
Acupuncture in Headache: A Critical Review [Case Report]

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Abstract:

Twenty-seven clinical trials that evaluated the efficacy of acupuncture in the treatment of primary headaches (migraine headache, tension-type headache, and mixed forms) were reviewed. In the majority of the trials (23 of the 27 trials), it was concluded that acupuncture offers benefits in the treatment of headaches. Conversely, the evaluation of physical forms of treatment, including acupuncture, has special difficulties, and certain

parameters in the study design need consideration. Acupuncture methods need individualization, a carefully selected placebo ("minimal acupuncture" seems to be best), and the crossover design must have adequate time between the two treatment periods. Clinical trials that evaluate acupuncture frequently are characterized by several inadequacies (including some from these evaluating headaches), but it seems that additional clinical research is necessary to confirm its efficacy and to clarify its indications.

Acupuncture is a therapeutic technique developed within the framework of traditional Chinese medicine that has been practiced continuously for approximately 3,000 years.¹ During the previous 25 years, acupuncture analgesia has attracted the interest of specialists in various medical fields. Neurologists, neurophysiologists, rheumatologists, psychiatrists, and other professionals have conducted clinical and neurophysiologic trials in an attempt to improve pain treatment.²⁻⁸

The National Institute of Health Consensus Conference on Acupuncture³ evaluated the use of acupuncture in the relief of various syndromes. Regarding the effectiveness of acupuncture in headache, it was concluded that acupuncture "may be useful as an adjunct treatment or an acceptable alternative or be included in a comprehensive treatment program." Because criticism regarding acupuncture continues, and special methodology for acupuncture trials is needed, we think that a critical review of clinical trials evaluating acupuncture would be useful.

METHODS [↑](#)

Search procedure [↑](#)

MedLine was the main source of literature; the key words used were "acupuncture," "electroacupuncture," "headache," and "migraine." Several textbooks and other sources with references to the subject also were used,⁴⁻¹¹ and the volumes of the *American Journal of Acupuncture* of the last 20 years were searched.

Published abstracts were used if they contained necessary information. All of the 20 studies included in the review were studied in the full form presented in the relevant journals. Since most acupuncture journals appear in MedLine and in Index Medicus, the vast majority of studies were included in MedLine.

Inclusion criteria [↑](#)

Studies were included in the review if they met the following criteria:

It was a prerequisite that the studies were conducted in Western countries. Acupuncture is a respected form of treatment in China because it is a part of a long tradition. This general acceptance may influence patient opinion regarding the effectiveness of acupuncture by enhancing the placebo effect. In addition, Chinese studies on this subject were not placebo-controlled; therefore this a priori acceptance would create more difficulties in the interpretation of the results.

It was necessary that the acupuncture method used be a form of traditional acupuncture or "trigger point deactivation" using acupuncture needles. Other forms of therapy, such as "ear acupuncture";¹² "scalp acupuncture"; trigger point injections with local anesthetics, steroids, or sterile water;¹³ and "acupuncture-like TENS"¹⁴ were not accepted. Also, the same was true with references about multidisciplinary pain management,

using acupuncture in combination with other medical or physical forms of treatment.

It was necessary that the study be on primary headaches (migraine headache, tension headache, and mixed forms). Studies that evaluated the effectiveness of acupuncture in secondary headaches, pain as a result of temporomandibular joint dysfunction,¹⁵⁻²² postlumbal puncture headache,²³ or atypical facial pain ²⁴ were excluded.

Studies that investigated possible mechanisms of acupuncture analgesia using the same patients who were presented in other studies were excluded.²⁵⁻²⁷ In addition, one study ²⁴ was excluded because it was a duplicate of a study, with the same author and the same patients.³⁰ Studies with an inadequate amount of information regarding results and their statistical significance were not included.

