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The effect of laser and botulinum toxin in the treatment of myofascial pain and mouth opening: A randomized clinical trial☆,☆☆,★,★★

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ABSTRACT

This study conducted a randomized clinical trial in 15 patients, who sought care at the Dental Clinic of the University of Passo Fundo, in order to compare the use of low-level laser and botulinum toxin in the treatment of myofascial pain and whether they alter the mouth opening of patients with temporomandibular disorder. The patients were divided into two groups: the Laser group received low-level GaAlAs laser, 100 mW of power at a wavelength of 830 nm in continuous light emission; and the Toxin group received 30 U of botulinum toxin type A (BTX-A) in the first session, and 15 U after fifteen days. The assessments were performed by measuring pain with Visual Analogue Scale (VAS), and mouth opening with a digital caliper. Data were submitted to Student's t test at 5% significance level. Regarding pain symptoms, the results indicate that groups treated with laser and toxin registered 7 U in VAS, at day 5 the scores were 4.75 and 4.86 U, respectively. The laser worked faster (day 12) at 2.75 U, and the group treated with BTX-A registered 2.86 U at day 30. Both therapies investigated were effective in reducing pain, but the effect of low-level laser was faster than the use of BTX-A. Both treatments showed no statistically significant improvement in mouth opening.

1. Introduction

Temporomandibular disorder (TMD) is characterized by pain and disorders in joints and/or muscles and associated structures [1]. Its etiology is currently known to be multifactorial [2], including psychological factors, unbalanced occlusion, parafunctional habits, and hereditary and psychological systemic factors [3]. TMD is considered a major cause of non-dental pain in the orofacial region [4]. Patients present several signs and symptoms, such as headaches, pain in the face and neck, joint noise, and limited mouth opening [5].

The collection of information about the potential etiological factors, signs, and symptoms must be done carefully for correct diagnosis. Early diagnosis may avoid complex treatments, such as surgery and invasive occlusal therapy [6,7].

Several treatments are suggested for TMD. Indications are the use of anti-inflammatory drugs, intake of soft food, physiotherapy, occlusal splints, and acupuncture [1,8]. In addition, there are several evidences of the reduction of myofascial pain symptoms with the application of low-level laser [1], and more recently, with the use of botulinum toxin type A [9].

The use of laser has grown extensively in all areas of dentistry because of its therapeutic properties, such as tissue repair and improvement of local microcirculation, besides the positive psychological effect, especially in patients with chronic pain [10]. Low-level laser is a non-thermal treatment that aims to reduce the pain of TMD through its anti-inflammatory, analgesic, and biostimulant effects [2,5]. Biostimulation occurs through metabolic activation, such as formation of fibroblasts, increased vascularization, and mitochondrial activity [11,12].

Botulinum toxin type A is a neurotoxin synthesized by *Clostridium botulinum* bacteria, which acts efficiently in myofascial pain and headache [13,14,15]. It is classified as a zinc endopeptidase that cleaves one or more proteins at the union of acetylcholine with the presynaptic

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membrane. This results in local chemodenervation with loss of muscle tone, promoting reduction in contractility [16].

Seeking better treatments to improve the quality of life of patients with myofascial pain, this study compares the effectiveness between low-level laser and botulinum toxin type A, testing the following null hypotheses: (1) there is no difference between both treatments for myofascial pain, and (2) the different techniques do not change the mouth opening of patients with TMD.

2. Material and Methods

2.1. Research Ethics Criteria

This study was approved by the Research Ethics Committee according to normative act n. 570/2011 (CAAE: 0312.0.398.000–11).

2.2. Type of Study and Sample Qualification

It is a randomized clinical trial with 25 patients who sought care at the Dental Clinic of the University of Passo Fundo. For the selection of individuals, the following criteria were used:

Inclusion criteria: unilateral or bilateral myofascial pain lasting more than a month; complaint of pain in mouth opening; bruxism, clenching or tooth wear.

Exclusion criteria: pregnancy and breastfeeding; heart disease and pacemaker; malignant tumors; degenerative joint diseases, psoriasis, and rheumatoid arthritis; myasthenia gravis and Lambert Eaton's syndrome; congenital abnormalities; recent history of trauma; treatment for pain in the month prior to the study; psychic disorders; dental diseases such as caries or pulpitis; epilepsy; use of chronic medication, occlusal splint or other treatment for pain control; use of aminoglycosides; allergy to lactose; tetanus vaccine in the last 12 months.

Therefore, after analyzing inclusion and exclusion criteria, 18 patients were able for treatment. Randomization was performed through an online program (www.random.org) so it would be as impartial as possible. After this initial step, only 16 patients showed up at the place indicated for the research, and one patient quit treatment during the experiment. For the purpose of results, a sample of 15 patients (8 from the Laser group and 7 from the BTX group) was considered.

