JOURNAL OF DENTISTRY 39 (2011) 341–350

available at www.sciencedirect.com

ScienceDirect

journal homepage: www.intl.elsevierhealth.com/journals/jden

Review

Acupuncture for treating temporomandibular joint disorders: A systematic review and meta-analysis of randomized, sham-controlled trials

Aram Jung [a], *Byung-Cheul Shin* [a,*], *Myeong Soo Lee* [b], *Hoseob Sim* [a], *Edzard Ernst* [c]

[a] *School of Korean Medicine, Pusan National University, Yangsan, South Korea*
[b] *Brain Disease Research Centre, Korea Institute of Oriental Medicine, Daejeon, South Korea*
[c] *Complementary Medicine, Peninsula Medical School, Universities of Exeter, Exeter, UK*

ARTICLE INFO

Article history:
Received 31 October 2010
Received in revised form
13 February 2011
Accepted 21 February 2011

Keywords:
Acupuncture
Temporomandibular joint disorder
Pain
Systematic review
Meta-analysis

ABSTRACT

Objective: The aim of this article was to assess the clinical evidence for or against acupuncture and acupuncture-like therapies as treatments for temporomandibular joint disorder (TMD).

Data: This systematic review includes randomized clinical trials (RCTs) of acupuncture as a treatment for TMD compared to sham acupuncture. The search terms were selected according to medical subject heading (MeSH).

Sources: Systematic searches were conducted in 13 electronic databases up to July 2010; Medline, PubMed, The Cochrane Library 2010 (Issue 7), CINAHL, EMBASE, seven Korean Medical Databases and a Chinese Medical Database.

Study selection: All parallel or cross-over RCTs of acupuncture for TMD were searched without language restrictions. Studies in which no clinical data and complex interventions were excluded. Finally, total of 7 RCTs met our inclusion criteria.

Conclusions: In conclusion, our systematic review and meta-analysis demonstrate that the evidence for acupuncture as a symptomatic treatment of TMD is limited. Further rigorous studies are, however, required to establish beyond doubt whether acupuncture has therapeutic value for this indication.

1. Introduction

A temporomandibular joint disorder (TMD) is clinically characterized by pain and dysfunction in the masticatory muscles or temporomandibular joint (TMJ).[1] TMDs are most common form of chronic orofacial pain.[2] The prevalence of TMD in the U.S.A. is between 40% and 75%.[2,3] TMD is common in adults aged 20–50 years, and it is more prevalent amongst women than men.[4,5] Its aetiology regards as multi-factorial, structure-related, and controversial.[2]

Current medical interventions for the management of TMD consist of jaw-appliance therapy, medications, physiotherapy, home self-care and surgery.[1] Noninvasive, nonsurgical therapies are most commonly used for TMD.[6] Though there is controversy exists in reporting whether they were successful for TMD treatments to date,[6] however, clinical research and experience have been reported TMD is successfully managed

* *Corresponding author at*: Division of Clinical Medicine, School of Korean Medicine, Pusan National University, Yangsan 626-870, Kyungnam, South Korea. Tel.: +82 51 510 8482; fax: +82 51 510 8420.
E-mail addresses: drshinbc@gmail.com, drshinbc@pusan.ac.kr (B.-C. Shin).
0300-5712/$ – see front matter
doi:10.1016/j.jdent.2011.02.006

by one or another of current modalities once the correct diagnosis and proper management are provided.[7]

A survey showed that 74% of TMD patients used complementary and alternative medicine (CAM) therapies. Most of the respondents reported being most satisfied with the ''hands on'' CAM therapies such as massage or acupuncture.[8] Acupuncture has been claimed to be effective in TMD treatments in the mechanism of pain reduction, anti-inflammation, and neurohormonal effects.[9,10]

In acupuncture clinical research, it is difficult to draw a reliable conclusion due to lack of appropriate placebo.[11] 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.[11] Furthermore, several recent studies reported sham acupuncture intervention is more relevance method than other physical placebos due to the effect of excluded psychological effect.[12,13] In one neurologic study based on brain-imaging analysis, the psychological responses to placebo analgesia were similar to those that were elicited by the administration of ''real'' analgesic substances.[14] Therefore, a sham control method is more rigorous than other controls for identifying the specific effects of acupuncture especially in pain.

Up to recently, four systematic reviews of acupuncture for TMD are available.[15–18] However, one review was out of date[16] and secondly published one reviewed 4 sham controlled randomized clinical trials (RCTs) without comprehensive meta-analysis.[17] The third one reviewed 19 RCTs (including 5 sham controlled) without meta-analysis[15] and the last published one did 9 RCTs (including 4 sham controlled) with meta-analysis.[18] All did not conduct full searches because three of them restricted their searches only in English.[16–18] Consequently, all were missing the important sham controlled RCTs.[19–21] In addition, none adopted subgroup analysis and sensitivity analysis of meta-analysis which were strictly recommended by PRISMA guideline.[22] Thus, their conclusions are unsafe, even can be biased.

Therefore, the aims of our review were to critically evaluate the totality of the most rigorous clinical evidence for or against the effectiveness of acupuncture-type treatments compared to relevant sham one in patients with TMD and to provide a comprehensive PRISMA-compliant systematic review with sensitivity and subgroup analysis.

2. Methods

2.1. Data sources

The following electronic databases were searched from their inceptions up to July 2010: Medline, PubMed, The Cochrane Library 2010 (Issue 7), CINAHL, EMBASE, seven Korean Medical Databases (DBPIA, OASIS, Korea Institute of Science and Technology Information, National Assembly Library, Korean Studies Information, The Journal of Korean Acupuncture and Moxibustion Society, The Korean Journal of Meridian and Acupoint) and a Chinese Medical Database (China Academic Journal, www.cnki.co.kr).

The search phrases used were [temporomandibular or temporomandibular joint or Temporomandibular joint disorder or TMD or Jaw disease or Craniomandibular disease or {(myofascial pain) or (myofascial pain dysfunction) and TMD}] and [acupuncture or Acup* or moxibustion or acupressure or ''laser acupuncture'' or ''auricular acupuncture''] in English, Chinese and Korean. We selected these terms according to medical subject heading (MeSH). In addition, the references in all located articles were manually searched for further relevant articles.

