

Acupuncture in the Treatment of Pain in Temporomandibular Disorders: A Systematic Review and Meta-analysis of Randomized Controlled Trials

Roy La Touche, MSc, PT,*† Greg Goddard, DDS,‡ José Luis De-la-Hoz, MD, DDS,§
Kelun Wang, DDS, PhD,||¶ Alba Paris-Aleman, PT, MSc,*†
Santiago Angulo-Díaz-Parreño, MSc,§ Juan Mesa, PT,§ and Mar Hernández, DDS§

Objectives: The aim of this study is to perform a qualitative and quantitative analysis of the scientific literature regarding the use of acupuncture in the treatment of pain associated with temporomandibular disorders (TMDs).

Methods: By using electronic databases, the goal was to search and evaluate all the randomized controlled trials (RCTs) in which acupuncture was used in the management of pain attributed to these clinical entities. For the meta-analysis, an adequate description of the results' statistical data was required along with a comparison of the treatment with a control group using a placebo or sham. Two independent reviewers evaluated the quality of the studies using the Jadad scale.

Results: A total of 8 RCTs were selected, and the quality of only 4 was considered acceptable. These 4 studies showed positive results such as reducing pain, improving masticatory function, and increasing maximum interincisal opening. By combining the studies ($n=96$) and analyzing the results, it was concluded that acupuncture is more effective than placebo in reducing pain intensity in TMD (standardized mean difference 0.83; 95% confidence interval, 0.41-1.25; $P=0.00012$).

Discussion: The results of this meta-analysis suggest that acupuncture is a reasonable adjunctive treatment for producing a short-term analgesic effect in patients with painful TMD symptoms. Although the results described are positive, the relevance of these results was limited by the fact that substantial bias was present. These findings must be confirmed by future RCTs that improve the methodologic deficiencies of the studies evaluated in this meta-analysis.

Key Words: acupuncture, temporomandibular disorders, orofacial pain, randomized controlled trial, meta-analysis, review

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From the *Faculty of Health Science, Department of Physical Therapy; †Group for Musculoskeletal Pain and Motor Control Research Universidad Europea de Madrid; §Faculty of Medicine, Department of Physical Therapy, Universidad San Pablo CEU, Madrid, Spain; ‡University of California at San Francisco, San Francisco, CA; ||Orofacial Pain Laboratory, Center for Sensory-Motor Interaction; and ¶Department of Health Science & Technology, Aalborg University, Aalborg, Denmark.

Reprints: Roy La Touche, MSc, PT, Facultad de Ciencias de la Salud/ Departamento de Fisioterapia, Universidad Europea de Madrid, C/ Tajo s/n, 28670 Villaviciosa de Odón, Madrid, Spain (e-mail: roylatouche@yahoo.es).

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Temporomandibular disorders (TMDs) refer to various conditions affecting the temporomandibular joint, masticatory muscles, and contiguous tissues components.¹ Different types of painful TMDs are encountered: myogenous or muscle-generated pain; arthrogenous or joint generated pain; or both.¹⁻⁴ According to Stohler,⁵ between 90% and 95% of TMD patients have facial pain of muscular origin without identifiable structural causes. Among the painful TMD of muscular origin, the most frequent is myofascial pain (MP).⁶ At present, the therapeutic management of TMD is approached using a medical multidisciplinary model, and the treatment options range from conservative, noninvasive therapeutic measures to more aggressive treatment interventions. However, in most of the mild and moderate cases of TMD, a significant clinical improvement can be obtained with conservative therapeutic modalities.^{7,8} Among the nonsurgical treatment procedures for TMD are self-management measures (home care), occlusal splints, medication, cognitive-behavioral techniques, and various forms of physiotherapeutic treatment.

Acupuncture is an increasingly used treatment modality for the therapeutic management of pain symptoms. A meta-analysis performed by Ter Riet et al⁹ showed that the majority of the studies documented positive results. However, the main conclusion obtained from that meta-analysis was that the methodologic quality of the studies analyzed required more evidence. For this reason, the investigators concluded that the effects of acupuncture for chronic pain are doubtful. In terms of TMD and acupuncture treatment, the results obtained were similar to those obtained in an earlier systematic review published in 1999.¹⁰ The studies analyzed in that review also had serious design flaws, the main one being that none of the studies were designed to control for a placebo effect. They concluded that even though all the studies were in accordance with the notion that acupuncture is effective for temporomandibular joint dysfunction, this hypothesis required confirmation through more rigorous investigations.

