



CLINICAL STUDY

A CLINICAL COMPARISON OF EMLA CREAM AND VIBRATORY ANESTHETIC DEVICE APPLICATION FOR ALLEVIATION OF PAIN ASSOCIATED WITH BOTULINUM TOXIN INJECTION FOR THE MASSETER MUSCLE HYPERTROPHY

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SUMMARY

Aim: Botulinum toxin injection (BTX-A) for the masseter muscle hypertrophy is a commonly used intervention for cosmetic and bruxism-related purposes. Achieving pain-free injection is important for patient comfort and satisfaction. Aim of this study was to compare the efficacy of Vibratory Anesthetic Device (VAD) versus Eutectic Mixture of Local Anesthetics (EMLA) cream in alleviation of pain during BTX-A injection for masseter muscle hypertrophy.

Methods Eight-teen patients were injected on both sides. Study was designed as a split-face right-left, self-controlled study: one side pain-alleviation was assured with EMLA application 45 minutes before injection whereas the contralateral side VAD application was used. Patients were asked to rate their injection-related pain based on Visual Analogue Scale (VAS)(0:Minimum 10:Maximum). Patients were also asked to rate each side in comparison to the other side and about the preferred method of injection for the next session.

Results: Mean VAS Score for EMLA-applied side was $3,3\pm 2,5$ whereas VAD-applied side was $3,6\pm 2,0$. Statistical analysis of VAS Scores revealed no significant difference ($p=0.696$). Eight out of 18 patients reported less pain on VAD side (44%). Six patients reported less pain on EMLA-applied side (39%), whereas three patients reported no difference between two methods (17%). Statistical analysis on preference revealed no significant difference between two methods ($p=0.743$). Preferred method for next injection was VAD for 11/18 patients (61%), whereas 7/18 patients preferred EMLA (39%) for next injection. Three patients who reported no difference between two methods preferred VAD for next session due to absence of 45 minute waiting interval before injection.

Conclusions: VAD seems to be a viable method to achieve pain-free injections in comparison to EMLA application. VAD has advantages timewise, costwise and absence of possible side effects.

Keywords: Masseter hypertrophy, botulinum toxin, EMLA, vibratory anesthetic device

MASSETER KASINA BOTULİNÜM TOKSİN ENJEKSİYONU SIRASINDA ANESTEZİ YÖNTEMİNİN HASTANIN HİSSETTİĞİ ACIYA ETKİSİNİN DEĞERLENDİRİLMESİ: EMLA KREM İLE VİBRASYONLU ANESTEZİ CİHAZI'NIN KARŞILAŞTIRILMASI

ÖZET

Giriş: Masseter kası hipertrofinde botulinum toksin enjeksiyonuyla kemodenerjasyon kozmetik gerekçelerle ve bruksizmin tedavisi amacıyla sık uygulanan bir tedavi yöntemidir. Acısız enjeksiyon hasta konforu ve memnuniyeti için önemlidir. EMLA krem yaygın kullanılan lokal etkili bir anestezi pomadır. Vibrasyonlu Anestezi Cihazı ise yüz enjeksiyonlarında yaygın kullanılan bir anestezi yöntemidir. Amaç: Bu çalışmanın amacı Vibrasyonlu Anestezi Cihazı (VAC) ile EMLA kremin masseter botulinum toksini uygulaması sırasında anestezi olarak kullanımının hastanın tecrübe ettiği acıyı engellemesindeki başarımın karşılaştırılmasıdır.

Gereç ve Yöntem : Toplamda 18 hastaya bilateral masseter botulinum toksin uygulaması yapıldı ($n=36$). Çalışma yarım-yüz sağ-sol karşılaştırmalı olarak dizayn edildi. Hastaların bir tarafında uygulama yapılacak bölgeye uygulamadan 45 dakika önce EMLA krem uygulandı, kontralateral tarafa ise enjeksiyon sırasında VAC uygulandı. Hastalar işlem sonrasında her iki taraftaki acıya ayrı ayrı Vizüel Analog Skala (VAS) ile puanlamaları ve karşılaştırmaları istendi. Hastalara aynı zamanda tercih ettikleri anestezi yöntemi soruldu.

