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Does Vibration Anesthesia Improve Pain Tolerance in Patients Receiving Cosmetic Facial Injections?

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Does vibration anesthesia improve pain tolerance in patients receiving cosmetic facial injections?

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A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

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ABSTRACT

Objective: The objective of this selective EBM review is to determine whether or not "Does vibration anesthesia improve pain tolerance in patients receiving cosmetic facial injections?"

Study Design: Review of three randomized, blind, placebo-controlled clinical trials published between the years of 2011 and 2017.

Data Sources: All studies were published in peer-reviewed journals that were located using PubMed database searches as well as Cochrane Collaboration.

Outcome Measured: Pain reduction was measured using a Likert-type pain scale which was either rated 0-10; 0 was rated as no pain, 5 being moderate and 10 being the worst pain ever experienced. The 5-point Likert-type scale had the patient rate the injection pain as 0 (no pain), 1 (mild pain), 2 (moderate pain), 3 (severe pain), or 4 (worst pain I have ever felt).

Results: All studies showed a statistical significance when comparing use of vibration anesthesia to no use of a vibration anesthetic prior to a cosmetic facial injection. With use of vibration anesthesia, pain scores were 3.82 ± 1.73 in the study by Guney et al., 1.3 in the study by Sharma et al., and 0.9 ± 0.6 in the study conducted by Malley et al. P-values for all studies <0.05.

Conclusion: According to the EBM review use of vibration anesthesia is effective in improving pain tolerance in patients receiving cosmetic facial injections. This method is efficacious, safe, easy to use, and affordable rendering it a useful technique to incorporate into practice.

Key Words: Vibration anesthesia, dermal filler

INTRODUCTION

In recent years the desire of a youthful appearance has become increasingly popular. This interest has facilitated the development of the use of dermatological procedures including cosmetic facial injections. Cosmetic facial injections offer rejuvenative and enhancing aesthetic improvements at a somewhat affordable price and with minimal recovery time as compared to surgery.[1] Dermal fillers are gel like substances that are injected under the skin. Facial fillers contain a variety of products including hyaluronic acid, calcium hydroxyl apatite, and collagen with the purpose of reducing or eliminating fine lines and wrinkles, augmenting lips and replenishing soft tissue volume loss through cosmetic injections.[2] Botulinum toxin (botox) is another agent that is commonly used for cosmetic facial injections which works by inhibiting release of acetylcholine at the neuromuscular junction.[3] Overall, cosmetic facial injections are indicated for soft tissue correction due to a disease process or age. Over time, the indications have expanded to include several volume replacement and enhancement procedures.

As awareness of facial injections grows, so does the popularity and number of patients. In 2017, there were 15.7 million cosmetic minimally invasive procedures which included botulinum toxin type A at 7.23 million procedures and soft tissue fillers at 2.69 million procedures. These numbers are projected to rise in the coming years. Other procedures included in this particular study were chemical peels, laser hair removal and microdermabrasion.[4] In a study performed by the American Society for Aesthetic Plastic Surgery, more than 2 million dermal filler treatments were performed in the year 2017 alone.[5] Furthermore, based on a National Ambulatory Medical Care Survey, from 2002-2010 there were "140,000 annual cosmetic visits for a dermal filler and 440,000 for a neurotoxin."[6] At each visit patients may be having several procedures performed.

While these injections are frequent, a major conflict experienced by patients when seeking facial injections is the pain inflicted during the procedure. Injection site pain is variable and depends upon individual sensitivity and exposure. Pain intensity has been shown to be minimized through the use of a smaller gauge needle such as a 30-32 gauge, insertion of the needle through the pilosebaceous unit, and pinching the skin prior to injection.[7] There are a variety of methods currently being used to help with pain management in relation to injections. Commonly used methods to alleviate pain include topical application of ice packs, cryoanalgesia, vapocoolant sprays and anesthetic creams.[8,9,10] These agents can help control pain levels associated with injections, but can also be associated with negative side effects, increased cost, and poor patient satisfaction. It is important to have a treatment regimen that can be added in to efficiently alleviate some of these factors. The use of vibration anesthesia is a proposed method that can be a safe, low cost, and effective tool for pain tolerance in patients undergoing facial injections.[8,9,10]

Cost for cosmetic facial injections varies depending upon the expertise of the providers performing the injection, the procedure selected, and the location as well as other factors.[2] The use of the vibration anesthesia device is approximately $16.[11] Though, price will vary depending upon which device is purchased. Not only are facial injections used for cosmetic reasons; they can be used for a vast variety of medical conditions which makes this topic applicable to physician assistants of all specialties. Physician assistants frequently have the opportunity to perform general injections in a variety of settings ranging from orthopedics, where joint injections are performed, to pediatrics where vaccines are commonly given. This paper evaluates three double blind randomized controlled trails comparing the efficacy of vibration anesthesia for improving pain tolerance in patients receiving cosmetic facial injections.

OBJECTIVE

The objective of this selective evidence based medicine (EBM) review is to determine whether or not "Does vibration anesthesia improve pain tolerance in patients receiving cosmetic facial injections?"

