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Perception and Duration of Pain After Office-Based Vocal Fold Injection Augmentation

Brianna K. Crawley, MD; Salem Dehom, MPH; Emily Kutzner, MS; Thomas Murry, PhD; Priya Krishna, MD; Justin Hata, MD

Objectives/Hypothesis: In-office laryngology procedures are important in the treatment of voice and swallowing disorders. Patient tolerance determines which procedures can be performed without sedation or formal anesthesia. This study examines pain perception during and after in-office vocal fold injection augmentation.

Study Design: Prospective cohort study.

Methods: Patients scheduled for office-based vocal fold injection augmentation were prospectively enrolled at an academic voice center. The short-form McGill Pain Questionnaire was administered before, during, and after the procedure and on postprocedure days 1, 3, and 7. Pre- and postprocedure vital signs were recorded and heart rate was continuously monitored. Telephone questionnaires were completed on postprocedure days 1 and 3.

Results: Forty-five patients consented to participate in our study (24 males, mean age 61 years). Most patients experienced mild to moderate pain with increasing heart rate during the procedure. Pain remained or increased 20 minutes after the procedure and improved but persisted for 1 day. Sensory and affective discomfort was endorsed by the majority. A minority of patients experienced bruising and changes in swallowing with diet modification for 3 days after the procedure. Sixteen percent had discomfort after 1 week.

Conclusions: This is the first prospective study examining patient perception of pain during and after in-office injection augmentation using a validated scale and pain descriptors with extended follow-up. The results may offer guidance for patient counseling, consent, and treatment to improve tolerance and success.

Key Words: Laryngology, pain, office-based procedures, in-office procedures, vocal fold injection augmentation, visual analog scale, McGill Pain Questionnaire.

Level of Evidence: 4.

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INTRODUCTION

Recent technological advances have enabled the return of otolaryngologic procedures to the office, with improved efficiency and convenience for patients and providers. The number of laryngologic procedures routinely performed in the office has increased in parallel to those of other subspecialties. Biopsies, panendoscopies, steroid injections, ablation of recurrent respiratory papillomas, and vocal fold injection (VFI) augmentation are now routinely completed under topical anesthesia. Performing procedures in the office instead of the operating room provides cost and time advantages and avoids general anesthesia, but success depends on the provision of appropriate analgesia. These procedures are generally considered to be well-tolerated, though few studies address pain or patient experience, and fewer still have applied a validated scale to quantify associated discomfort. No studies have previously reported quality of pain and the contributions of affective components to the overall experience.

With this study, we hoped to characterize the patient experience of in-office VFI augmentation through subjective surveys and objective measures, including a validated pain scale, during and for the week following the procedure. Our goal was to explore the severity, quality, and duration of pain inflicted and its impact on patient behavior to guide informed consent and to help plan interventions to minimize discomfort.

MATERIALS AND METHODS

Adult patients were recruited from those presenting to the Loma Linda University Voice and Swallowing Center with glottic insufficiency between February 2015 and December 2016. Each of these patients participated in the standard informed consent process and agreed to undergo VFI augmentation in the office. All were able to read and write English, and all consented to participate in this prospective study. No patient had had a previous VFI or VFI attempt in the office or operating room.
Injection procedures were performed by one attending laryngologist at the Loma Linda Voice and Swallowing Center. The patients took only their own routine medications and were not provided with additional systemic analgesia or anxiolytics. They were not required to suspend anticoagulation therapy. All subjects underwent VFI with a 25-gauge needle via the transcricothyroid approach to the medial paraglottic space, receiving local and topical anesthesia.

In preparation for transcutaneous injection, all patients received topical 4% lidocaine mixed 1:1 with oxymetazoline, initially sprayed and then applied with neuro patties placed along the floor of the nose. One milliliter or less 1% lidocaine with 1:100,000 epinephrine was injected subcutaneously over the cricothyroid membrane. One milliliter of topical 4% lidocaine was then administered via transtracheal injection. Lidocaine doses were carefully monitored to stay well below the 4 mg/kg dose limit.

