

The Efficacy of Acupuncture for Migraine Prophylaxis

China



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Duration: June 2007 - February 2009.

Total cost: USD 70,000.

Summary

A multicentre, double-dummy, single-blinded, randomized controlled clinical trial was conducted at the acupuncture outpatient departments at five hospitals in China to evaluate the effectiveness of acupuncture. A total of 140 patients with migraine without aura were recruited and randomly assigned to two different groups: the acupuncture group treated with verum acupuncture plus placebo and the control group treated with sham acupuncture plus flunarizine. Patients

were treated using acupuncture three times per week and drugs every night; patients from both groups were evaluated at week 0 (baseline), week 4, and week 16. The results suggested that acupuncture was more effective than flunarizine in decreasing days with migraine attacks, whereas no significant differences were found between acupuncture and flunarizine in reduction of pain intensity and improvement in the quality of life.

Background and Justification

Migraine is a common recurrent headache disorder with characteristics of unilateral location, pulsating quality, moderate or severe in intensity with associated symptoms of photophobia, phonophobia, nausea, vomiting, etc. The one-year prevalence for migraine was 14.7% (19.2% women and 6.6% men) in the United States and 8–13% in Asia. Because patients with migraine usually have frequent, severe, and disabling headache attacks, medical treatment is often required. Based on the recommendations of the European Federation of Neurological Societies guidelines on drug treatment, oral non-steroidal anti-inflammatory drugs (NSAIDs), and triptans are recommended for acute migraine attacks. However, patients may experience some side effects from pharmacological therapies, such as gastrointestinal and cardiovascular disorders. Moreover, headaches from overuse of medication and increased headache frequency may be caused by regular use of analgesics or specific anti-migraine treatments.

As a major component of traditional Chinese medicine (TCM), acupuncture has been used to treat headache in China for thousands of years. Over the past few decades, acupuncture has also been used widely as a treatment for migraine in western countries as well. Because of the growing use of acupuncture, the US Headache Consortium has suggested that acupuncture might play an important role in managing migraine without any side effects.

The evidence for acupuncture's effect on migraine has been questioned with regard to the quality and methodology of the acupuncture clinical trials performed in China, such as inappropriate group setting control, inadequate outcome measurements,

unclear classification between acute and preventive treatment, and the lack of detailed randomization and blinding information. In addition, researchers have argued that results from trials with different forms of intervention between experimental groups and control groups (such as acupuncture vs. medicine) cannot be used to compare and evaluate the efficacy of acupuncture.

Description

The acupuncture treatment consisted of three 30-minute sessions per week, administered over 4 weeks. The acupoints, including both obligatory and additional points, were selected based on the consensus of clinical experiences of acupuncture experts. The obligatory points included DU20 (Baihui), DU24 (Shenting), GB13 (Benshen), GB8 (Shuaigu), and GB20 (Fengchi). Additional points were chosen individually depending on the syndromes presenting: SJ5 (Waiguan) and GB34 (Yan-glingquan) for Shaoyang headache (TE-GB); LI4 (Hegu) and ST44 (Neiting) for Yangming headache (LI-ST); BL60 (Kunlun) and SI3 (Houxi) for Taiyang headache (SI-BL); LR3 (Taichong) and GB40 (Qixu) for Jueyin headache (PC-LR); PC6 (Neiguan) for nausea and vomiting; and LR3 (Taichong) for dysphoria and susceptibility to rage.

In light of our clinical experience and previous studies, for traditional acupuncture providing long lasting effects in decreasing both pain intensity and medication intake and in line with theories of TCM, it is important to choose acupoints on the basis of syndrome differentiation. In our trial, the acupoints were selected according to the national clinical guideline and late masters' experiences complying with the methodology of syndrome differentiation of meridians.

Acupoints were punctured perpendicularly with lifting, thrusting, and twirling for obtaining *DeQi*. The sensation of *DeQi* was defined as numbness, distension, soreness and heaviness around the point felt by patients. As exceptions, acupoints of DU20 (Baihui), DU24 (Shenting), GB13 (Benshen), and GB8 (Shuaigu) were punctured horizontally: the needle being inserted obliquely under the galea aponeurotica and then turned horizontally with twirling.

Results

The prophylactic effect with acupuncture being as good as flunarizine persisted from the end of the treatment (week 4) through the next three months, with acupuncture performing slightly better than flunarizine. The proportion of responders and migraine days of the acupuncture group was significantly improved. Additionally, the number

of patients that required acute medication in the acupuncture group was significantly reduced compared to the control group. However, no statistically significant differences were encountered in visual analogue scale (VAS) scores and the physical and mental components summary scores for SF-36 during the trial (Table 1).

During the follow-up period, several patients in the acupuncture group reported that the attacks seemed to be a prodrome of a migraine episode, such as tense paresthesias in the head, and lasted from several seconds to a few minutes. These attacks failed to develop into a typical migraine and required no medication. These symptoms perhaps demonstrate that acupuncture might reduce the chances of a migraine attack after a prodrome occurs.

