Effect of cathodal high-voltage electrical stimulation on pain in women with TMD

Efeito da estimulação elétrica de alta voltagem catódica sobre a dor em mulheres com DTM

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Abstract

Background: Pain is the main symptom of patients with temporomandibular disorder (TMD). **Objective:** To evaluate the effect of cathodal high-voltage electrical stimulation (HVES) on pain intensity in women with TMD. **Methods:** Twenty women with TMD (24.25±8.90 years old) participated in the study. They were divided into experimental group (EG, n=10), which received 10 applications of HVES, and placebo group (PG, n=10), which received sham treatment with disconnected HVES equipment. For the sample selection, we used the Research Diagnostic Criteria for Temporomandibular Disorder (RDC/TMD). Pain level was evaluated using a visual analog scale (VAS) applied prior to and after the tenth application of HVES. Data were analyzed using the Wilcoxon signed-rank test and the Mann-Whitney test. **Results:** Ten applications of HVES reduced pain intensity in the EG (p=0.01). In the PG, there was no significant difference (p=0.20). After the application of HVES, no difference was found (p=0.65) between the groups. **Conclusion:** The cathodal HVES was effective in reducing pain in women with TMD. Trial Registration RBR-4bk94x.

Keywords: physical therapy; clinical trial; temporomandibular joint disorders; electrical stimulation.

Resumo

Contextualização: A dor é o principal sintoma dos pacientes com disfunção temporomandibular (DTM). **Objetivo:** Avaliar o efeito da estimulação elétrica de alta voltagem catódica (EEAV) sobre a intensidade da dor em mulheres com DTM. **Métodos:** Participaram do estudo 20 mulheres (24,25±8,90 anos) com DTM, divididas em grupo experimental (GE n=10), no qual as mulheres receberam dez aplicações de EEAV, e grupo placebo (GP n=10), no qual foi aplicada a EEAV, porém com o aparelho desligado. Para seleção da amostra, utilizou-se o critério de diagnóstico em pesquisa para DTM (RDC/TMD) e, para avaliação da dor, utilizou-se a Escala Visual Analógica (EVA) aplicada antes do início do tratamento (pré-tratamento) e após a décima aplicação da EEAV (pós-tratamento). Os dados foram analisados pelos testes Wilcoxon das ordens assinaladas e Mann-Whitney. **Resultados:** As dez aplicações de EEAV promoveram redução da intensidade da dor no GE (p=0,01); no GP, não se observou diferença significativa (p=0,20). Comparando-se os grupos após a aplicação da EEAV, não se notou diferença (p=0,65). **Conclusão:** A EEAV catódica é efetiva para redução da dor em mulheres com DTM. Registro de Ensaio Clinico RBR-4bk94x.

Palavras-chave: fisioterapia; ensaio clínico; transtornos da articulação temporomandibular; estimulação elétrica.

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Introduction

Temporomandibular disorder (TMD) is characterized by functional and pathological changes affecting the temporomandibular joint (TMJ), masticatory muscles, and other structures of the stomatognathic system[1]. It presents as joint sounds, muscle and/or joint pain, headaches, difficulty chewing, limited and/or abnormal jaw movement[2]. An epidemiological study carried out by Gonçalves et al.[3] found that the most prevalent symptoms of TMD in the Brazilian urban population are joint sounds followed by joint and muscle pain, with higher frequency in women.

In contrast, Cooper and Kleinberg[4] reported that pain is one of the main complaints of patients with TMD. The authors conducted a retrospective analysis of data from 4528 patients with TMD assessed by a single evaluator (dentist) over 25 years. Of the 4528 patients, 96.1% reported pain, and of that total, 79.3% had headaches, 75% had temporomandibular dysfunction or discomfort, and 82.4% had ear dysfunction or discomfort.

The musculoskeletal conditions of the mandibular and cervical regions found in TMD are the major causes of non-dental pain in the orofacial region[5]. Such conditions have a major impact on the quality of life of individuals affected by TMD[6]. It is known that, in TMD, the high intensity of pain is associated with decreased blood flow to muscles, however treatments that improve blood flow are effective in relieving muscle pain[7,8].

