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Oral acupuncture in the therapy of craniomandibular dysfunction syndrome – a randomized controlled trial (RCT)

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Einsatz von Mundakupunktur als Akuttherapie bei Störungen des Craniomandibulären Systems – eine randomisierte kontrollierte Studie

Zusammenfassung. *Einführung:* Patienten mit Störungen des stomatognathen Systems beschreiben als Hauptsymptome Schmerzen und Knackphänomene. Eine rasche Besserung des Schmerzes soll eine gute Patientencompliance sicherstellen.

Fragestellung: Ziel dieser Studie ist es, die Effekte von Akupunktur in der Akutbehandlung von Schmerzpatienten mit Störungen im craniomandibulären System im Vergleich zu einer Placebogruppe zu untersuchen, wobei die subjektive Schmerzintensität die Hauptzielgröße darstellt.

Design: Randomisierte, Placebo-kontrollierte Studie.

Patienten und Methoden: 23 Patienten mit Störungen des craniomandibulären Systems wurden ausgewählt und randomisiert den beiden Gruppen zugeteilt. Die eine Gruppe erhielt eine Akupunkturtherapie nach der Very Point-Methode, die andere eine Laserplacebotherapie. Vor und nach der Behandlung wurden bei beiden Gruppen folgende Befunde für den Befundenden verblindet erhoben: subjektiver Schmerz, Mundöffnung in mm und Druckdolenzen der Gesichts- und Nackenmuskulatur. Weiters wurden die Kiefergelenksbahnen mittels elektronischer Axiographie aufgezeichnet.

Ergebnisse: Die Verbesserungen des Schmerzscores (Skala 0–100) in der Akupunkturgruppe ($19{,}1 \pm 11{,}9$) waren gegenüber der Placebogruppe ($6{,}2 \pm 14{,}8$) signifikant ($p = 0{,}03$). Bei der Mundöffnung lässt sich ein Trend zur Verbesserung in der Akupunkturgruppe ($5{,}0 \pm 6{,}2$ mm) im Gegensatz zur Placebogruppe (1.0 ± 4.7 mm) erkennen, der aber nicht signifikant war ($p > 0{,}1$). Die Unterschiede der Druckdolenzen der Nacken- und Kaumuskulatur sind bei den meisten vor der Behandlung druckdolenten Muskeln in der Akupunkturgruppe signifikant ($p < 0{,}05$). Die Axiographiekurven wurden auf die Merkmale Qualität, Symmetrie und Charakteristik der Kurven ausgewertet. Es lassen sich bei Aufzeichnung der Öffnungs- und Schließbewegung in der Akupunkturgruppe vermehrt Verbesserungen in den Kurvenparametern im Vergleich zur Placebogruppe erkennen. Auch bei der Protrusions- und Retrusionsbewegung zeigen sich in der Akupunkturgruppe vermehrt Verbesserungen, allerdings sind diese nicht statistisch signifikant.

Konklusion: Aufgrund der Ergebnisse der vorliegenden Studie scheint die Akupunktur ein geeignetes Mittel zur Akuttherapie bei craniomandibulären Störungen zu sein, allerdings sollten weitere Studien mit größerer Patientenzahl und Untersuchungen der Langzeitwirkungen angeschlossen werden.

Summary. *Context:* Patients with disorders of the stomatognathic system describe pain and clicking phenomena as primary symptoms. Rapid improvement of the pain is required to ensure and maintain adequate patient compliance.

Objective: The study was intended to assess the effects of acupuncture in patients with temporomandibular disorders as compared to placebo therapy (sham laser); the primary target parameter was the subjective pain sensation.

Design: Randomized, placebo controlled trial.

Patients and methods: 23 patients were enrolled and randomly assigned to one of the two groups. One group received acupuncture treatment according to the very-point technique, the other group received sham laser treatment. The following observer-blinded findings were evaluated before and after treatment: subjective pain, mouth opening, and muscular tenderness and pain on pressure. In addition, mandibular joint movement pathways were recorded using electronic axiography.

