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Integrative Medicine Research

journal homepage: www.imr-journal.com

Original Article

Adjacent, distal, or combination of point-selective effects of acupuncture on temporomandibular joint disorders: A randomized, single-blind, assessor-blind controlled trial

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ARTICLE INFO

Article history:
Received 18 September 2012
Received in revised form
26 September 2012
Accepted 30 September 2012
Available online 17 October 2012

Keywords:
acupuncture
adjacent points
distant points
point-selective effect
temporomandibular disorders

ABSTRACT

Background: The objectives of this study were to compare the efficacy of acupuncture among different types and to evaluate point-selective pain relief effects between selected adjacent or distant points in participants with temporomandibular joint disorders (TMDs).
Methods: Forty-two participants were randomly allocated to three groups: an adjacent point selection group (Trt, $n = 14$), a distant point selection group (Con1, $n = 14$), or a combination group (Con2, $n = 14$). All three groups received a total of six acupuncture sessions (twice a week for 3 weeks), the outcomes being assessed pain intensity using a 10-cm visual analogue scale, and the palpation index of the muscle and temporomandibular joint every week of treatment and 4 weeks after the end of treatment.
Results: The pain intensity was reduced in the Trt (34%), Con1 (31%), and Con2 (36%) groups after 3 weeks compared with each group's baseline, with no significant difference among the three groups ($p = 0.5867$). Similarly, the palpation index was decreased by 52% (Trt), 62% (Con1), and 50% (Con2) after 3 weeks of treatment, but no significant differences between groups were shown ($p = 0.3289$).
Conclusion: Our results suggest that point-selective effects among adjacent, distal, or a combination of acupoints are hardly associated with pain intensity or palpation index in participants with TMDs. Larger sample size trials are required to overcome the shortcomings of the study.

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http://dx.doi.org/10.1016/j.imr.2012.09.004

1. Introduction

Temporomandibular joint disorders (TMDs) are defined as a subgroup of craniofacial pain symptoms that involve the temporomandibular joint (TMJ), masticatory muscles, and associated musculoskeletal structures of the head and neck.[1] A variety of symptoms, such as pain around the affected joint and soft tissues, tinnitus, dizziness, neck pain, and headache, can decrease the quality of life of patients with TMD,[1,2] especially in patients with a chronic history of refractory pain and psychological symptoms. Approximately one-third of adults are affected by symptomatic TMD.[1,3] The current treatment options include analgesics, physiotherapy, antidepressants, occlusal adjustment, stabilization splints, arthrocentesis and lavage, and TMJ surgery. However, there is insufficient evidence to support the use of most of these interventions in TMD.[4–7]

Acupuncture has been used for relieving pain in various conditions. One of the main issues in acupuncture research is that acupuncture treatment techniques, such as the frequency of acupuncture administration and the rationale of point selection, must be validated in clinical trials. Previous randomized controlled trials (RCTs) for chronic neck pain and tension-type headache have reported that different acupuncture points have different clinical effects.[8–10] A previous review of RCTs of acupuncture for TMD provided details of a suggested acupuncture regimen to provide an optimal effect.[11] Additionally, clinicians select adjacent acupoints, generally called "Ashi" points, or choose distal points for treating TMD, but no studies showing which treatment method is better have been identified. Therefore we aimed to examine whether selecting different acupuncture regimens (adjacent points vs. distant points vs. a combination) affected the pain intensity and palpation index (PI) in participants with TMD.

2. Methods

2.1. Design, ethics, and randomization

A randomized, participant-blind, assessor-blind, controlled trial was carried out at the clinical research center of the Korea Institute of Oriental Medicine from July 31, 2006 to September 27, 2006. The study was approved by the institutional review board of the Dunsan Oriental Medical Hospital of Daejeon University in South Korea. After baseline assessment, eligible participants were randomly allocated to one of three groups: one group received adjacent-point acupuncture (Trt), one group received distant-point acupuncture (Con1), and the other group received combined acupuncture of an adjacent and a distant point (Con2). For assignment to the groups, random numbers were generated by the clinical statistician with a ratio of 1:1:1 (Trt:Con1:Con2) using the SAS statistical package (version 9.1.3; SAS Institute Inc., Cary, NC, USA). The study protocol was registered at the Clinical Research Information Service (registration number: KCT0000269).