METHODS

In order to be considered and included, the population studied had to be patients 18 years or older receiving a cosmetic facial injection. The study had to be a randomized controlled trial that included a treatment group receiving vibration anesthesia 2-3 seconds prior to being injected and a control group that did not receive the vibration anesthesia. Outcomes were measured using a Likert-type pain scale which was a self-report of pain reduction. Patients were asked to rate the pain they felt during the injection on a scale from 0-10, or 0-5 depending on the study. The pain scores were then analyzed for significance.

To find appropriate articles, keywords that were used included: "Vibration Anesthesia"; "Dermal Filler". Articles had to be in the English language and published in peer-reviewed journals. Articles were selected based on their relevance to the clinical question and if the study included patient-oriented outcomes (POEMS). The author used the listed keywords to search online PubMed database and Cochrane Collaboration that addressed the objective of this review and used a patient centered outcome to measure the overall effect on a patient's quality of life. Inclusion criteria was as follows, the articles had to be randomized, blinded, placebo-controlled trial using Vibration Anesthesia as a treatment option. The articles had to be published within the last 10 years. Studies evaluating patients under the age of 18 were excluded. Statistics were

reported through p-values. The specific demographics and characteristics for each individual study can be found in Table 1.

TABLE 1: DEMOGRAPHICS & CHARACTERISTICS OF INCLUDED STUDIES

Study	Type	#Pts	Age (yrs)	Inclusion Criteria	Exclusion Criteria	W/D	Interventions
Guney[8] (2017)	RCT	25	21-47 range with the mean age of 31.36 years	Healthy, female patients that presented to the plastic surgery clinic between July 2016 and February 2017 requesting lip augmentation with hyaluronic acid fillers.	Pt with known illnesses. Anticoagulants. Pregnant/lactating patients. <18 y.o. Active infection at injection site. Hx of adverse reactions to hyaluronic acid fillers.	0	Topical anesthetic 20 minutes prior to disinfection and vibration stimulus for 2-3 seconds prior to injection.
Sharma[9] (2011)	RCT	50	52 years +/- 10.5 (range, 28-82)	Patients seeking temporary minimization of their glabellar folds with BTX-A. At least 18 y.o. Naïve and repeat patients to BTX-A.	Previous allergic reaction to BTX-A. Preexisting disorders affecting neuromuscular junction. Infection or inflammation at injection sites. Pregnancy/lactation.	0	Vibration stimulus 2-3 seconds prior to injection of BTX-A with a 32 gauge needle.
Mally[10] (2014)	RCT	41	58 ± 9 years (range 37–76 years)	At least 18 y.o. Naïve and repeat patients to dermal fillers.	<18. Patients desiring perioral/lip injections. Hx allergies/ rxn to lidocaine. Anticoag usage. Bleeding d/o, infection, inflammation. Pregnancy/lactation.	0	Lidocaine mixed in with dermal filler injection. Vibration stimulus 2-3 seconds prior to injection.

OUTCOMES MEASURED

The outcomes were measured using a Likert-type pain scale which is a type of rating scale that measures attitudes or opinions. Respondents are asked to rate items on a level such as "strongly agree" to "strongly disagree." Depending whether the patient used the 5-point or the 10-point scale a rating of 0 signifies no pain whereas a score toward the higher end of the scale would represent more pain felt by the individual. Patients were asked to score their level of pain at the end of the procedure once the injecting surgeon had left the room. Patients were followed up 10 days later with a visit to ensure optimal results and asked by the same assistant their likelihood of using their next treatment with or without vibration anesthesia. All data were recorded and analyzed for significance.[8-10]

RESULTS

The three studies selected compared the effectiveness of applying vibration anesthesia vs. a placebo of no vibration anesthesia when administering cosmetic facial injections. All studies used the Likert-type pain scale questionnaire to evaluate if the treatment given caused an overall improvement in pain tolerance (Table 2,4). Each study also included a P-value to show the statistical significance of vibration anesthesia versus no use of vibration (Table 3). Each of the three studies had 100% compliance, as no subjects were lost to follow up.

TABLE 2. TREATMENT OUTCOMES

	Study 1[8]	Study 2[9]	Study 3[10]
CER	0.08	0.12	0.14
EER	0.92	0.74	0.86
RBI	10.5	5.2	5.14
ABI	0.84	0.62	0.72

NNT	1	2	1

TABLE 3. STATISTICAL SIGNIFICANCE OF INTERVENTION VS. PLACEBO

	Study 1	Study 2	Study 3
P-Value	<0.001	0.000	0.0001

**Statistical significance was considered to be a p-value <0.05.*

TABLE 4. MEAN CHANGE FROM BASELINE

	Study 1	Study 2	Study 3
Mean Change from Baseline ± SD with Vibration Anesthesia	3.82 ± 1.73	1.3	0.9 ± 0.6
Mean Change from Baseline ± SD with no Vibration Anesthesia	5.6 ± 1.76	2.4	2.7 ± 0.9

The study conducted by Guney et al., aimed to determine the effect of vibration anesthesia during lip augmentation procedures. A split lip study was performed on 25 female patients who received hyaluronic acid fillers with or without inclusion of the vibratory stimulus on either half of their lips. All inclusion and exclusion criteria of the study can be found in Table 1. The overall pain score on the vibration-assisted side versus the side with no vibration was 3.82 ± 1.73 versus 5.6 ± 1.76 respectively. The p-value was < 0.001. Of this study, 92% felt less pain with the addition of vibration. Twenty three of the 25 patients would like to have vibration anesthesia when getting future lip injections.