It is important to emphasize that in the last 10 years, additional studies have been published using acupuncture to treat TMD. This meta-analysis will review the publications of the last 10 years to include the improved evidence that has accumulated over that time. The aim of this study is to perform an analysis that evaluates the quality of the studies and the effectiveness of acupuncture treatment in relieving painful TMD symptomatology.

MATERIAL AND METHODS

Inclusion and Exclusion Criteria

When considering the studies to include in this analysis, 2 groups were identified and selected based on the criteria required for the systematic review and the criteria for the meta-analysis.

The inclusion criteria for the systematic review were the following: (1) only randomized controlled trials (RCTs); (2) studies performed on patients diagnosed with TMD who suffered painful symptoms; (3) studies in which manual acupuncture and/or electroacupuncture were used; (4) studies published in scientific journals between 1960 and 2009; (5) studies performed on adult patients (more than 18 y old); (6) studies in which the technical aspects of the acupuncture treatment were described, for example, location of the acupuncture points and duration of treatment; (7) studies in which the control group (CG) received a placebo treatment, a regular TMD treatment, or no treatment of any kind; (8) English language publications.

For the meta-analysis, the same inclusion criteria were used as for the systematic review, except that 2 more criteria were added: (1) in the results there was detailed information regarding the comparative statistical data of the exposure factors, therapeutic interventions, and treatment responses and (2) the acupuncture treatment was compared with a CG using a placebo or sham.

All studies that had multiple therapeutic interventions applied in the study groups (SGs) or those that did not fulfill the criteria of a RCT were excluded. Figure 1 shows the methodologic development of the review and the studies excluded.

Search Strategy

Articles were researched using the following databases: MEDLINE (from 1970), EMBASE (from 1974), CISCOR (from 1985), CINAHL (from 1980), and Pedro (from 1980). The terms used for the search were derived from a combination of the following words: "acupuncture," "temporomandibular joint dysfunction," "temporomandibular disorders," "orofacial pain," "myofascial pain," "facial pain," "pain", and "randomized controlled trial." The first analysis of the studies was based on the information provided by the summary, the title, and the key words. This process was performed by 2 independent reviewers. The articles selected for this analysis were evaluated in detail using the complete text in the analytic phase.

Quality Assessment of the Studies

The assessment of the quality of the studies' methodology was performed using the Jadad scale.¹¹ This scale is one of the oldest and most commonly used to evaluate the quality of clinical trials. It was created using psychometric

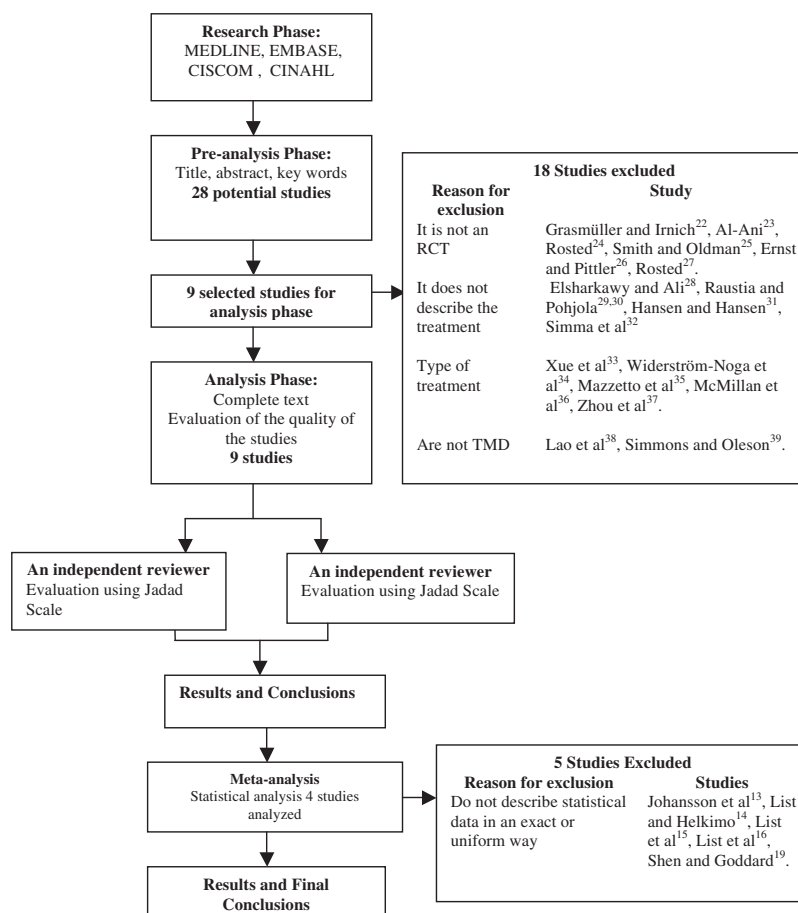


FIGURE 1. Representation of the systematic review phase.