2.2. Study selection

2.2.1. Types of studies

This review included parallel or cross-over RCTs that assessed the efficacy of acupuncture regardless of blinding, language and type of reporting. Studies in which no clinical data were reported were excluded. We also excluded complex interventions in which acupuncture was not a sole treatment. Dissertations and abstracts were included, if provided they contained sufficient detail.

2.2.2. Types of patients

This study included subjects with TMD that was diagnosed by any defined or specified diagnosis criteria, regardless of their age, race and gender. The conditions of patients in the included RCTs were classified into articular-, muscular or the two types combined of TMD. Studies in which patients were reported as having pain or functional symptoms in the jaw muscle, temples, face, pre-auricular area, or in the ear were included. Our study excluded patients with TMD found to be caused by psychogenic, neurologic and metabolic disorders.

2.2.3. Types of interventions

Acupuncture is defined as the stimulation of acupuncture points or trigger points by needles that pierce the skin, or by heating the mugwort herb (moxibustion) in combination with needles, or by electrical stimulation.[23] Methods of stimulating acupuncture points that do not involve needle insertion (e.g., laser, acupressure, moxibustion) are also included in this review. We included only sham acupuncture (such as penetrating or non-penetrating sham needle, non-activated laser acupuncture) as controls.

2.2.4. Outcome measures

One of the following outcome measures was required for inclusion: pain intensity or pain relief in TMJ measured by visual analogue scale (VAS), verbal scale, or algometer. Other clinically important outcomes included measured maximum inter-incisal mouth opening (MO), or range of motion (ROM) of TMJ, or response rate (responder vs. non-responder).

2.2.5. Data extraction and quality assessment

Copies of all articles of RCTs were obtained and read in full. All articles were read by two independent reviewers (ARJ, BCS) and data from the articles were validated and extracted according to pre-defined criteria.[24] Quality assessment was assessed using the Cochrane risk of bias criteria. The quality of the RCTs was addressed as follows amongst 6 domains: (1) Was the allocation sequence adequately generated? (2) Was allocation adequately concealed? (3) Was knowledge of the allocated intervention adequately prevented during the study?

(4) Were incomplete outcome data adequately addressed? (5) Are reports of the study free of suggestion of selective outcome reporting? (6) Was the study apparently free of other problems that could put it at a high risk of bias? As practitioner blinding may not be possible due to the nature of acupuncture, patient blinding was assumed for cases in which the control intervention was indistinguishable from acupuncture, even if the word 'blinding' did not occur in the report. The point for evaluator blinding was only given if specified in the text. We resolved any disagreements by referring to the trial report and through discussion between reviewers (ARJ, BCS) and if needed, by seeking the opinion of a third reviewer (MSL).

2.3. *Data synthesis*

To summarize the effects of acupuncture on each outcome, we abstracted the risk estimates (relative risk: RR) for dichotomous data and standardized mean difference (SMD) for continuous data with 95% confidence interval (CI). RR or SMD or weight mean difference (WMD) with 95% CI were calculated using Cochrane Collaboration software [Review Manager 5 (RevMan) Version 5.0.25 for Windows. Copenhagen: The Nordic Cochrane Centre]. The variance of the change was imputed using a correlation factor of 0.5 as suggested by the Cochrane Collaboration.[25] We then pooled data across studies using random effect models if excessive statistical heterogeneity did not exist. The chi-square test and the Higgins I^2 test were used to assess heterogeneity.[26] For more comprehensive understanding of meta-analysis or if any kinds of heterogeneity exist, we conducted subgroup analysis or sensitivity analysis additionally. Publication bias was assessed by funnelplot using the Cochrane software.

2.4. *Statistical analysis*

To estimate sample size, we set the mean with standard deviation from the difference of VAS between real and sham groups. Sample size was estimated by 80% power (0.2 in beta error) and 0.05 alpha error by using SigmaPlot software for Windows Version 11.0 (Systat Softwere Inc., San Jose, CA, U.S.A.).

