Injection Pharyngoplasty With Calcium Hydroxylapatite for Velopharyngeal Insufficiency

Patient Selection and Technique

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Objective: To identify children who may benefit from calcium hydroxylapatite (CaHA) injection pharyngoplasty for symptomatic velopharyngeal insufficiency (VPI).

Design: Retrospective review of children with VPI who underwent injection pharyngoplasty with CaHA.

Setting: Multidisciplinary pediatric aerodigestive center.

Patients: Children with symptomatic VPI as defined by abnormal speech associated with subjective and objective measures of hypernasality.

Intervention: Posterior pharyngeal wall augmentation with injectable CaHA.

Main Outcome Measure: Nasalance scores recorded as number of standard deviations (SDs) from normalized scores, and perceptual scoring recorded as standardized weighted score and caretaker satisfaction from direct report.

Results: Twelve children who had undergone injection pharyngoplasty with CaHA were identified. Of the 12 children, 8 demonstrated success at 3 months as defined by nasalance (<1 SD above normal nasalance scores), perceptual scoring (decrease in weighted score), and overall caretaker satisfaction. Four children who failed the procedure all failed before the 3-month evaluation and demonstrated increased baseline severity of VPI as defined by increased preoperative nasalance scores (5.25 SD vs 2.4 SD above normalized scores), perceptual scores (weighted score, 4.25 vs 3.85), and characteristic nasendoscopy findings of a broad-based velopharyngeal gap or unilateral adynamism. Three of the 4 treatment failures occurred early in the senior author’s (C.J.H.) experience with the technique.

Conclusions: Injection pharyngoplasty with CaHA is a useful adjunct in the treatment of children with mild VPI. Efficacy and safety have been demonstrated more than 24 months after injection. Patient selection and operative technique are critical to the success of the procedure. Success is seen most often in children with mild VPI and small well-defined velopharyngeal gaps consistent with touch closure.


VELOPHARYNGEAL INSUFFICIENCY (VPI) is a multifactorial deficit of the ability to effectively seal the nasopharynx, which in turn results in a loss of resonant speech control and possibly a loss of optimal introral pressure to attain orally directed speech sounds. Targeted speech therapy is recommended for mild cases. However, surgical management is required to correct the tissue deficit seen in most moderate to severe cases. The primary surgical procedures used to correct the anatomical deficit are the sphincter pharyngoplasty and the posterior pharyngeal flap. Both serve to provide an increase in tissue bulk to the nasopharynx, although the sphincter pharyngoplasty has been postulated to provide some degree of dynamic muscle action. However, both procedures are relatively invasive, are associated with a moderate degree of pain, and may have a difficult postoperative recovery period.

A less frequently used third option in some children is augmentation of the posterior pharyngeal wall. The concept involves displacing the posterior pharyngeal wall anteriorly in such a way that provides an easily reached contact point for the soft palate, allowing adequate velopharyngeal closure. The procedure has been described using a superiorly based, rolled, posterior pharyngeal wall flap as well as autologous and nonautologous implant...
materials. Implant materials previously advocated include cartilage, fat, fascia, paraffin, silicone, acellular dermis, polytetrafluoroethylene, and injectable calcium hydroxylapatite (CaHA).4,9 Although posterior pharyngeal wall augmentation has shown promise in some children with VPI, patient selection is critical in determining the success of the procedure. By reviewing our extended experience with CaHA injection pharyngoplasty, we sought to better define the population of children who seem to derive the most benefit from the procedure.

METHODS

We retrieved the medical records of all children who underwent CaHA injection pharyngoplasty between December 2005 and October 2008 at the Massachusetts Eye and Ear Infirmary, Boston. A multidisciplinary team, including pediatric otolaryngologists and speech-language pathologists, had previously evaluated all children. Each child underwent a minimum of 3 months of targeted speech therapy directed at reducing nasal resonance. Based on the findings of nasal endoscopy, multi-view fluoroscopy, and clinical symptoms, the caretaker of each child was offered surgical treatment of their child’s VPI. Based on clinical features, possible surgical alternatives included a posterior pharyngeal flap, sphincter pharyngoplasty, Furlow palatoplasty, or injection pharyngoplasty with CaHA. Children with subjectively small velopharyngeal gaps and mild to moderate VPI were offered CaHA injection pharyngoplasty as an alternative to the above described procedures. Caretakers were informed that although CaHA was approved by the Food and Drug Administration for human use in the other anatomical locations, it was not approved for use in the posterior pharyngeal wall and as such was considered an off-label use.