TABLE 1. The Jadad Scale

Criteria	Score	
	Yes	No
Is the study randomized?		
Is the study double blinded?		
Is there a description of withdrawals?		
Is the randomization adequately described?		
Is the blindness adequately described?		
Score: Assign a score of 1 point for each "yes" or 0 for each "no."		

principles¹² and evaluates the quality of the design of the clinical trial by using 5 items (Table 1).

The Jadad scale classifies the clinical trials using a 0-to-5-point interval. A study is considered acceptable when the points add up to 3 or more, and are considered of low quality when 2 or less.

Two independent reviewers evaluated the quality of each of the articles selected by using the same methodology for the analysis. To reach a consensus, the disagreements between the 2 reviewers were to be resolved by a third if necessary. The phases of the study are described in Figure 1.

Statistical Analysis

The statistical analysis was performed by using the EPIDAT Software Program (version 3.1, the local Galician Government and the Pan-American Health Organization). The variable analyzed in the meta-analysis phase was the intensity of the pain according to the visual analog scale (VAS). The statistical data used was the difference between the VAS average from the SG and the CG, before and after the treatment (Table 2).

To contrast the data, the following statistical tests were performed: the DerSimonian and Laird Q test to measure the level of heterogeneity, the Begg test to measure the bias of the publication, and finally, the standardized difference in the means was used to compare the variables studied. All the calculations were performed with a 95% confidence level.

RESULTS

From a total of 28 RCTs, only 9 fulfilled the inclusion criteria and 9 RCTs were selected for the systematic review.^{13–21} In Figure 1 are shown the articles that were potentially included in this study after the research. All used acupuncture for treating TMD. Table 3 presents a general description of the mean features of the studies.

Results of the Quality Assessment of the Studies

According to the 2 reviewers' analysis, 5 of the study methodologies were acceptable in terms of quality,^{17–21} and the other 4 were considered deficient.^{13–16} The reviewers' analysis was coincident in all the studies without exception. As a result, the use of a third reviewer was not necessary. Table 4 shows the results of the evaluation according to the Jadad scale.

Characteristics of the Population Used in the Studies

In all the RCTs, the SGs consisted of adult patients. In 4 of the studies, the symptoms related to a TMD were secondary to muscular pain, specifically MP.^{17,19–21} From the study of Schmid-Schwap et al,¹⁸ one can deduce from the inclusion criteria and the evaluation of the sample, that they were patients with MP. In the other 4 studies, the specific diagnostic category of muscular pain of the patient group is not described, but by reviewing the inclusion and exclusion criteria it can be assumed that the sample was composed of TMD patients of muscular origin and that the chief symptom was pain in the head and neck.^{13–16} The VAS was the measurement tool in all the RCTs evaluated in this analysis (Table 3).

Characteristics of the Intervention

In all the RCTs published between 1991 and 1993,^{14–17} acupuncture treatment is compared with one group using occlusal splints and with a CG not receiving any type of treatment. The RCTs between 2002 and 2009^{17–21} used acupuncture treatment in the SG and compared it with a placebo treatment in the CG.

Seven of the studies only evaluated the effects of short-term acupuncture treatment.^{13,15,17–21} The remaining 2 studies evaluated the short- and long-term effects, as they re-evaluated the patients at 6 months^{14,16} and 1 year¹⁴ after the study was completed. The study performed by List and Helkimo¹⁴ was the only one to show positive long-term effects (Table 3).

In terms of the technical aspects of the acupuncture treatment used in the RCT, the duration of each session varied between 15,^{19,21} 20,²⁰ and 30 minutes,^{13–17} the latter being the most common duration for the studies that were reviewed. The acupuncture points used go from proximal points, which are those found in specific anatomic areas of the cranio-cervical-mandibular area (ST 6,^{14–17} ST 7,^{14–16,20} GB 20,^{14–16} EX 2^{14–16}), to distal points, which are mainly found on the upper (LI 4,^{13–19,21} SI 2,¹⁸ SI 3¹⁸) and lower extremities (ST 36^{14–16}). Only 4^{17,19–21} of the studies described how deep the needles were inserted. This insertion depth varied from 6 to 30 mm. Four of the studies^{17–19,21} investigated short-term effects, applying only 1

TABLE 2. Mean Differences and Standard Deviations From the Visual Analog Scale

Authors	Year	SG (Acupuncture)			CG (Placebo)		
		N	Mean	SD	N	Mean	SD
Goddard et al ¹⁷	2002	10	30.2	24.7	8	17.3	20.9
Schmid-Schwap et al ¹⁸	2005	11	19.1	11.9	12	6.2	14.8
Smith et al ²⁰	2007	15	33.2	31.0	12	0.8	5.1
Shen et al ²¹	2009	16	16.0	18.0	12	8.0	16.0

CG indicates control group; SG, study group.

