

The Efficacy of Acupuncture for the Treatment of Masticatory Musculature Myofascial Pain Syndrome: State of the Art

Gui-Youn Cho-Lee^{1*}, Hoon Cho-Jung², Sergio Castrejón-Castrejón³, Mario-Fernando Muñoz-Guerra⁴, Francisco-José Rodríguez-Campo⁴ and Luis Naval-Gías⁴

¹Department of Oral and Maxillofacial Surgery, Torrejón University Hospital, Madrid, Spain

²Golden Clover Foundation for Natural Medicine, Madrid, Spain

³Department of Cardiology, La Paz University Hospital, Autónoma University, Madrid, Spain

⁴Department of Oral and Maxillofacial Surgery, La Princesa University Hospital, Autónoma University, Madrid, Spain

*Corresponding Author: Gui-Youn Cho-Lee, Department of Oral and Maxillofacial Surgery, Torrejón University Hospital. Madrid, Spain.

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Abstract

Objectives: 1) To evaluate the effectiveness of using acupuncture treatment for masticatory muscles myofascial pain syndrome (MMMPs), according to all the randomized clinical trials and critical reviews published in the last decades. 2) To summarize the data from all those studies.

Methods: The information was gathered using the MEDLINE database. The inclusion criteria for selecting the studies were the following: (1) only randomized controlled trials (RCTs) and systematic reviews of RCTs were selected; (2) studies had to be carried out on patients with Temporomandibular Dysfunction (TMD) of muscular origin; (3) studies had to use acupuncture treatment.

Results: A total of 11 RCTs and 3 systematic reviews were chosen. All of the studies included in the present review compared the acupuncture treatment with a placebo treatment or splint and pharmacological therapy. All of them described results that were statistically significant in relation to short-term improvement of TMD signs and symptoms of a muscular origin, except one of the analyzed studies that found no significant difference between acupuncture and sham acupuncture.

Conclusions: In the authors' opinion, research into the long-term effects of acupuncture in the treatment of TMD is needed. We also recommend larger samples sizes and three parallel arms of treatment (acupuncture, sham acupuncture and splint therapy) for future studies, so the results will be more reliable and enlightening.

Keywords: Acupuncture; Masticatory Muscles; Myofascial Pain Syndrome; Randomized Clinical Trials; Review

Abbreviations

MMMPs: Masticatory Muscles Myofascial Pain Syndrome; TMD: Temporomandibular Dysfunction; RCTs: Randomized Controlled Trials; TMJ: Temporomandibular Joint; MP: Myofascial Pain; MM: Masticatory Muscles; TCM: Traditional Chinese Medicine; S: Stomach; SI: Small Intestine; GB: Gallbladder; LI: Large Intestine; TW: Triple Warmer; MMO: Maximal Mouth Opening; VAS: Visual Analogue Scale; RA: Real Acupuncture; SA: Sham Acupuncture; mm: Millimeters; cm: Centimeters

Introduction

Temporomandibular disorders (TMD) are a set of musculoskeletal disorders affecting the temporomandibular joint, masticatory muscles or both. TMD's are comprised of diverse diagnoses with similar signs and symptoms affecting the masticatory system that can be acute, recurrent or chronic conditions. TMD's are rarely life threatening but can impact heavily on a person's quality of life [1-5].

Patients with TMD frequently suffer not only from pain and dysfunction in the temporomandibular joint (TMJ) and the masticatory muscles (MM), but also from headaches, cervical spine disorders, impaired opening of the mouth, joint clicking, sinusitis, chronic neck pain, and reduced cervical spine mobility. This variety of pain symptoms apply not only to dentistry or maxillofacial surgeon, but also to many other disciplines of medicine [1-5].

Muscular conditions are the main cause of TMD. One of muscular conditions that affect the craniomandibular system is myofascial pain (MP) of the masticatory muscles (MM), which is the most frequent type of TMD. MP is described as a musculoskeletal condition presenting a series of signs and symptoms caused by myofascial trigger points [6-10].

TMD occur disproportionately in women of childbearing years in a ratio of between 4 to 1 and 6 to 1. Prevalence drops off dramatically for both males and females after age 55. Seventy-five percent of population has at least one sign and 35% have at least one symptom. Etiology is variable and uncertain; it is thought to be multifactorial in most cases [1-5].