2.2. Blinding

Only the doctors who performed the treatment were aware of the group assignment of each participant. In addition, the outcome assessors were blind to the group allocation and not involved in providing the intervention.

2.3. Participants

Participants were recruited through newspaper advertisements, signs posted at the university-affiliated hospital, university libraries, apartment entrances, and presentations at community meetings. Potential participants were told that they had an equal chance to be assigned to one of three active acupuncture interventions. Written informed consent reviewed by the institutional review board was obtained before randomization from each participant if they agreed with participation.

The participants for potential eligibility were men and women aged between 18 and 71 years who had no other medical co-morbidities except for unilateral or bilateral TMD. Participants with TMD were diagnosed following the Research Diagnostic Criteria for TMD and were required to have an Axis I, Group I diagnosis. Participants were to have no contraindications to acupuncture treatment. No restrictions were placed on the duration of symptoms.

The exclusion criteria were previous surgery on the TMJ, a history of rheumatoid disease or degenerative arthritis, extensive anatomical destruction or deterioration of the TMJ, pain of neuropathic or odontogenic origin, patients who were planning to become pregnant within the next 3 months, and patients whose TMD had been caused by non-mechanical or psychological factors. Additionally, participants were excluded if they scored less than 4 points (or 4 cm) on the Temporomandibular Function scale and on the visual analogue scale (VAS).

2.4. Interventions

All treatments were performed by two qualified, experienced acupuncture practitioners who had at least 6 years of training in acupuncture and were licensed as Oriental medicine doctors in South Korea.

In this study, standardized fixed acupuncture points with manual stimulation were adopted for each group. All the classic acupuncture points were located according to the World Health Organization/Western Pacific Regional Office standard acupuncture point locations. For the adjacent point treatment group (Trt), we selected points that were located on the same side as the pain, close to the affected side of the TMD: TE17, GB20, ST7, ST6, SI19, and EX21, with 1.5–3 cm depths.

Sterile, single-use, 40 mm × 0.30 mm stainless steel acupuncture needles (Dongbang Co, Boryeong, Korea) were inserted at the six points and the "*deqi*" sensation was evoked by rotating each needle 10 times manually, being confirmed by the participant's response. The needles were then connected to an electric stimulator (PG 306; Suzuki Ltd, Tokyo, Japan) using crocodile clips. A continuous wave of alternating current with a frequency of 2 Hz was applied to the acupuncture needle for 15 ± 3 minutes per session. An infrared light (IRH-3100; Wonhyo Ltd. Seoul, Korea) was then applied above the participant's abdominal area.

In the distant point control group (Con1), all of the processes were same as in the Trt group, except for point