2.3. Methodology

For the Laser group, a low-level device (Photon Lase III, DMC equipment, São Carlos, SP, Brazil) was used with GaAlAs (Gallium Arsenide and Aluminum) active medium, 100 mW of power, at a continuous emission mode, wavelength of 830 nm, and dose of 80 J/cm^2 per application point. This dose appears calibrated on the device display when the TMD function is selected. The laser light was applied with the tip of the device perpendicular to and in contact with the tissue to be irradiated, in two points of the superficial bundle of the masseter muscle (in the upper portion and the lower portion), and in one point of the temporal muscle (central portion). Applications were performed in the endplate of muscles, and they were always bilateral.

Seven applications were performed at 48-h intervals between each application (session), excluding weekends. Laser dose was determined according to the manufacturer's protocol (DMC).

For the Toxin group, 500 U of botulinum toxin type A was used. In the first session, 30 U were applied per point, in two points of the superficial bundle of the masseter muscle (in the upper portion and the lower portion), and in one point of the temporal muscle (central portion). Fifteen days later, 15 U were applied per point, likewise the first session. Applications were performed in the endplate of muscles, and they were always bilateral. For the purpose of application, the botulinum toxin type A was reconstituted with a 10 ml luer syringe containing 1.1 ml of 0.9% saline solution, which was introduced into the vial containing the botulinum toxin type A, so the toxin may be stored and refrigerated (from +2 °C to +8 °C) inside its container. Upon reconstitution, the central portion of the exposed rubber stopper was cleaned with alcohol, immediately prior to piercing the septum. A ratio of 5:1 U was used because there is no specific syringe to apply the toxin. Thus, for 30 U of toxin, 6 strokes of the syringe were determined for 30-unit insulin, and 3 strokes for 15 U. Two syringes were used per patient in each application.

Prior to application, the muscles were sterilized with 2% chlorhexidine solution with no alcohol and soaked in gauze. Application points were determined with a marker where topical anesthetic cream was applied with a stick spreader, and there was a 30-min wait until the botulinum toxin type A was applied.

Next, the aforementioned muscles were pressed by the index finger and thumb for needle insertion perpendicular to the tissue. Toxin injection proceeded with the insulin syringe of ultrathin, sterile, 23-gauge, and 12-mm length needle.

Mouth opening assessment for both groups was performed in patients with orofacial pain, evaluating the interincisal distance (in millimeters) at pre- and post-treatment with a digital caliper (Mitutoyo — Japan), and pain was measured with the Visual Analogue Scale (VAS) before the first application and prior to the following applications.

The experiment was performed by an evaluator who measured mouth opening and pain, and by two applicators - one for the laser and one for the botulinum toxin type A. All operators were previously trained.

2.4. Statistical Analysis

Data were subjected to Student's t test to assess the experimental groups at 5% significance level.

3. Results

We observed 15 patients — thirteen women and two men. The average age was thirty-eight years.

Regarding pain symptoms reported by the patients of the groups assessed, we found that in the Laser group there was statistically significant reduction of pain after 12 days of irradiation ($p = 0.019$). On the other hand, in the Toxin group, we found that the reduction of symptoms only occurred 30 days after the first application ($p = 0.043$). However, there was no statistically significant difference between both groups studied regarding the reduction of pain symptoms 30 days after starting the treatment ($p = 0.985$) (Fig. 1).

Regarding mouth opening, we found no significant statistical difference between the Laser group and the Toxin group, considering that both groups showed no significant increase in mouth opening during treatment ($p = 0.272$) (Fig. 2).

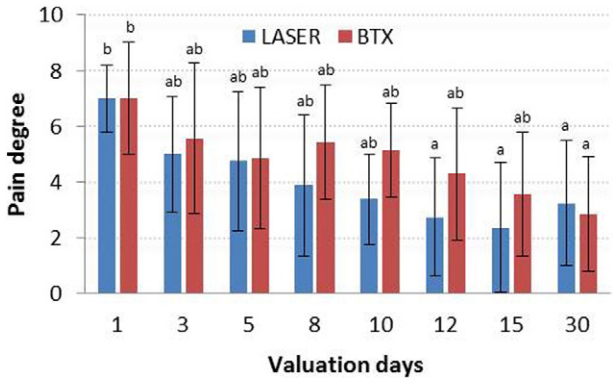

Fig. 1. Degree of pain (VAS scale) in the groups studied in relation to the assessment days. Same letters indicate no statistical differences between groups.