Among the therapeutic procedures used by physical therapists to treat TMD are acupuncture[9], jaw exercises[10], massage[11], manual therapy[12], laser[13], and transcutaneous electrical nerve stimulation (TENS)[14,15]. Another resource used in physical therapy is high-voltage electrical stimulation (HVES). With this current, it is possible to perform numerous treatments because it has a single-phase wave, thus it can be effective in controlling and absorbing acute edemas, accelerating dermal and subdermal tissue repair, and controlling pain[16].

For the administration of HVES, both positive (cathodal) and negative (anodic) polarity can be used. Anodic HVES promotes protein denaturation, reduction in the mast cells of wounds, and stimulation of new capillary growth. In contrast, the application of cathodal HVES stimulates tissue granulation, reduces edema, promotes the proliferation of fibroblasts, and increases blood flow[16,17]. Although the physiological effect of each of the poles is well-established, the clinical effects of the polarity in humans have not been well defined. Nevertheless, among the effects of HVES, the most important are pain relief and increased blood flow, which can be obtained with both poles[18].

Most HVES experiments performed in humans so far have focused on the circulatory and regenerative effects; however, analgesia can also be obtained with the use of this current, as reported by the studies of Rodrigues-Bigaton et al.[15], Almeida[19], and Schwarzenbeck[20]. These authors evaluated the effect of ten applications of anodic HVES on pain[15,19,20], on the electromyographic (EMG) signal of the masticatory muscles, and on the clinical characteristics of TMD[19,20].

Almeida[19] and Schwarzenbeck[20] observed that anodic HVES improved the classification and severity of TMD, changing the clinical characteristics of the disease. Regarding the EMG signal, Almeida[19] noted improvement in muscle activity evaluated at rest and in isometric conditions. In contrast, Schwarzenbeck[20] noted improvement in the muscle activation pattern assessed by means of isotonic activity. According to these authors, the clinical benefits obtained with ten applications of anodic HVES are due to the current's circulatory and analgesic actions.

Although the aforementioned studies used HVES to treat pain in individuals with TMD, the effect of HVES on the placebo group has not been described in the literature, therefore the presence of this group must be taken into consideration, particularly for HVES application due to the lack of studies on the clinical applicability of this resource for analgesia. In addition, it is important to emphasize that, in the current literature, only HVES applications with positive polarity were found, thus it is crucial to study the effect of negative polarity on pain, given that analgesia can be obtained with both polarities[18].

Another factor that justifies the importance of this study is that, as shown in other studies[15,19,20], HVES has beneficial effects on TMD treatment and, if its effectiveness is actually proven, this therapeutic resource can be incorporated into the clinical practice of physical therapists who treat TMD. Although HVES is more cost-effective and yields good results with shorter treatment periods than galvanic current[21] and TENS[15], its use is restricted in Brazil, and one of the reasons for this is the lack of publications on its application[21].

Considering that HVES is indicated for analgesia, we hypothesized that cathodal HVES contributes directly to pain reduction in women with TMD. Therefore, the goal of the present study was to evaluate the effect of cathodal HVES on pain in women with TMD.

Methods

Study design

The study design is a randomized, double-blind clinical trial, approved by the Research Ethics Committee of

Universidade Metodista de Piracicaba (UNIMEP), Piracicaba, SP, Brazil, under protocol number 21/08. All participants signed the informed consent form. The participants and evaluators were blinded, therefore the participants did not know which group they belonged to, and the evaluators did not know whether the participant belonged to the experimental group (EG) or to the placebo group (PG).

Sample

Patients were recruited from the waiting list of the UNIMEP Physical Therapy Clinic and from the university community.

Sample loss

For the sample selection, we used the Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD). Forty-seven women with pain in TMJ and/or masticatory muscles were selected. Of these, 22 were excluded because they did not meet the inclusion criteria for the present study.

The sample size (n) was determined by means of sample calculation based on standard deviation values obtained by a Visual Analog Scale (VAS), which provided a measure of pain intensity in centimeters. The sample calculation was performed using GraphPad StatMate, version 1.01i, a power of 80%, and alpha=0.05. The sample size was calculated to be 18 participants, divided between the EG and the PG.