TECHNIQUE

The surgical technique has been previously described.9 In short, children were endotracheally intubated, induced into an adequate plane of general anesthesia, placed supine on the operating table, and suspended in the Rose position as for a tonsillectomy using a Crowe-Davis mouth gag. Red rubber catheters were passed transnasally and retrieved transorally to retract the soft palate. A 120° endoscope with a palate retractor allowed direct visualization and correlation of anatomical landmarks with the preoperative nasendoscopy (Figure 1). Visualization and palpation confirmed the absence of pulsations consistent with carotid arteries in the posterior pharyngeal wall. The CaHA (Radiesse Voice Injectable Implant No. 8044MO; Bioform Medical Inc, San Mateo, California) was packaged in a prefilled 1-mL syringe. Injection was performed with a 25-gauge needle. A precise injection was made into the posterior pharyngeal wall at the site of the velopharyngeal gap into the retropharyngeal soft tissues (Figure 2). Injection was accomplished by inserting the needle through the posterior pharyngeal wall mucosa to a depth where bone contact was made and then withdrawing the needle approximately 2 mm, with a goal of depositing the CaHA into the retropharyngeal space. Injection volumes ranged from 1 to 4 mL. All children were discharged home the same day and given a prescription for postoperative antibiotics.

DATA COLLECTION

Charts were reviewed to identify demographic details, cause of VPI, surgical history, and outcomes. Specific data were recorded on objective measures of VPI, including nasometry and a weighted speech scale. Nasometry was performed in accordance with the MacKay-Kummer SNAP test,10 and nasalance scores are reported as the number of standard deviations (SDs) above normal. Weighted speech scores are reported as whole numbers correlating with increasing severity based on the scoring scale initially described by McWilliams and Phillips.14 Scores of 0 or 1 are considered to be consistent with a competent valving mechanism; a score of 2 indicates inconsistent competence; and scores of 3 or more are consistent with an increasing level of valving incompetence. The caretakers of children who demonstrated success at 3 months were contacted if more than 24 months had elapsed since the CaHA injection was administered. The child’s current symptoms were discussed, and caretakers were asked to return for further objective follow-up measures.

OUTCOMES

Success was defined by several measures. The requisite for a procedure to be considered successful was subjective satisfaction on the part of the caregiver. Furthermore, for the treatment to be considered a success, no further surgical procedure was needed to treat symptomatic VPI. Objective measures of success included a postoperative nasalance score of less than 1 SD above normal or a decrease in the weighted speech score. Meaningful statistical analysis was precluded by the small sample size.
RESULTS

Twelve children were identified who had undergone injection pharyngoplasty with CaHA between December 2005 and September 2008. The Table summarizes each child’s demographics and clinical course. Injection pharyngoplasty was the primary procedure in 8 children and was used to revise prior surgical techniques in the remaining 4 children. The mean age at the time of procedure was 7.67 years (age range, 3-16 years). Of note, during the study period, 22 non-CaHA injection procedures were performed for VPI at our institution.

OUTCOMES AT 3 MONTHS

As depicted in the Table, 8 of the 12 children demonstrated success at 3 months. The caretakers of all 8 children expressed satisfaction with the results of the procedure, and none of the children required further surgical interventions. All children underwent targeted resonance-based speech therapy. Of the 8 children, 7 had postoperative nasalance scores available at 3 months. Each child demonstrated nasalance scores within 1 SD of normal. Furthermore, 7 of the 8 children experienced an improvement in their weighted speech score. The child who did not improve her weighted speech score had marked articulation deficits and a long-standing history of idiopathic VPI. Her primary difficulty associated with VPI was inconsistency in sustained conversational speech. The child and her mother feel that she subsequently had a significant improvement in the sustainability of her speech that was not reflected in her formal weighted score measure.

Failures at 3 months included 4 children. The 4 children who failed CaHA injection pharyngoplasty had a mean baseline weighted speech score of 4.25 and a mean preoperative nasalance score of 5.25 SDs from normal. In contrast, the 8 children who were successfully treated with CaHA injection pharyngoplasty had a mean baseline weighted speech score of 3.86 and a mean preoperative nasalance score of 2.40 SDs from normal. Although the sample size is small, the children who failed appear to represent a higher degree of VPI before surgery.

OUTCOMES AT 24 MONTHS

Four of the 8 children who demonstrated success at 3 months have been followed up for 24 months or longer. All 4 have continued to show stable outcomes. Two of the 4 children have undergone postoperative nasometry, which demonstrated sustained nasalance scores in the normal range. The other 2 children have not undergone further nasometry but are subjectively doing well according to their caretaker or local speech pathologist and have not sought further surgical therapy.

