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DOUBLE BLIND RANDOMIZED CLINICAL TRIAL ON ARNICA MONTANA 6CH IN MUSCLE THERMAL CHANGES BY ISOMETRIC STRESS IN PATIENTS WITH TMD AFTER ENDODONTIC PROCEDURES

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Abstract: The Arnica montana 6CH is a medicine for general muscular alterations and by isometric and thermography is a resource for the diagnosis of these alterations. Goal: The objective of this double-blind randomized clinical study was to verify the role of Arnica montana 6CH in the thermographic muscle changes of patients submitted to isometric stress in prolonged sessions of endodontics. Materials and methods: 70 patients were selected after a positive response to the RDC questionnaire (Research Diagnostic Criteria for Temporomandibular Disorder) for confirmation of TMD (Temporomandibular Dysfunction). Muscular Masseter and temporalis muscle temperatures on both sides were taken and recorded before and after the first endodontic consultation. Arnica montana 6CH was randomly prescribed to 35 patients, constituting group I, and placebo to 35 patients of group II. In the second endodontic consultation, a new measurement of muscle temperatures was performed and clinical evaluation was performed with the crossing of data from the RDC/TMD questionnaire. Data were tabulated and analyzed. Statistical analysis: Student's t test was used for paired samples, significant at the level of $\geq 0.05\%$. **Results:** The average decrease in comparative temperature between G I and G II was 0.6°C, and in the GI group (Arnica montana 6CH), the lower thermal results were statistically significant compared to GII (p=0.0022). Regarding the anamnetic data from the RDC questionnaire, 86% of the individuals in the GI had lower pain rates at the second consultation, compared with 22% in the GII. Conclusion: The medicine Arnica montana 6CH was shown to be effective in preventing muscle changes and clinical symptoms resulting from isometric efforts with a statistically significant difference (p=0.0022).

Keywords: Isometry, Thermography, Homeopathy, Endodontics.

INTRODUCTION

Craniomandibular myofascial pain interferes with the physiological behavior of the masticatory muscles when the mandible is at rest. Prior investigation of signs and symptoms of dysfunction before endodontic interventions in individuals with Temporomandibular Disorders (TMD) is necessary.¹

Isometrics or isometric contraction is muscle hyperactivity². It occurs when the muscle contracts, producing force without changing position³. There is fixation of two ends of the muscle, which does not allow a change in its length ⁴.

The mechanism causing muscle pain has been described in part by the accumulation of metabolic waste that occurs when blood supply is insufficient in a given muscle, forcing it to anaerobic metabolism. The increase in metabolic waste in the muscle becomes a stimulus that generates and perpetuates spasm and pain, even after eliminating the causal factor.

This way, thermotherapy relieves pain through the vasodilation it provides, with a consequent increase in local blood circulation and, therefore, oxygenation and removal of metabolic waste^{5,6}.

Other benefits provided by heat are the reduction of tension and muscle stretching due to the increase in the extensibility of the collagen present in the muscle, with a consequent increase in mouth opening and improvement of jaw functions⁷.

Thermotherapy is contraindicated in cases of acute inflammatory and hemorrhagic processes and cryotherapy prevents the inflammatory evolution⁸.

Isometric activities in cervical and masticatory muscles were studied using the RDC/TMD questionnaire(*Research Diagnostic Criteria for Temporomandibular Disorder*) and greater muscle activation was observed at mandibular rest, by isometric¹.

The official Portuguese version of the RDC/TMD questionnaire/form allows for the standardization and replication of research methods reliably in the various centers in Brazil and worldwide that investigate the most common forms of temporomandibular disorders^{9,10}.

The homeopathic use of Arnica montana in the 6CH dilution is recommended whenever there are physical or emotional traumas and their consequences on the muscles and vascular tissue¹¹. Likewise, other authors ^{12, 13, 14} affirmed its activity in bruises, toothaches and myalgias caused by physical or masticatory effort, muscle fatigue, dislocations and inflammatory processes^{15,16,17}.

