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Is Acupuncture An Effective Treatment For Acute Migraine?

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A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

In partial Fulfillment of the Requirements For

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In

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Philadelphia College of Osteopathic Medicine
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ABSTRACT

OBJECTIVE: The objective of this selective EBM review is to determine whether or not acupuncture is an effective treatment for acute migraines.

STUDY DESIGN: Review of three English language randomized controlled trials, published between 2003 and 2012.

DATA SOURCES: Three randomized controlled trials published in peer reviewed journals found using PubMed, Medline, and EBSCOhost.

OUTCOMES MEASURED: The outcomes measured included complete absence of migraine pain, measured by Visual Analog Scale scores and a headache diary, and progression to a fully formed migraine, measured by the Validated Pain Scale by Heller.

RESULTS: The studies by Li et al and Wang et al found a statistically significant number of patients were pain free, 24 hours following acupuncture, compared to sham acupuncture. The study by Melchart et al found statistically significant fewer patients progressed to a full migraine, 48 hours following acupuncture, compared to a Sumatriptan placebo.

CONCLUSIONS: The results showed acupuncture is an effective treatment for acute migraines, as evidenced by a significant number of patients experiencing complete absence of pain, or avoiding a full migraine after receiving acupuncture, as well as low numbers needed to treat (NNT) for all three studies. Additional research is needed in order to determine the type of acupuncture that is most effective in the treatment of migraines.

KEY WORDS: Migraine, acupuncture

Introduction

Migraine headache is a common diagnosis, which impacts a patient both professionally and socially. By definition, a migraine is a headache that is characterized by unilateral location, pulsating quality, moderate to severe intensity, and associated symptoms of photophobia, phonophobia, nausea and vomiting¹. Migraine headaches are a result of the brain being particularly sensitive to environmental and sensory stimuli. Although the exact pathophysiology of migraines is unknown, it is believed that this sensory oversensitivity is due to a dysfunction in the monoaminergic sensory control systems in the brainstem and thalamus. Dopamine and Serotonin are also both believed to play a role in migraine headaches².

Migraines are the second most common cause of headache, with approximately 15% of women and 6% of men experiencing a migraine in a one year period². In 2010 there were 1.2 million visits to emergency rooms in the United States for migraines³. This prevalence places a financial burden on both the health care system and employers of people who suffer from migraine headaches. It is estimated that 2-3 billion dollars are spent on the treatment of migraines annually and that US employers lose an additional 13 billion dollars in lost labor due to migraine headaches each year⁴.

Symptoms of migraines include a unilateral throbbing headache, anorexia, nausea, vomiting, photophobia, phonophobia, osmophobia, cognitive impairment, and blurring of vision⁵. A migraine may or may not be preceded by an aura of transient neurologic symptoms. The most common form of an aura is a visual alteration. Visual alterations include hemianopic field defects, scotomas, and scintillations that spread peripherally⁶.

Treatment of acute migraine headaches focuses on symptom relief. Symptomatic relief is provided by simple analgesics, such as Acetaminophen and NSAIDs, Ergotamines, Triptans and antiemetics. In some cases Opioid analgesics are required if other treatment modalities fail to relieve pain⁵. These medications are typically effective at alleviating or getting rid of acute migraine pain, however, some patients are unable to take these medications due to underlying medical conditions or interactions with other medications, while others would prefer an alternative non-medicinal form of therapy.

An alternative to pharmacologic therapy for the relief of acute migraine pain is acupuncture. Acupuncture is an oriental medical practice that uses needles to stimulate specific anatomic points, in order to promote proper flow of energy, thereby treating illness and promoting health. Acupuncture is performed with four to fifteen thin, solid, stainless steel needles that are inserted into selected acupuncture points for 10-30 minutes. These needles are stimulated manually or with electricity or heat⁷.

OBJECTIVE

The objective of this selective EBM review is to determine whether or not acupuncture is an effective treatment for acute migraines.