Sonuç : Ortalama VAS Skoru EMLA krem uygulanan tarafta $3,3\pm 2,5$ ve VAC uygulanan tarafta $3,6\pm 2,0$ idi. İstatistiki olarak aralarında anlamlı fark görülmedi ($p=0.696$). Onsekiz hastanın sekizi VAC uygulanan tarafta daha az acı hissetti (%44), Altı hasta EMLA uygulanan tarafta daha az acı hissetti (%39), üç hasta ise iki taraf arasında bir fark olmadığını bildirdi (%17). Yapılan istatistiki analizde iki yöntem arasında anlamlı bir fark bulunmadı. ($p=0.743$). Bir sonraki işlemde tercih edilen yöntem sorulduğunda hastaların %61'i (11/18) VAC yöntemini, %39'u (7/18) ise EMLA krem uygulamasını tercih etti.

Tartışma : EMLA ile VAC uygulaması arasında hastanın hissettiği acı ve konfor açısından anlamlı fark bulunmamaktadır. Bekleme süresinin olmaması ise pratik uygulamada hasta ve hekim açısından tercih sebebidir. Hekim için ise maliyetin nispeten daha düşük olması VAC yöntemini rutin kullanımı açısından avantajlıdır.

Anahtar Sözcükler: Masseter hipertrofi, botulinum toksini, EMLA, vibrasyon, acı

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INTRODUCTION

Achieving pain-free practice is important for patient comfort, satisfaction and continuation of patient demand for cosmetic treatments¹. Botulinum toxin injections (BTX-A) are one of the most frequently applied cosmetic procedures.



BTX-A injection for masseter muscle is a commonly applied procedure for both facial contouring cosmetic purposes and is among treatment options for bruxism². Patients require BTX-A approximately three times annually for an adequate treatment. Pain-free injection is one of the most important factors determining patient comfort, satisfaction and future demand for cosmetic treatments.

Many methods are present to alleviate pain associated with BTX-A injections. Utilization of finer needles, application of Eutectic Mixture of Local Anesthetics (EMLA) cream, icepacking, skin cooling with ethyl chloride spray and Vibratory Anesthetic Device are frequently used methods to reduce pain³⁻¹⁰.

Vibratory anesthetic device (VAD)(Figure 1) is an effective pain-alleviating technique for facial cosmetic injections¹¹. Many studies were carried out showing usefulness of VAD for pain alleviation. Aim of this study was to evaluate the efficiency of VAD versus EMLA cream in alleviation of pain during botulinum toxin injection for masseter muscle hypertrophy.

MATERIAL and METHODS

This study was conducted between December 2018 – December 2019. Local ethics committee approval was obtained prior to study. Study was designed as a split-face right-left, self-controlled study: one side pain-alleviation was assured with EMLA (EMLA cream 5% 25 g lidocaine, 25 g prilocaine; Astra Zeneca, London, UK) whereas the contralateral side VAD application was used.

Patient was explained about the procedure. Unwillingness to contribute to the study was a reason to exclude from the study. Patients were questioned about history of fibromyalgia. Breast-feeding and possibility of pregnancy were among contraindications for BTX-A injection.

Injection Technique

All patients were injected with BTX-A (Botulinum toxin type A, Allergan etc). 30 Gauge (0,3 x 13mm, BD Microlance™ 3) was routinely used for injection. One bottle of BTX-A was diluted with 2 cc saline and half of the vial was used for each patient, giving 25 units in 0,5 cc to each side of the patient. Either EMLA side was injected first or vice-versa; this was

randomly assigned. EMLA was applied to one side 45 minutes before injection⁴. Both sides were cleaned with cleaning solution just before injection. Botulinum toxin injection was applied in three stabs for each side.

Evaluation Parameters

Following injection, patients were asked to evaluate their injection pain. Visual Analogue Scale was utilized for this similar to most of the previous studies in the literature^{3-5, 10}. 0 points represented minimum pain and 10 points represented maximum pain. Mean and standard deviation values were calculated. These data were also interpreted as 1) EMLA side less pain compared to VAD side 2) VAD side less pain compared to EMLA side 3) no difference between sides. The side with less pain got 1 point, the side with more pain got -1 point and when there was no difference both sides got 0 points. Patients were also asked about their preferred method for injection for next session and two options were given: either EMLA or VAD.

Statistical Analysis

Statistical analysis was carried out using Statistical Package for the Social Sciences version 22.0 for Windows (SPSS Inc., Chicago, IL, USA). Nonparametric Mann Whitney U test was used to compare between groups. All statistical analysis was done with SPSS software (version 20.0; SPSS, Inc). $P < .05$ was considered statistically significant.