Data collection began with the administration of the baseline short-form McGill Pain Questionnaire (SF-MPQ) (Fig. 1A). This questionnaire was chosen for its common use in pain research and its inclusion of both the overall visual analog scale (VAS) and individually rated pain descriptors that include 11 addressing sensory pain and 4 characterizing affective components of pain. Medications taken the day of the procedure and any pain medications taken regularly were recorded. Vital signs were measured before, during (heart rate [HR] continuously for maximum HR reached), and 20 minutes after the procedure. Patients completed the SF-MPQ again immediately at the completion of the procedure to record discomfort during the procedure. The third questionnaire was completed before discharge, between 20 and 30 minutes after completion of the procedure.

The second phase of data collection included three additional SF-MPQs that were completed on postprocedure day (PPD) 1, 3, and 7. In addition, on PPD1 and PPD3, a physician member of the study team called to check on the patient. During these phone follow-ups, five questions were asked (Fig. 1B). The patients returned their last three surveys at their next appointment.

![Fig. 1. (A) Short-form McGill Pain Questionnaire (Melzack). (B) Pain questionnaire administered by telephone on postprocedure days 1 and 3.](image-url)
Demographic data including age and gender were collected as well as data regarding the type of injectable material, site of injection (unilateral or bilateral), and volume of injection. All data were deidentified and compiled for analysis. The medical internal review board of Loma Linda University approved this study prior to its initiation.

**Statistical Analysis**

Descriptive statistics were given as mean, median, or percentage, as appropriate. An independent samples t test was performed to compare patients according to change in VAS with an independent samples Mann-Whitney U test when the assumption of the independent samples t tests was not met. The Pearson χ² procedure was used to assess the association between qualitative variables. The mixed model repeated measures procedure was used to evaluate VAS and HR by time point. Post hoc tests were done on least squares means using the Tukey adjustment for multiple comparisons. Log transformation was used when the assumptions were not met. A paired sample t test procedure was used to compare blood pressure and temperature changes, and a repeated measures analysis of variance was applied to HR values. The Friedman test was used to detect significant change over time in median sensory and affective scores, with a Wilcoxon signed ranks test to assess the change between any two time points. Alpha was set at .05 significance level.

**RESULTS**

Forty-five patients participated in this study, 24 male and 21 female. Their ages ranged from 34 to 96 years (mean = 61 years). The majority were treated for glottic insufficiency resulting from paralysis/paresis of the vocal folds with or without atrophy. Twenty-two percent of the patients were diagnosed with vocal fold atrophy alone. The injectable materials included Prolaryn Gel (sodium carboxymethylcellulose) in 19 patients, Prolaryn Plus (calcium hydroxyapatite) in eight patients, and Restylane (hyaluronic acid) in 18 patients. A mean of 0.45 mL (standard deviation [SD] = 0.37) was injected into the left paraglottic space of 33 vocal folds and 0.35 mL (SD = 0.18) was injected on the right (31 vocal folds). Nineteen patients had bilateral injections.

Vital signs were recorded before and after the procedure. HR was the only vitals parameter that was measured during the procedure. Preprocedure HR mean was 74.18 beats per minute, and the postprocedure mean was 70.58 beats per minute. HR rose significantly (mean = 84.93, 95% confidence interval [CI]: 79.91-89.95, P < .001) during the procedure and returned to baseline within 20 minutes of the conclusion of the procedure.

Pre- and postprocedure blood pressure and temperature values did not significantly change (preprocedure mean arterial pressure [MAP] = 94.58, postprocedure MAP = 94.32, P = .881; mean preprocedure temperature 97.57°F, postprocedure temperature 97.60°F, P = .876).