Outcomes: Improvements in pain scores (scale: 0–100) in the acupuncture group (19.1 ± 11.9) were significant ($p = 0.03$) versus those in the placebo group (6.2 ± 14.8). Mouth opening showed an insignificant trend

towards improvement ($p > 0.1$) in the acupuncture (5.0 ± 6.2 mm) versus the placebo group (1.0 ± 4.7 mm), differences in tenderness and pain on pressure in neck and masticatory muscles were significant ($p < 0{,}05$) for most of the muscles having shown pretreatment tenderness/pain. The axiographic tracings were assessed for quality, symmetry and curve characteristics. Recordings of the opening and closing movement in the acupuncture group showed an increased frequency of improvements of curve characteristics as compared to the placebo group. The acupuncture group also showed an increased frequency of improvement in protrusion and retrusion movements though no statistical significance could be obtained.

Conclusion: Based on the results of the present study, acupuncture may be recommended as acute treatment of craniomandibular disorders, but studies with larger numbers of patients as well as about long term treatment outcomes should be conducted.

Key words: Temporomandibular disorders, VAS facial pain rating, acupuncture, randomized controlled study, placebo.

Introduction

Patients with disorders of the stomatognathic system often describe pain and clicking phenomena in the temporomandibular joints (TMJ) as primary symptoms. Other symptoms frequently reported include problems with neck and masticatory muscles, restricted range of jaw motion, parafunction, headache and tinnitus [1, 2]. Psychological factors – in particular (failure of) coping with stress – also play a major role [3, 4].

Pain in the craniomandibular system may originate in the jaw musculature, in the temporomandibular joint or in both though muscular causes appear to predominate [4, 5]. Use of splint therapy as well as physiotherapy have proven effective in treating this type of pain [6–11].

Pain frequently radiates into the jaws or the ears; thus, patients sometimes only attend an outpatient unit for dysfunction after having consulted various specialists. It is especially in such cases that rapid improvement of the complaints (in particular, relief of pain and improvement of a potential restriction of mouth opening) is required to ensure and maintain adequate patient compliance. Rapid treatment is also critical for avoiding a potential chronification of pain [12, 13].

Over recent decades the use of complementary and alternative medicine has become increasingly popular in western industrial societies [14]. In a study evaluating anthroposophic vs. conventional therapy of acute respiratory and ear infections 70% consulted an anthroposophic physician [15]. However, there are few randomized/controlled clinical trials evaluating these alternative methods [16]. Patients with osteoarthritic problems showed improvements under acupuncture treatment or pulsed magnetic field therapy [17, 18].

Acupuncture has been used in Chinese medicine for over 3000 years. It involves inserting needles into so-called acupuncture points. Today, this technique has been further developed (electroacupuncture, laser acupuncture). Treatment of pain certainly is one of the primary indications of acupuncture. Though controversial reports and discussions of the effects of acupuncture in patients with temporomandibular disorders can be found in literature, its positive effects have been confirmed in most of the cases [19–28].

The very-point technique has been described by Gleditsch [29–33]. It involves dabbing the needle very gently across the area of the acupuncture point so that slight contact stimuli are evoked. If the very point is hit, the patient experiences an electrifying sensation (dechi) which is signaled by mimics, and in many cases also verbally; the needle is then inserted at exactly this point. The appropriate area or zone is located by diagnostic palpation.

The study was intended to evaluate the effects of acupuncture with the very-point technique in the acute treatment of pain in patients with disorders of the craniomandibular system as compared with a placebo therapy.

Patients and methods

Patients

Between Nov 2001 and June 2003 female patients with TMJ pain and tenderness on pressure of the craniomandibular musculature were offered to participate in the study. Exclusion criteria: Patients with crepitation noises suggesting arthrotic changes and pretreated patients. Twenty-six female patients with disorders of the craniomandibular system attending the Outpatient Unit for Dysfunction at the University Clinic of Dentistry were enrolled. Three patients did not appear at the arranged date and were excluded (Fig. 1). Prior to randomization of the patient, the patient's general medical and dental history was obtained. Subjective pain was assessed using a visual analog scale (VAS). In addition, neurological status (trigger points cranial nerve V, ocular motor function and sensitivity cranial nerve VII), muscle status, clicking phenomena, dental class and mouth opening (interincisal distance) in mm were evaluated.