We selected 25 women with a diagnosis of TMD, confirmed by RDC/TMD, axis I. They were randomly divided into two groups: EG (n=13), aged between 17 and 32 years (22.50±7.07 years), in which the participants received ten applications of cathodal HVES; and PG (n=2), aged between 17 and 44 years (26±10.55 years), in which the participants also received ten applications of HVES, however with the equipment turned off. Over the course of the treatment, five participants dropped out of the study, three from the EG and two from the PG. Stratified randomization was used to assign the participants to the groups. After the completion of the study, effective treatment was offered to the PG participants.

Figure 1 shows the flowchart for the sample distribution.

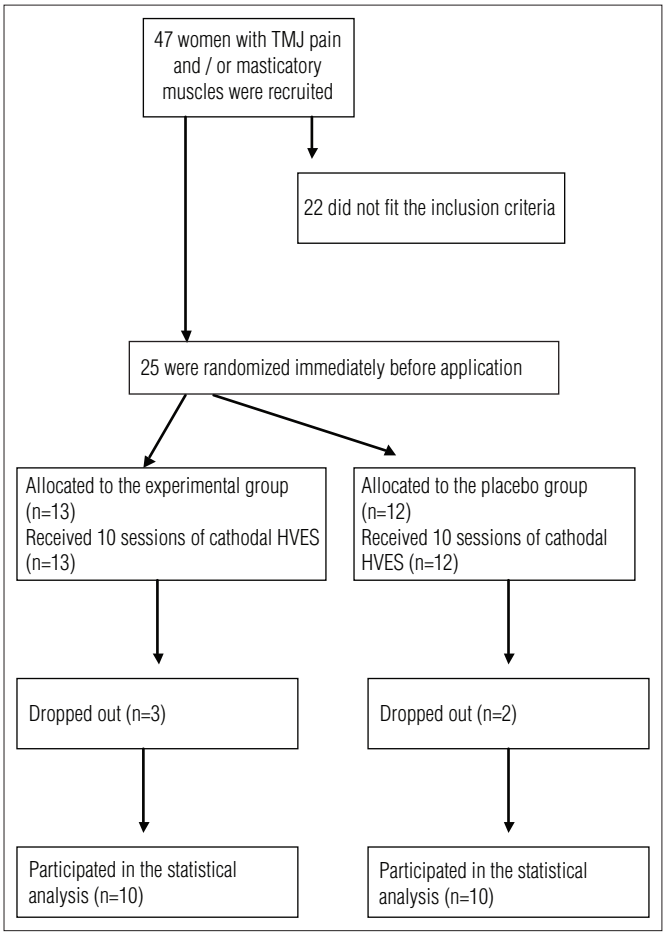

Figure 1. Flowchart for the sample distribution.

Inclusion criteria

The participants of both groups had to have a diagnosis of TMD, according to the RDC, axis I, accompanied by pain and/or fatigue in the masticatory muscles during functional activities for a minimum of one year and a maximum of five years. In addition, they could not be undergoing orthodontic treatment, drug therapy (pain relievers, anti-inflammatories, muscle relaxants) or physical therapy treatment.

Experimental procedure

For the sample selection, all participants were submitted to a physical therapy assessment that consisted of collection of personal data, anamnesis, previous history, and individual visual examination, followed by the assessment based on the RDC/TMD. The participants diagnosed as group I of the RDC/TMD assessed pain intensity through the VAS and began treatment with effective cathodal HVES or placebo. The randomization was carried out immediately before the start of treatment.

Intervention

For the application of cathodal HVES in both groups, the participants remained in the dorsal decubitus position with a roll under the knees during the sessions. The HVES

was delivered by the Neurodyn High Volt® (ANVISA number 10360310008 - Ibramed) with microcontrollers, two channels, four active transcutaneous rectangular electrodes (3x5 cm) made from carbon-silicone rubber, and a rectangular dispersive electrode (10x18 cm) consisting of an aluminum sheet wrapped in felt moistened with water.