The amount of pain experienced as a result of the procedure was quantified in various ways. Overall pain recorded with a VAS increased during the procedure and decreased following the procedure, both in a significant fashion, but the pain reported at 20 minutes following the procedure was significantly greater than at baseline (Fig. 2).\(^5\). One patient reported pain after the procedure, though he experienced none during the procedure, and eight others reported worsening pain at the postprocedure measurement. Almost 80% of patients reported increased pain from baseline to during the procedure and from baseline to after the procedure. Patients almost uniformly reported increased pain from before to during the procedure, but more variability was seen in the changes patients reported in pain during to after the procedure, with two-thirds reporting decreased pain and 18% reporting increased pain (Fig. 3). Because of this divergence, we looked for factors that might influence whether pain would be expected to improve, worsen, or remain stable immediately after the procedure. Age, gender, baseline HR and VAS scores, and volume of material injected per side were not significantly associated with pain experienced postprocedure (Table I). When bilateral or unilateral injections were scrutinized, no significant difference was detected between changes from before to during the procedure and before to after the procedure (P = .24 and .22, respectively). VAS scores in females were higher than males at each time point surrounding the procedure, but these differences failed to reach significance unless all time points were combined.

The SF-MPQ allowed us to characterize the quality of the pain patients experienced during and after the procedure. Eleven of the pain descriptors characterize the sensory experience of the pain, and four describe affective elements of the pain. Changes in both sets of scores were significant over time (P < .001). One-fifth of our patients acknowledged an increase in every affective sensation measured during the procedure, with 44% acknowledging mild to severe fearful sensations and 40% mild to severe tiredness associated with the procedure. These affective elements largely improved after the procedure, though the portion of patients complaining of tiredness increased to 62%. Of the sensory descriptors, 78% of patients felt an increase in sharp,

![Fig. 2. Change in visual analog scale scores before, during, and after the procedure. CI = confidence interval; LS = least squares. [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]](image)
stabbing, hot-burning, and gnawing sensations during the procedure. After the procedure, 67% of patients experienced aching pain and 62% endorsed tenderness. Half of the patients still had sharp, stabbing, hot-burning, and gnawing pain even 30 minutes after the procedure.

Forty-one patients provided information after the day of the procedure (four were completely lost to follow-up). Thirty patients reported some measure of discomfort on PPD1, ranging from mild tenderness to severe hot-burning pain. The majority of these patients reported mild pain. Overall, 15 patients (37%) reported some pain on PPD3. Further analysis revealed no significant relationships between the presence of pain on PPD1 and gender, preprocedure HR, age, or the increase in VAS score from before to during the procedure. However, the presence of pain on PPD3 was significantly correlated with the increase in before to during VAS scores ($P = .02$). All other correlations for PPD3 were not significant.

Thirty-four of our patients were reached to complete telephone surveys (76%). Fifteen patients had pain with swallowing on PPD1. Seven of these had changed their diet due to swallowing discomfort. Thirty had pain with speaking. Five patients reported some minor bruising, though only one was taking anticoagulant therapy; this patient is the only one who reported bruising that lasted beyond 3 days. Four other patients were taking anticoagulation therapy and did not report any bruising at the injection site. Fourteen patients (41%) required additional medication during PPD1 for procedure-related pain. By PPD3, only five patients had pain with swallowing, and two patients required additional pain medication.

Thirty-one of our patients returned their postprocedure questionnaires addressing PPD1, 3, and 7. Six

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TABLE I.
Characteristics of Study Participants Stratified by VAS Change.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>VAS Change During to Postprocedure</th>
<th>$P$ Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Decreased</td>
<td>No Change/Increased</td>
</tr>
<tr>
<td>Age, yr, mean ± SD</td>
<td>59.64 ± 10.39</td>
<td>62.81 ± 14.71</td>
</tr>
<tr>
<td>Preprocedure heart rate, mean ± SD</td>
<td>72.18 ± 12.98</td>
<td>79.06 ± 14.53</td>
</tr>
<tr>
<td>Volume R, mean ± SD</td>
<td>0.31 ± 0.13</td>
<td>0.41 ± 0.23</td>
</tr>
<tr>
<td>Volume L, mean ± SD</td>
<td>0.47 ± 0.45</td>
<td>0.43 ± 0.21</td>
</tr>
<tr>
<td>Preprocedure VAS, median (range)</td>
<td>0.00 (0–5)</td>
<td>0.00 (0–1.4)</td>
</tr>
<tr>
<td>Gender, no. (%)</td>
<td>15 (53.6)</td>
<td>6 (37.5)</td>
</tr>
<tr>
<td>Female</td>
<td>13 (46.4)</td>
<td>10 (62.5)</td>
</tr>
</tbody>
</table>