Randomization

A randomization list applying blocks of 10 was prepared. For each list entry the respective treatment (acupuncture or placebo) was written on a card and put into an opaque envelope numbered consecutively and sealed. After enrollment of a patient the envelope was opened and the respective therapy assigned.

Therapy

Patients were blinded for treatment. Before randomization they were told that therapy might be a sham treatment. The patients were randomized into one of 2 groups: group 1 (acupuncture group) received treatment by needle acupuncture, group 2 (placebo group) received a placebo treatment with sham laser acupuncture. For the needle acupuncture, the painful points were selected from the following points by very-point method after palpation: Intraoral: Maxilla retromolar, Mandible retromolar, Maxilla – vestibulum and Mandible – vestibulum; extraoral: large intestine 4, small intestine 2 and 3 (hand), ear and sternum. The intraoral points were infiltrated with insulin syringes 0.33 mm (BD® microfine 1 ml) with 0.5 ml procaine (Röwo®), while the extraoral points were punctured with acupuncture needles (Seirin® B-type needle No 3 or No 8). The needles remained in situ for about 20 minutes.

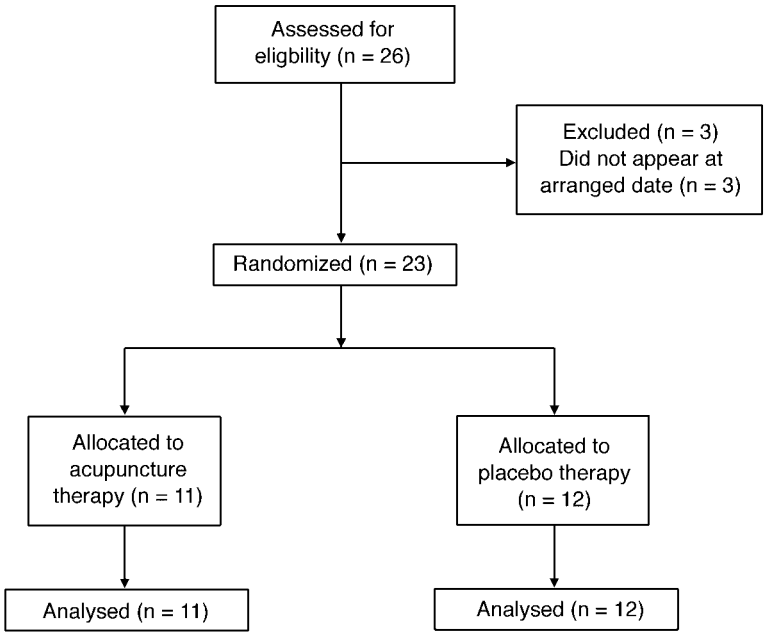

Fig. 1. Trial profile

In the placebo group, therapist and patients had to wear protective goggles and the laserlight was demonstrated before placebo treatment. After palpation the laser (Minilaser 2000 Helbo®) was placed on various randomly selected points (small intestine 2 and 3, ear and Maxilla and Mandible retromolar) without contact and without being activated. The patient was encouraged to count the time (15s) when the laser was in place and had no possibility to see the "treated points". This sham treatment was also maintained for 20 minutes.

Both, acupuncture and placebo treatment was performed at the University Clinic of Dentistry, Vienna by a doctor of dentistry and otolaryngology specialized in pain therapy (J.G.).

Outcome measures

The assessments before and after therapy was done by a dentist specialized in diagnostics of craniomandibular dysfunction syndrome (M.S-S, E.P, A.S, M.S). Personnel doing the assessment was blinded for treatment. Before and after treatment the following findings were evaluated for the patients in both groups: subjective pain using a visual analog scale (VAS) with the endpoints "no pain" and "worst pain imaginable" (Scale: 0–100), mouth opening in mm (interincisal distance) and muscle status. For the latter, the muscle was palpated bilaterally by the examiner and the patient indicated whether the pressure was stronger or more unpleasant on one side, whether he/she felt pain and whether the pressure caused the same kind of pain the patient also felt usually ("destruction pain"). The values obtained were entered into a table [lateral difference +(1), tenderness/pain on pressure ++(2), and spontaneous destruction pain +++(3)].