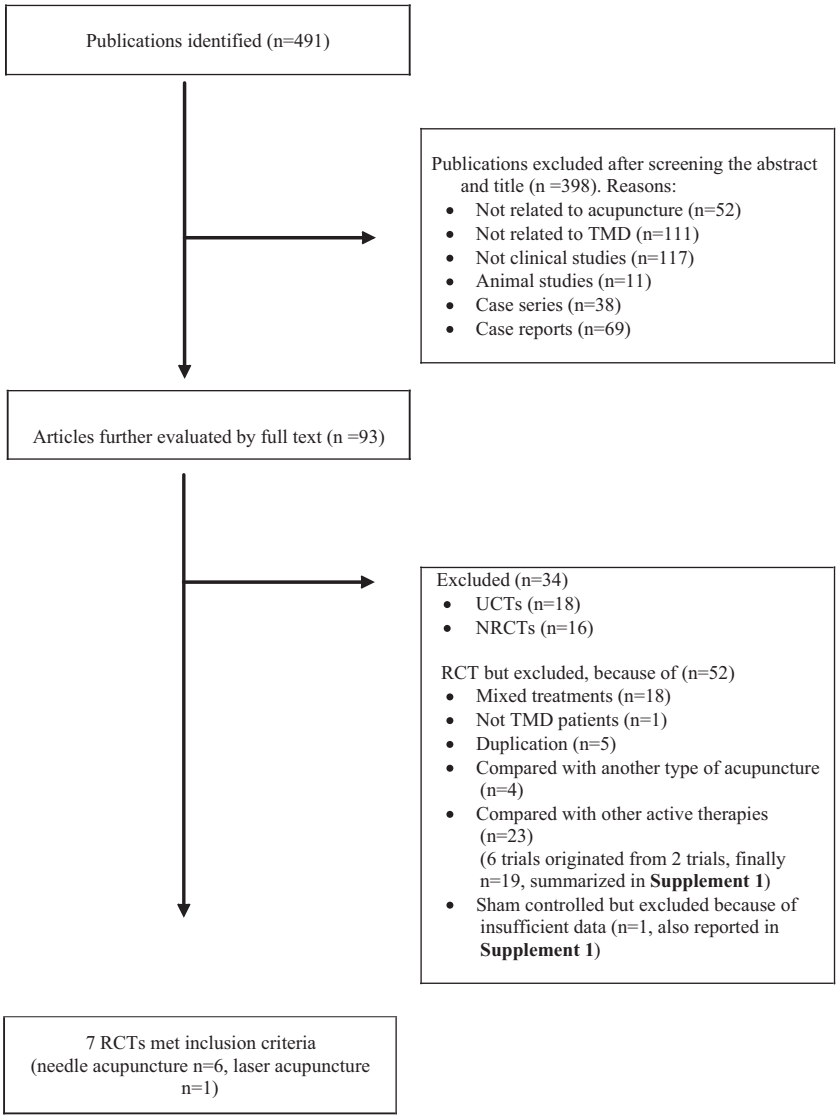


Fig. 1 – Flow chart of the trial selection process. TMD: temporomandibular joint disorder; UCT: uncontrolled clinical trial; NRCT: non-randomized controlled clinical trial, and RCT: randomized clinical trial.

Table 1 – Summary of RCTs of acupuncture versus Sham acupuncture for TMD.

First author (year)	Design/blinded Randomized Duration of TMD (week) Types of TMD	Intervention group (regime)	Control group (regime)	Main outcomes	Intergroup differences	AT method / acupoint/deqi	Adverse event / risk of bias
Goddard (2002)[29]	2 parallel/DB 18 >12 Muscular	(A) AT (30 min, once, $n = 10$)	(B) Sham AT (30 min once, nonacupoint, penetrating skin, 2–4 mm depth, $n = 8$)	(1) 100-mm VAS (pain intensity)	(1) $P = 0.27$, MD, −0.53 [−1.48, 0.42]	Fixed point/ LI4, ST6/n.r.	n.r./Y,U,Y,Y,Y,U
Smith (2007)[31]	2 parallel/DB 27	(A) AT (20 min, 6 times for 3 weeks, $n = 15$)	(B) Sham AT (Park sham needle, acupoint, non-penetrating skin, 20 min once, 6 times for 3 weeks, $n = 12$)	(1) 10-cm VAS (pain intensity)	(1) (A) MD;33.2 (B) MD;0.8[a] (pre-post)	Fixed point/ST7/ considered	n.r./Y,Y,Y,Y,Y,N
	>24			(2) MO (mm)	(2) (A) MD; 3.2 (B) MD; 1.5[a] (pre-post)		
	Combined			(3) Muscle tenderness	(3) $P = 0.12$, RR, 4.80[1,35]		
Shen (2007)[20]	2 parallel/DB 15	(A) AT (15 min, once, $n = 9$)	(B) Sham AT (1 cm distal to LI4, non-penetrating, 15 min once, $n = 6$)	(1) 10-cm VAS (pain intensity)	(1) $P = 0.06$, MD, −1.09 [−2.21, 0.04]	Fixed point/ LI4/n.r.	n.r./U,U,Y,Y,Y,Y
	>12 Muscular			(2) NRS (facial pain)	(2) $P = 0.22$, MD, −1.22 [−3.16, 0.72]		
Shen (2009)[28]	2 parallel/DB 28	(A) AT (15 min, once, $n = 16$)	(B) Sham AT (1 cm distal to LI4, non-penetrating, 15 min once, $n = 12$)	(1) 10-cm VAS (pain intensity)	(1) $P = 0.24$, MD, −0.45 [−1.21, 0.31]	Fixed point/ LI4/n.r.	n.r./Y,U,Y,Y,Y,Y
	n.r. Muscular			(2) NRS (facial pain)	(2) $P = 0.84$, MD, −0.20 [−2.14, 1.74]		
Schmid-Schwap (2006)[30]	2 parallel/DB 23	(A) AT (20 min, 6 times for 3 weeks, $n = 11$)	(B) Sham laser (acupoint, non-activated sham laser, 20 min once, $n = 12$)	(1) 100-mm VAS (pain intensity)	(1) $P = 0.04$, MD, −0.92 [−1.79, −0.05]	Fixed point/ LI4, SI2, SI3/n.r.	no/U,Y,Y,Y,Y,Y
	n.r.			(2) MO (mm)	(2) $P = 0.10$, MD, 0.71 [−0.14, 1.55]		
	Combined			(3) Muscle tenderness	(3) $P = 0.002$, MD, −1.52 [−2.47, −0.57]		

Simma (2009)[21]	2 parallel/DB 23 n.r. Muscular	(A) AT (n.r., once, $n = 11$)	(B) Sham laser (acupoint, non-activated sham laser, n.r., once, $n = 12$)	(1) 100-mm VAS (pain intensity) (2) Muscle tenderness	(1) $P = 0.40$, MD, −0.35 [−1.18, 0.47] (2) $P = 0.10$, MD, −0.70 [−1.55, 0.14]	Fixed point/LI4, SI2, SI3/n.r.	n.r./Y,U,Y,Y,Y,Y
Katsoulis (2010)[19]	2 parallel/DB 7 n.r. Muscular	(A) Laser AT 15 min each, 2 treatment/week, 6 sessions for 3 weeks, $n = 4$)	(B) Sham laser (acupoint, non-activated sham laser, 1session = 15 min each, 2 times/week, 6 sessions, $n = 3$)	(1) 100-mm VAS (pain intensity) (2) Verbal scale (pain free %)	(1) $P = 0.52$, RR, 0.80 [0.40, 1.58] (2) $P = 0.56$, RR, 2.40 [0.13, 44.41]	Fixed point/ ST6, SI18, SI3, LI4/n.r.	n.r./U,U,Y,Y,N,U

AT: acupuncture; MO: mouth opening; TMD: temporomandibular joint disorder; VAS: visual analogue scale (100 mm scale); NRS: numeric rating scale (0–10 point, 11point scale); NS: non-significant; RR = relative risk; MD: mean difference; RCT: randomized clinical trial; n.r.: not report; Risk of bias: yes (Y): low risk of bias; No (N): high risk of bias; Unclear (U); DB: double blind, this means patient and assessor-blind.