METHODS:

The studies used in this systematic review include three randomized, placebo controlled clinical trials, which were selected based on specific criteria. The population studied included both males and females, 18-65 years old, who were diagnosed with migraine headaches. The intervention used in each of the studies was acupuncture. In the

studies by Li et al and Wang et al, comparisons were made between the treatment group, in which patients received acupuncture, and the control group, in which patients received sham acupuncture^{8,1}. In the study by Melchart et al, a 1 ml NaCl injection, which was a visually matched placebo for Sumatriptan was used as the control intervention⁹. Outcomes measured included complete pain relief 24 hours after treatment with acupuncture and progression to a full migraine 48 hours after treatment.

All studies were published in the English language in peer-reviewed journals. Research for each study was done by the author via PubMed, Medline, and EBSCOhost using the keywords “migraine” and “acupuncture”. Studies were selected based on relevance to the clinical question and the inclusion of patient oriented outcomes. Inclusion criteria for the studies included randomized controlled trials, published between 2003 and 2012, which used acupuncture as an intervention for acute migraine headaches. Exclusion criteria included patients under the age 18 and use of the intervention for prophylaxis of migraines. Statistics used in this review included p-values, numbers needed to treat (NNT), relative risk reduction (RRR), absolute risk reduction (ARR), and number needed to harm (NNH), which were calculated by the author using the dichotomous data found in each study. Table 1 displays the characteristics and demographics of the included studies.

Table 1: Demographics & Characteristics of included studies

Study	Type	# Pts	Age (yrs)	Inclusion Criteria	Exclusion Criteria	W/D	Interventions
Li et al ⁸ (2009)	Single Blind, Placebo controlled RCT	175	18-65	Men and women with a diagnosis of migraine for 1 year with one or more	Subarachnoid hemorrhage, cerebral hemorrhage, cerebral embolism, cerebral	12	Verum acupuncture vs. sham acupuncture

				migraines per month during the last 3 months.	thrombosis, vascular malformation, bleeding disorders, or allergies.		
Melchart et al ⁹ (2003)	Placebo controlled RCT	179	18-65	Men and women with a diagnosis of migraine for 3 years, with a frequency of at least 2/month, who rated the intensity of their migraine as mild or less.	Ischemic heart disease or other vascular diseases, HTN, asthma, blood coagulation disorders or other neurological or psychiatric disorders, use of psychoactive drugs, history of drug or alcohol abuse, pregnancy or lactation.	0	Verum acupuncture vs Sumatriptan visually matched placebo, 1 ml NaCl solution injection.
Wang et al ¹ (2012)	Single Blind, Placebo controlled RCT	150	18-65	Men and women with a history of migraine for more than 1 year, with at least 1 migraine attack during the last 4 weeks.	Other headache disorders, pregnancy, lactation, psychosis, immunodeficient patients, bleeding disorders, or allergies. Prophylaxis with acupuncture or drugs in the past 3 months.	10	Verum acupuncture vs. sham acupuncture

OUTCOME MEASURES

The outcome measures in each of the studies focused on the progression or resolution of migraine pain. The studies by Li et al, and Wang et al measured whether or not complete pain relief occurred 24 hours after the intervention. The study by Li et al measured pain relief by asking patients to keep a headache diary and record the time when

the pain started to ease and note whether or not there was complete pain relief 24 hours after treatment⁸. The study by Wang et al measured if complete pain relief occurred 24 hours after treatment, by using Visual Analog Scale (VAS) scores for pain (0=no pain, 10=worst pain)¹. The study by Melchart et al measured whether or not the patient progressed to a full migraine. This measurement was based on the Validated Pain Scale by Heller, on which a score greater than 30 was considered to be a full migraine⁹.

RESULTS

The three studies used in this review examined the effect of acupuncture on pain relief in patients experiencing an acute migraine headache. Each of the studies contained dichotomous data, which could be used to calculate RRR, ARR, and NNT. Two of the studies examined the efficacy of acupuncture in the achievement of complete pain relief within 24 hours. The third study examined if acupuncture was effective at stopping the progression of a mild migraine to a fully developed migraine headache.

In the study by Li et al, 175 patients with an acute migraine were randomly assigned to either the verum acupuncture group (n=58), sham acupuncture group one (n=60) or sham acupuncture group two (n=57)⁸. For the purpose of this review sham acupuncture group two was excluded. The patients assigned to the acupuncture group received needling in genuine acupoints, whereas the patients in the two sham acupuncture groups received needling in two different sets of predesignated nonacupoints. This was a single blinded study, in which the participants were unaware of the intervention they were receiving, however the clinician performing the acupuncture was not blinded. 12 of the patients enrolled in the study did not complete the study, 5 of these patients were lost to

follow-up, 4 withdrew due to adverse events, and 3 withdrew for unclear reasons or protocol violations. In total 6.9% of subjects were lost to follow-up. Outcomes were measured with intention to treat analysis⁸.