There is no standard treatment for reducing MM myofascial pain. Thus, a number of different therapies, isolated or combined, have been used. Pain relief is the main goal of such treatments. TMD is basically treated using conservative approaches such as pharmacological treatment, occlusal splints, occlusal adjustment, jaw exercise, psychotherapeutic and physiotherapeutic treatments; but other options, such as acupuncture and dry needling therapies, have been used with good clinical results [1-5].

Long-term administration of pharmacological treatment need to be seriously considered. Moreover, the natural history of orofacial pain, with treatment-independent remissions and exacerbations,

bations, makes mandatory to have treatments that can be applied chronically without adverse events of long-term administration.

Occlusal splint therapy in MP related to the craniomandibular system has been shown to be effective when compared with a control group not receiving treatment. However, these results must be interpreted with great care, as the research design of some of the studies was not completely reliable [11,12]. Besides, these results are based on short-term results, but not on long-term relief of painful symptoms.

Acupuncture has been reported to have a beneficial role in the management of TMD and is frequently used for treating TMD. Acupuncture has been claimed to be effective in TMD treatments in the mechanism of pain reduction, antiinflammation, and neurohormonal effects [13-26].

Acupuncture has been acknowledged to be effective in pain relief for more than 3000 years (Traditional Chinese Medicine, TCM). According to TCM, the life energy Qi flows in energy pathways, the so-called meridians, under the body surface. It is thought that pain and tension result when the Qi flow is disrupted. Specifically stimulating a few (of the more than 360) acupuncture points (acupoints) is thought to alleviate these blockages [27]. Local acupoints are those situated near the affected area and produce greater and faster pain reduction. On the other hand, distal acupoints produce long lasting effects.

Modern pain research has disclosed the various effects of acupuncture, providing, at the same time, neurophysiological explanations. Purposeful needle stimulation applied to specific skin or mucosa points activates the organism's self-regulation and modulation abilities. Pain modulation is affected in many different ways. One of the more outstanding results of pain research is the activation of endorphins and neurotransmitters when acupuncture stimuli are being applied [13-26].

Studies using this type of therapy have been systematically reviewed previously. Up to recently, three systematic reviews of acupuncture for TMD are available [28-30]. Although positive results were found in those reviews, the authors concluded that the research design of the trials was seriously inconsistent, and that the samples of the study, in some cases, were not very representative. It is also important to note that some of the studies analyzed in these reviews took place before 1994 and a systematic review related to the effectiveness of acupuncture in the treatment of TMD of muscular origin is lacking.

Therefore, the aim of our review is to critically evaluate the most rigorous clinical evidence for or against the effectiveness of acupuncture treatment compared to relevant sham one or splint therapy, in patients with MMMPS; according to RCT results published in the medical literature.

Methods

The information was gathered using the MEDLINE database. The inclusion criteria for selecting the studies were the following: (1) Only randomized controlled trials (RCTs) and systematic reviews of RCTs were selected; (2) Studies had to be carried out on patients with Temporomandibular Dysfunction (TMD) of muscular origin; (3) Studies had to use acupuncture treatment. We decided to include all RCTs regardless their date of publication, given that both acupuncture treatment and splint therapy regimens have not experimented substantial changes along the past decades, and moreover, there are only a few RCTs that meet all the inclusion criteria.

Results and Discussion

A total of 11 RCTs and 3 systematic reviews were chosen. All of the studies included in the present review compared the acupuncture treatment with a placebo treatment or splint and pharmacological therapy.

RCTs comparing acupuncture and splint therapy

Four RCTs and one systematic review were found in this group of studies. All of them conclude that acupuncture is effective in the treatment of MMMPS with no significant differences between acupuncture and splint therapy. These are the individual study methodology and results.

Raustia., *et al.* [31-33] compared acupuncture with standard stomatognathic treatment, including any combination of counseling, occlusal adjustment, muscle exercises, and occlusal splints. The subjects' mean ages were 27.8 years in the first group and 26.4 years in the second group. Seventy-eight percent were female. The 2 treatment modalities had a similar marked effect on the dysfunction index: stomatognathic treatment was significantly better 1 week after treatment ($P = .04$) but not at 3 months' follow-up ($P = .12$). There was also a significant difference between the effects on mouth opening ($P = .05$), with acupuncture proving superior with low initial opening values, and standard therapy superior at high initial values. There was no difference between the subjective patient estimates of the results of the 2 treatments.

The same workers presented individual dysfunction index scores for individual subjects, analyzing the components of the index (such as muscle pain and TMJ pain) for sub groups with high and low initial scores. There were no clear differences between the 2 treatments for any component.