RESULTS

Eight-teen patients (36 masseters) were injected with BTX-A. Six patients were male and 12 patients were female. Mean age was 33.9 ± 9.5 (Range, 20 - 61). Five out of 18 (28%) patients' sole aim was facial slimming in lower-third of the face, 8 out of 18 (44%) patients sole aim was treatment of bruxism. Whereas 5/18 patients aimed both (28%). Ten out of 16 (63%) patients were being injected for the first time.

Mean VAS Score for EMLA-applied side was $3,3 \pm 2,5$ whereas VAD-applied side was $3,6 \pm 2,0$ (Figure 2). Statistical analysis of VAS Scores revealed no significant difference ($p=0.696$). Eight out of 18 patients (44%) reported less pain with VAD, 7 out of 18 patients reported less pain with EMLA and 3 patients

reported no difference between two sides (Figure 3). Statistical analysis revealed no significant difference between methods ($p=0.743$). Preferred method for next BTX-A session questioned. Eleven out of 18 (61%) patients preferred VAD and 7 patients (39%) preferred EMLA. (Figure

4) Main reason for choosing VAD for patients who reported similar pain on both sides was absence of preinjection waiting time for VAD method.



Figure 1. Vibratory Anesthetic Device (VAD)

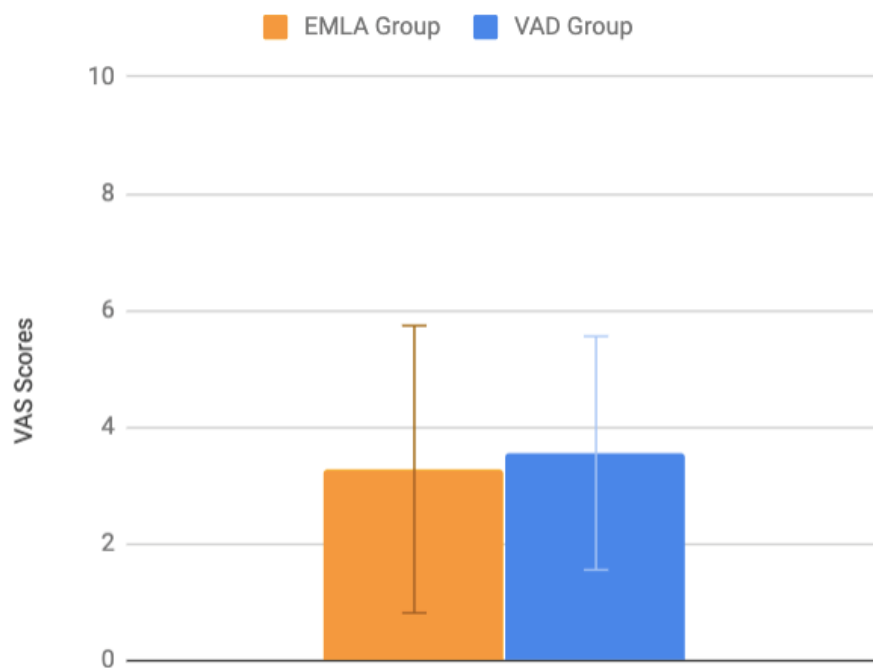


Figure 2. Injection-associated pain VAS Scores

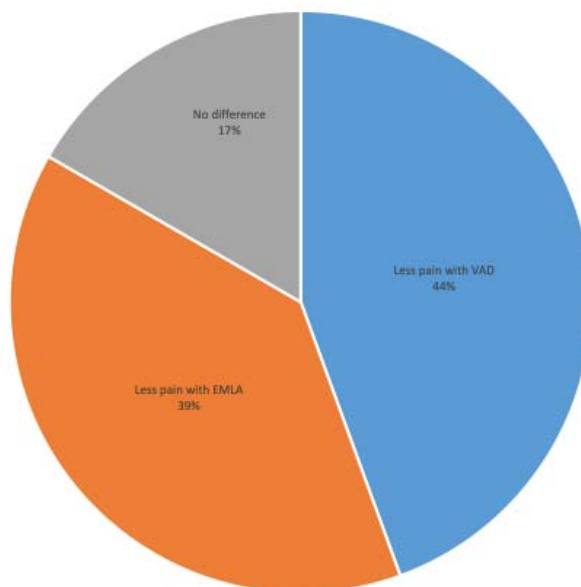


Figure 3. Comparison of Anesthetic Method associated Pain

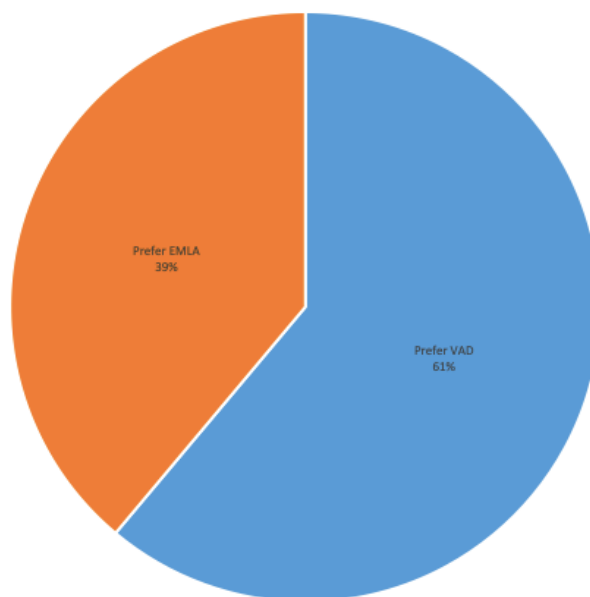


Figure 4. Preference of Anesthetic Method for Next Injection Session

DISCUSSION

The botulinum toxin chemodenervates the muscles temporarily by inhibition of the release of acetylcholine from the presynaptic nerve. Mean duration is about 4 months, hence repeated injections are required. Injections can be painful therefore the clinician should seek ways to make the procedure more pain-free and comfortable for the patient. This has a positive

effect on practice volume and number of referrals by happy patients¹.

According to ‘The Gate Control Theory of Pain’; vibratory stimulus inhibits the perception of strong painful stimuli, hence alleviates pain¹². Literature shows vibratory stimulus is very useful for pain alleviation for cosmetic botulinum toxin injections¹¹. Yet, its usefulness for masseter injection, to our



knowledge, until this study remained to be evaluated in the literature. Study by Park et al. revealed that subcutaneous thickness from the skin surface to the masseter muscle is approximately 5 millimeters and masseter muscle thickness is more than 15 millimeters¹³. Hence, injection depth of the needle is much longer compared to cosmetic upper face rejuvenation BTX-A injections that can be carried out with 4-mm needles.