Each participant received 1 session of either verum or sham acupuncture and was followed for a 24 hour period following the intervention. Each patient was asked to keep a headache diary and note if they experienced complete pain relief 24 hours after receiving the intervention. The study found that 40.7% of patients in the acupuncture group and 16.7% of patients in the control group achieved complete pain relief 24 hours after the intervention. This represents a statistically significant difference ($p < 0.05$) in the percentage of patients who achieved complete pain relief 24 hours following the intervention⁸. This data demonstrated a relative risk reduction (RRR) of 143.7% and an absolute risk reduction (ARR) of 24.0%. The number needed to treat (NNT) was 5, meaning that 5 patients needed to be treated with acupuncture in order for 1 more patient to experience complete pain relief than the control 24 hours after treatment (Table 2).

Table 2: Percent of patients pain free 24 hours after treatment and NNT

	% Pain free (Acupuncture group)	% Pain free (control group)	p-value	RRR*	ARR*	NNT*
Li et al ⁸	40.7%	16.7%	<0.05	1.437	24.0%	5
Wang et al ¹	20.0%	9.3%	0.001	1.151	10.7%	10

*RRR=relative risk reduction, ARR=absolute risk reduction, NNT=numbers needed to treat

In the study by Wang et al, 150 patients with an acute migraines were randomly assigned to either the verum acupuncture (n=75) or sham acupuncture group (n=75). 10 patients, 3 from the verum acupuncture group, and 7 from the sham acupuncture group, withdrew from the study due to fear of needling or time restrictions. In total 6.7% of

subjects were lost and outcomes in the study were analyzed with the intention to treat method¹.

Each patient in the study received 30 minutes of either acupuncture or sham acupuncture and recorded their pain using Visual Analog Scale (VAS) scores, in which 0=no pain and 10=worst pain. 20% of patients in the acupuncture group and 9.3% of patients in the sham acupuncture group were pain free (VAS score of 0) 24 hours after the intervention. There was a statistically significant difference ($p=0.001$) in the percentage of patients who were pain free following the two interventions¹. The data demonstrated a relative risk reduction (RRR) of 115.1% and an absolute risk reduction (ARR) of 10.7%. The NNT in this study was 10 (Table 2).

The study by Melchart et al looked at the number of patients who avoided a fully developed migraine 48 hours following the intervention. In this study, 179 patients were randomly assigned to the acupuncture group ($n=60$), the group receiving Sumatriptan ($n=58$), or a Sumatriptan visually matched placebo ($n=61$). In order to be included in the study patients needed to report their initial pain as a 20 or less (Table 1). There were no withdrawals from this study⁹. For the purpose of this review the group receiving Sumatriptan was excluded.

48 hours after receiving the intervention, patients were asked to assess headache intensity, using the validated pain scale by Heller. The validated pain scale by Heller is a 50 point categorical scale, on which 0=no pain and 50=most severe pain. A score greater than 30 represented a fully developed migraine. A full migraine was prevented in 35% of the patients receiving acupuncture and 18% of the patients receiving the placebo injection. There was a statistically significant difference ($p=0.028$) between acupuncture and the

placebo⁹. This data demonstrated a relative risk reduction (RRR) of 94% and an absolute risk reduction (ARR) of 17%. The NNT in this study was 6, meaning that 6 patients needed to be treated with acupuncture in order for 1 more patient to avoid progression to a fully developed migraine than with the control (Table 3). There was a 95% confidence interval for the estimate of the treatment effect⁷.