TABLE 3. General Characteristics of the Studies

Authors	Design	Study Participants	Treatment	Instrument used to Measure	Results
Johansson et al ¹³	RCT	N = 45 Age: not specified	SG1 = Acupuncture SG2 = Occlusal splint therapy CG = no treatment	VAS SDS CDS Palpation of painful muscular points	SDS, CDS, and the intensity of pain were reduced significantly in SG1 and SG2 after treatment ($P < 0.05$). SG1 and SG2 compared with CG showed a reduction in CDS values ($P < 0.01$) and in the number of palpable painful points ($P < 0.05$). When comparing study groups, no differences were observed.
List and Helkimo ¹⁴	RCT	N = 80 Age: between 37 and 44 y 58 women 22 men	SG1 = Acupuncture SG2 = Occlusal splint therapy CG = No treatment	VAS Frequency of pain Anamnestic index ADL index scale Anamnestic questionnaire CDS Index for occlusal state Incisal and occlusal tooth wear	After 6 ($P < 0.001$) and 12 mo (SG1. $P < 0.01$) (SG2. $P < 0.001$), both study groups showed statistically significant improvement in the ADL index The 2 study groups showed statistically significant results in reducing the intensity of pain immediately after the study ($P < 0.001$) and in the frequency of pain (SG1. $P < 0.001$) (SG2. $P < 0.05$), as well as 6 and 12 mo after ($P < 0.001$) In both groups, the results showed a reduction in CDS at the end of the study (SG1. $P < 0.001$) (SG2. $P < 0.01$), as well as 6 and 12 mo after ($P < 0.001$) In the control group, there were no statistically significant results There were no statistically significant differences in the value of the ADL scale SG1 and SG2 showed statistical differences in reducing the VAS value ($P < 0.01$) and the CDS ($P < 0.001$) SG1 showed a reduction in the frequency of pain ($P < 0.01$) compared with SG2 and the CG
List et al ¹⁵	RCT	N = 110 Age: between 39 and 45 y 87 women 23 men	SG1 = Acupuncture SG2 = Occlusal splint therapy CG = No treatment	VAS Frequency of pain Anamnestic index ADL scale Anamnestic questionnaire CDS Index for occlusal state Incisal and occlusal tooth wear PPT/algometer	SG1 and SG2 reduced the VAS values (GE1. $P < 0.01$; GE2. $P < 0.05$), the CDS (GE1. $P < 0.001$; GE2. $P < 0.01$), and PPT SG1 and SG2 did not show any differences when the evaluation was carried out 6 months after the end of the study In the CG, there were no statistically significant differences.
Goddard et al ¹⁷	RCT	N = 55 Age: between 43 and 37 y old 46 women 9 men	SG = Acupuncture CG = Sham acupuncture	VAS CDS PPT/algometer	Both groups reduced the pain intensity value ($P = 0.001$). There were no significant statistical differences in the comparison of both groups ($P = 0.255$)
Schmid-Schwab et al ¹⁸	RCT	N = 18 Age: SG. 35.4 ± 10.63. CG. 34.53 ± 6.78 15 women, 3 men	SG = Acupuncture CG = Laser placebo	VAS Manual palpation Electronic axiograph	There was no improvement in the opening of the mouth ($P = 0.114$) There was no improvement in the range of protrusion movements ($P = 0.084$) Reduction in pain intensity ($P = 0.033$) Improvement in the tolerance to manual palpation ($P = < 0.05$)
Shen and Goddard ¹⁹	RCT	N = 23 Age: average 35 ± 14 23 women	SG = Acupuncture CG = Laser placebo		
		N = 15 Age: average			