Thermography is a non-invasive test that detects the extent of functional, nerve and vascular changes¹⁸. There is high sensitivity for muscle physiology associated with thermal changes in the first 24 hours after physical exercise. Dibai-Filho et al., 2015¹⁹, checking its applicability in myofascial pain, they observed the possibility of diagnosing myofascial trigger points in the trapezius muscle and thermography was indicated for clinical and research practices.

This technique provides an assessment of acute and chronic pain by recording the increase and decrease in microcirculation in the affected region²⁰. Likewise, the effectiveness of thermography in detecting muscle changes was found in athletes after prolonged exertion²³. An approximate increase of 1°C was observed, comparing previous results and after the accomplishment of the effort, in body areas where muscle injuries appeared.²¹

Thermography was considered an adequate tool for the evaluation and prevention of muscle injuries due to isometric effort, although there is some care with the control variables during its use, such as taking the body temperature in an environment with temperatures between 18 and 25°C, after a minimum acclimatization of 15 minutes. The infrared method captures the radiation that is radiated by the examined part of the body, basically heat in the form of electromagnetic waves²².

Endodontics is the specialty of Dentistry responsible for treating diseases in the pulp and periapical tissues. Endodontic treatment consists of several steps aimed at debridement, disinfection, cleaning and adequate sealing of the root canal system ^{23,24}. This procedure requires the proper training and skill of the specialist in order to promote such maneuvers while preserving the anatomical structures so that the affected tooth can later be returned to function²⁴. The time for its performance tends to be long (60 minutes, on average, depending on the clinical situation), which places the mouth opening muscles in isometrics, which can have serious consequences in patients already suffering from Temporomandibular Disorders (TMD), especially those of muscular origin²⁵.

Therefore, the objective of the present study is to evaluate the performance of the homeopathic medicine *Arnica montana*, in the dilution of 6CH, in the control of vascular/ inflammatory alterations of the masseter and temporal muscles of patients with TMD, submitted to consultation for endodontic procedure, worth a temperature measurement method.

MATERIALS AND METHODS

This research was approved by the Ethics and Research Committee of UniFOA – COEPS and approved with CAAE: 48680015.3.0000.5237 on 7/22/2015.

To carry out the study, RDC/TMD questionnaires (Portuguese version) were provided to 168 patients treated between September 2017 and July 2018 at the postgraduate clinic in Endodontics of the UNIFOA Dentistry Course, in Volta Redonda/ RJ. Seventy patients, of both genders, aged between 18 and 63 years (mean 34.8 years), who answered the questionnaire and had their clinical assessment confirmed with the diagnosis of TMD were selected for the present study. In the first consultation, the selected individuals remained seated in the dental chair, with the light on for the entire session, with a standardized time of 60 minutes, with an average ambient temperature of 22°C. Then, the surface temperature of the masseter and temporal muscles was measured with the aid of an Ebai® digital thermometer, which uses a reading system by infrared irradiation. The measurement was performed by placing the thermometer on the musculature, between the origin and insertion of the masseter muscle and in the anterior bundle of the temporal muscle, on both sides. Then the infrared ray was shot over the surface of the muscle and the temperature was identified through a digital display. After measuring the temperature, in degrees Celsius, the data were recorded. After the first session, the randomization for the medication was performed, using a coin and the "heads and tails" method. Thirty-five patients received the drug Arnica montana, in the dilution of 6CH, in a 30% hydroalcoholic solution, with the recommendation that the patient take five drops, three times a day, for seven days. This group was determined as Group I. In group II, another thirty-five patients were given a bottle of 30% hydroalcoholic solution, with the same recommendations given to patients in group I: take 5 drops, sublingually, three times a day. day for seven days. The vials were all properly labeled in the same way, not allowing patients to have access to which type of medication they would use. In the second endodontic consultation, the same procedure for measuring temperature and environmental conditions was repeated. Prior to initiation,

an assessment of the level of muscle pain was also performed, providing patients in groups I and II with a visual analogue scale, aiming to identify the effects caused on the muscles by the first consultation. All data were recorded, tabulated and sent for statistical analysis, where the responsible professional only had access to the data and not to the context of what they were about. Data were submitted to analysis of variance with a 5% significance level. Student's t test was used for paired samples with p \leq 0.05. The null hypothesis was that there would be no difference in the performance of both substances (Arnica montana and placebo).