Table 3: Percent of patients who avoided a fully developed migraine 48 hours after treatment and NNT

	% of patients who avoided a fully developed migraine (acupuncture group)	% of patients who avoided a fully developed migraine (control group)	p-value	RRR*	ARR*	NNT*
Melchart et al ⁹	35%	18%	0.028	94%	17%	6

*RRR=relative risk reduction, ARR=absolute risk reduction, NNT=numbers needed to treat

In the study by Li et al, adverse events included fainting during needling, nausea and vomiting, mild bleeding and hematoma. These adverse effects were experienced by 9 people in the study, however it was not specified which treatment group these individuals belonged to⁸. In the study by Wang et al, adverse effects reported included bleeding after needle removal and fatigue. 4% of patients in the acupuncture group and 5.3% of patients in the control group experienced an adverse effect¹. The number needed to harm for this study was -76, meaning that for every 76 patients who were treated with acupuncture, 1 fewer patient would experience an adverse effect than the control (table 4). In the study by Melchart et al, adverse effects included elevated blood pressure, dizziness, vertigo, and other non-specified adverse effects. 23.3% of patients in the acupuncture group experienced an adverse effect and 16.4% of patients receiving the placebo experienced an adverse effect⁹. The number needed to harm (NNH) for this study was 15, meaning that

for every 15 patients who were treated with acupuncture, 1 more patient would experience an adverse effect than compared to the control (table 4).

Table 4: Percent of patients with an adverse effect and NNH

	Percentage of patients who experienced an adverse event (acupuncture group)	Percentage of patients who experienced an adverse event (control group)	NNH
Wang et al ¹	4.0%	5.3%	-76
Melchart et al ⁹	23.3%	16.4%	15

DISCUSSION

The randomized controlled trials in this review examine acupuncture as an alternative form of treating acute migraine pain. With statistical significance of $p < 0.05$, all three of the studies demonstrated that acupuncture is an effective treatment for an acute migraine. Two of the studies showed that acupuncture effectively eliminated migraine pain within 24 hours as compared to sham acupuncture. The third study showed that acupuncture was effective at preventing a fully developed migraine headache compared to a placebo for a commonly used migraine medication.

There are several limitations in this review. One limitation is that the studies had a relatively small sample size making it more difficult to generalize the results to the majority of patients. Another limitation was this review only examined studies of individuals aged 18-65 and migraines can occur at any age. Another limitation was that the studies were only single blinded, since the clinicians who were performing the acupuncture needed to know if they were giving the experimental or control intervention. Lastly, it is hypothesized that sham acupuncture may produce certain effects on pain relief

regardless of the sham point selection. This is known as a “DeQi” sensation and it may have interfered with testing in the control groups in the studies by Li and Wang¹. A limitation that this author experienced when searching for relevant studies was that there are many studies that examine the efficacy of acupuncture for the prophylaxis of migraines and not the actual treatment of an acute migraine. Another limitation was that due to the oriental nature of acupuncture many of the published studies were not in the English language.

Acupuncture is becoming increasingly popular in Western medicine, with more than 18,000 licensed acupuncture practitioners and more than 3,500 physician acupuncturists in the United States⁷. Acupuncture is currently used to treat a wide variety of conditions, including chronic pain, osteoarthritis, back pain, and the management of postoperative pain, dental pain, nausea and vomiting. Many insurance companies will pay for acupuncture if the patient has a diagnosis of migraines, however, companies typically will only cover 12-20 visits per year. The cost of acupuncture varies from \$50-\$150 per session¹⁰.

Adverse effects to acupuncture are generally mild, and include pain, bleeding, fatigue, nausea, and dizziness. Serious adverse effects, such as pneumothorax or vascular injuries are rare¹¹. There are no absolute contraindications for acupuncture, however it should be avoided in pregnant patients, malignant tumors, and patients with bleeding disorders or patients on anticoagulant therapy¹².

CONCLUSION

The three randomized control trials in this review provide statistically significant evidence that acupuncture is an effective treatment for acute migraine. According to these results acupuncture may be a good treatment option for patients who are unable to achieve migraine relief with traditional pharmacologic therapy or who want an alternative therapy option. Further research is warranted to evaluate which acupoints are most beneficial in the treatment of migraines and future studies are needed to determine if acupuncture is a cost effective form of therapy. Only one of the RCTs used in this review compared the efficacy of acupuncture to current pharmacologic therapies for migraines, therefore, additional research is needed to see how acupuncture compares to pharmacologic therapy for migraine headaches. Currently research is being done to assess the use of acupuncture as a prophylactic treatment of migraine headaches.

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