In addition, electronic axiography (Gamma®) was performed. A conventional double face-bow system is attached to the patient. The mandibular bow is used for transmitting hinge axe movements of the mandible to the upper face-bow. The upper bow carries sagitally mounted flags, that are used in the electronic registration of hinge axis movement. This permits the recording of hinge axis translation for all mandibular kinetics in two dimensions. In case of asymmetrical movement, the recording styli deviate corresponding to the individual lateral shift of the mandible. Opening and closing movement, protrusion and retrusion as well as lateral movements to both sides were recorded. Measurements of these parameters were obtained in observer-blinded fashion. The axiographic curves were evaluated for quality (good, moderate, poor), symmetry (good, moderate, poor) and curve characteristics (cranially concave, cranially convex, linear). Unchanged persistence of the characteristics or deterioration post therapy were evaluated as "not improved". A curve was considered as "improved", if several criteria showed an improvement or at least one criterion was improved and the remaining criteria were unchanged.

Statistical evaluation

The primary target parameter was the subjective pain sensation (VAS), secondary target parameters included maximum mouth opening and characteristics, symmetry and quality of axiographic pathways and muscle pain on palpation. Acupuncture and sham treated groups were compared by Mann-Whitney U tests. Differences between groups in axiographic findings were tested by one-sided Fisher's exact probability test. A p-value below 0.05 was considered significant, a p-value below 0.1 as statistical tendency. No correction for multiple testing was applied.

Results

The 23 female patients evaluated were between 17 and 68 years of age, with an average age of 35 ± 14 (17–59) years in the acupuncture group (11 patients) and 40 ± 14 (23–68) years in the placebo group (12 patients). The age difference between the two groups was not statistically significant.

Evaluation of the average pain score in the visual analog scale showed a significantly higher reduction of subjective pain in the acupuncture group as compared to the placebo group although neither the pretreatment nor the post-treatment values were statistically different (Table 1).

Table 1. Mean values and standard deviations, medians and quartile ranges of pain sensation on the visual analog scale (VAS, scale 0–100) and of mouth opening (MO) in mm before and after therapy in the acupuncture and placebo group. P-values from Mann-Whitney U-tests

	Acupuncture group mean ± s.d	Acupuncture group Md (QR)	Placebo group mean ± s.d	Placebo group Md (QR)	p-value
VAS before therapy	44.0 ± 23.3	40 (34)	34.1 ± 22.7	35 (32)	0.231
VAS after therapy	24.9 ± 22.2	16 (36)	27.8 ± 16.2	30 (29)	0.751
VAS Improvement before/after	19.1 ± 11.9	17 (10)	6.2 ± 14.8	6 (12)	0.033
MO before therapy	40.4 ± 9.6	40 (13)	36.2 ± 11.7	33 (14)	0.316
MO after therapy	45.4 ± 7.6	45 (12)	37.2 ± 12.1	37 (9)	0.091
MO Improvement before/after	5.0 ± 6.2	4 (6)	1.0 ± 4.7	1 (3)	0.114

For mouth opening a tendency towards an improvement in the acupuncture groups was seen (Table 1). In the acupuncture group, none of the patients showed a deterioration of the interincisal distance, while mouth opening after placebo therapy was reduced in two patients. Considering only those patients with restricted mouth opening prior to therapy, the difference between the two groups reached statistical significance ($p = 0.037$).

Evaluation of muscle status shows a non-significant difference between the two groups for the M. infrahyoideus, a trend towards a difference for the M. temporalis anterior and posterior and for the M. omohyoideus; for all other muscles exhibiting tenderness on pressure before treatment a significant difference between the improvement in the acupuncture as compared to the placebo group was found (Table 2). In the acupuncture group all muscles showed improvement after therapy, in the placebo group six muscles showed increased tendenderness on pressure after placebo treatment.

The recordings of opening and closing movements by axiography showed an increased frequency of improvements in curve characteristics in the acupuncture (8 curves improved, 2 curves not improved) versus the placebo group (4 curves improved, 6 not improved). Fisher's exact p test showed a tendency ($p = 0.0849$). Protrusion and retrusion movements also showed an increased frequency of improvements in the acupuncture group (6 cases with improvement versus 4 cases with improvement in the placebo group), but without reaching statistical significance ($p = 0.3281$).