RESULTS[‡]

Using the aforementioned criteria, 27 studies were selected. Eight of these studies were regarding patients with tension headache, and 20 of the studies were regarding patients with migraine headache or mixed forms. The total number of patients in all trials was 1,088. Of the 27 studies, 19 studies had a control group and 8 studies did not have a control group (Tables 1, 2). Of the 19 studies with control groups, 2 studies had control groups that underwent physiotherapy,^{30,31} 12 studies used sham acupuncture in control participants,^{29,32,33,34,36,38,39,40,41,45,46,47} 1 study used pseudo-TENS,³⁵ and 4 studies used pharmacotherapy.^{37,39,43,44} In one of them, a cross-over design with placebo acupuncture plus metoprolol and placebo pharmacotherapy plus acupuncture on trigger points was used.³⁹ A cross-over design was used in five studies ^{29,32,33,36,39} and partially in another study.³⁷

Author study	Patient number	Type of headache	Type of treatment in control group	Number of treatments	Follow-up	Overall results according to authors	Comments
Jehnsen et al. (29)	29	TTH	Ps-Ac (min Ae/crossover)	TG = 1 CG = 1	2 months	+	Significant reduction in headache frequency and drug consumption.
Ahonen et al. (30)	22	TTH	PT	TG = 4 CG = 8	28 weeks	+	Four AC sessions had the same effect with 8 PT sessions.
Carlsson et al. (31)	62	TTH	PT		7-12 months	+	Improvement with AC and PT.
Hansen & Hansen (32)	18	TTH	Ps-Ac (crossover)	TG = 6 CG = 6	15 weeks	+	Reduction (31%) of pain index.
Vincent (33)	14	TTH	Ps-Ac (crossover)	TG = 4 CG = 4	4 months	+/-	Ac was superior to PS-Ac in 4 of 14 patients.
Tavola (34)	39	TTH	Ps-Ac	TG = 8 CG = 8	12 months	-	Ac = Ps-Ac but drug consumption decreased by 58% in treatment group and by 22% in the control group.
Dowson et al. (35)	39	MG	Ps-TENS	TG = 6 CG = 6	4 weeks	+	Ac has a superiority of 20% compared to PS-Ac.
Lenhard & White (36)	16	MG	Ps-Ac (crossover)	TG = 4 CG = 4	2 months	+	50%-100% improvement in 40% of patients.
Lah et al. (37)	48	MG/MXT (R)	Med T (Partially crossover)		3 months	+	Ac was superior to medical treatment (59% of treatment group and 22% of the control group were treated successfully).
Kubierna (46)	30 (TG = 15; CG = 15)	MG	Ps-Ac		2 years	+	Class-Ac superior to Ps-Ac, however, noteworthy improvement with Ps-Ac
White (47)	9 (TG = 4; CG = 5)	TTH (CDH?) (>15 headache days/month)	Ps-Ac	TG = 6 CG = 6	28-36 weeks	+/-	Less number of headache free weeks in TG than in CG ($p < 0.05$).

TABLE 1. No caption available.

Author study	Patients number	Type of headache	Type of treatment	Number of treatments	Follow up	Overall result according to authors	Comments
Vasilakos et al. (48)	50	TTH MG (R)	Class Ac	15	8 months	+	64–69% of patients had significant reduction of HI after 8 months
Boivie et al. (49)	25	TTH MG (R)	Class Ac	6–8	25 weeks	+	MG: HI decreased by 40% in 25 th week.
Jensen & Tallgren (50)	21	TTH	Class Ac	1	4 months	+	60% of patients had significant improvement.
Marcus (51)	12	MG (R)	Class Ac	5–7	16–158 weeks (mean 64)	+	Seven patients stopped the medication; four reduced dosage.
Kim & Yount (52)	28	MG/MXT	Class Ac	5–11		+	48% of patients, headache free. 20% no medication.
Laitinen (53)	39	MG (R)	Class Ac	5	6 months	+	92% improved. After six months, 54% remained improved.
Junnila (54)	115	TTH MG (R)	Class Ac	3–6, followed by more when necessary	2–8 years	+	74% of patients obtained more than 30% relief of symptoms that lasted for an average of 22 months. 75% of patients reduced analgesics by more than 50%
Baischer (55)	22	MG	Class Ac	6–13	3 years	+	69% of patients showed more than 33% fall of the migraine index at posttreatment and 58% of them after three years.
Vincent (38)	30	MG	Ps-Ac	TC = 6 CG = 6	12 months	+	Ac was superior to Ps-Ac
Hesse et al. (39)	77	MG	Metoprolol + Ps-Ac (crossover)	TG = 6 CG = 6	17 weeks	+	Ac = drug therapy
Pintov et al. (40)	22 (children)	MG	Ps-Ac (Min Ac)	TG = 10 CG = 10	10 weeks	+	Overall opioid activity and β -endorphin blood levels increased in TG
Baust et al. (41)	44 (TG = 23; CG = 21)	MG (R)	Ps-Ac	TC = CG = 10	20 weeks	+/-	Ac slightly superior to Ps-Ac
Doerr-Pröske (42)	30 (TG = 10; CG = 10; Waiting 1st + 10)	MG	Relaxation Waiting list	TG = 10	3 months	+	Relaxation technique slightly superior to acupuncture
Heidenreich (43)	150 (TG1 (Class Ac) = 50; TG2 (EI Ac) = 50; CG (Med T) = 50)	MG	TG = CG = 10–12 CG = Med T (Dihydroergotamine)		3–6 months	+	Class-Ac and EI-Ac superior to Med. T (Dihydroergotamine + Iprazochrom)
Lehmann et al. (44)	63 (Class Ac = 20; EI-Ac = 22; CG = 21)	MG (R)	Med T (Propranolol 75–150 mg/day)	CG = 12	1 year	+	Class-Ac/EI Ac superior to Med T (propranolol, 75–150 mg)
Weinschutz (45)	81 (TG = 40; CG = 41)	MG	Ps-Ac	TG = CG = 10	1 year	+	Class-Ac superior to Ps-Ac