The second study by Sharma et al., was a randomized controlled trial of 50 female patients that evaluated the safety and efficacy of vibration-assisted anesthesia for reducing pain associated with BTX-A injections. Inclusion criteria was as follows: patients seeking temporary minimization of their glabellar folds with BTX-A, at least 18 years old, and they could be naïve or repeat patients to BTX-A. Per the posttreatment analysis, patients had less injection pain on the vibration-treated half of the face when compared to the control side. Pain values showed an average of 1.3 vs. 2.4 on a five-point scale with a p-value of 0.000. When asked about future treatments, 86% of patients preferred to receive vibration. Five patients experienced adverse side effects such as abnormal teeth sensations, bruising, and headaches; which were all transient.

The purpose of the study conducted by Mally et al., study 3, was to determine the safety, efficacy, and tolerability of vibration anesthesia in lowering the pain tolerance of patients receiving facial dermal filler injections. This study was a randomized controlled trial which analyzed 41 female patients receiving dermal filler injections to the nasolabial folds, tear troughs, cheeks, as well as other facial sites. Injections were given following a randomly assigned split face design. This design allowed the researchers to administer a vibratory stimulus to half of the face while the other half received dermal filler injections alone. Following the treatment, patients completed a questionnaire which showed clinically and statistically significant pain reduction with vibration stimulus administration. The study specifically excluded patients less than 18, desiring perioral/lip injections, history of allergies/ reaction to lidocaine, anticoagulation usage, infection, inflammation and pregnancy/lactation.

Pain values were calculated and showed 0.9 ± 0.6 on the vibration-treated side and 2.7 ± 0.9 on the control side. The mean scale difference of 1.8 was statistically significant ($p = 0.0001$). Upon treatment with vibration, 6 patients (14 %) reported no pain, 29 patients (72 %)

reported mild pain, 6 patients (14 %) reported moderate pain, and no patients reported severe or ‘‘worst pain ever.’’ For the side of the face not treated with vibration, no patients reported complete absence of pain, whereas five patients (12 %) reported mild pain, 11 patients (27 %) reported moderate pain, 18 patients (44 %) reported severe pain, and seven patients (17 %) reported experiencing the ‘‘worst pain ever.” Ninety-five percent of patients stated they would like vibration anesthesia if they were to get more dermal filler injections in the future.

DISCUSSION

The goal of this study was to determine if vibration anesthesia could improve pain tolerance in patients receiving cosmetic facial injections. After analyzing data from each of the three studies evaluated, vibration anesthesia proved to improve pain tolerance. The significant findings from each of the studies discussed bring promise in regard to future research involving the use of vibration as an anesthetic. No outliers were observed in the aforementioned studies.[8-10]

A therapeutic vibration device was approved by the FDA in 2001 with the intent of relieving minor aches and pains.[12] Contraindications to handheld vibrators include certain skin disorders and diseases, history of thrombosis or phlebitis, bruising or scar tissue, swelling, and varicose veins.[13] This study is generalizable with patients interested in getting cosmetic facial injections. In addition to reducing acute pain as shown in these studies, vibration has been researched for chronic pain conditions.[14] This is just one example of how this data could be applicable to a variety of specialties and procedures. The vibration device is safe, inexpensive, easy to apply/operate, has rapid onset of effect and minimal side effects as compared to other methods of alleviating pain with injections. Limits on individual pain experience, tolerance and small sample size could limit generalizability to a larger patient population. All of these listed

factors could affect the validity of results. There have been studies showing that chronic exposure to vibration can be linked to causing or exacerbating pain, even causing nerve dysfunction.

CONCLUSION

According to this EBM review, vibration anesthesia is effective in improving pain tolerance in patients receiving cosmetic facial injections. Vibration anesthesia is efficacious, safe, easy to use, and affordable, rendering it a useful technique to incorporate anesthesia locally as well as for minimally invasive procedures. One downfall is that vibration anesthesia does not induce complete analgesia; however, this technique could be added to topical anesthetics, nerve blocks, or cryotherapy. Limits on individual pain experience and tolerance, lack of a placebo, and small sample size could limit generalizability to a larger patient population. Another limitation was the subjective nature of rating pain as well as the way in which the questionnaires were completed. Patients may also have varying pain thresholds.

In the future it would be more helpful to do rating after each injection than after the complete treatment. Due to limitations of these studies, further research needs to be done to provide additional information. In addition, future studies should include more diverse and larger sample sizes while also including blinding in the methods. With more trials of larger population sizes it will be easier to assess factors such as vibration amplitude, frequency, or time of application in the overall outcome.

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