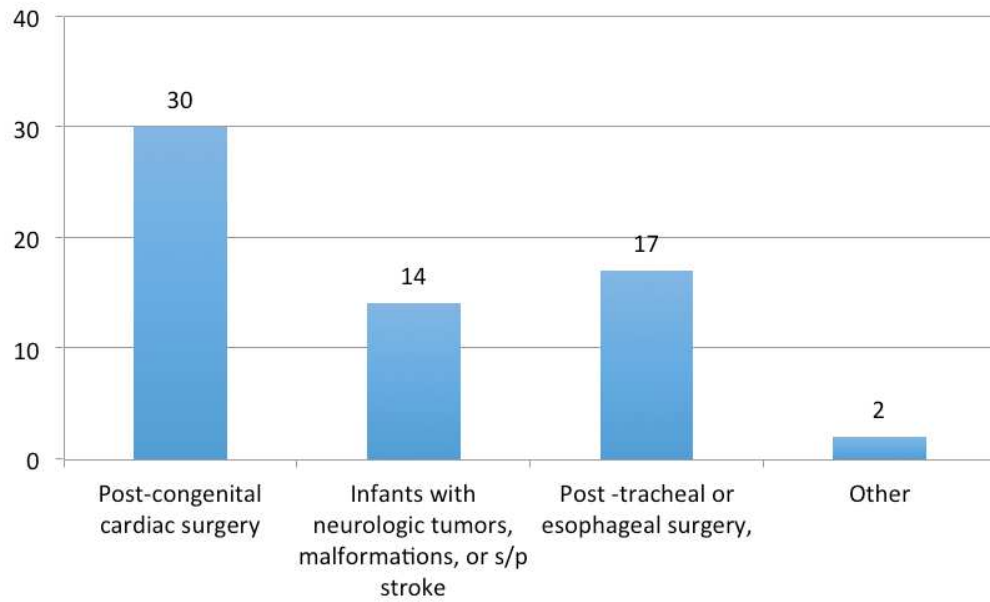


Figure 4. Is there a minimum age at which you will consider injection laryngoplasty in infants?

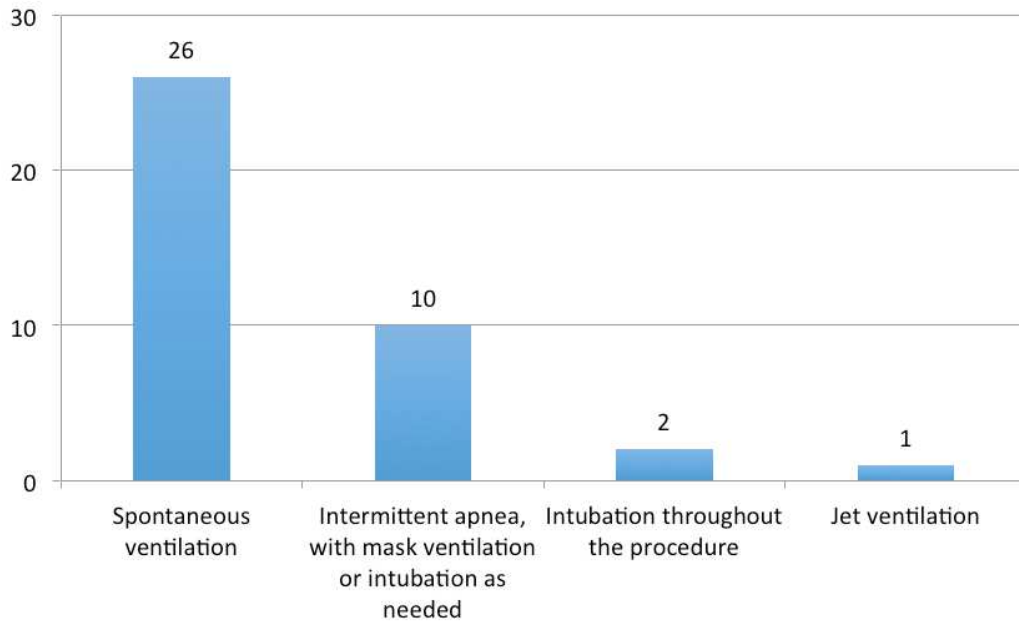


Figure 5. How do you prefer to manage ventilation while performing injection laryngoplasty under general anesthesia in infants?