TABLE 2. No caption available.

Tables 1 and 2 show that the selected studies selected differ significantly, not only regarding project design, but also regarding number of patients, follow-up time, and other parameters. Patient selection differed significantly among studies. More recent studies used the criteria of the International Headache Society and are more strictly followed. Significantly, in at least eight studies,[37,39,41,44,48,51,53,54](#) the patients treated were referred to acupuncture treatment because of cases resistant to conventional treatment.

If the studies in which the authors concluded that acupuncture is a useful analgesic method in treatment of headache are considered to be "positive," and the studies in which the authors concluded oppositely are considered to be "negative," 23 studies can be considered to be "positive" and only 1 study must be considered to be "negative."[34](#) In one study acupuncture is considered to be "a potentially useful method needing more

clinical evaluation."³³ In two studies, the authors do not end in a real outcome as in one ⁴¹ acupuncture was slightly superior to pseudo-acupuncture and in another one ⁴⁷ the number of patients was small (but there was a decrease in headache days).

DISCUSSION [‡]

It is generally accepted that it is not easy to evaluate pain control accurately, especially when physical forms of treatment are used.² To evaluate the analgesic efficacy of a method that uses a form of peripheral stimulation, a number of different parameters must be taken into account.

What is the proper stimulus? [‡]

As part of a folk medical system, acupuncture has its own traditional framework.¹ There is much controversy between acupuncturists regarding the "correct" form of acupuncture treatment, and many different "recipes" appear in well-known acupuncture textbooks.^{1,9} This discrepancy creates many problems in standardization of the method because, according to the classical theory, point selection is never the same, and individualization of it is needed in each patient.

Clinical experience [‡]

Clinical experience is in agreement with this belief as in some patients certain acupuncture points in combination with trigger points have to be selected. Testing acupuncture analgesia in the laboratory differs from testing its effectiveness in a hospital setting. Neurophysiologic studies in animals and in humans provide evidence that acupuncture increases the pain threshold and works through activation of an endogenous analgesic system by increasing the levels of certain endogenous opioids and/or other neurotransmitters (e.g. serotonin ⁴⁸⁻⁵⁰). This theory was supported by the study of Mayer et al., which demonstrated that acupuncture analgesia is reversible by naloxone.⁵¹ The decrease of the sensitivity to pain usually is extended to widespread areas or even to the whole body.⁵²⁻⁵⁴ From a neurophysiologic view, it is imperative to make a distinction between acupuncture analgesia and diffuse noxious inhibitory control (DNIC) analgesia.^{68,69,70} From a clinical view, it is more important to determine the effect of acupuncture on pain tolerance rather than on pain threshold. Pain threshold, defined as the minimal stimulus (thermal, mechanical etc.) causing pain, is of little clinical interest. Pain tolerance, defined as the maximum pain that is tolerated by the patient, is more important because patients seek medical attention not when pain is felt minimally, but when pain is strong enough to be tolerated. To determine the effectiveness of acupuncture on pain tolerance, well-designed clinical trials are necessary.