A study by Wahlgren et al showed that depth of cutaneous anesthesia after application of EMLA was time-dependent. Biopsy punch insertions with acceptable pain could be made to depths of 1 to 2 mm after 60 minutes, to 2 to 3 mm after 120 minutes, and to 6 mm after 3 to 4 hours of EMLA cream application¹⁴. Timewise its not very practical to make the patient wait for longer durations for injection in clinical practice. This is the main motive of three patients who reported similar pain preferred VAD method for next time.

When injection-associated pain VAS Scores are examined; EMLA group's mean VAS Score - although not statistically significant-slightly higher (Figure 2) compared to the VAD group. Contradictorily, more patients preferred VAD application over EMLA cream (Figure 3 and 4). For the clinician it has advantages because it is inexpensive, safe and practical in a time-wise perspective. In our practice VAD application in combination of 30G needles very tolerable by the patients. Combination of VAD and EMLA is another option for anxious patients with low pain threshold and tolerance.

Although transient and mild; EMLA can cause irritation such as itching, pain, erythema, edema. These EMLA-related complications were not observed in our series. VAD avoids these mild complications as well.

Limitations

The small sample size is a limit of our study and additional studies with more patients may be more helpful to compare the pain free way of masseter BTX-A injection. Pain data was not compiled by objective measurements but rather by subjective patient-reported scores which might also be affected by anxiety. Literature review shows pain was most frequently evaluated by VAS Scores, therefore we utilized this methodology similar to the

literature. Other limitation is the amount of pain perceived by the patient during intramuscular injection of BTX-A because it varies according to the depth of the needle and the injection technique. To minimize this variance, all injections in this study were carried out by a single doctor.

EMLA cream must be left on the skin for at least 45 minutes to be effective, and this interval may not be practical or optimal. It is known that leaving EMLA on the skin longer increases its effects. This is another limitation of the study.

CONCLUSION

VAD is a viable option for anesthesia during masseter botulinum toxin injections and is also preferred by the patients over EMLA. We suggest routine use of VAD for anesthesia during masseter botulinum toxin injections.

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