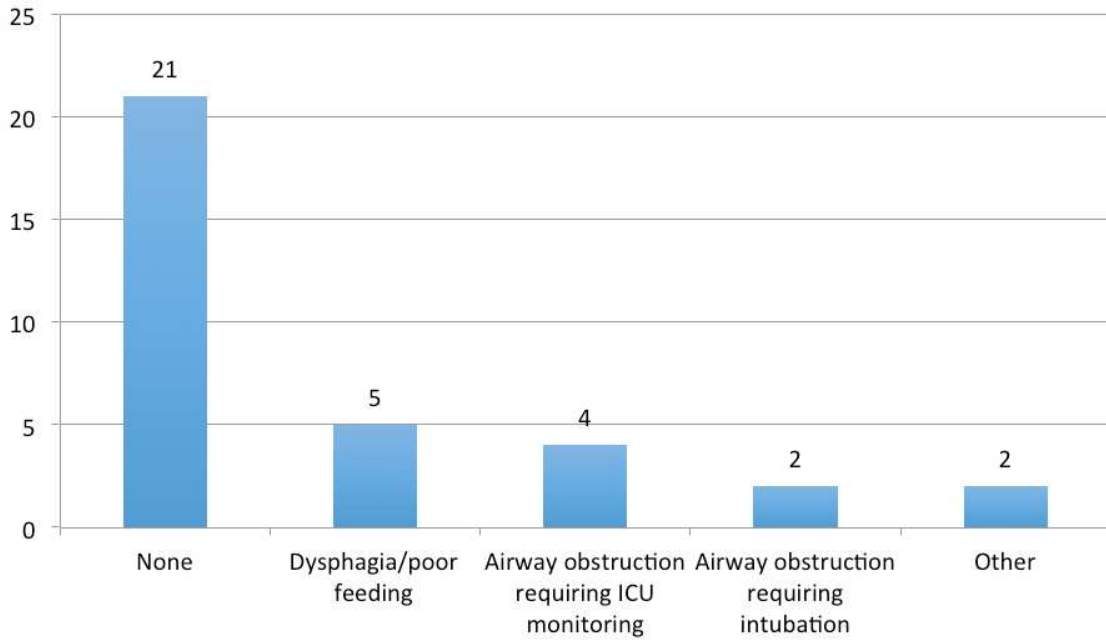


Figure 6. What complications have you experienced with injection laryngoplasty in infants?

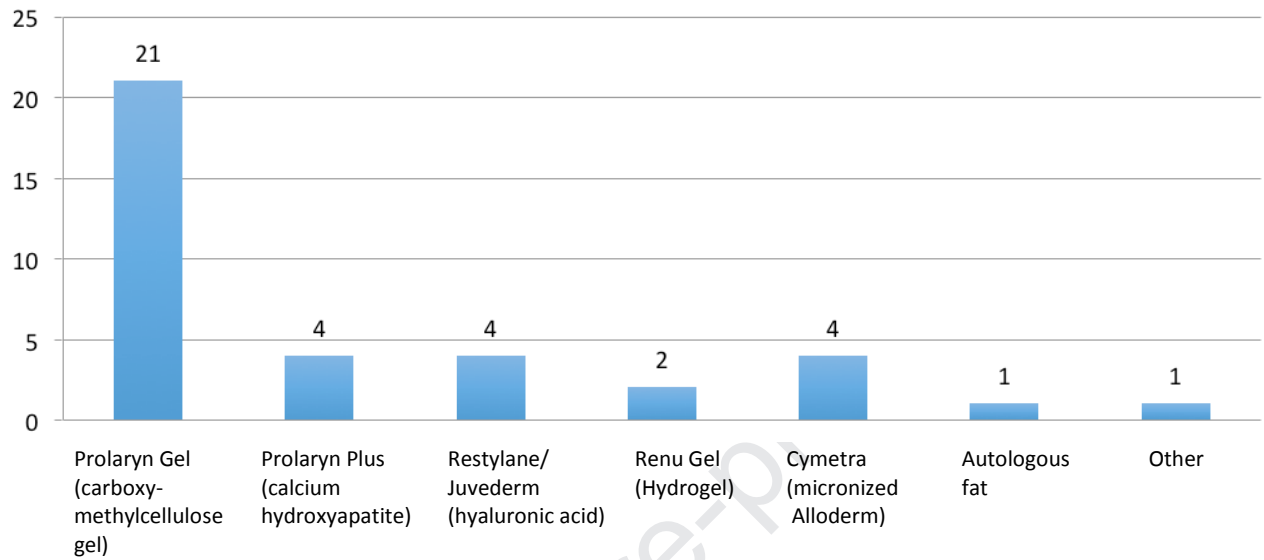


Figure 7. What material do you prefer to use for injection in infants?

