Investigating the Efficacy of Vibration Anesthesia to Reduce Pain From Cosmetic Botulinum Toxin Injections

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Abstract

Background: Many analgesic modalities have been employed with limited success to alleviate the pain associated with botulinum toxin type A (BTX-A) injections. Vibration is an effective method of reducing pain during facial cosmetic injections, but it has not been previously studied in the context of clinical cosmetic procedures.

Objectives: The authors evaluate the safety and efficacy of vibration-assisted anesthesia for reducing pain associated with BTX-A injections.

Methods: In this prospective study, 50 patients received BTX-A injections for cosmetic rhytid reduction. Injections were given in a split-face design that was randomly assigned. A vibration stimulus was coadministered with BTX-A injections on one side, while the other side of each patient’s face received BTX-A injections alone. Patients completed a questionnaire immediately posttreatment and were contacted for follow-up three to four weeks later.

Results: Patients reported less injection pain on the vibration-treated half of the face as compared to the control side (an average of 1.3 vs 2.4 on a five-point scale; \(P = .000\)). Overall, 86% of patients preferred to receive vibration with their next BTX-A treatment. There was no significant difference between first-time and repeat BTX-A patients in terms of preference for vibration. Five of 50 patients experienced transient side effects perceived to be associated with vibration, including tingling teeth, increased bruising, and headaches. Of the patients who did not request vibration with subsequent BTX-A injections, none cited decreased BTX-A efficacy as the reason for their preference.

Conclusions: Vibration is a safe and effective means of reducing patient discomfort during BTX-A injections for cosmetic rhytid reduction and may have applications in other cosmetic procedures.

Keywords

Botox, cosmetic injectables, rhytids, vibration anesthesia, analgesia, botulinum toxin

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likely by reducing pain transmission from peripheral receptors to the brain. The mechanism of action for vibration anesthesia is explained in part by the “gate control” theory, which posits that pain sensation can be dampened by costimulation of nerve fibers transmitting nonnoxious stimuli such as vibration. Much empirical evidence exists to support the use of vibration-assisted anesthesia, but there is a paucity of prospective controlled trials in the literature. Additionally, none of the previous studies pertain to clinical cosmetic procedures. Therefore, the aim of this study was to evaluate the efficacy, safety, and patient satisfaction associated with topical vibration anesthesia for reducing pain from cosmetic BTX-A injections.

**METHODS**

An independent institutional review board (Abington Memorial Hospital, Abington, Pennsylvania) prospectively reviewed and approved the study protocol before patient enrollment and monitored the clinical investigation. Informed consent was obtained for each patient according to institutional review board protocol.

**Patient Selection**

This prospective randomized study enrolled 50 patients seeking temporary minimization of their glabellar folds with BTX-A. All were above 18 years of age. Naïve patients (ie, not previously treated with BTX-A) and repeat patients (ie, previously treated with BTX-A at the same anatomic site) were eligible to participate. Exclusion criteria included previous allergic reaction to BTX-A, preexisting disorders affecting neuromuscular junction function (eg, myasthenia gravis and motor neuron disease), presence of infection or inflammation at injection sites, and pregnancy or lactation.

**Study Design**

Injections were given in a split-face design (right vs left) that was randomly assigned. A vibration stimulus was coadministered with BTX-A injections on one side (treatment), while the other side of each patient’s face received BTX-A injections alone (control). There was no placebo. Vibration was administered with a small handheld battery-operated device (Pin Point Personal Massager, Brookstone, Inc., Merrimack, New Hampshire; Figure 1). The BTX-A injections were administered with a 32-gauge needle on a 1-mL syringe. To begin the procedure, a trained assistant gently placed the tip of the vibrator on the patient’s skin a few centimeters away from the treatment site (Figure 2). The vibration stimulus was initiated two to three seconds before the BTX-A injection to ensure adequate anesthesia, and it was continued until the needle was withdrawn from the skin. The vibrating device was repositioned in tandem with the needle, approximately 1 to 2 cm from the site of injection. Treatment to one side of the face (with or without vibration) was completed before proceeding to the other side. Symmetric locations in the glabella and forehead...
were treated. The same physician (AEW) administered all injections. After all injections were completed, the vibrating device was sanitized with sterilization wipes (Sani-cloth Plus Germicidal Disposable Cloth, PDI, Orangeburg, New York).

After the procedure, the physician (AEW) left the room as the patient completed an anonymous questionnaire regarding the treatment. This survey was collected and stored by the assistant. Patients were contacted by telephone approximately three to four weeks after the procedure to inquire about any potential side effects they had experienced.

### Patient Questionnaires

Participants were informed before the procedure that they would be asked to make posttreatment comparisons between the pain associated with injections administered on each side of the face. The potential effects of the vibration stimulus were not discussed.

Patients were provided with a five-point Likert-type scale on which to rate the injection pain for each side, with zero representing no pain, one representing mild pain, two representing moderate pain, three representing severe pain, and four representing the worst pain I have ever felt. Patients were also given the opportunity to report any posttreatment pain, bruising, or adverse effects. Finally, they were asked whether they would prefer vibration with their next BTX-A treatment, with potential response choices being yes, no, or unsure.