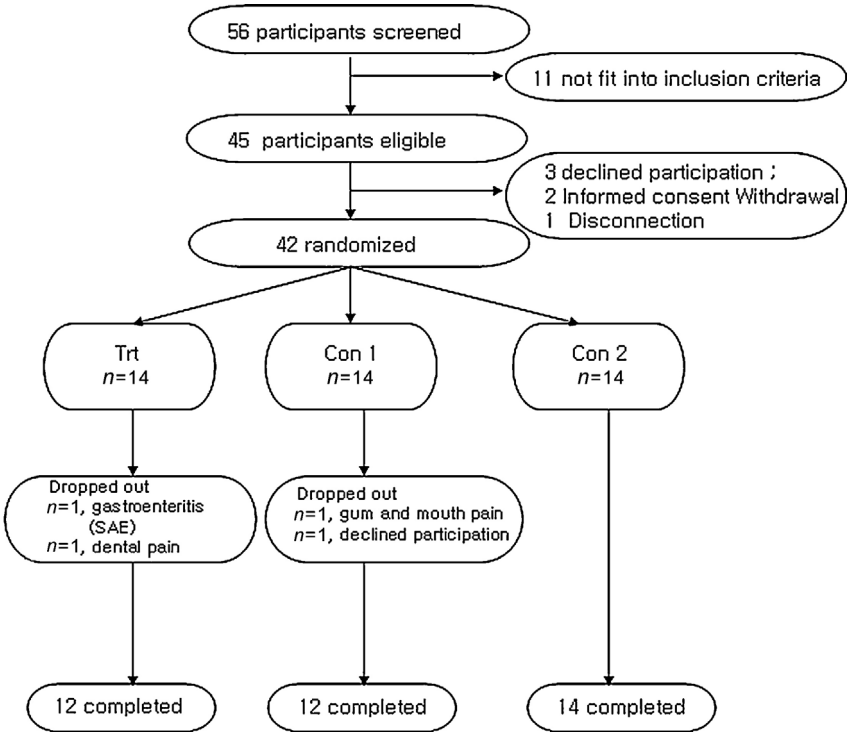

Fig. 1 – Study design and the flow of participants.

selection. We needled only acupoints that were distant from the affected joints: ipsilateral acupuncture (LI4 and SI3) and contralateral acupoints (ST36, BL60, TE5 and GB41). In the combination control group (Con2), six different adjacent and distant points were selected, as previously described: TE17, GB20, ST7 from the adjacent points and ST6, LI4, ST36 from the distant points, in order to use same number of acupuncture points.[12] The treatment strategies for each group were based upon recommendations in the study by Rosted et al[11] and an expert committee.

2.5. *Outcome measures*

The primary outcome was the change in TMD-related pain intensity on a VAS of 0 cm (no pain) to 10 cm (the maximum pain imaginable) at every week during treatment and at 4 weeks follow-up after the acupuncture treatment.

The secondary outcome was the objective severity of TMD problems as measured by the muscle and TMJ PI of the Craniomandibular Index (CMI), which was developed as a clinical method of evaluating TMJ function.[13] The muscle and TMJ PI consists of four different items: extraoral palpation (18/18), intraoral palpation (6/6), neck palpation (12/12), and TMJ palpation (6/6). The total score was the sum of the four scores and ranges from 0 to 42 points.

All adverse events were observed related or not related to acupuncture treatment during the study. All the possible adverse events were reported by the participants or observed by the researchers.

2.6. *Statistical analyses*

Analyses were performed with the "intention to treat" method, including all participants who were randomized (missing data were coded using the last observation carried forward). Analysis of variance was used to test baseline differences among the three groups. We conducted analysis of covariance (ANCOVA) to evaluate the effect of treatments on the mean changes in scores between baseline and Week 3 for all of the continuous variables. Baseline values were used as covariance for ANCOVA in each analysis. Statistical analyses were performed using the SAS statistical package, and the level of significance was established at $p < 0.05$. As this was a pilot trial to evaluate the applicability and validity of the study design, the smallest number of required participants (14 for each group) was considered without sample size estimation.

3. Results

3.1. *Participants*

Fifty-six individuals were assessed for eligibility, 42 participants meeting the eligibility criteria. Each participant was randomly allocated into the Trt group ($n = 14$), the Con1 group ($n = 14$), or the Con2 group ($n = 14$). Of the participants, 38 completed all the weeks of treatment and were followed-up at 4 weeks after the end of treatment (Fig. 1). Three participants discontinued the treatment due to adverse events, and one declined to participate in the study (Fig. 1). There were no significant baseline differences in age, TMD duration, or TMD severity as assessed by VAS (all $p > 0.05$; Table 1), but a significant baseline difference in sex between the three groups was shown ($p = 0.0207$; Table 1).