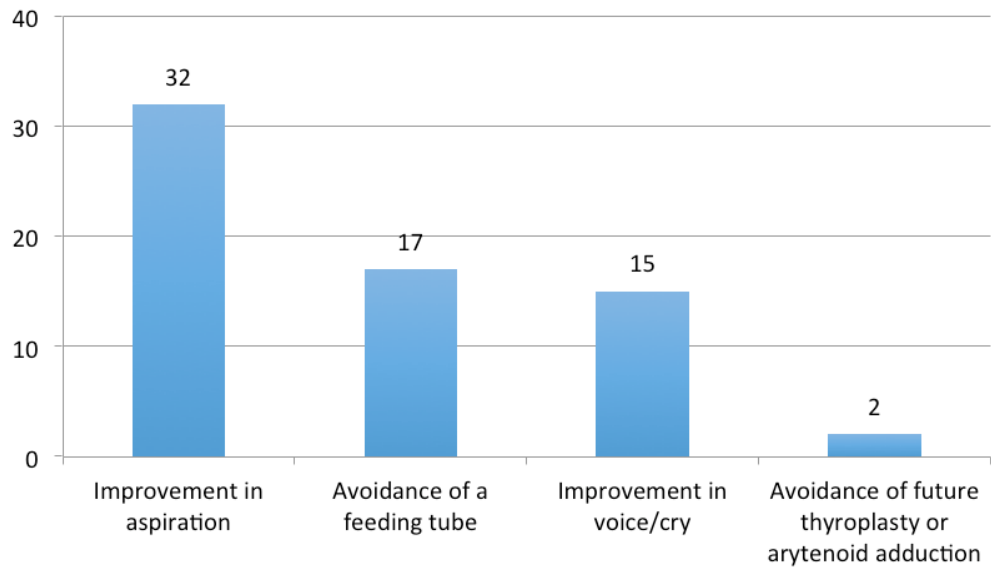


Figure 8. How do you define success of injection laryngoplasty? (select all that apply)

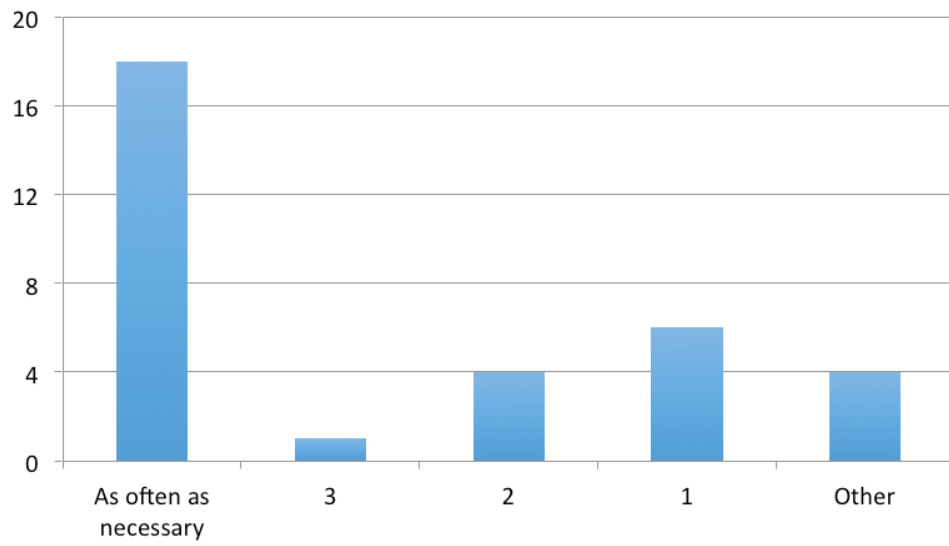


Figure 9. How many times will you repeat injection if patient has benefit with the initial injection?