In this study, acupuncture treatment consisted in 3 sessions. Patients with TMJ pain were also included. Previous duration of the symptoms was not reported.

Johansson., *et al.* [34] compared acupuncture to 3 to 7 local points and 1 distant point (LI 4) with maxillary full-coverage occlusal splints made of acrylic resins and an untreated control

group. Patients who had previously experienced either acupuncture or occlusal splints were excluded. The age and sex distribution of the subjects was not stated. Sample size included 45 patients randomly allocated in the three groups. Study variables included Anamnestic and Dysfunction Helkimo Index and pain measured in a VAS. Follow up period lasted 3 months. Ninety percent of the acupuncture group and 86% of those who received occlusal therapy improved, and both the subjective symptom scores and objective clinical examination scores were significantly better for both treatment groups compared with the untreated controls ($P < .01$), with no significant difference between the 2 active groups.

List, *et al.* described the short-term results [35] of a large trial involving 110 subjects selected by applying inclusion and exclusion criteria to the department's waiting list of 950 patients. Patients were not excluded for previous occlusal splint or acupuncture therapy. Twenty-three were male and 87 female, with median ages of 39 and 45 years, respectively. Median duration of pain was 4 years. Occlusal splints were full-coverage hard acrylic resin appliances constructed to fit the maxillary arch. Only in 3 patients with loss of molar support in the mandible was the splint applied there instead. Acupuncture treatment group patients received a session once a week, of 30 minutes, along 6 - 8 weeks. The treatment included stimulation of both local (2S, 3S, 18SI, 19SI, 20GB, 21GB) and distal (4LI, 36S) acupoints. In each session, 4 to 15 acupoints were stimulated (mean 12 points). The authors explained that treatment was standardized as much as possible, but in some cases, other acupoints were also stimulated; existing variations in the treatment of each patients. A battery of 7 outcome measures was used: anamnestic index, subjective evaluation, activities of daily living, pain visual analog scale, pain frequency, use of medication, and clinical dysfunction index. Results were presented for 96 patients, although it was stated that there were no dropouts. Acupuncture was significantly superior ($P < .05$) to occlusal therapy and waiting list in anamnestic index, subjective evaluation, and activities of daily living. Acupuncture and occlusal therapy were significantly superior to the waiting list control in pain visual analog scale ($P < .01$) and clinical dysfunction index ($P < .05$). There was a statistically significant reduction in pain frequency in the acupuncture group only ($P < .01$); there were no significant changes in medication in any group.

The results in the 2 treatment groups of the above study after 6 months and 1 year were presented separately by the same authors [36]. Overall, 21 (53%) of patients in the acupuncture group and 25 (63%) of those treated with occlusal splints remained improved on subjective evaluation at 12 months without additional treatment. (These percentages had been recalculated from the data by means of an intention-to-treat analysis).

Patients whose condition had not improved were offered the alternative treatment or another therapy; they were not considered further here. Of the 40 subjects who initially received acupuncture, 22 were studied; of the 40 who initially received occlusal splints,

25 were studied. Long-term improvements were noted in both groups assessed by an amnestic index and activities of daily living at the significance level of $P < .01$. Pain visual analog scale, pain frequency, and clinical dysfunction index improved at the significance level of $P < .001$. Changes in medication were not reported. There were no significant differences between the groups for any end point.

In the third article from this group [37], pressure pain threshold of the masseter muscle on each side was measured with a pressure algometer applied to the muscle bellies. It is not clear how the subgroup of 55 patients was selected from the total 110 subjects. There were significant increases in the threshold immediately after treatment, which were significantly different from the changes in the untreated control group ($P < .05$). There were further small increases in the thresholds after 6 months that were not significant.

Ernst, *et al.* published a systematic review of RCT comparing acupuncture and splint therapy in TMD patients of muscular origin [28]. This systematic review included the 3 previous studies and concluded that without exception, the results of the 3 studies suggest that acupuncture is effective. The benefit of acupuncture seems to be comparable with that of combinations of standard therapy or occlusal splint therapy alone. Both pain and joint function (these variables are obviously interrelated) seem to respond. According to these data, the effect seems to be sustained and noticeable even 1 year after therapy [36]. No trials were found that controlled for possible placebo effects of acupuncture. More important, none of the studies was designed in a way that a placebo effect of acupuncture can be excluded as the underlying mechanism of action. The overall message that seems to emerge from these data favors acupuncture as a symptomatic treatment of TMD. However, these results should be interpreted with caution. None of the trials was performed with blinded evaluators, details of randomization were not given, and therefore all studies are subject to important bias. It is notable that all studies come from Scandinavia. To increase their liability, one would therefore wish to see further confirmatory studies from other areas. In conclusion, the trial data available suggest that acupuncture is a useful symptomatic treatment of TMD. Whether acupuncture has any specific effects or acts through non-specific effects should be investigated with rigorously sham-controlled and blinded trials.