3.2. *Pain intensity of TMD using the VAS*

Compared with baseline, pain intensity was significantly reduced as 34% ($p < 0.05$, Trt group), 31% ($p < 0.05$, Con1), and

Table 1 – Baseline characteristics of participants.

Characteristics	Trt ($n=14$)	Con1 ($n=14$)	Con2 ($n=14$)	p
Age (y)*	31.43 ± 12.48	32.14 ± 18.96	30.14 ± 11.41	0.9780
Sex (M/F)‡	9/5	14/0	8/6	0.0207
TMD duration (mo)†	1.54 ± 2.37	8.03 ± 10.61	10.79 ± 24.27	0.6405
TMD severity (VAS)*	5.57 ± 1.70	5.57 ± 1.87	5.07 ± 1.98	0.7138

All continuous values are expressed as the means ± SD.
* Analysis of variance was used.
† Kruscal-Wallis test was used.
‡ Chi-squared test was used.
Con1, distant point selection group; Con2, combination-point selection group; Trt, adjacent point selection group; VAS, visual analogue scale.

Table 2 – Outcome measures for acupuncture treatment in the three groups.

Outcome		Acupuncture regimen			
		Trt	Con 1	Con 2	p
VAS*,†	Baseline	5.57 ± 1.70	5.57 ± 1.87	5.07 ± 1.98	0.7138
	Visit 5 (2 wks)	3.83 ± 1.95	4.21 ± 1.93	3.75 ± 1.42	0.6151
	Visit 7 (3 wks)	3.67 ± 2.02	3.85 ± 2.61	3.25 ± 1.48	0.5867
	Visit 8 (7 wks)	3.91 ± 1.30	4.29 ± 2.09	3.00 ± 1.95	0.2991
TMJ*	Baseline	12.21 ± 6.70	13.71 ± 7.31	13.21 ± 5.70	0.8300
	Visit 2	9.86 ± 5.90	9.57 ± 5.14	11.50 ± 5.61	0.6449
	Visit 7 (3 wks)	5.92 ± 3.82	5.15 ± 5.18	6.58 ± 5.62	0.3289
	Visit 8 (7 wks)	5.42 ± 4.27	4.43 ± 5.21	7.17 ± 6.38	0.7633

* Analysis of covariance adjusted by the baseline values was used.
† 10 cm VAS.
Con1, distant-point selection group; Con2, combination-point selection group; TMJ, muscle and TMJ palpation index; Trt, adjacent-point selection group; VAS, visual analogue scale.

Table 3 – Muscle and Temporomandibular Joint Palpation Index subscores.

Visit (wk)	Items	Trt	Con 1	Con 2	p*
Visit 7 (3)	Extraoral palpation	1.83 ± 2.12	2.33 ± 2.42	1.31 ± 1.93	0.0602
	Intraoral palpation	1.50 ± 1.09	1.58 ± 1.44	0.77 ± 0.93	0.4577
	Neck muscle palpation	1.75 ± 1.36	2.08 ± 2.39	2.15 ± 2.38	0.5578
	TMJ palpation	0.83 ± 1.34	0.58 ± 1.00	0.92 ± 1.12	0.2572
Visit 8 (7)	Extraoral palpation	1.92 ± 2.07	1.17 ± 2.21	1.07 ± 1.64	0.0508
	Intraoral palpation	1.25 ± 1.22	1.67 ± 1.37	1.14 ± 0.86	0.8468
	Neck muscle palpation	1.50 ± 1.57	2.50 ± 2.50	1.57 ± 2.24	0.3311
	TMJ palpation	0.75 ± 0.97	0.83 ± 1.40	0.64 ± 0.93	0.1561

* Analysis of covariance adjusted by the baseline values was used.
Con1, distant point selection group; Con2, combination point selection group; Trt, adjacent point selection group.

36% ($p<0.05$, Con2) groups after 3 weeks. However, no significant group difference was shown among the three groups ($p=0.5867$; Table 2).