There were no complications or adverse reactions during the treatment in both groups.

Table 2. Evaluation of muscular pressure points before and after therapy in the acupuncture and placebo group. The values listed represent means and standard deviations of the combined four point score for the left and right side. Determination of significance of the difference between acupuncture and placebo group with regard to improvements of tenderness on pressure was done using the Mann-Whitney U-test

	Acupuncture before therapy	Acupuncture after therapy	Placebo before therapy	Placebo after therapy	Significance (p =)
Shoulder and neck muscles	1.64 ± 0.67	0.73 ± 0.65	0.92 ± 1.00	0.88 ± 0.93	0.000503
Atlanto-occipital joints	0.73 ± 0.85	0.18 ± 0.40	0.42 ± 0.93	0.54 ± 0.86	0.031839
M. temp. pars anterior	0.41 ± 0.80	0	0.33 ± 0.62	0.33 ± 0.62	0.058325
M. temp. pars intermed.	0.32 ± 0.64	0	0.08 ± 0.19	0	0.441868
M. temp. pars posterior	0.36 ± 0.64	0.18 ± 0.60	0.25 ± 0.58	0.25 ± 0.58	0.058325
M. mass. pars superior	1.81 ± 0.51	0.68 ± 0.68	0.96 ± 0.86	0.96 ± 0.96	0.003077
M. mass. pars profunda	2.05 ± 0.52	0.32 ± 0.51	1.08 ± 0.90	0.92 ± 1.02	0.000120
M. pteryg. lat.	1.91 ± 1.04	1.23 ± 0.93	1.21 ± 0.99	1.17 ± 0.96	0.037692
M. pteryg. med.	2.18 ± 0.40	0.77 ± 0.82	1.58 ± 0.85	1.50 ± 0.71	0.002356
M. mylohyoideus	0.41 ± 0.74	0.09 ± 0.30	0.13 ± 0.31	0.08 ± 0.29	0.430197
M. digastricus	1.2 ± 0.90	0.55 ± 0.85	0.83 ± 1.03	1.17 ± 1.11	0.005593
M. suprahyoideus	0	0	0	0.04 ± 0.14	1.0
M. infrahyoideus	0.18 ± 0.60	0.09 ± 0.30	0.17 ± 0.58	0	0.949771
M. sterno-cleido-mastoideus	0.95 ± 0.88	0.05 ± 0.15	0.42 ± 0.70	0.54 ± 0.81	0.009150
M. omohyoideus	0.45 ± 0.72	0.09 ± 0.30	0.33 ± 0.78	0.50 ± 0.80	0.066343
TMJ lat. pole static	1.36 ± 0.98	0.45 ± 0.42	0.75 ± 0.69	0.67 ± 0.62	0.002356
TMJ lat. pole with rotation	1.86 ± 0.90	0.55 ± 0.47	0.88 ± 0.91	0.79 ± 0.72	0.001225
Retral joint space	1.91 ± 1.09	0.77 ± 0.85	0.79 ± 0.92	0.75 ± 0.94	0.000479
Lig. temporo-mandibulare	1.36 ± 1.05	0.23 ± 0.34	0.42 ± 0.76	0.63 ± 0.80	0.001341

Discussion

In both groups pain score and mouth opening improved, but the improvements in the acupuncture group were more pronounced (significant for VAS) than in the placebo group. Differences in muscle tenderness were significant in most of the tested muscles.

Craniomandibular dysfunction syndrome is frequently encountered in clinical practice of orofacial dentistry. According to Diedrichs und Bockholt, it ranks third in frequency among orofacial disorders [34]. Predominance of female gender among patients with craniomandibular problems is a well-known phenomenon with some authors describing a percentage of more than 80% [35, 36]. In this study only female patients were enrolled. Average age of 35–40 years is close to the results of other authors [24, 36].