[a] Outcomes cannot be estimated because this study does not provide standard deviation.

3. Results

3.1. Study description

The searches identified 491 potentially relevant studies, of which 484 were excluded (Fig. 1). Of the excluded studies, 24 RCTs were excluded because they included other active treatments as controls instead of sham one, or because of scanty data.[27] Those studies are separately summarized without explanation in Supplement 1. Finally, 7 RCTs met our inclusion criteria. The key data are summarized in Table 1. Three trials originated from U.S.A.,[20,28,29] two from Austria,[21,30] one from U.K.,[31] and one from Germany.[19]

A total of 141 patients were included in these studies (mean sample size: 20, female:male = 19.1:1, mean age: 37.3 years). The diagnostic methods of TMD used were two trials[29,31] diagnosed the subjects by Research diagnosed criteria (RDC/TMD),[2] the others did not report which diagnostic systems were used.[19–21,28,30] In all studies, for the types of TMD, five studies were muscular type,[19–21,28,29] none was articular type, and two were combined type of both.[30,31] Six trials evaluated needle acupuncture,[20,21,28–31] and one trial evaluated laser acupuncture.[19] The duration of TMD was generally more than 12 weeks. The duration of total treatment ranged from 1 treatment to 3 weeks (mean: 1.4 weeks). The subjective outcome measures of these trials were the VAS, numeric rating scale (NRS), muscle tenderness (4 point scale) or verbal scale (response rate of pain free) and an objective one was MO (millimetre). The baseline comparison of TMD symptoms was reported in five trials,[20,21,28–30] but not in two.[19,31]

3.2. Description of acupuncture treatment

Of the 7 total studies, six studies comparatively tested needle acupuncture against penetrating sham acupuncture,[29] non-penetrating sham acupuncture,[20,28,31] or sham laser acupuncture,[21,30] whilst the remaining study tested laser acupuncture against sham laser acupuncture.[19]

A total of 6 acupuncture points were used (see Fig. 2). Of them, LI 4 was used the most (34 times/total 91 points), followed by SI 3 (19/91), ST 6 (13/91), SI 18 (12/91), SI 2 (7/91), and ST 7 (6/91). Three of these 6 adopted acupoints were located in the face, especially in the affected mandible (50%), whilst three acupoints were in the hand (50%).

3.3. Adverse event

Only one RCT reported adverse event data of acupuncture and sham acupuncture and this stated that there were no adverse events.[30] None of others mentioned adverse events.

3.4. Risk of bias in the included studies

The methodological quality of the RCTs was variable. Four studies described an appropriate method of sequence generation.[21,28,29,31] One used a random number table,[29] and the others used a computerized randomization method.[21,28,31] The other three studies did not clearly report how the allocation sequence was generated. Allocation was concealed in two studies.[30,31] All

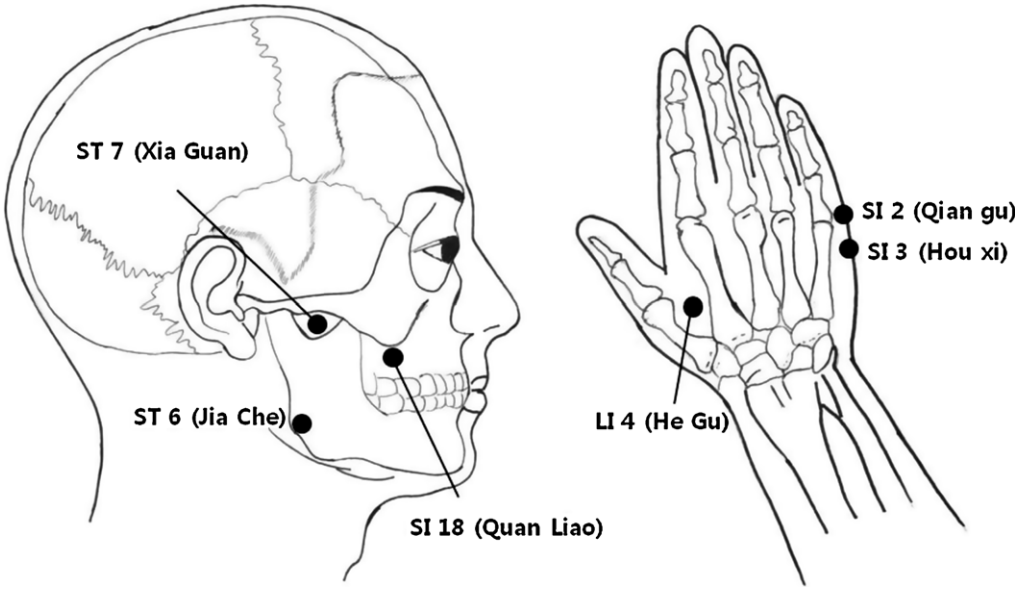


Fig. 2 – Acupuncture points used in included studies.

RCTs adopted both patient- and assessor-blinding and analysed all participants without dropouts and withdrawals. Only two studies reported details about the dropouts and withdrawals.[20,31] Five studies were considered quality in high (low risk of bias)[21,28–31] and two studies reported blinding but unclear randomization methods without appropriate allocation concealment thus the quality of them was in moderate.[19,20] In addition, there was no publication bias because of symmetrical distribution by funnel-plot (data was not shown).