3.3. *Muscle and TMJ palpation index*

There were no significant baseline differences in the scores from the muscle and TMJ PI ($p=0.8300$; Table 2). From baseline to the third week after treatment, scores on the muscle and TMJ PI decreased by 52% (Trt), 62% (Con1), and 50% (Con2), while there was no significant difference among three groups at 3 weeks' treatment or at 4 weeks of follow-up (Table 2). Also, no significant group difference in TMJ PI subscores was shown among the three groups at 3 weeks' treatment or at 4 weeks of follow-up (Table 3).

3.4. *Safety*

During the study, three participants discontinued participation because of gastroenteritis or dental, and gum and mouth pain. The participant with gastroenteritis required hospital admission due to the severity of the symptoms. One case of dental pain and one case of gum and mouth pain were observed in the adjacent-point acupuncture group and combination treatment group, respectively, suggesting that needle placement in this area may cause dental or mouth pain. However, the episode of gastroenteritis is not likely to have been caused by the acupuncture treatment.

4. Discussion

Our study tested whether there were point-selective effects of acupuncture treatment among adjacent, distal, or combination acupuncture in participants with TMD. Although each group showed a significant improvement in patient-reported pain after the acupuncture treatment, no significant differences were observed among the three groups. From this result, it seems that there is no difference in the effect of

acupoint selection among adjacent-point, distal-point, and combination acupuncture in participants with TMD. However, acupuncture itself might be an effective intervention with comparatively good safety. Adjacent, distal, and a combination of points in our study had similar effect sizes of 1.06, 1.28, and 0.62, respectively, meaning that the effect size of acupuncture on pain was higher than that of occlusal splint therapy (effect size = 0.44).[14] From this pilot study, different types of acupuncture treatment can be suitable for patients with TMD. Future clinical trials with an adequate sample size might suggest how different types of acupuncture contribute to the treatment effect in TMD.

Even though we were not able to show a statistically significant improvement in the VAS and muscle TMJ PI scores among three groups, subscores such as extraoral palpation at Visits 7 and 8 showed a marginal effect in favor of the adjacent and combination regimens compared with the distant regimen. Considering the comparatively small size of this trial, this result might be different in a trial with a larger sample size.[15] Additionally, one of the strengths of this study is the presence of a combination group for comparing the effects of different regimens. Many acupuncture practitioners prefer using a combination of adjacent and distal points to using only a single adjacent or distal point. To the best of our knowledge, this study is the first RCT to compare the several different acupuncture point selections for treating TMD and may be a model for designing future trials to answer novel clinical questions on acupuncture regimens.

This study, however, has several limitations. The first is that the sample size may have been too small to fully evaluate the treatment effect. Originally, this trial was designed as a pilot study to test the feasibility of acupuncture treatment for TMD. This study will provide basic information for the estimation of sample size for future trials.

The second problem was the comparatively short treatment and follow-up duration. Generally, at least 3 months of follow-up are required to evaluate symptom reduction in TMD.[14,16]

The third limitation was the lack of allocation concealment, possibly leading to bias related to foreknowledge of the treatment assignment. Additionally, because there was no placebo arm, we cannot exclude the possibility that the improvement resulted from the natural course of disease or regression to the mean. However, one rigorous systematic review on acupuncture for TMD suggested that acupuncture shows a greater effect on TMD pain reduction than does a sham acupuncture control.[17] The methodological flaws, however, prevent this trial from providing conclusive results that could add evidence on the choice of acupuncture points in the treatment of TMD.

In conclusion, our results suggest that adjacent-point, distal-point, and combination acupuncture show similar effects on pain intensity and muscle and TMJ PI. Future randomized studies with larger sample sizes are needed to verify the point-specific effects of acupuncture in TMD.

Conflict of interest

None of the authors has a financial relationship with a commercial entity that has an interest in the subject of this manuscript.

Acknowledgements

This study was supported by the Development of Acupuncture, Moxibustion and Meridian Standard Health Technology Project (K11010) of the Korea Institute of Oriental Medicine.

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