CLINICAL FEATURES OF SUCCESSES

As demonstrated in the Table, 7 of the 8 children who underwent successful injection pharyngoplasty did not have an underlying craniofacial or developmental anomaly. Of the 4 children who developed VPI after un-

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Table. Characteristics of Children Undergoing Injection Pharyngoplasty

<table>
<thead>
<tr>
<th>Success</th>
<th>Age, y/ Sex</th>
<th>Primary procedure</th>
<th>Pathogenesis</th>
<th>VPI Sev. Score</th>
<th>Nasometry, No. of SDs From Normal</th>
<th>Preoperative Nasometry Endoscopy Findings</th>
<th>&gt;24 mo of Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Y</td>
<td>6/F</td>
<td>Y</td>
<td>After adenoidectomy</td>
<td>NA</td>
<td>3</td>
<td>NA</td>
<td>0.50</td>
</tr>
<tr>
<td>Y</td>
<td>3/M</td>
<td>Y</td>
<td>Idiopathic</td>
<td>2</td>
<td>1</td>
<td>NA</td>
<td>0.50</td>
</tr>
<tr>
<td>Y</td>
<td>12/F</td>
<td>Y</td>
<td>After adenoidectomy</td>
<td>3</td>
<td>0</td>
<td>2.00</td>
<td>0.25</td>
</tr>
<tr>
<td>Y</td>
<td>3/F</td>
<td>N</td>
<td>After adenoidectomy, SMC</td>
<td>4</td>
<td>2</td>
<td>NA</td>
<td>0.00</td>
</tr>
<tr>
<td>Y</td>
<td>11/M</td>
<td>Y</td>
<td>After adenoidectomy</td>
<td>5</td>
<td>2</td>
<td>1.67</td>
<td>0.67</td>
</tr>
<tr>
<td>Y</td>
<td>8/M</td>
<td>Y</td>
<td>Idiopathic</td>
<td>4</td>
<td>3</td>
<td>5.00</td>
<td>0.50</td>
</tr>
<tr>
<td>Y</td>
<td>5/M</td>
<td>Y</td>
<td>Idiopathic</td>
<td>6</td>
<td>4</td>
<td>3.33</td>
<td>NA</td>
</tr>
<tr>
<td>Y</td>
<td>16/F</td>
<td>N</td>
<td>Idiopathic</td>
<td>3</td>
<td>3</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>N</td>
<td>3/M</td>
<td>N</td>
<td>After adenoidectomy, SMC</td>
<td>5</td>
<td>5</td>
<td>6.00</td>
<td>6.00</td>
</tr>
<tr>
<td>N</td>
<td>2/F</td>
<td>Y</td>
<td>Pierre Robin sequence</td>
<td>3</td>
<td>2</td>
<td>NA</td>
<td>5.75</td>
</tr>
<tr>
<td>N</td>
<td>13/M</td>
<td>N</td>
<td>Hemifacial microsomia</td>
<td>5</td>
<td>5</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>N</td>
<td>10/M</td>
<td>Y</td>
<td>Idiopathic</td>
<td>4</td>
<td>4</td>
<td>4.50</td>
<td>NA</td>
</tr>
</tbody>
</table>

Abbreviations: N, no; NA, not applicable; SDs, standard deviations; SMC, submucosal cleft palate; VPI, velopharyngeal insufficiency; Y, yes.
deteriorating an adenoidectomy, only 1 had a previously identified submucosal cleft palate. The child with the submucosal cleft palate initially underwent a Furlow palatoplasty. Clinically, most children demonstrated mild VPI that primarily manifested during conversational speech. During targeted resonance therapy sessions with a speech language pathologist, the children often were able to attain adequate closure. However, by caretaker report and direct observation, these children would exhibit worsening of their symptoms as they became fatigued or directed less attention to their speech and to the resonance techniques that they learned in therapy. On nasal endoscopic examination, each successful child demonstrated a small central velopharyngeal defect.

**CLINICAL FEATURES OF FAILURES**

As shown in the Table, 3 of the 4 failures occurred in children with associated craniofacial anomalies. Two children had previously undergone a palatoplasty and demonstrated moderately sized, broad-based gaps on nasal endoscopy. One of the 2 children had previously undergone repair of a submucosal cleft palate, and the other had a history of Pierre Robin sequence and had undergone palatoplasty at another institution. After initially undergoing injection pharyngoplasty, both children demonstrated persistent VPI immediately after surgery. Subsequently, both underwent successful pharyngeal flap procedures. The third child had a history of multiple congenital anomalies that were consistent with hemifacial microsomia. Notably, he had unilateral adynamism of his soft palate. He had previously undergone a variety of procedures, including a pharyngeal flap and a sphincter pharyngoplasty, after which he experienced significant but not complete resolution of his VPI. An injection was attempted in the region of his lateral defect, and failure was noted immediately after surgery. Ultimately, he was treated with a revision sphincter pharyngoplasty.