### Statistical Analysis

Analysis was conducted with SPSS 19 (IBM Corporation, Somers, New York). Appropriate nonparametric analysis methods were applied to the ordinal (Mann-Whitney) and categorical data (Fisher exact test) to determine the statistical significance of differences between the two sides. Each patient served as his or her own control for pain analyses.

### RESULTS

#### Patient Demographics

Three men and 47 women participated in the trial. The average patient age was 52 years ± 10.5 (range, 28-82). Six patients were receiving their initial treatment during the trial, whereas 44 had previously undergone BTX-A injections at the same anatomic sites.

#### Pain Reduction

The mean patient-reported pain scores were 1.3 ± 0.6 for the vibration-treated side and 2.4 ± 0.8 for the control side, a difference that was highly statistically significant (Mann-Whitney test, \( P = .000 \)). On the vibration-treated side, 4% of patients (two of 50) reported no pain; 70% (n = 35), mild pain; 22% (n = 11), moderate pain; 4% (n = two), severe pain; and none reported “the worst pain I’ve ever felt.” On the control side, zero patients reported no pain; 12% (n = six), mild pain; 44% (n = 22), moderate pain; 35% (n = 17), severe pain; and 10% (n = five) reported feeling “the worst pain I’ve ever felt” (Table 1).

Overall, 41 of 50 patients rated the injections they received on the vibrated side as less painful than the nonvibrated side. Nine patients rated the pain as being equal on both sides of the face; the mean pain score for these patients was 1.4 ± 0.7. In comparing these patients with the 41 who did notice a difference in pain (mean pain score = 2.6 ± 0.7) we found a statistically significant difference (Mann-Whitney test, \( P = .000 \)). No patients reported greater injection pain on the vibration-treated side.

#### Adverse Effects

Five patients experienced transient side effects perceived to be associated with vibration. Two patients described a “tingling sensation” in their teeth as the vibration was being administered, and one patient noted that her skin felt “tingly” immediately posttreatment. One experienced increased bruising on the vibration-treated half of her face, and another developed a headache the day after injections were administered. All these adverse effects resolved by the three- to four-week follow-up visit. Of the patients who reported adverse effects, only two (one with tingling teeth and another with bruising) declined vibration concurrent with subsequent BTX-A injections.

There was no statistically-significant difference in postprocedure pain (Fisher exact test, \( P = 1.0 \)) or bruising (Fisher exact test, \( P = 1.0 \)) between the vibrated and nonvibrated sides of the face.

#### Preference for Vibration

Forty-three of 50 patients (86%) stated that they would prefer to receive vibration with their next BTX-A treatment. A small percentage (8%, n = four) were uncertain
whether they would request vibration with subsequent BTX-A treatments; all these patients had rated the injection pain as being equal on both sides of the face during this trial. A few patients (6%, n = three) declined vibration with subsequent BTX-A injections; as noted, two of these patients reported adverse effects. One found the injection pain to be equal with or without vibration. Of the patients who did not prefer vibration with subsequent BTX-A treatments, none cited decreased BTX-A efficacy as the reason for their preference during the follow-up telephone survey. Of the six naïve patients, four reported that they would prefer to receive vibration with their next BTX-A treatment, and 39 of the 44 of repeat patients preferred vibration. There was no statistically significant difference between first-time and repeat patients in terms of preference for vibration (Fisher exact test, \( P = 1.0 \)). Anecdotally, of the nine patients in our study who rated BTX-A injection pain as being unchanged by vibration, five nonetheless reported that they would request vibration with subsequent BTX-A injections.

**DISCUSSION**

Maximizing patient comfort is an important consideration for all procedures, especially elective aesthetic procedures. Anticipated injection pain has been shown to be a factor in delaying BTX-A treatments for naïve and repeat patients. A survey of cosmetic patients revealed that concerns about procedure discomfort rated third in importance to surgical result and physician communication. The few studies on vibration anesthesia stem mostly from dental and dermatology literature, but these studies have demonstrated that it is an effective means of minimizing injection pain. The mechanism of vibration anesthesia depends largely on a theory published in 1965 by Melzack and Wall, who termed it the “gate control theory,” and postulated that pain sensation was subject to modulation by intrinsic neurons and controls descending from the brain. The authors hypothesized that a gate hypothesis ultimately controls the amount of pain signal that ascends to the brain. According to the gate control theory, activation of A-B fibers (“vibration” fibers) stimulates inhibitory interneurons in the spinal cord, which in turn act to decrease the amount of pain signal transmitted by A-D and C fibers (“pain” fibers). It has since been recognized that pain transmission is likely more complex, since rosignatures, can be generated by sensory stimuli but also independently of them. Thus, counterstimulation by vibration can minimize the sensation of pain at the brainstem/spinal cord level, but other central and peripheral mechanisms likely contribute to the analgesic effect of vibration. Additional hypotheses to explain the anesthetic properties of vibration include distraction, self-hypnosis, and even the power of suggestion in susceptible patients. Of note, five patients in our study who did not feel that vibration reduced injection pain still preferred vibration with subsequent BTX-A treatments, suggesting that their preference was influenced by a factor other than pain reduction.