The primary objective of this study was to assess the effect of acupuncture as acute therapy for patients with disorders of the craniomandibular system in a randomized controlled trial. Pain being frequently accompanied by a restriction of mouth opening is associated with an impairment of the quality of life. We used a visual analog scale to assess the subjective pain sensation of the patient. The scale utilizes various color indexes for the patient's assessment and numerical values (1–100) for the physician. This will avoid a conscious change or recollection of the numerical value by the patient in repeated measurements [6, 24]. The improvement of pain after acupuncture treatment correlates with the findings of other investigations [20, 21, 24, 25].

While assessment of pain on a visual analog scale represents a purely subjective parameter and the assessment of pain/tenderness of musculature on pressure also relates to a subjective experience of the patient, mouth opening and axiographic curves are objective parameters [37, 38].

Improvement of mouth opening showed overall an insignificantly higher improvement after acupuncture; however, in patients with restricted mouth opening prior to treatment significance was obtained, which is of particular clinical significance regarding the taking of impressions for a splint therapy.

Imaging of the pathways of the temporomandibular joint using electronic axiography is well suitable as part of a more detailed diagnostic evaluation of the temporomandibular joint [39, 40]. It are especially electronic recordings that allow for excellent assessment of the quality, but also of the characteristics of the curve shape. For the evaluation of quality jaggedness and congruence of excursion and incursion pathway are assessed. Pain and muscular problems may result in vacillation of the curve [41]. The curve characteristics may include curves being cranially concave, cranially convex or linear with a cranially concave one representing the normal characteristics. For the assessment of symmetry, curves of the left and those of the right side are compared [41].

As a notable result of this study the opening and closing movements showed a tendency towards an improvement in the acupuncture group, while no statistical significance was seen for the improvements of protrusion and retrusion movements. This may be due to the fact that opening and closing movements primarily take place in the lower joint space and therefore are mainly muscle-controlled, while protrusion and retrusion movements mainly take place in the upper joint space and are therefore determined to a larger extent by joint morphology.

Several reports in literature have confirmed the effectiveness of acupuncture in the treatment of patients with temporomandibular joint disorders [20, 22, 24, 42, 43]. Some reports compared the effectiveness of acupuncture therapy with that of other established therapies [24, 42], while others evaluated its effectiveness in comparison with a placebo group [23]. When using needle acupuncture in non-acupuncture points as placebo therapy, the differences between acupuncture and placebo group are not significant [18]. In our study, a sham laser acupuncture was used as placebo treatment. This type of placebo acupuncture has also been recommended by other authors [44, 45]. Placebo needle acupuncture may already induce effects by mechanical stimulation [19] which may be avoided with sham laser acupuncture. Nevertheless, slight improvements for all muscles were also seen in the placebo group. This could be explained by the palpatory examination of musculature since acupressure has also been shown to be effective for the treatment of pain in the craniomandibular system [46]. The effects of the intraoral acupuncture with application of local anesthetics may be comparable to trigger point reactions. In contrast to trigger point injections only small amount of anesthetics were applied (0,5 ml) and it is very important to find the exact point using the very point method [29–33].

In the present study, statistically significant improvements for the acupuncture group versus the placebo group were seen for the parameters of subjective pain and tenderness/pain on palpation for most muscles examined. The objective parameters of mouth opening, quality, characteristics and symmetry of the axiographic curves for opening and closure movements showed a statistical tendency towards improvement, while improvements for protrusion and retrusion curves were without statistical significance. A shortcoming of the present investigation were the somewhat higher pain scores and the higher intensity of pain on muscle palpation in the acupuncture group prior to therapy. Part of the difference in improvements observed between acupuncture and placebo group may be due to these differences in initial values. However, mouth opening was initially slightly better in the acupuncture group and axiographic findings were about equal and still these endpoints indicated similar improvements.

Conclusion

Based on the results of the present study, which evaluated only the immediate effects of acupuncture therapy on pain, jaw movements and muscle tenderness, acupuncture may be recommended as acute treatment of craniomandibular disorders, but studies with higher numbers of patients are needed to investigate long term treatment outcomes.

Acknowledgement

This study has been approved by the Ethics Committee of the Medical School of the University of Vienna and the General Hospital of the City of Vienna (No.: 427/2001).

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