**COMMENT**

Posterior pharyngeal wall augmentation with CaHA offers an easily performed surgical alternative for children with mild VPI and a small central velopharyngeal gap. In some children, the morbidity associated with undergoing a pharyngeal flap or a sphincter pharyngoplasty can be avoided. However, proper patient selection is critical to the success of the procedure.

Advantages of CaHA as an implant material include the ready availability, ease of injection, and proven track record of CaHA in other anatomical locations. Calcium hydroxyapatite has been reported to have sustained results in vocal fold augmentation for periods of 12 months. Of note, however, is a single description of a 46-year-old woman with a history of multiple orthopedic implants who developed a giant cell foreign body reaction in the larynx, requiring surgical removal of the CaHA.

To date, we have had no major intraoperative or postoperative complications, and the procedure has been generally well tolerated. One child required a single-day readmission for pain control and rehydration on postoperative day 2. As described in our previous report, 4 children who underwent imaging of the neck for other reasons have demonstrated no evidence of migration of the implant between 4 and 10 months. Although our long-term experience is small, the 4 children who were followed up for 24 months after initial success appear to have sustained results, suggesting that resorption is not a major issue. Of primary importance is the fact that subsequent pharyngeal flap or sphincter pharyngoplasty procedures in children who failed CaHA injection have not been technically compromised and have demonstrated successful outcomes.

As our experience with the procedure has grown, we have become more adept at identifying children who are most likely to succeed. Three of our 4 failures occurred early in the senior author’s (C.J.H.) experience. As described above, 3 of these children had associated craniofacial anomalies and moderately sized velopharyngeal gaps with a lateral extent. At this point, our experience with CaHA injection for lateral closure defects has been unsuccessful.

Children with marginal velopharyngeal competence benefit most from the technique. Specifically, children who have undergone adenoidectomy with a resultant small central gap seem to be ideal candidates. Furthermore, success is seen in children who demonstrate “touch” closure whereby, although velopharyngeal approximation is attained, the anatomical deficiency results in a failure to make an effective seal to permit consistently normal speech patterns.

Previous authors have suggested a variety of clinical profiles in children with marginal velopharyngeal competence, including children with consistent mild nasalization and children with variability noted during speech tasks. We have had particular success in the latter group. This subset of children often presents a therapeutic dilemma to speech pathologists because the inconsistency becomes particularly difficult to manage in the child’s daily interactions despite success in the office. Subjecting such children to a pharyngeal flap or a sphincter pharyngoplasty seems excessive. Injection pharyngoplasty may serve as an intermediate and less invasive procedure between continued therapy and traditional procedures. Because our patients generally have mild symptoms, their caretakers uniformly report the greatest degree of satisfaction in decreasing the variability within sustained speech. As stated above, after surgery, all of our children remain in directed resonance therapy with a speech language pathologist. One hypothesis is that in children with very small gaps or touch closure, injection pharyngoplasty may serve as an adjunct to therapy by helping the child to effectively learn how to maintain sufficient velopharyngeal closure under a variety of circumstances. Under such a hypothesis, the resorption of CaHA becomes less important over time.

In addition to the proper selection of patients, technical considerations have become apparent as our experience has grown. Injecting an adequate volume of the implant is imperative during the procedure. We routinely use between 2 and 4 mL depending on the size of the defect and the amount of augmentation viewed on direct visualization. Furthermore, we always view the preoperative nasal endoscopy in the operating room to identify appropriate landmarks and to ensure that the injection site precisely corresponds to the location of the velopharyngeal gap. As described above, to determine the
adequate plane for injection, the needle is placed through the posterior pharyngeal wall, contacted to bone, and then withdrawn approximately 2 mm. This procedure avoids injection in a plane that is too superficial yet prevents the injection from filling the deep neck spaces.

Theoretical concerns regarding meningitis or thromboembolic phenomena have been raised. A potential anatomical issue is the previously described valveless plexus of posterior pharyngeal wall venous drainage from the submucosa that communicates with the subarachnoid space.\textsuperscript{16} Potential introduction of nasopharyngeal flora into the plexus could theoretically result in hematogenous seeding of the subarachnoid space and thus meningitis. However, it must be noted that many of the same venous structures would be exposed during traditional pharyngeal flap or sphincter pharyngoplasty procedures, which have not been associated with an increased meningitis risk. Also, inadvertent arterial injection of CaHA could potentially embolize and result in cerebral vasculature occlusion. This possibility is minimized by palpation for arterial pulsation of the posterior pharyngeal wall.

In conclusion, CaHA injection pharyngoplasty appears to be a safe, easily performed procedure with low morbidity in properly selected children with clear indications. In such children, it can serve as a valuable adjunct to resonance-based speech therapy and does not preclude the child from undergoing more invasive procedures.

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REFERENCES