3.5. *Outcomes*

3.5.1. *VAS for pain intensity*

All seven RCTs reported the results of manual acupuncture contrasted with sham acupuncture in terms of pain intensity by VAS.[19–21,28–31] The point of time for measuring the VAS was referring to 'now' in six trials,[20,21,28–31] that of the other one to 'over last 14 days'.[19] VAS scale on subjective pain in patients was evaluated in same region in all studies, where were the main area surrounding the TMJ, generally face, jaw and masseter muscle.[19–21,28–31] The time for evaluating VAS scale was immediately after treatment in 6 studies,[20,21,28–31] the other one evaluated it after 16 weeks.[19] Five trials showed favourable effects of acupuncture, whilst the others did not. The pooled meta-analysis of data showed significant improvements in pain intensity for VAS (5 studies, $n = 107$, WMD, −13.63; 95% CI of −21.16 to −6.10, $P = 0.0004$, heterogeneity: $\chi^2 = 1.46$, $P = 0.83$, $I^2 = 0\%$).[20,21,28–30] A subgroup analysis of VAS for pain intensity by conditions showed favourable effects on real acupuncture superior to sham acupuncture regardless of types of TMD; muscular type (4 studies, $n = 84$, WMD, −14.28; 95% CI of −24.66 to −3.90, $P = 0.007$, heterogeneity: $\chi^2 = 1.42$, $P = 0.70$, $I^2 = 0\%$), or combined type of TMD (1 study, $n = 23$, WMD, −12.90; 95% CI of −23.83 to −1.97, $P = 0.02$) (Fig. 3A1). By the number of treatments, included four RCTs that used only one-time acupuncture treatment also showed favourable effects of acupuncture in pain intensity by VAS[20,21,28,29] (4 studies, $n = 84$, WMD, −14.28; 95% CI of −24.66 to −3.90, $P = 0.007$, heterogeneity: $\chi^2 = 1.42$, $P = 0.70$, $I^2 = 0\%$) (Fig. 3A2). Further subgroup analysis showed acupuncture to be superior to non-penetrating sham control methods in pain reduction by VAS in 4 studies ($n = 89$, WMD, −13.73; 95% CI of −21.78 to −5.67, $P = 0.0008$, heterogeneity: $\chi^2 = 1.45$, $P = 0.69$, $I^2 = 0\%$).[20,21,28,30] No significant difference was shown between acupuncture and a penetrating sham method in 1 study ($n = 18$, WMD, −12.95; 95% CI of −34.05 to 8.15, $P = 0.23$) (Fig. 3A3).[29] Sensitivity analysis showed same results with above meta-analysis regardless of study quality (data are not shown).

Two RCTs were not pooled (though they used pain intensity by VAS as an outcome measure) because of insufficient original data (no standard deviation),[31] or dichotomous data instead of continuous data.[19]

3.5.2. *NRS for facial pain*

Two RCTs[20,28] reported on facial pain using NRS as pain measurement. Although they reported a more favourable effect of needle acupuncture in the original article, our recalculation showed no significant difference between real and sham groups ($P = 0.30$,[20] $P = 0.84$[28]).

3.5.3. *Muscle tenderness*

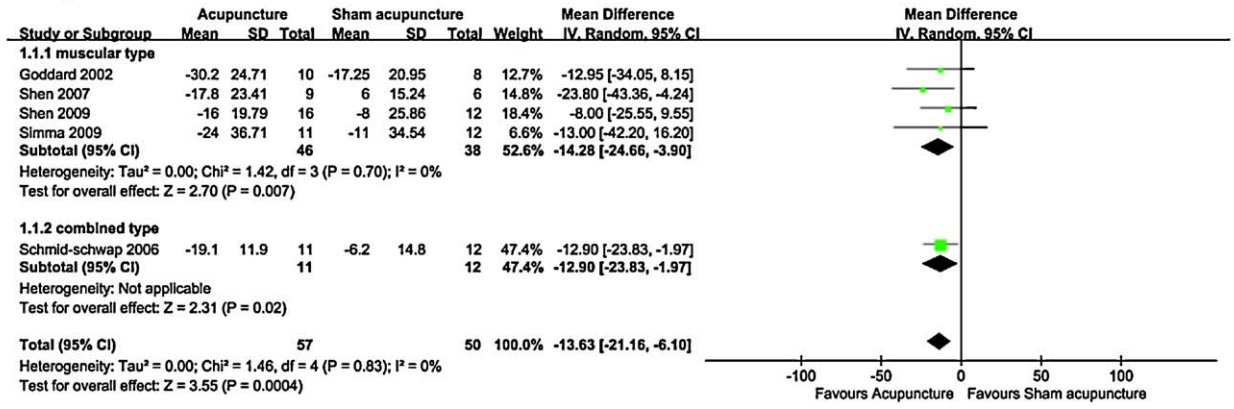
Three RCTs[21,30,31] assessed the effect of manual acupuncture on muscle tenderness (4 point scale). All trials reported favourable effects of acupuncture. One of them could not be pooled in our meta-analysis, because of the scanty of the original data (no standard deviation).[31] A meta-analysis of these data also showed significant, favourable effects of needle acupuncture (2 studies, $n = 46$, SMD, −1.08; 95% CI of −1.88 to −0.28, $P = 0.008$, heterogeneity: $\chi^2 = 1.58$, $P = 0.21$, $I^2 = 37\%$) (Fig. 3B).

3.5.4. *Mouth opening*

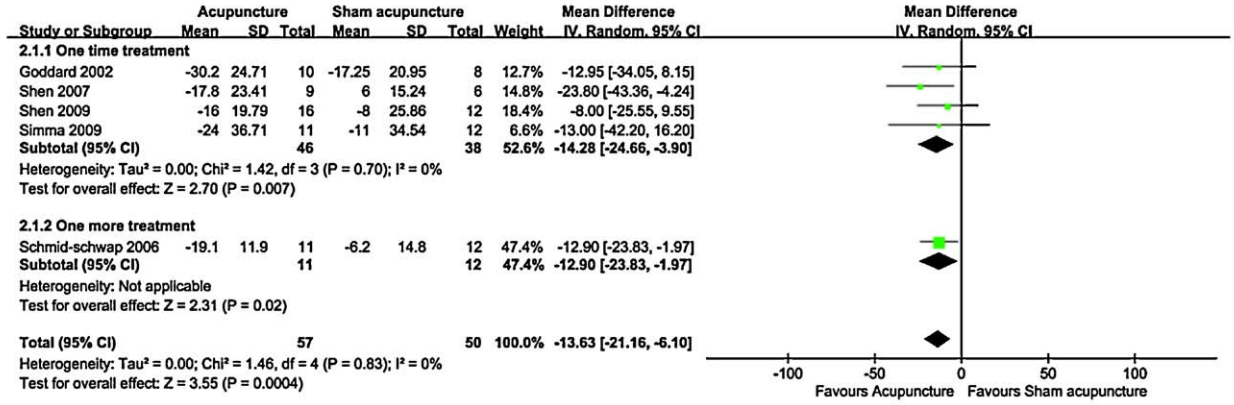
Two RCTs[30,31] reported the effect of manual acupuncture on maximum MO measured in millimetres. Although one RCT showed a favourable effect in the needle acupuncture group,