*Independent samples t test.  
†Mann-Whitney U test.  
‡Pearson $\chi^2$ test.  
L = left; R = right; SD = standard deviation; VAS = visual analog scale.
patients indicated a PPD1 VAS score that was worse than their immediate postprocedure VAS score, signifying that their pain had gotten worse overnight. The most common sensory descriptors used were aching in 19 patients (60%) and tenderness in 17 patients (53%) during the first postprocedure day. Nine patients endorsed moderate to severe sensory pain (throbbing, shooting, stabbing, sharp, gnawing, hot-burning, tender) on PPD1, which was consistent with their VAS scores. By PPD3, only four patients still endorsed sharp or stabbing pain, with an additional eight patients reporting tenderness and/or aching. Mean VAS scores declined continuously over the week following the procedure (PPD1 = 1.69, median = 0.31; PPD3 = 0.91, median 0; PPD7 = 0.41, median 0). Each change was significant. Five (16%) patients still endorsed tenderness or aching by 1 week after the procedure. Twelve patients endorsed affective discomfort associated with their procedure on PPD1. Six and four patients endorsed these sensations 3 and 7 days after the procedure, respectively.

The Cronbach’s $\alpha$ score was 0.93, signifying the excellent reliability of the SF-MPQ in collecting information regarding pain in this population.

**DISCUSSION**

Office-based awake VFI augmentation is a highly successful and relatively convenient procedure for the diagnosis and treatment of glottic insufficiency. Major advantages over its operative counterpart include the avoidance of general anesthesia, the location of the affected vocal fold(s) in the awake functional position at the time of injection, the ability to justify a trial augmentation, the immediate assessment of injection results, and the cost and time required.\(^1\,^6\,^7\) The benefits of VFI in awake patients are significant and have inspired the development of other methods for injection augmentation under anesthesia that more closely preserve awake vocal fold positioning.\(^8\,^9\)

Though office-based VFI augmentation has been in use for over a century, little has been reported of the patient experience during this procedure.\(^10\) Most studies cite procedure completion, willingness to recommend the procedure to another patient, willingness to undergo a repeat procedure, or tolerability of pain as markers of adequate patient comfort.\(^11\,^14\) Success rates are generally high, with the rate of procedure noncompletion ranging from 3% to 8%.\(^1\,^15\,^16\) These failures are attributed to patient discomfort (pain, cough, gag reflex) as well as unfavorable anatomy. It is notable that patient fear, anxiety, or strong gag reflex are contraindications to even attempting an in-office procedure, ensuring a high success rate. When procedure-related discomfort is quantified, a few studies apply a validated pain measure such as the VAS.\(^15\,^17\) No previous publications have addressed the quality of pain, the persistence of pain, and the behavioral alterations that may be expected after this procedure.

This study confirmed that the pain associated with VFI is not insignificant. The majority of our patients experienced mild to moderate pain during and after the procedure, though a few reported severe pain. This pain was not predicted by age, gender, disease severity, or baseline parameters, which is in agreement with one previous study.\(^17\) It is not surprising that pain significantly increased during the procedure, but it is notable that discomfort remained significantly higher than pre-procedure levels even 30 minutes following the procedure. Though most patients reported the pain did improve during this postprocedure period, in 18% the pain remained the same and increased in another 18%. Eighty-two percent of patients experienced pain that persisted for at least half an hour after the procedure was completed. The physiologic parameters returned to normal at the conclusion of the procedure, but the pain level did not. Surgeons are accustomed to assessing patients’ physiologic parameters for indications as to their well-being, but in this office scenario, simply appraising the vital signs would have given a false impression that patients were comfortable and back to baseline.