Smith et al ²⁰	RCT Single blind	43.1 ± 13.6 14 women, 1 man N = 27 Age: average 40.5 ± 13.63 24 women, 3 men	SG = Acupuncture CG = Sham acupuncture SG = Acupuncture CG = Sham acupuncture	NRS VAS PPT/algometer VAS Maximum interincisal opening Articular sounds/Stereo- stethoscope Distribution of pain	Reduction of facial pain ($P = 0.003$), neck pain ($P = 0.011$) and headaches ($P = 0.0159$) Increase of PPT ($P = 0.027$). General improvement of function ($P = 0.003$) Reduction in pain intensity ($P = 0.001$) Reduction in pain distribution zones: right ($P = 0.0003$), left ($P = 0.005$) Improvement of maximum interincisal opening ($P = 0.029$). Improvement of active maximum opening ($P = 0.029$). Values of lateral movements: right ($P = 0.06$), left ($P = 0.008$) Reduction of painful muscular points ($P = < 0.05$) No improvement in articular sounds could be observed ($P = 0.317$) Reduction in jaw/face pain (NRS)($P = 0.04$) Reduction in jaw/face tightness (NRS) ($P = 0.04$) Reduction in neck pain (NRS) ($P = 0.04$) Improvement of master muscle pain tolerance (VAS) ($P = 0.001$)
	RCT Double blind	N = 28 Age: SG 36.94 ± 13.82. CG 44.83 ± 11.61 28 women	SG: Acupuncture CG: Sham acupuncture	NRS Algometer/VAS	

ADL indicates activity of daily living; CDS, clinical dysfunction score; CG, control group; NRS, numerical rating scale; PPT, pressure pain threshold; SDS, subjective dysfunction score; SG1, study group 1; SG2, study group 2; VAS, visual analog scale.

session, but the rest of them used a mean of 6 to 8 sessions of acupuncture. The acupuncture treatments with manual stimulation were used in all of the studies, except for 3¹⁴⁻¹⁶ in which electro-acupuncture was combined with manual acupuncture.

The interventions in the CGs of the different studies varied, being occlusal splint,¹³⁻¹⁶ sham acupuncture,^{17,19-21} sham laser acupuncture,¹⁸ and no treatment.^{13,15,16} The sham laser acupuncture was applied randomly on several acupuncture points.¹⁸ In the sham acupuncture interventions, 2 procedures were used; one penetrating the skin 2 to 4 mm, 1 cm distal to the verum acupoints,¹⁷ and the other procedure was only skin contact without skin penetration.¹⁹⁻²¹ The minutes and number of sessions were identical for acupuncture and sham acupuncture.¹⁷⁻²¹

Results of Statistical Analysis

For the meta-analysis, only 4 RCTs were selected.^{17,18,20} The result of the heterogeneity test ($P = 0.4101$) lead to the conclusion that the studies were homogeneous. For this reason, the latter statistical treatment was performed considering only the fixed effects. Galbraith's graph also contrasts the homogeneity of the studies (Fig. 2).

From the results, it can be seen that acupuncture is more effective than placebo in reducing the intensity of pain (standardized mean difference 0.83; 95% confidence interval, 0.41-1.25; $P = 0.00012$). Table 5 and Figure 3 represent the standardized mean difference through the fixed effects for each of the studies, together with a confidence interval and the weight that corresponds to it in the calculation of the global standardized mean difference. According to the result of the Begg test, the null hypothesis is contrasted with the absence of a publication bias ($P = 0.8154$).

DISCUSSION

Systematic Review

From the qualitative analysis of the 9 RCTs,¹³⁻²¹ the conclusion that can be drawn is that acupuncture is effective on short-term basis for the reduction of intensity of TMD pain of muscular origin. It is also important to note that in the study performed by Goddard et al,¹⁷ no statistically significant effects were observed in pain reduction when compared with the CG. However, in the pretreatment and posttreatment phase of such an acupuncture treatment, there was a significant statistical difference. Some of the RCTs analyzed also showed that the interincisal opening and the general function of the masticatory apparatus did improve for patients with a TMD of muscular origin.

In an earlier research (RCT), little difference has been found between the effects of acupuncture and placebo acupuncture but a substantial difference has been found between placebo and no acupuncture.⁴⁰⁻⁴² But this is different from a systematic review comparing placebo interventions with no treatment, in which they found only a small-to-moderate analgesic effect of placebo, which was possibly because of the placebo acupuncture bias.^{43,44} In a recent meta-analysis,⁴² a greater effect of placebo acupuncture was found in 10 of the many trials that used penetrative placebo needles compared with only 2 trials that used nonpenetrative placebo needles. This is similar to the results obtained in a randomized clinical trial⁴⁵ reporting no better analgesic effect between acupuncture and 3 sham acupuncture treatments: acupuncture for an unrelated condition, needle insertion at nonacupoint locations, or noninsertive

