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Primary augmentation pharyngoplasty with calcium hydroxylapatite for treatment of velopharyngeal insufficiency: Surgical and speech outcomes

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ABSTRACT

Introduction: Augmentation pharyngoplasty (AP) is a technique that may effectively treat velopharyngeal insufficiency (VPI), while avoiding typical short and long term surgical risks. This study seeks to determine if children with VPI treated by AP with calcium hydoxylapatite (CaHa) demonstrate clinically significant improvement in speech outcomes.

Methods: Retrospective review (2012–2016) of prospectively collected database of children with VPI, cared for at a single tertiary children's hospital. Preoperative speech assessment, nasometry, and video nasendoscopy were used to identify patients with VPI treated by AP with CaHa. Demographics, surgical/speech outcomes, complications, novel surgical technique and follow-up were recorded. Main outcome measures included pre and postoperative nasality and perceptual speech assessments, based on the Pittsburgh Weighted Values for Speech (PWS).

Results: 17 patients treated with AP with CaHa, as initial primary treatment for VPI, were identified. 8 patients had cleft palate, 9 patients had isolated VPI. Mean age at treatment was 6.6 years, with no operative complications. Mean nasality scores before and after surgery were 3.2 vs. 0.5 ($p < 0.001$). Mean PWS before and after surgery were 9.7 vs. 2.1 ($p < 0.001$). Based on the PWS scoring, 4/8 of cleft patients (50%) and 8/9 of isolated patients (89%) achieved a competent/borderline competent nasopharyngeal valve. 17/17 of patients (100%) had improvement in nasality. Mean length of follow-up was 32.8 months (range 10–64 months).

Conclusion: In this largest series of patients to date, AP with CaHa is a safe, minimally invasive, enduring treatment for VPI in properly selected patients. Nasality and speech scores significantly improved, especially in patients with isolated VPI.

1. Introduction

Velopharyngeal insufficiency (VPI) describes an anatomical or structural deficit that prevents adequate velopharyngeal closure during speech [1]. If the velopharyngeal sphincter is insufficient, speech is characterized by hypernasal resonance, decreased intraoral pressure for pressure consonants, and possible audible nasal emission (ANE) [2]. Despite a trial of targeted speech therapy, many patients with persistent VPI require surgical intervention to correct the deficit. Traditional surgical options include pharyngeal flap and sphincter pharyngoplasty, which are often tailored to the velopharyngeal defect or closure pattern [3]. While these techniques are frequently successful in improving VPI, there are associated short and long term surgical risks [4].

Posterior pharyngeal wall augmentation, either by injection with filler or grafts, can be used for the treatment of VPI. This technique is typically reserved for smaller velopharyngeal gaps, but can be effective in properly selected patients. Potential benefits of augmentation include: ease of surgery, diminished postoperative pain, decreased short and long term airway complications, and less risk of obstructive sleep apnea (OSA) [5].

The current study seeks to research the safety, efficacy, and speech outcomes in patients augmented with nasopharyngeal injection of calcium hydroxylapatite (CaHa). CaHa microspheres in a carboxymethylcellulose carrier is commercially available as Prolaryn Plus (Merz North America, Raleigh, NC). Specifically, the cohort includes only patients diagnosed with VPI that have not undergone other surgeries for VPI correction. Additionally, the study is comprised of both patients with isolated VPI and VPI associated with cleft palate. Main outcome measures included improvement in nasality and perceptual speech assessment of VPI severity. Secondary outcome measures included need for further VPI surgery, surgical complications, and length of follow-up to measure duration of efficacy. A novel endoscopic

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technique is also described.

2. Material and methods

A retrospective review of prospectively collected database of children with VPI cared for at a single tertiary children's hospital was conducted after IRB approval. The study period was from 2012 to 2016. All pediatric patients were included that underwent augmentation pharyngoplasty (AP) injection with CaHa to treat symptomatic VPI. Patients with previous speech surgery for VPI were excluded. Parents were instructed that CaHa was FDA approved for human use in other anatomic locations, but was considered off-label for use in the nasopharynx.

Medical charts were reviewed for demographics, comorbidities, cause of VPI, speech assessment, surgical complications, and follow-up results. A team consisting of a pediatric otolaryngologist and speech-language pathologist evaluated all the children. All children underwent a minimum of 3 months targeted speech therapy prior to surgical intervention.

2.1. Speech assessment

A single speech pathologist, specializing in VPI, completed a preoperative perceptual speech assessment on each patient using the Pittsburgh Weighted Values for Speech Symptoms Associated with Velopharyngeal Incompetence instrument (PWS) [6]. Additionally, nasometry was performed in accordance with the MacKay-Kummer SNAP test [7] (Nasometer II Model 6400; PENTAX Medical, Montvale, NJ). The nasality/resonance severity was scored as follows: 0, normal; 1, mild hypernasality; 2, mild to moderate hypernasality; 3, moderate hypernasality; and 4, severe hypernasality. The PWS scores include nasality, phonation, and articulation and are reported as whole numbers with increasing severity. Scores of 0 are considered to be consistent with a competent valving mechanism; a score of 1–2 indicates borderline competence; a score of 3–6 indicates borderline incompetence; and a score of 7 or higher indicates incompetence of the valving mechanism. Perceptual speech assessment and nasometry were repeated 3–6 months postoperatively on all patients.