The electrodes were placed bilaterally on the anterior portion of the temporal muscle (channel 1) and on the belly of the masseter muscle (channel 2). The dispersive electrode was positioned over the lower cervical region and the upper thoracic region because, according to Holcomb[18], this electrode must be larger than the active electrodes to reduce the current density and must be positioned over large areas. In addition, the greater the distance between the active and dispersive electrodes, the deeper the current will be[16].

The parameters used in HVES were: 10 Hz frequency; pulse width fixed by the equipment with two twin pulses of 20 μs each with interpulse interval of 100 μs; voltage above 100 volts to motor threshold (visible muscle contraction) with a threshold variation between 100 and 170 volts; negative polarity (cathodal HVES) in both channels applied for 30 minutes, two to three times per week. The equipment was calibrated with an oscilloscope (Tektronix TDS 210), and all of the physical parameters of the current were according to manufacturer specifications. The device's timer was calibrated using three timers (Technos), and this variable was according to equipment specifications. Gel was used under the silicone-carbon electrodes to allow the conduction of current to the tissue. The electrodes had not been previously used.

Measurement of pain intensity

To measure pain intensity, we used the VAS, which consists of a 10-cm horizontal line marked "no pain" on the left end and "worst possible pain" marked on the right end. The participants were instructed to draw a vertical line over the horizontal line, indicating at which point of the line the pain was. The VAS was applied before the start of treatment (pre-treatment) and after the tenth HVES application (post-treatment), respecting the period of at least 24 hours and a maximum of 48 hours after the last application of cathodal HVES. This period was observed with the purpose of evaluating the overall effect of the treatment and not its immediate effect.

The VAS data were analyzed using a ruler graded in centimeters. Pain intensity was measured from the left end, which coincided with the zero value of the ruler, until the vertical line drawn by the participant. It is worth noting that the examiner who analyzed the VAS data did not know which group the participants belonged to or whether the scales referred to the pre- or post-treatment.

Statistical analysis

Due to the subjectivity of the response variable pain intensity, non-parametric tests were used for intra- and intergroup comparisons. For intragroup comparison, the Wilcoxon signed-rank test was used. For intergroup comparison, we considered as response variable the difference between the pain intensity values obtained in pre- and post-treatment moments, and these values were analyzed using the Mann-Whitney test. For data analysis, we used the program SPSS 11.0, and the results were shown by the median and its first and third quartiles. For both analyses, the two-tailed significance level was used, with alpha equal to 5%.

Results

Through intragroup comparison, it can be observed that the ten applications of cathodal HVES promoted a reduction in pain intensity in the EG (p=0.01), while no difference was observed in the PG (p=0.20), as shown in Table 1. In the same table, which also shows the intergroup comparison, it can be observed that, before treatment, the EG and the PG did not shown any differences in pain intensity (p=0.23), a fact that demonstrates the homogeneity of the sample.

Table 2 shows that there is no difference between the EG and the PG after the application of HVES (p=0.65). However, when examining the values of the difference between the pre- and post-treatment and the range between the first and third quartiles, it can be seen that the EG presented greater reduction in pain intensity when compared to the PG.

Discussion

The results of this study showed that ten applications of cathodal HVES reduced pain intensity in the EG. In the PG, no changes were observed. When comparing both groups post-treatment, we found no significant differences between them. However, from a clinical point of view, the results indicated that the EG had a greater reduction in pain intensity than the PG.

The results of the present study agree with the findings of Almeida[19], who assessed the effect of ten applications of anodic HVES (frequency of 10 Hz, twin pulses lasting 20 μs with interpulse interval of 100 μs, voltage above 100 volts with stimulation at motor threshold) on women with TMD and found pain reduction, evaluated through VAS, both between sessions and at the end of treatment. Pain reduction was also observed by Rodrigues-Bigaton et al.[15], who concluded that

both TENS (10 Hz modulated in 50%, 200 μs, and intensity at the motor threshold) and anodic HVES (10 Hz, 20 μs twin pulses with interpulse interval of 100 μs, voltage above 100 volts with stimulation at motor threshold) promoted the reduction in pain intensity in women with TMD, showing that HVES is also indicated for the treatment of these patients.