A. VAS for pain intensity

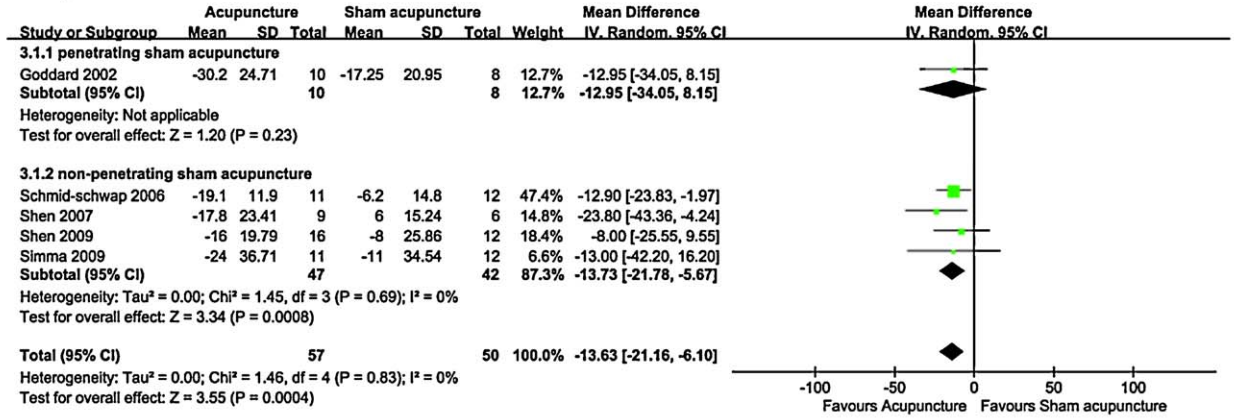
1. By conditions



2. By number of treatment



3. By sham control methods



B. Muscle tenderness

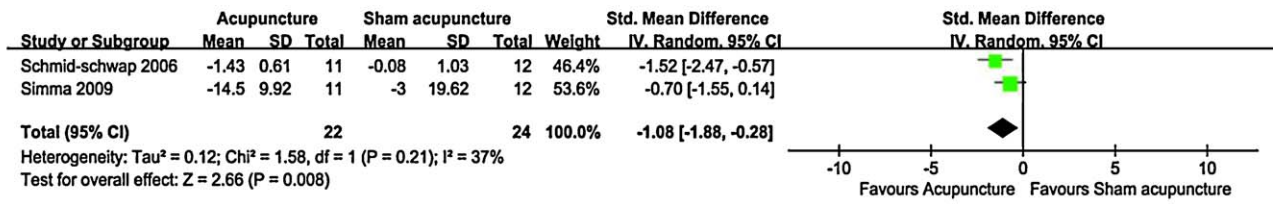


Fig. 3 – Meta-analysis of acupuncture for TMD. VAS: visual analogue scale.

this study did not provide a clear standard deviation.[31] Therefore, no further pooled analysis was completed due to insufficient original data. Another RCT showed no statistical difference between real and sham groups.[30]

4. Discussion

A total of 7 RCTs tested the effects of acupuncture compared to sham acupuncture.[19–21,28–31] This systematic review produced limited evidence that acupuncture is more effective than sham acupuncture in alleviating pain and masseter muscle tenderness in TMD.

The methodological quality based on the Cochrane risk of bias is generally moderate. Although each RCT adopted assessor- and patient-blinding procedures, only four RCTs used an appropriate sequence generation method.[21,28,29,31] Only two RCTs employed allocation concealment.[30,31] Trials with inadequate sequence generation cause selection bias.[32] Only two RCTs reported details of dropouts and withdrawals.[20,31] This may lead to exclusion or attrition bias.[32]

All included trials suffered from lack of sufficient sample size without power analysis, therefore, they are susceptible to type II error.[33] Small trials may also overestimate treatment effects by about 30%.[34] In our re-calculation of sample size based on the mean difference value, at least 26 samples (in each group) are needed for sufficient power (set at 80% power and 0.05 in alpha error).[35] None were met this power. Clinically significant changes of pain VAS in patients with muscular TMD was suggested by 24.2 mm,[36] also in general pain severity by 13–30 mm.[37,38] Of included studies, the pain changes were greater than 24.2 mm in two of included studies (one was 30.2 mm[29] and the other was 33.2 mm[31]), however, four of them were smaller.[20,21,28,30] Thus, the reliability of the evidence presented here is clearly limited.

In this review, various sham control methods have been presented. The methods range from the use of a penetrating needle on non-acupoints[29] to non-penetrating needles on acupoints[19,21,30,31] or non-acupoints.[20,28] 'Real' acupuncture was found to be superior to non-penetrating sham acupuncture control in pain outcomes[20,21,28,30] but showed no difference from penetrating sham acupuncture[29] from our subgroup meta-analysis. There are several possible explanations for these findings; acupuncture might indeed be ineffective, alternatively, penetrating sham control may have a similar effect to real one, then the penetrating sham control may be invalid. Recently, one study reported that a penetrating placebo needle could be considered as having a similar effect of acupuncture, because it is not inert.[39]

Furthermore, in another recent study,[40] which was reporting about relevance of non-penetrating sham acupuncture, there was no significant difference in the correct guessing of the real and sham acupuncture type amongst blinded subjects. This may serve non-penetrating sham acupuncture as a credible sham control. However, for confirming this, rigorous studies between 2 types of sham are needed for overcoming the controversy.