TABLE 4. Results of Methodologic Quality Evaluation According to Jadad Scale

Authors and Year of Publication	A	B	C	D	E	Total Sum
Johansson et al ¹³	1	0	1	0	0	2
List and Helkimo ¹⁴	1	0	1	0	0	2
List et al ¹⁵	1	0	1	0	0	2
List et al ¹⁶	1	0	1	0	0	2
Goddard et al ¹⁷	1	1	1	1	1	5*
Schmid-Schwab et al ¹⁸	1	0	1	1	0	3*
Shen and Goddard ¹⁹	1	0	1	1	0	3*
Smith et al ²⁰	1	1	1	1	1	5*
Shen et al ²¹	1	1	1	1	1	5*

*Studies that have an acceptable quality.

simulated acupuncture. However, some studies indicate that penetrating a needle through the skin, whether at an acupuncture point or not, has physiologic effects.^{46–48}

Quality of the Studies

The results of this study must be cautiously interpreted because the quality of 4 of the RCTs^{13–16} selected was deficient according to the Jadad scale. It is important to recognize that the lack of quality identified in these studies coincides with the conclusions described by other investigators in other systematic reviews.^{10,49,50}

The quality of the other 5 studies included in this systematic review, which happen to be those published in the last decade,^{17–21} are acceptable. A problem is that the sample sizes were very small. However, when considering the positive aspects of these studies,^{17–21} it was definitely appropriate to include comparisons with a CG using a placebo. With respect to the latter point, White et al⁵⁰ recommend using a placebo in the CG to evaluate the real effects of acupuncture more adequately. They also suggested using the double-blind technique for patients and for the evaluators, as it is an important factor in determining the quality of the research design of these RCTs. Future RCTs must reproduce this research, but with larger samples to obtain more reliable data.

Another negative issue in the studies is that the term TMD of muscular origin is used as a very general term

because of the inconsistencies in some RCTs^{13–16} in defining the specific type of muscular dysfunction that the patients in the study suffered. If we look at the definitions and diagnostic criteria of TMD, there is some controversy about which terms adequately define the various types of TMD. For example, one of the most cited classifications in the research is the one described by Dworkin and LeResche,⁵¹ and this is the Research Diagnostic Criteria for TMD. They classify these disorders into 3 categories: muscular dysfunctions, disc disorders, and arthropathy. The muscular dysfunctions, in turn, are subdivided into MP with or MP without limited mouth opening. More recently, Okeson⁵² also proposed a more extensive classification for TMD of muscular origin. Currently, we can say that MP is the most frequent cause of TMD of muscular origin. We consider that using this general term is correct; however, not all TMDs of muscular origin meet the diagnostic criteria of MP.

Five of the studies included in the systematic review, included patients with MP.^{17–21} In the other 4 studies, the type of TMD of muscular origin is described unclearly.^{13–16} For this reason, it was decided to use the general term, TMD of muscular origin. In this aspect, the authors of this review would like to point out the importance of an adequate taxonomic categorization of patients, as we see a trend to use scientifically incorrect terms or ones that are too general. These include a wide range of clinical entities with very different etiopathogenic and physiopathologic

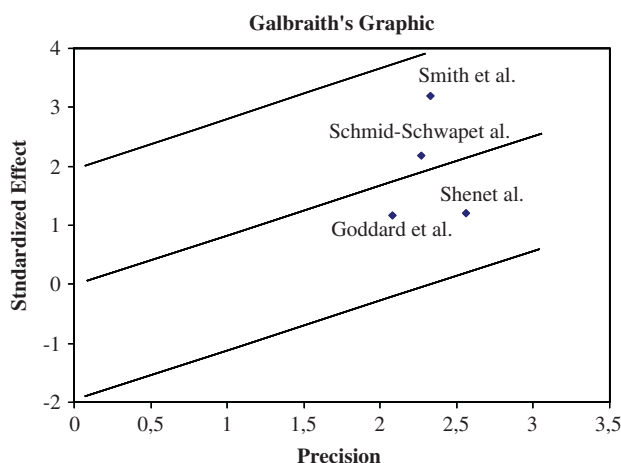
**FIGURE 2.** Galbraith graph with homogeneity zone.

TABLE 5. Results of Meta-Analysis: Confidence Intervals for Standardized Mean Difference and Global Interval With Fixed Effects

Study	N	Standardized Mean Difference	CI (95%)		Weight (%)
Goddard et al ¹⁷	18	0.56	-0.39	1.51	19.89
Schmid-Schwab et al ¹⁸	23	0.96	0.09	1.82	23.94
Smith et al ²⁰	27	1.37	0.53	2.22	25.13
Shen et al ²¹	28	0.47	-0.29	1.22	31.04
Global with fixed effects	96	0.83	0.41	1.25	

CI indicates confidence interval.

nature, which can lead to errors or confusion in terms of the results and conclusions. It is advisable that the research projects use the diagnostic guides of prestigious and renowned scientific associations to classify its patients,⁵³ thus ensuring that the results can be more practically applied on a daily basis at the clinics. Finally, for future studies, we recommend the use of the Simons et al⁵⁴ and Gerwin et al⁵⁵ diagnostic criteria for the description of MFP patients. It would be interesting for future research to use the Research Diagnostic Criteria for TMD so it will lead to a better classification of patients.