RESULTS

It is observed that in all tests, the calculated value of t is outside the test acceptance area. Therefore, the null hypothesis considered was rejected. That is, the use of Arnica *montana* 6CH influenced the temperatures in the masseter and temporal muscles with an average reduction of 0.6°C.









Left time



In the graphs above (Right Masseter, Left Masseter, Right Temporal, Left Temporal) it is possible to observe the results of the alteration of.

Regarding the anamnetic data of the RDC questionnaire and visual analogue scale, all 70 patients, as they had muscular TMD, reported some level of discomfort, such as pain symptoms and/or mouth opening difficulty, after the first endodontic session (session control) of approximately 40 minutes of isometric effort for maximum mouth opening. After one week of medication use, in the second endodontic session (test session), in the IG, 86% (30) of the patients reported no symptoms and only 14% (5) complained of discomfort. In GII, only 22% (6) reported no symptoms after isometric exercise and 82% (29) complained of pain and/or difficulty opening the mouth.

DISCUSSION

Myofascial pain is a limiting condition and its report can sometimes be confused with endodontic postoperative pain. Pain caused by isometric effort resulting from prolonged sessions with maximum mouth opening is a frequent type of myofascial pain and can also trigger TMD1,2,3 Anamnesis and preventive clinical examinations to identify and take the necessary precautions are necessary.

The stomatognathic system is a delicate structure where the synchronicity of action of the elevator and lower jaw muscles must occur for the correct functioning of the mouth opening and closing mechanism. In the opening movement, the depressor muscles perform isotonic contraction and the elevators, isometric contraction25. Thus, when performing endodontic consultations, where the working time is usually long, this condition can trigger deleterious effects on the musculature by overcoming the muscular metabolic capacity and causing the fibers to enter an anaerobic regime, with the consequent production of lactic acid and other substances. residues that, when accumulating, generate tissue damage and trigger inflammation and pain. Prolonged muscle contraction also causes blood ischemia, also favoring the onset of pain, contracture and discomfort, perpetuating a vicious cycle.

The waste generated during this process is susceptible to elimination and drainage when subjected to an increase in temperature by thermotherapy, for example, which promotes vasodilation, increased local blood circulation and oxygenation and removal of metabolic waste^{6,7}.

Local and systemic resources to favor the increase of blood circulation and local cryotherapy, in the first hours, are recommended in the presence of muscle contracture by isometric^{6,7,8}. In the present study, a similar effect was identified with the use of the drug Arnica montana 6CH, where a reduction in local muscle temperature was observed. This fact may have been caused by the better blood flow provided by the action of the drug, with consequent favoring of the drainage of metabolic waste produced at the site. The average reduction found was 0.6°C of muscle temperature, when comparing GI with GII, during the second consultation. It is important to emphasize that in both groups the clinical data were obtained from the validated questionnaire, RDC/TMD (Research diagnostic criteria for temporomandibular disorders), in this study, they corroborate the clinical results favorable to the reduction of pain and contracture in the face of heat reduction therapies place^{1,7,8}

Since thermotherapy is contraindicated in cases of acute inflammatory and hemorrhagic processes^{8,20,21}, and cold contains the evolution of the inflammatory process, a systemic drug with anti-inflammatory properties, of muscular action, and especially in cases of

contractures and muscular excessive effort, represents a viable therapeutic possibility in the treatment and prevention of these conditions^{13, 14, 15, 16, 17, 18, 19}.

Although some previous studies consider thermography an adequate tool for the prevention of muscle injuries^{22, 23,24} and the data from this study have found a reduction in muscle temperature and absence of symptoms in the presence of medicine *Arnica montana 6CH*, further studies will be needed to clarify the physiological pathways of these findings.

CONCLUSION

It is observed that in all tests, the use of Arnica montana, preoperatively, reduces the temperatures of the masseter and temporal muscles, in the face of isometric effort.

The drug Arnica montana 6CH proved to be effective in preventing muscle changes resulting from isometric efforts with a statistically significant difference of (\geq 0.05%) presenting benefits such as pain relief, reduction of muscle tension, improvement of jaw functions and increase in mouth opening, which justifies further studies on its clinical use in dentistry.

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