Vicente-Barrero, *et al.* [38] compared acupuncture and splint therapy in a RCT including 20 TMD patients with articular or muscular components and movements restriction, of at least 3 months of duration. Patients who had received acupuncture or splint therapy previously or had malocclusion or partial/total edentulism were excluded. Acupuncture therapy consisted in local (21TW, 19SI, 17SI, 2GB, 7GB) and distal (4LI, 36S, 5SI, 34GB) acupoints stimulation. Patients allocated in this group received 15 sessions and were not allowed to use pharmacological therapy. The outcome measures of the study were: maximal mouth opening, mus-

cle tenderness measured by an algometer and pain measured in a VAS. Immediate results were evaluated, without a follow up period.

RCTs comparing real acupuncture (RA) and sham acupuncture (SA)

Seven RCTs and two systematic reviews were found in this group of studies. These are the individual study methodology and results.

Goddard, *et al.* [39,40] underwent an RCT of 18 TMD of muscular origin patients, allocated in RA (10 patients) and SA (8 patients) groups. RA treatment consisted in 10 - 30 mm depth needle punctions in four acupoints: 2S as local point and 4LI as distal point; bilaterally. For SA, needle punctions were performed 1 cm away from real acupoints and 2 - 4 mm deep. Each session of RA or SA lasted 30 minutes. Penetrating SA was chosen because it provides a similar perceived experience as RA for the patient. The outcome measure of the study was the muscles tenderness measured by an algometer in a VAS scale. The effects of only one session were evaluated, without follow up period. The study was single blinded for the patient.

Schmid-Schwab, *et al.* [41] compared RA and SA in a RCT including 23 TMD of muscular origin patients, with 11 and 12 patients, respectively. Patients suffering articular pain were excluded. RA acupoints were situated intraorally: maxilla retromolar, mandible retromolar, maxilla vestibular and mandible vestibular; and extraorally: 4LI, 2SI and 3SI. The 18 sessions of 20 minutes were performed during 3 weeks (six per week). For SA, a laser terminal was placed on various randomly selected points (2SI, 3SI, maxilla and mandible retromolar) without contact and without being activated. This sham treatment was also maintained for 20 minutes and only one session was performed. The outcome variables were: pain measured in a VAS, MMO in mm and muscle tenderness. Measurements of these parameters were obtained in observer-blinded fashion, at the end of the last session in the RA group and at the end of the unique session in the laser SA group. There was not follow up period.

Smith, *et al.* [42] published a RCT including 27 MMMPS patients who had the condition for at least 6 months. RA group included 15 patients and SA group, 12. It was double-blinded (for the patient and for the evaluator). Patients who suffered TMJ pain were not excluded from the study. Patients were advised to continue any other ongoing treatment such as medication or splint therapy for the condition at the same level as usual. Each patient received six acupuncture treatments bilaterally at 7S (local point). These took place over a 3 weeks period. The needle was inserted 6 - 12 mm into the skin until resistance or pain were felt. For the SA group, the blunt needle end only touched the skin. The needle was retained in position for 20 minutes in both groups. The following outcome measures were assessed: 1) Patient functional perspective. About 10 cm VAS functional scale was used. A reading of 0 cm was equal no functional impairment, e.g. in eating, talking or sleeping. A reading of 10 cm meant maximal functional impairment, severely limiting the subject in all such functions; 2) Pain intensity (VAS); 3) Pain distribution; 4)

MMO in mm; 5) Muscle tenderness; 6) TMJ tenderness; 7) Headaches; 8) Deviation; 9) TMJ sounds; 10) Improvement or elimination of the above-mentioned outcome measures were considered as a positive treatment outcome. These outcome measurements were registered immediately after the last session, 3 and 7 days after.