Acupuncture trials are not double-blind; ideally, they are single-blind. The clinician administering acupuncture is aware of which is the true treatment and which is the control. His or her behavior during treatment inadvertently may give improper clues to the patient regarding the type of treatment being used. Exceptionally, there are two trials in the literature in which acupuncture was performed in anesthetized patients.^{64,65}

Placebo acupuncture is not an ideal placebo. The evaluation of the analgesic action of acupuncture is part of the general problem of evaluating various physical forms of treatment. Drugs are much more easily tested in their action with measurable doses, pharmacokinetics, and placebo testing. The use of adequate placebo is much more difficult when one deals with physical forms of treatment, such as acupuncture. Placebo acupuncture is not identical to therapeutic placebo because it does not produce the specific "Deqi" sensation (i.e., a special paresthetic feeling consisting of soreness, numbness, and heaviness) that real acupuncture does. This may create suspicions for the patient regarding the authenticity of the therapy, especially in the case of crossover trials in which real and placebo acupuncture are administered alternatively. Two different procedures of placebo acupuncture ⁶⁶ are commonly used:

"Sham" acupuncture [↑](#)

Depth of insertion and intensity of stimulation by the needles are the same in "sham" acupuncture as in real acupuncture; only location differs. The locations selected are close to the classical points (usually within few millimeters). Initially, sham acupuncture was assumed to be ineffective and, therefore, ideal as a placebo. However, Lewith and Machin [67](#) noted that sham acupuncture has an analgesic effect in 40 to 50% of patients, in comparison with the effectiveness of 60% of real acupuncture. This analgesic effect was attributed by them to the DNIC mechanism [68,69,70](#) in which noxious stimuli in one part of the body inhibit dorsal horn nociceptive neurons in spinal segments innervating distal body parts. Brainstem structures seem to be involved in DNIC because the phenomenon is not observed in patients with Wallenberg syndrome who are not affected by thalamic lesions. However, the hypothesis that DNIC is responsible for sham acupuncture analgesia (or even real acupuncture analgesia) is debatable because the effect of DNIC disappears after ceasing heterotopic stimulus application. A more likely mechanism to explain the analgesic effect of sham acupuncture would be that of deactivation of adjacent trigger points. This hypothesis is strengthened because of trigger points that usually are in common sites with classical acupuncture points and because trigger points are wider areas, with a diameter of several centimeters.[71](#) Therefore, by puncturing the skin and muscle 1 cm away from a classical acupuncture point, it is possible to puncture an existing trigger point in the area.

Another form of placebo acupuncture used is "minimal" acupuncture. In this procedure, the needles are placed away from classical points, are inserted only 1 to 2 mm, and are not stimulated. This procedure precisely minimizes the specific effects of the needling but maintains the psychological impact.[66](#)

Mock transcutaneous electrical nerve stimulation [↑](#)

Mock transcutaneous electrical nerve stimulation (TENS) commonly is used in physical therapy. Using electrodes, electrical stimuli are delivered to the painful area. These stimuli activate A[beta] nerve fibers, thereby closing the pain "gate" in the dorsal horns. In mock TENS, the stimulator and electrodes are used in the same manner, but it does not deliver true electrical stimuli.[66](#) This form of placebo is disadvantageous in that it differs significantly from acupuncture, and it does not produce feeling to the patient.

Crossover trials may create incorrect conclusions, Acupuncture analgesic effect lasts not only from weeks to several months, but also may increase further after the end of acupuncture treatment, as some trials have shown.[38,72](#) If, in a crossover trial, acupuncture precedes the placebo treatment, it is possible that the analgesic effect being attributed to placebo may be a result of the long-lasting effect of acupuncture.

In conclusion, with the data that we have available, the use of acupuncture for the treatment of headache seems promising because the vast majority of clinical trials (23 out of 27 trials) had positive conclusions regarding its effectiveness. Conversely, evaluation of physical forms of treatment, including acupuncture, presents special difficulties, and certain parameters in the study design need consideration. Acupuncture methods need to be individualized, and the type of placebo must be selected carefully ("minimal acupuncture" seems to be the best method), and the crossover design must leave adequate time between the two treatment periods. Clinical trials that evaluate acupuncture frequently are characterized by several inadequacies because some of the aforementioned parameters are not taken into consideration.[28,42,44,55,56,57,58,59,60,61,62,63](#)

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