Acupuncture Points

Many of the studies use specific acupuncture points located in the anatomic areas of the cranio-cervical-mandibular zone, but also use points located distally, as is the case of the LI 4 point. It is interesting to point out that the most frequently used acupoint is LI 4.^{13-19,21} Hui et al,⁵⁶ studied a neuroimage after the stimulation of LI 4 and observed the activation of specific areas of the somatosensorial cerebral cortex related to specific anatomic zones. Linking with this, Hsieh et al⁵⁷ showed while studying a tomogram that different areas of the hypothalamus can be activated by the stimulation of LI 4. They suggest that the analgesic efficacy of the acupuncture stimuli could be measured using this technology.

About the specific proximal points used for TMD treatment, there are some investigators that state the myofascial trigger points (MTrPs) of the masseter muscle may be coincident with these proximal points.⁵⁸ A recent meta-analysis suggested that treatment by needling on MTrP was more effective than no intervention, and obtained contradictory results when the needling of MTrP is compared with needling elsewhere in the muscle.⁵⁹

Effectiveness of Acupuncture: A Meta-analysis

This meta-analysis suggests that acupuncture is more effective than the placebo in reducing the intensity of pain associated with TMD of muscular origin. On the other hand, one must take into account that only 4 RCTs^{17,18,20,21} were included, which represents a relatively small global sample (n=96). The problem of a meta-

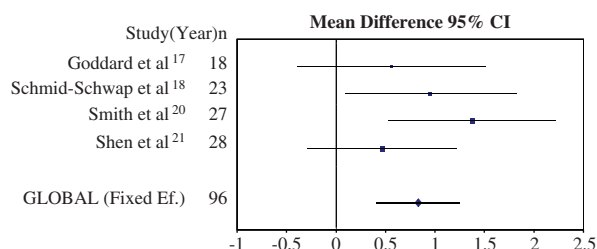
analysis carried out with few studies is that detecting a bias is more limited.⁶⁰ For this reason, the result obtained in terms of a publication bias must be interpreted with great caution.

In the end, there were only 4 RCTs in the meta-analysis as a result of the meticulous planning and the inclusion criteria applied to the studies. The main reason for exclusion was the defective quality and lack of uniformity in the statistical analysis of the VAS registration data. Furthermore, in 4 of the studies,¹³⁻¹⁶ the acupuncture treatment is not compared with a CG using a placebo. However, it is important to consider that adequate inclusion criteria is a key element for designing a meta-analysis that is related to the study of pain.¹⁰

A positive aspect of the RCTs included in the meta-analysis is that all 4 of them were considered, according to the Jadad scale, to have good quality.¹⁷⁻²¹ In terms of this latter point, Jüni et al⁶¹ describe that it is important to select good quality studies to carry out a meta-analysis, as poor quality studies can alter the estimated effect. Furthermore, evaluating the quality of the studies should be a mandatory criteria to be included in all meta-analysis using RCT.

Clinical and Statistical Significance

A treatment effect is defined as clinically significant when there is a statistically significant change and also a change that the patient or doctor considers beneficial.⁶² A study carried out by Bird and Dickson⁶³ described that the change, which represents a clinically significant change in pain intensity, is not uniform along the VAS scale. When the baseline pain intensity is less than 34 mm, the change has to be 13 ± 14 mm and for a baseline VAS greater than 67 mm, the change has to be 28 ± 21 mm. This is different from the concept of Todd et al,⁶⁴ who determined a clinically significant change in the VAS as 13 mm, independent from the patient's baseline VAS. Using Todd's definition, in this review only 6 of the studies^{13,14,17,18,20,21} are statistically and also clinically significant. Only these 6 have a difference large enough to consider their results clinically significant, compared with each one of the baseline VAS scores (decreases of 28, 14, 30.2, 17, 33, 16 mm with baseline values of 55, 22, 70, 40, 62, 74 mm respectively^{13,14,17,18,20,21}).