The double blind (i.e., blinding of the patient and the evaluator) method was adopted in all of the trials. One study suggested that either a penetrating or non-penetrating needle placebo is effective in masking patients, whether the patients were informed or not.[41] Therefore, these sham control methods seem to have potential uses in double blind studies. However, the success of blinding was not confirmed in the included studies. Future trials should consider testing and reporting the success of blinding. Blinding of the therapist remains an unresolved problem in studies of acupuncture. Recent studies show that the ''style'' of the acupuncturists significantly impacts on the clinical outcome.[42] It would therefore be important for future trials to find ways for controlling for such confounding variables.

The optimal duration and number of acupuncture treatments is an important clinical consideration.[43] Four[20,21,28,29] of the seven studies used only single acupuncture treatments to test acute effects, whilst the other three[19,30,31] studies adopted 6–12 acupuncture treatments. Regardless of the number of treatments, our meta-analysis of the pooled data showed superior effects of acupuncture. These results either indicate that acupuncture has a significant acute effect on TMD pain or that the (non-blinded) acupuncturist's ''style'' generates immediate effects (see above).

Needle sensation (*de-qi*) was considered in one RCT,[30] whilst the other 6 trials did not report such details.[19–21,28,29,31] None of the studies reported the stimulation and manipulation methods. Recently, one f-MRI study reported that needle sensation changed the brain response.[44] Therefore, this seems to affect treatment outcomes. However, there was no significant difference between groups whether the trial adopted *de-qi* or not. Hence, we do not know yet whether *de-qi* exerted an important influence on the clinical outcomes or not.

A possible mechanism of acupuncture-mediated effects on TMD, based on an electromyographic (EMG) study, is that acupuncture causes the spinal cord and brain to release calming agents such as serotonin, endorphins and neurotransmitters with anti-inflammatory action.[45] In addition, after treatment with acupuncture, a better distribution of EMG activity was observed that indicated a greater muscular balance with the predominance of masseter muscles.[45] However, none of these effects have been independently confirmed.

Only one RCT addressed adverse events, but provided no details.[30] The fact that most studies fail to mention adverse effects is remarkable. Adverse effects of acupuncture are well known and thus need to be considered in any clinical research. The lack of reporting of adverse effects seems to reflect the often poor reporting of acupuncture trials. None of the included trials reported ethical approval. This suggests the need for an ethical review of acupuncture research.

In conclusion, the evidence for acupuncture for TMD management, especially for TMJ and masseter muscles pain, is weak. Thus, 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 are needed to establish whether acupuncture has definite therapeutic value.

Acknowledgments

Byung-Cheul Shin was supported for two years by a Pusan National University Research Grant.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at doi:10.1016/j.jdent.2011.02.006.

Conflict of interest

The authors declare no conflicts of interest.