2.2. Nasopharyngoscopy

A single pediatric otolaryngologist examined all patients using a flexible distal chip pediatric endoscope (ENT 7000, Cogentix, Minnetonka, MN). The velopharyngeal valve (VPV) movement was recorded while the patient repeated speech samples directed by the speech pathologist. Patients with subjectively small velopharyngeal gaps, with touch or near closure between the velum and posterior pharyngeal wall on endoscopy, were offered AP with CaHA.

2.3. Surgical technique

Under general anesthesia, the nasal cavity is decongested with oxymetazoline soaked cottonoids. A 0° rigid endoscope is used to directly visual the nasopharynx. A Crowe-Davis mouth gag is suspended to visualize the oropharynx. Visualization and palpation confirms no evidence of pulsations consistent with medialized carotid arteries in the posterior pharyngeal wall. A 22-gauge spinal needle is then passed posterior to the soft palate and visualized by the rigid endoscope (Fig. 1). The needle is then inserted into the retropharyngeal space between the superior constrictor muscle and pharyngobasilar fascia. Site of injection is directly correlated to the preoperative gap on nasopharyngoscopy, under direct intraoperative view (Fig. 2). Typically 2 ml of CaHA is injected. All patients are discharged home the same day and given prescription for postoperative antibiotics.

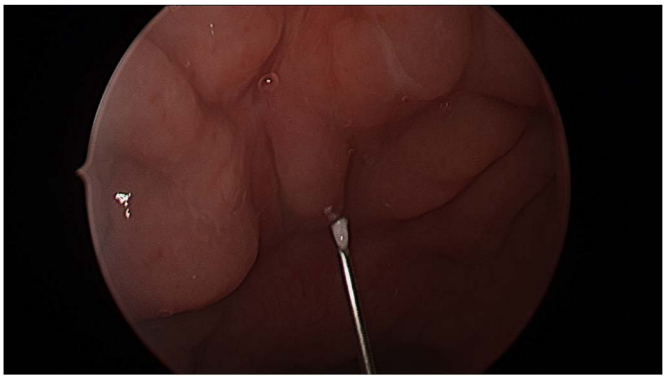

Fig. 1. Direct nasal endoscopic visualization of needle at nasopharynx prior to injection.

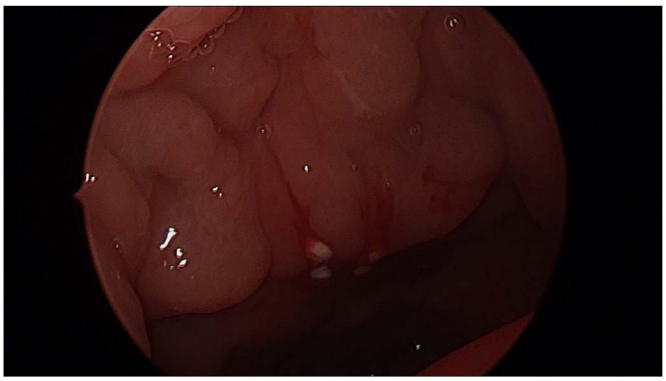

Fig. 2. Endoscopic appearance of augmentation pharyngoplasty after injection.

2.4. Outcomes

Initial outcomes were measured by surgical complications. Surgical and speech outcomes were measured with paired *t* tests, by comparing nasality/resonance scores before and after surgery. Additionally, PWS scores before and after surgery, were compared to assess the overall competence of the VPV. Statistically significant *P* values were deemed to be those $< .05$. Durability of the CaHa was measured by length of follow-up and need for repeat injection.

3. Results

Seventeen patients were identified who had undergone AP with CaHa over the study period from 2012 to 2016. Table 1 summarizes the demographic, clinical, and operative data. In all patients, AP was the primary and initial surgical correction for VPI. Two subgroups included 8 patients with VPI secondary to cleft palate and 9 patients with isolated (non-cleft) causes. While, 6 of the isolated patients had previously had an adenoidectomy, in only one patient was there direct correlation of introduction of VPI post-adenoidectomy. No patients with isolated VPI had evidence of submucous cleft palate. Mean age at the time of surgery was 6.6 years (age range, 3–14 years). There were no surgical complications. Mean volume of CaHa injected was 1.75 ml (range 1–2 ml). Mean length of follow up from time of AP was 32.8 months (range, 10–64 months). No patients required repeat injection. One patient went on to have a secondary speech surgery with pharyngeal flap.

Pre- and postoperative speech results were available for all 17 patients. There was significant improvement in nasality scores for both subgroups and the overall cohort ($P < 0.001$) (Table 2). All 17 patients had overall improvement in nasality. Additionally, the overall velopharyngeal function based on PWS was significantly improved again for both subgroups and the overall cohort ($P < 0.01$) (Table 3). Based on the overall PWS scoring, 4/8 of cleft patients (50%) and 8/9 isolated