Group	Time point	Acupuncture group n = 70		Control group n = 70		P [†]
		Mean ± SD	95% CI	Mean ± SD	95% CI	
Responder rate [‡] (ITT)	Week 4	41 (59%)	–	28 (40%)	–	.043
	Week 16	39 (56%)	–	26 (37%)	–	.042
Difference from baseline in days of migraine (ITT) [‡]	Week 4	4.1 ± 3.5	(3.2–4.9)	1.9 ± 2.3	(1.4–2.5)	<.001
	Week 16	4.1 ± 3.5	(3.3–5.0)	2.0 ± 2.7	(1.4–2.6)	<.001
Visual Analogue Scale (ITT) [‡]	Baseline	6.9 ± 1.7	(6.5–7.3)	6.7 ± 1.9	(6.2–7.1)	.143
	Week 4	4.3 ± 2.7	(3.7–5.0)	5.2 ± 2.0	(4.7–5.7)	
	Week 16	4.6 ± 2.6	(3.9–5.2)	5.4 ± 2.3	(4.9–6.0)	
	P [‡]	<.001		<.001		
SF-36 (ITT), Physical [§]	Baseline	49.7 ± 7.3	(48.0–51.5)	50.6 ± 6.4	(49.1–52.1)	.249
	Week 4	55.9 ± 7.7	(54.1–57.7)	53.6 ± 7.1	(51.9–55.3)	
	Week 16	57.0 ± 7.5	(55.2–58.8)	54.8 ± 7.2	(53.0–56.5)	
SF-36 (ITT), Mental [§]	Baseline	49.7 ± 9.0	(47.5–51.8)	51.0 ± 7.5	(49.2–52.8)	.213
	Week 4	56.0 ± 7.1	(54.3–57.7)	52.6 ± 7.4	(50.8–54.3)	
	Week 16	55.5 ± 6.9	(53.9–57.2)	53.6 ± 7.0	(52.0–55.3)	
Reduction in the number of people with acute medication, n (%) (ITT)	Week 4	20 (61%)	–	4 (14%)	–	.001
	Week 16	17 (52%)	–	5 (18%)	–	.014

CI, confidence interval; ITT, intention-to-treat; SF-36, 36-item short-form health survey.
 Significant difference, P < .05. Data presented as mean ± SD, number (percentage) and 95% CI.
[†] P for comparison with control group.
[‡] P values based on chi-square test.
[§] P values based on analysis of covariance analysis.
^{||} P values based on repeated measures.
[¶] P for comparison within each group.

Table 1: The primary and secondary outcomes of the measures undertaken.

Partnerships

This study was designed and carried out cooperatively by a group of experienced acupuncture experts, acupuncture practitioners, neurologists, methodologists, and statisticians from the following participating institutions: the Acupuncture Department of Beijing Traditional Chinese Medical Hospital, the Neurology Department and Pain Department of the Third Hospital of Peking University, the Neurology Department of Beijing Tiantan Hospital, the Acupuncture Department of Huguosi Hospital, and the Acupuncture Department of Dongzhimen Hospital.

Impact

This study is the first acupuncture clinical research paper in China included and recommended by the Faculty of 1000 (F1000). The acupuncture intervention applied in this trial was embodied in the new edition of TCM Clinical Guidelines for Headache.

Our department was the first one to systematically evaluate the effects of acupuncture on different categories of headache according to ICHD-3, published in a report in 2013. After this study, we conducted clinical research to demonstrate the effect of acupuncture on menstrual-related migraine and acute migraine attacks, with experimental studies explore the mechanism underlying its effect.

The success of this experience mainly relied on the knowledge of syndrome-meridians differentiation by the participating acupuncture experts, the manipulation techniques of the acupuncture practitioners and migraine-related neurological knowledge of the neurologists. The methodology of syndrome differentiation of meridians and the selection of acupoints played key roles in the beneficial effects of acupuncture.

Replicability

To apply this experience successfully, an acupuncturist with clinical experience of acupuncture of no less than 5 years and a basic knowledge of TCM's differentiation of syndromes and meridians together with headache-related neurology is necessary.

Lessons Learned

The clinical trials described here have added to the gradual accumulation of knowledge surrounding migraine and its understanding in terms of both traditional Chinese medicine theory and neurology.

Migraine has certain trigger factors, which are not often known by patients. A lack of migraine-related education means our patients cooperate poorly with the treatment, exposing themselves to various trigger factors in their daily lives. In addition, the population susceptible to migraine – largely young females – is less careful in regard to therapy regulation and trigger factor avoidance. These factors all represent major disadvantages in achieving a good clinical outcome.

Future Plans

The effect of acupuncture on acute migraine attack and menstrual-related migraine is due to be evaluated by further randomized clinical trials. In addition, basic research is currently being conducted on the mechanisms of acupuncture involved in migraine prophylaxis.

Potential collaborations with researchers from Germany, the UK and the USA are being developed with a view to conducting joint clinical trials. Further acupuncture training based on the present experience for European and American practitioners will be provided at that time.

Publications

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