REFERENCES

1. Scrivani SJ, Keith DA, Kaban LB. Temporomandibular disorders. *The New England Journal of Medicine* 2008;**359**: 2693–705.
2. Leeuw R. American academy of orofacial pain: guidelines for assessment, diagnosis and management. 4th ed. Chicago: Quintessence Publishing; 2008. pp.129–75.
3. Lipton JA, Ship JA, Larach-Robinson D. Estimated prevalence and distribution of reported orofacial pain in the United States. *The Journal of the American Dental Association* 1993;**124**:115–21.
4. List T, Wahlund K, Wenneberg B, Dworkin SF. TMD in children and adolescents: prevalence of pain, gender differences, and perceived treatment need. *Journal of Orofacial Pain* 1999;**13**:9–20.
5. Manfredini D, Piccotti F, Ferronato G, Guarda-Nardini L. Age peaks of different RDC/TMD diagnoses in a patient population. *Journal of Dentistry* 2010;**38**:392–9.
6. Jerjes W, Upile T, Abbas S, Kafas P, Vourvachis M, Rob J, *et al.* Muscle disorders and dentition-related aspects in temporomandibular disorders: controversies in the most commonly used treatment modalities. *International Archives of Medicine* 2008;**1**:23.
7. Syrop SB. Initial management of temporomandibular disorders. *Dentistry Today* 2002;**21**:52–7.
8. DeBar LL, Vuckovic N, Schneider J, Ritenbaugh C. Use of complementary and alternative medicine for temporomandibular disorders. *Journal of Orofacial Pain* 2003;**17**:224–36.
9. Lin JG, Chen WL. Acupuncture analgesia: a review of its mechanisms of actions. *The American Journal of Chinese Medicine* 2008;**36**:635–45.
10. Zhao ZQ. Neural mechanism underlying acupuncture analgesia. *Progress in Neurobiology* 2008;**85**:355–75.
11. Clinical research into the effectiveness of acupuncture.White AR, Cummings M, Fishie J, editors. *An introduction to western medical acupuncture*. Edinburgh, UK: Churchill Livingstone/Elsevier; 2008. p. 93–118.
12. Linde K, Niemann K, Meissner K. Are sham acupuncture interventions more effective than (other) placebos? A re-analysis of data from the Cochrane review on placebo effects. *Research in Complementary Medicine* 2010;**17**:259–64.
13. Sites BD, Neal JM. Placebo or intervention? Is it all a sham? *Anaesthesia* 2011;**66**:73–5.
14. Greene CS, Goddard G, Macaluso GM, Mauro G. Topical review: placebo responses and therapeutic responses. How are they related? *Journal of Orofacial Pain* 2009;**23**:93–107.
15. Cho SH, Whang WW. Acupuncture for temporomandibular disorders: a systematic review. *Journal of Orofacial Pain* 2010;**24**:152–62.
16. Ernst E, White AR. Acupuncture as a treatment for temporomandibular joint dysfunction: a systematic review of randomized trials. *Archives of Otolaryngology—Head & Neck Surgery* 1999;**125**:269–72.
17. La Touche R, Angulo-Diaz-Parreno S, de-la-Hoz JL, Fernandez-Carnero J, Ge HY, Linares MT, *et al.* Effectiveness of acupuncture in the treatment of temporomandibular disorders of muscular origin: a systematic review of the last decade. *Journal of Alternative and Complementary Medicine* 2009;**16**:107–12.
18. La Touche R, Goddard G, De-la-Hoz JL, Wang K, Paris-Alemany A, Angulo-Diaz-Parreno S, *et al.* Acupuncture in the treatment of pain in temporomandibular disorders: a systematic review and meta-analysis of randomized controlled trials. *The Clinical Journal of Pain* 2010;**26**: 541–50.
19. Katsoulis J, Ausfeld-Hafter B, Windecker-Getaz I, Katsoulis K, Blagojevic N, Mericske-Stern R. Laser acupuncture for myofascial pain of the masticatory muscles. A controlled pilot study. *Schweiz Monatsschrift fuer Zahnmedizin* 2010;**120**:213–25.
20. Shen YF, Goddard G. The short-term effects of acupuncture on myofascial pain patients after clenching. *Pain Practice* 2007;**7**:256–64.
21. Simma I, Gleditsch JM, Simma L, Piehslinger E. Immediate effects of microsystem acupuncture in patients with oromyofacial pain and craniomandibular disorders (CMD): a double-blind, placebo-controlled trial. *British Dental Journal* 2009;**207**:E26.
22. Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gotzsche PC, Ioannidis JP, *et al.* The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: explanation and elaboration. *PLoS Medicine* 2009;**6**:e1000100.
23. Liu J, Fei Y, Alraek T. Acupuncture for treatment of erectile dysfunction (protocol). *Cochrane Database of Systematic Review* 2008:CD007241.
24. Higgins J, Green S, Higgins JPT, Green S, editors. *Cochrane handbook for systematic reviews of interventions version 5.0.2 [updated September 2009]*. The Cochrane Collaboration; 2009 www.cochrane-handbook.org.
25. Follmann D, Elliott P, Suh I, Cutler J. Variance imputation for overviews of clinical trials with continuous response. *Journal of Clinical Epidemiology* 1992;**45**:769–73.
26. Higgins J, Thompson S, Deeks J, Altman D. Statistical heterogeneity in systematic reviews of clinical trials: a critical appraisal of guidelines and practice. *Journal of Health Services Research & Policy* 2002;**7**:51–61.
27. Elsharkawy TM, Ali NM. Evaluation of acupuncture and occlusal splint therapy in the treatment of temporomandibular joint disorders. *Egyptian dental journal* 1995;**41**:1227–32.
28. Shen YF, Younger J, Goddard G, Mackey S. Randomized clinical trial of acupuncture for myofascial pain of the jaw muscles. *Journal of Orofacial Pain* 2009;**23**:353–9.
29. Goddard G, Karibe H, McNeill C, Villafuerte E. Acupuncture and sham acupuncture reduce muscle pain in myofascial pain patients. *Journal of Orofacial Pain* 2002;**16**:71–6.
30. Schmid-Schwap M, Simma-Kletschka I, Stockner A, Sengstbratl M, Gleditsch J, Kundi M, *et al.* Oral acupuncture in the therapy of craniomandibular dysfunction syndrome – a randomized controlled trial (RCT). *The Middle-European Journal of Medicine* 2006;**118**:36–42.
31. Smith P, Mosscrop D, Davies S, Sloan P, Al-Ani Z. The efficacy of acupuncture in the treatment of temporomandibular joint myofascial pain: a randomised controlled trial. *Journal of Dentistry* 2007;**35**:259–67.
32. Juni P, Altman DG, Egger M. Systematic reviews in health care: assessing the quality of controlled clinical trials. *British Medical Journal* 2001;**323**:42–6.
33. Litiere S, Alonso A, Molenberghs G. Type I and Type II error under random-effects misspecification in generalized linear mixed models. *Biometrics* 2007;**63**:1038–44.

34. Moore A, Edwards J, Barden J, Mcquay H. Bandolier's little book of pain. Oxford: Oxford University Publishing; 2003.
35. Chow SC, Shao J, Wang H. Sample size calculations in clinical research. 2nd ed. Boca Raton, FL: Chapman & Hall/CRC; 2008. pp. 49–81.
36. van Grootel RJ, van der Glas HW. Statistically and clinically important change of pain scores in patients with myogenous temporomandibular disorders. *European Journal of Pain* 2009;**13**:506–10.
37. Gallagher EJ, Liebman M, Bijur PE. Prospective validation of clinically important changes in pain severity measured on a visual analog scale. *Annals of Emergency Medicine* 2001;**38**:633–8.
38. Lee JS, Hobden E, Stiell IG, Wells GA. Clinically important change in the visual analog scale after adequate pain control. *Academic Emergency Medicine* 2003;**10**:1128–30.
39. Lund I, Lundeberg T. Are minimal, superficial or sham acupuncture procedures acceptable as inert placebo controls? *Acupuncture Medicine* 2006;**24**:13–5.
40. Lee H, Bang H, Kim Y, Park J, Lee S, Park HJ. *Non-penetrating sham needle is it an adequate sham control in acupuncture research? Complementary therapies in medicine* 2011;**19**:S41–8.
41. Takakura N, Yajima H. A placebo acupuncture needle with potential for double blinding – a validation study. *Acupuncture in Medicine* 2008;**26**:224–30.
42. Witt CM, Ludtke R, Wegscheider K, Willich SN. Physician characteristics and variation in treatment outcomes: are better qualified and experienced physicians more successful in treating patients with chronic pain with acupuncture? *Journal of Pain* 2010;**11**:431–5.
43. Slopeck A, Feng HT. Qi, time and acupuncture. *Journal of Aupuncture and Tuina Science* 2010;**8**:199–264.
44. Asghar AU, Green G, Lythgoe MF, Lewith G, MacPherson H. Acupuncture needling sensation: the neural correlates of deqi using fMRI. *Brain Research* 2009;**1315**:111–8.
45. Rancan SV, Bataglion C, Bataglion SA, Bechara OM, Semprini M, Siessere S, *et al*. Acupuncture and temporomandibular disorders: a 3-month follow-up EMG study. *Journal of Alternative and Complementary Medicine* 2009;**15**:1307–10.