**FIGURE 3.** Forest plot: standardized difference in the means with confidence intervals.

The smallest detectable difference values of the VAS scores of pain intensity vary between 38% (short term) and 49% (long term). It is suggested that about 55% of the variation in the patients' behavior to TMD pain is explained by the variation in pain intensity. The magnitude of a relevant improvement varies inversely with the severity of a condition, that is, a large change is expected for acute or nondegenerative conditions whereas a small change is satisfying for degenerative conditions.⁶⁵

An interesting fact is that 2 of the studies^{14,20} that obtained both statistically and clinically significant effects in pain reduction used the proximal point ST 7. Another proximal point, ST 6, was used in 2 studies^{14,17} that obtained statistically and clinically positive effects. About the distal points, 2 of the studies used only LI 4,^{19,21} but only in 1 study,²¹ the results obtained were statistically and clinically significant. More research is required to find out if there is a real difference in the effects of needling at the local or distal points.

About Placebo Effect

There are specific and nonspecific factors that can influence the treatment of pain with acupuncture. Many studies have shown that true acupuncture and placebo/sham acupuncture seem to be clinically effective.⁶⁶ There has recently been research manipulating the patients' expectations. Expectations and beliefs are understood as pre-existing mental/brain states and influence the pain experience.⁶⁶ Recent publications regarding this issue have found more improvement in patients with higher outcome expectations.⁶⁷ On account of this, it is concluded that pain involves a complex psychophysiologic matrix interrelated with expectation. Acupuncture affects this matrix in 2 ways: specific and nonspecific; these are: clinical effects and expectation on pain relief. Even though Smith et al,²⁰ showed that real acupuncture had a greater influence on the clinical outcome measure of TMD MP than those of sham acupuncture and the majority of these reached a level of statistical significance, although sham acupuncture had no significant influence on the clinical outcome measures, other studies^{17,68} have shown contradictory evidence that sham acupuncture does have an influence. Expectation is one possible reason why it seems that both real and placebo acupuncture can obtain significant pain relief in many people. Another possible reason is that sham and placebo acupuncture may have a specific effect by simply touching the skin at an acupoint. Placebo effects depend on the type of sham and/or placebo acupuncture used and are influenced by factors such as insertion depth, whether or not the needle penetrates the skin or muscle, and patient expectation and belief. Acupuncture should be seen as a low-risk treatment for patients with different types of pain.⁶⁶

Current the treatment of TMD includes a variety of procedures ranging from dental and surgical procedures to physical and cognitive-behavioral therapies.^{69,70} The use of alternative and complementary medicine is becoming popular, but there is limited evidence of efficacy. There is not 1 therapy for TMD that elicits a clear efficacy, and no therapy has shown great superiority when compared with placebos. Both splints with only palatal coverage and placebo acupuncture produced a high percentage of positive responses.

The placebo effect can be very important. It is interesting to note that in an earlier review,¹⁰ all the studies

included did not control for possible placebo effects, which is an important bias generator and a big deficiency of the research in this field. In this review there are 9 articles in total, 4 of them coincident with the ones included in the Ernst and White review.¹⁰ There are 5 new studies that have better quality and a placebo CG. Ernst and White suggest that acupuncture has a powerful placebo effect and propose future research with nonpenetrative placebo acupuncture to see the real effect of acupuncture. We have included 3 studies^{19–21} that have sham acupuncture performed with nonpenetrative acupuncture. The results obtained are an improvement in facial pain and in general function. There is still a lack of quality in all the studies and a lot to discuss about the placebo effect, so these results should be interpreted with caution. There is a new and interesting study by Goddard et al¹⁷ in which sham acupuncture is performed by needling outside of the acupuncture points, and the results did not show statistically significant differences between the treatments; this could explain that besides the possible placebo effect of the acupuncture, there is a real effect based on the neurophysiology of the needling and the placement of the needles does not have to be on an acupoint for the reduction of pain. Needling outside of an acupoint may still have the possibility to inactivate a tender point and/or MTrP leading to pain reduction. A study by Kong et al⁶⁸ provides brain-imaging evidence for the existence of different mechanisms underlying acupuncture analgesia and expectancy evoked placebo analgesia. More research is required, including research comparing the effects of a true acupuncture treatment, an acupuncture treatment needling nonacupoints not on the acupuncture meridians, and a CG either with sham needling with no skin penetration or a CG with no treatment at all.

CONCLUSIONS

According to the results of this meta-analysis and the systematic review, acupuncture shows a statistically significant short-term analgesic effect on patients with TMD of muscular origin. These findings are similar to another review of acupuncture performed on low back pain, neck pain, and osteoarthritis involving the knee.⁷¹ More research is necessary, using larger samples sizes, improved design quality, and long-term evaluation to confirm the usefulness of acupuncture in the management of pain in TMD.

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