A comparison of the results of the present study and those found by Almeida[19] and Rodrigues-Bigaton et al.[15] suggests that the analgesia can be obtained with both the anodic and cathodal HVES, which corroborates the assertion by Holcomb[18] that both poles are suitable for analgesia. Therefore, it appears that the analgesic effect of HVES is more closely connected to the frequency and voltage of the current (motor threshold) than to the polarity.

Mohr, Akers, and Wessman[22] observed that HVES promoted increased blood circulation in rats' hindlimbs and suggested that this increase was more closely related to the intensity of muscular contraction than to the polar effect produced by the current. The polar effect of HVES is discussed because Mendel and Fish[23] believe that, in this type of stimulation, the duration of the pulse is too small to promote chemical reactions under the electrodes. In contrast, Davini et al.[24] reviewed the literature on HVES as a treatment option and concluded that, despite the controversies, open wound repair is faster when there is alternating polarity starting with cathodal stimulation and that the circulatory effect is most effective when cathodal HVES is used at motor threshold. Thus, it can be stated that the polar effect of HVES with the purpose of promoting analgesia must be better investigated.

Generally, it is already known that when electrical stimulation is performed at the motor threshold and with low frequency (non-tetanic muscle contraction), in addition to increasing the arterial blood flow to the stimulated area, the current generates analgesia due to the stimulation of group III and IV afferent fibers causing the release of endogenous opioids from the central nervous system[25]. In this way, the electrical stimulation applied at motor threshold and at low frequency is effective in modulating clinical pain and experimentally-induced pain[26].

In the present study, as in the work of Almeida[19] and Rodrigues-Bigaton et al.[15], HVES was applied using low frequency and high voltage, therefore it is believed that the analgesic effect promoted by HVES is more closely related to the frequency and voltage of the current than to its polar effect. In the intra-group comparison, it was possible to observe that the current did not reduce pain intensity in the PG after the ten applications of cathodal HVES. Thus, the presence of the PG in this study was of great importance as it allowed the verification of the selected method.

Table 1. Comparison of pain intensity recorded in the VAS in cm before HVES (pre-treatment) and after HVES (post-treatment) in the experimental group (n=10) and the placebo group (n=10).

Visual Analog Scale (cm)				
Group	Pre-treatment	Post-treatment		
	Median (Q1, Q3)	Median (Q1, Q3)	p	z
Experimental	1.70 (0.85, 2.60) †	0.25 (0, 0.73)	0.01*	-2.35
Placebo	2.50 (1.73, 4.13) †	2.70 (0.45, 3.50)	0.20	-1.28

Q1=quartile 1; Q3=quartile 3; (*) indicates significant difference (p<0.05); Wilcoxon Test; (†) indicates intragroup comparison using the Mann-Whitney Test (p=0.23 and z=1.21).

Table 2. Intergroup comparison obtained by the difference in pain intensity recorded in the VAS in cm before HVES (pre-treatment) and after HVES (post-treatment) in the experimental group (n=10) and the placebo group (n=10).

Visual Analog Scale (cm)				
Group	Experimental	Placebo		
	Median (Q1, Q3)	Median (Q1, Q3)	p	z
Pre-post	1.25 (0.13, 2.28)	1 (-0.18, 1.88)	0.65	-0.45

Q1=quartile 1; Q3=quartile 3; (*) indicates significant difference (p<0.05); Mann Whitney Test.

Tramèr et al.[27] observed that, in clinical contexts with no gold standard and in treatments with wide-ranging values, the absence of the PG results in improbable conclusions. In many cases, the recruitment of patients in clinical trials is questionable and, therefore, the absence of this group can produce unrealistic results. Also according to the author, the PG allows the estimation of the effectiveness of the treatment.

Although the comparison between the EG and the PG did not show any statistical differences, it was clinically possible to observe that the EG had a greater reduction in pain intensity compared to the PG. It has been suggested that, in order to obtain significant results in the intergroup comparison, it would be necessary to increase the sample size, which is a limitation of the present study.

The hypothesis of the study was confirmed because the results showed that cathodal HVES reduced pain intensity in women with TMD. Therefore, this resource can be incorporated into the clinical practice of physical therapists.

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