Vibration also appears to be a safe method of achieving local anesthesia. Occupational studies indicate that chronic exposure to high-intensity whole-body vibration may be associated with increased risk of spinal degeneration and that long-term hand-transmitted vibration may cause vascular or neural changes in the upper limbs. However, to the best of our knowledge, exposure to brief periods of topical vibration is not associated with any significant temporary or permanent side effects. Of the adverse effects experienced by five patients in our study, tingling of the skin and/or teeth was transitory, and headache and bruising were likely independent of the vibration stimulus.

Experience has shown that the best measures for minimizing injection site pain include a gentle injection technique, the use of small-gauge needles, prompt replacement of dulled needles, and injection of the least possible volume. Other modalities commonly utilized to minimize injection pain, with varying degrees of effectiveness, are topical application of ice packs, cryoanalgesia or vapocoolant sprays, and anesthetic creams. Contact cooling is most widely used and, intuitively, contact cooling (typically with ice) followed by injection with small-gauge needles has become the standard of comparison for achieving patient comfort during injections. We elected not to compare vibration with other types of topical anesthesia, because in our experience, vibration is equally effective, with improved patient tolerability. Inherent advantages of vibration over other forms of topical anesthesia include ease of application, rapid onset of action, and a minimal side effect profile. Handheld vibrating devices are readily available at low cost. The application technique is unobtrusive and may be adapted to eliminate the need for an assistant, since the injector can place a fingertip massager on his or her nondominant hand. In comparison and despite their popularity, topical coolants do have some drawbacks. Ice packs are cumbersome to apply and are not completely effective in reducing or eliminating injection pain. Vapocoolant sprays (or topical anesthetic skin refrigerants) do have a quick onset of action but may lead to frostbite and subsequent tissue necrosis if not properly applied. Particular care must be taken when administering vapocoolants around the periorbit, necessitating protective eye shields. Vapocoolants have also been associated with skin hypopigmentation or hyperpigmentation. The anesthetic effect of ice or cooled air is often variable, as these modalities cannot be administered accurately or precisely.

Topical anesthetic ointments such as EMLA (lidocaine 2.5% and prilocaine 2.5%) have a topical application time of 20 to 60 minutes, limiting their applicability for in-office procedures. Topical anesthetics may also cause
transient local skin blanching, followed by erythema, in up to 55% of patients, or they may cause a localized contact dermatitis. Additionally, anesthetic ointments may not be appropriate in conjunction with BTX-A. One study showed that topical anesthetics may reduce the efficacy of BTX-A, perhaps because the nerve-inactivation effect of topical anesthetics interferes with the nerve stimulation necessary for BTX-A effect. That study relied on cryoanalgesia in conjunction with a numbing cream, which may have had an additive effect.

Further study is needed to determine the optimal parameters of vibration as an anesthetic. In our study, 41 of 50 of patients experienced less pain when BTX-A injections were coadministered with vibration, while nine patients reported no pain alleviation. The difference in mean injection pain between these cohorts was statistically significant. This could be due to either the subjective nature of grading or an elevated or lowered global pain tolerance in certain patients. It is also possible that variations in vibration amplitude, frequency, or time of application may provide a greater anesthetic effect. Additionally, the combination of vibration with other counterstimulatory techniques, such as skin pinching or stroking, may have a synergistic effect on pain relief.

One limitation to this study is the lack of a placebo. It is difficult to mimic the administration of vibration without relying on other counterstimulatory techniques. In another study of vibration-assisted anesthesia, the placebo consisted of a “switched-off” vibrating device applied to the test sites, while a second “switched-on” vibrating device was held nearby. This may not represent a true placebo, as merely placing the vibrating device on the skin may have a counterstimulatory effect similar to skin stroking. Another possible weakness is the absence of a control group, which would be challenging given the variability in pain experiences among individuals.

In our study design, patients graded injection pain posttreatment rather than during the injection itself, which may have affected the accuracy of the data due to errors in recollection. We attempted to minimize the potential for error by informing the participants pretreatment that they would be making posttreatment comparisons of the injections and by administering the questionnaire immediately posttreatment. Additionally, the individual tendency of participants to overrecall or underrecall pain would likely apply to injections on both sides of the face, still permitting comparisons between the sides. Finally, patients rated overall pain for all vibrated versus nonvibrated injections, rather than per injection, because we did not anticipate significant variability in pain within various sites on the forehead and glabella. It is unlikely that this aspect of the study protocol significantly affected our results.

CONCLUSIONS

Vibration is a safe and effective means of achieving local anesthesia and maximizing patient comfort during cosmetic BTX-A injections. Vibration may be applied during a variety of medical and cosmetic procedures, and the advantages of vibration include ease of application, rapid onset to action, and affordability.

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REFERENCES