Shen, *et al.* [43] underwent a RCT including 28 MMMPS patients who had the condition for at least 3 months. Those patients who had received acupuncture treatment previously were excluded. Both RA and SA groups included 14 patients. RA or SA was administered at 4LI (distal point) for 15 minutes. SA technique was a non-penetrating one. Outcome measurement was pain in a VAS before and after treatment.

Simma, *et al.* [44] presented a double-blinded RCT in which 23 MMMPS patients were allocated in 2 groups of treatment: RA (11 patients) and Laser SA (12 patients). RA treatment used 4 intraoral points (maxilla retromolar, mandible retromolar, maxilla vestibular and mandible vestibular) and 3 extraoral points (4LI, 2 SI and 3SI). Only one session was administered. Laser SA used a soft laser pen which had been inactivated. To make this placebo procedure appear real to the patient, visual and acoustic signals accompanied the red-light emission. Criteria of point selection were the same as in the RA group. The laser pen did not touch the skin but was held at a distance of about 0.5 - 1 cm. Outcome measures included pain in VAS and muscle tenderness. Muscle palpation included the following muscles and areas: atlanto-occipital junction, temporalis posterior muscle, muscles of the craniomandibular junction, pterigoid muscles, masseter muscles, digastric muscle and sternocleidomastoideus, bilaterally. Pain sensation at muscle palpation was rated on a four-point scale rising according to intensity from 0 to 3. These measurements were performed at the end of the session.

Katsoulis, *et al.* [45] selected 11 MMMPS patients who had the condition for at least 14 days and a pain intensity value of at least 30 mm in a VAS. Four patients chose RA treatment and the remaining 7 patients were randomly allocated into two groups: 3 to RA group and 4 to SA group. In both groups local and distal points were stimulated. Local points included 3S and 18SI. Distal points included 3SI and 4LI. RA treatment was administered during six sessions (twice a week, 3 weeks) and lasted 15 minutes. A needle was introduced 10 - 30 mm from the skin in each acupoint. Laser SA employed laser needles attached to the skin but without being activated. Outcome measures included pain in a VAS and pain measured in a verbal scale (no pain, mild pain, intense pain, severe pain). Relevant clinical response was considered as a pain decrease of at least 50% from de initial value or less than 30 mm in VAS. Outcome measures were assessed in weeks 1, 2 and 3 and 3 months after the end of the sessions.

Both La Touche, *et al.* [29] and Jung, *et al.* [30] systematic reviews reported the same limitations of the previous RCT: small

sample size and lack of follow up period. Except Katsoulis, *et al.* study [45], the rest of the RCTs evaluated the immediate effects of the treatments. Another noticeable limitation regards on the fact that some of the previous studies used only one acupoint, which is not the usual treatment regimen in acupuncture treatments.

Itoh, *et al.* [46] underwent a double-blinded RCT in 15 TMD patients with muscular or articular origin, who had the condition for at least 6 months. Seven patients were allocated in RA group and 8 patients in SA group. Patients who had received acupuncture treatment previously were excluded. RA treatment was performed needling trigger points situated in temporal, masseter, lateral pterygoid, digastric and sternocleidomastoideus muscles. The depth of the punctions was of 15 mm maximum. SA used non-penetrating needles. Both treatments were administered within 5 sessions (once a week, 5 weeks) and lasted 30 minutes. Outcome measures included pain in VAS and MMO. They were evaluated 10 weeks after the first session was performed.

The studies that used non penetrating techniques for SA treatments concluded that RA was significantly superior than SA. Only Goddard, *et al.* study [40] used a penetrating SA and did not find statistical differences between RA and SA, concluding that both of them resulted effective in decreasing pain intensity.

In acupuncture clinical research, it is difficult to draw a reliable conclusion due to lack of appropriate placebo. Of various placebo controls, "sham" procedure can be defined as one performed on a control group to ensure that they have the same experiences like real group subjects do. Therefore, a sham control method is more rigorous than other controls for identifying the specific effects of acupuncture especially in pain [47].

Conclusion

Based on this review, we can conclude that there is evidence that acupuncture is an effective and useful treatment for MMMPS. This conclusion is clearly limited due to the small sample sizes and the small number of included RCTs. Therefore, large-scale, rigorous studies with standardized treatment method in high quality, sham-controlled and blinded trials are needed to establish more enlightening and reliable results. It would seem the evidence is (1) limited in amount, (2) shows short-term benefit for acupuncture for TMD pain of muscular origin; (3) a lot more research is needed as to which points and/or combination of points to use and duration of efficacy of acupuncture.

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