One of the most important outcomes of this study was the discovery of how many patients continued to experience pain for days after the procedure. The majority of patients reported that their pain persisted or worsened during the first PPD. Almost half of patients took additional pain medication. A third of patients were still experiencing some discomfort at PPD3. These findings allow otolaryngologists to counsel patients for this likelihood, but also to establish interventions to mediate pain. Patients may be encouraged to premedicate with pain medications or anxiolytics, especially if they regularly take these medications. In addition, injectable implants containing local anesthetics may be considered to minimize the prolonged pain experienced by many of these patients.\(^16\) The addition of volume into the paraglottic space requires tissue stretching that can cause pain or tissue damage. This process involves the release of inflammatory mediators from injured cells, plasma, and sensory nerves themselves, increasing the sensitivity of nociceptive afferent fibers. The magnitude of this sensitivity or more prolonged sensitization is dependent upon a number of factors but can be attenuated through various means, including the treatment of acute pain.\(^19\) Adequate pain medication during or before the procedure could prevent sensitization of nerve fibers resulting in hyperalgesia or allodynia that may be responsible for the persistence of pain with talking or swallowing for days after the procedure. Our finding that the magnitude of the increase in pain during the procedure is significantly associated with the presence of pain on PPD3 supports the hypothesis that this nociceptive sensitization is responsible for lingering pain.

The SF-MPQs allowed for analysis of the different contributors to pain. In this study, patients reported a significant increase in sickening and punishing sensations as well as exhaustion and fear during the procedure. There are many medical and situational interventions that could be employed to minimize these sensations, including more comprehensive patient education, virtual reality, music, empathy, and self-hypnotic relaxation.\(^20\,^25\) Nonpharmacologic interventions have
not been rigorously explored for in-office otolaryngology procedures, but may prove effective in increasing tolerance, completion, and willingness to undergo repeat procedures.

It is probable that the regular use of pain medication changes the experience of procedural pain, as in opioid-induced hyperalgesia. All but 13 of our patients used a wide variety of pain interventions with regularity, and a third of our total group used opioids habitually. The widespread baseline use of pain medications in this patient population may influence patient counseling, the decision to plan a procedure in the operating room, and the use of premedication or nonpharmacologic interventions.

Pain is not a phenomenon that is easily measured, and it varies significantly among individuals. There are several limitations to this study, the most important being the inability to control for differences in our patients’ backgrounds. A few patients experienced no pain at all with the procedure, whereas many experienced moderate pain. Some patients underwent repeated procedures subsequent to this study and reported a different pain experience. This variability is consistent with the concept of pain as a complicated experience influenced by multiple factors. An inherent difficulty is the limitation of any tool used to measure pain. We attempted to control for this by providing different methods for long-term follow-up (e.g., telephone and paper), and we found that these largely agreed with each other. However, two verbal reports in the follow-up from specific patients were in direct contradiction to the measures that they reported during the study; in both cases the patients recalled pain when each had previously reported none. This calls into question memory and the meaning of the patient experience. In addition, the presence of pain syndromes was not specifically elicited. At least one patient had a history of fibromyalgia, and it is presumed that other pain syndromes may have been present to affect these results. Another limitation is the difficulty in obtaining follow-up surveys as patients are lost to follow-up or cannot be contacted. This could have introduced a response bias skewing our data in favor of a worse experience, as those who had no problems might be less likely to return for follow-up. Conversely, it is possible that those lost to follow-up did not return because the procedure was so uncomfortable, causing our data to reflect more positive experiences.

Despite its limitations, this study has served to broaden our informed consent for patients who will undergo VFI in the office. It will guide our future efforts to improve patient experience by providing adequate medication and nonpharmacologic interventions.

CONCLUSION

The perception of pain during in-office procedures is substantial and multifaceted, with significant sensory and affective contributors. The experience of pain is not predicted by age, gender, preprocedure status, volume, or site of injection. Pain after VFI persists for at least a day in two-thirds of patients, causing some patients to change their behavior. This knowledge is useful for patient informed consent and to support enhancing patient comfort and tolerance to ultimately improve procedural success.

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BIBLIOGRAPHY